Eudent ov	
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Good Manufacturing Practice	
1. Introduction	1. 緒言
1.1. Scope	1.1. 適用範囲
1.10. Compliance with good manufacturing practice ("GMP") is	1.10. 販売承認を得ている全ての医薬製品についてはGMPに従う事が
mandatory for all medicinal products that have been granted a	法的要求事項である。同様に、治験薬の製造もGMPに従わなければな
marketing authorisation. Likewise, the manufacture of investigational	らない。Directive 2001/83/EC (いわゆる医療行為の除外規定)の第3
medicinal products must be in accordance with GMP. Advanced therapy medicinal products that are administered to patients under	条(7)(製造所が存在する現地の法規制における医療行為の除外規 定)に基づいて患者に投与されるATMP製品は、販売承認を有する
Article 3(7) of Directive 2001/83/EC (so called "hospital exemption")	とうに参ういて思想に及与されるATMP裂品は、販売承認を有する ATMP製品の製造と同等の品質基準の下で製造されなければならない。
must be manufactured under equivalent quality standards to the	
manufacturing of advanced therapy medicinal products with a marketing	
1.11. Article 5 of Regulation (EC) No 1394/2007 mandates the	1.11. Regulation (EC) No 1394/2007の第5条は欧州委員会にATMPに
Commission to draw up guidelines on good manufacturing practice	特化したGMPを作成することを義務付けている。Regulation (EU) No
specific to advanced therapy medicinal products ("ATMPs"). Article	536/2014の第63条の(1)も委員会にATMPの治験薬に適用するGMPの
63(1) of Regulation (EU) No 536/2014 also empowers the Commission to adopt and publish detailed guidelines on good manufacturing practice	詳細なガイドラインを採択しパブリッシュする権限を与えている。
applicable to investigational medicinal products.	
1.12. These Guidelines develop the GMP requirements that should be	 1.12. これらのガイドラインは販売承認が与えられているATMP及び治験
applied in the manufacturing of ATMPs that have been granted a	に使用されるATMPの製造に適用されるGMPの要求事項を展開する。こ
marketing authorisation and of ATMPs used in a clinical trial setting.	れらのガイドラインはATMP以外の医薬品には適用されない。Directive
These Guidelines do not apply to medicinal products other than	2001/83/ECの第7条の第2節及びRegulation (EU) No 536/2014の第63
ATMPs. In turn, the detailed guidelines referred to in the second	条の(1)は、これらに特定の参照がない限りATMPには適用されない。
paragraph of Article 47 of Directive 2001/83/EC and Article 63(1) of Regulation (EU) No 536/2014 do not apply to ATMPs, unless specific	
reference thereto is made in these Guidelines.	
Throughout these Guidelines, the term "ATMP" should be understood	1.13. これらのガイドラインを通じて、ATMPの用語は販売承認が与えら
as referring to both advanced therapy medicinal products that have	れたATMP製品及び治験での被検薬或いは対照薬として使用される(即
been granted a marketing authorisation, and advanced therapy	ち治験用ATMP)製品双方を指すものとして理解するべきである。特定の
	規定が販売承認が与えられたATMP製品にのみ該当する場合は「承認
clinical trial (i.e. advanced therapy investigational medicinal products). When specific provisions are only relevant for advanced therapy	されたATMP」という用語が用いられる。特定の規定が治験用ATMPのみ に該当する場合は「治験用ATMP」という用語が用いられる。
medicinal products that have been granted a marketing authorisation,	に該当りる場合は「加級用ATMP」という用語が用いられる。
the term "authorised ATMPs" is used. When specific provisions are	
only relevant for advanced therapy investigational medicinal products,	
the term "investigational ATMPs" is used.	
No provision in these Guidelines (including the risk-based approach)	1.14. これらのガイドラインの規定は(リスクベースのアプローチを含め
can be regarded as derogation to the terms of the marketing	て)販売承認や治験承認の要件を引き下げるものとみなすことはできない。しかし、治験承認申請資料に記載された手順及び情報に対する実
authorisation or clinical trial authorisation. It is noted, however, that non-substantial amendments can be made to the procedures and	間的とならない変更は管轄当局の事前の同意を得ずに行う事が出来
information stated in the investigational medicinal product dossier	る。本文書を通して「治験承認」は治験申請資料に対して行われた実質
without the prior agreement of the competent authorities. Throughout	
this document, the term "clinical trial authorisation" should be	
understood as including also non-substantial amendments that have	
been made to the investigational medicinal product dossier.	 1.15. これらのガイドラインは新技術の新たなコンセプトの開発に対して
1.15. These Guidelines do not intend to place any restrain on the development of new concepts of new technologies. While this	1.13. これらのガイトラインは新技術の新たなコンセントの開発に対して 如何なる抑制もかけることを意図してはいない。本文書は標準的な期待
document describes the standard expectations, alternative approaches	要件を述べているが、代替のアプローチが同じ目的に適合している事を
may be implemented by manufacturers if it is demonstrated that the	示せるならば製造業者により代替アプローチが実施されることは可能で
alternative approach is capable of meeting the same objective. Any	ある。行われた如何なる適応の調整も製品の品質、安全性、有効性及
adaptation applied must be compatible with the need to ensure the	びトレーサビリティを保証する要求事項に適合しなければならない。更
quality, safety, efficacy and traceability of the product. Additionally, it	に、販売/治験承認の要件は遵守されなければならないことを強調す ス
is stressed that the terms of the marketing/clinical trial authorisation Role of marketing authorisation holder / sponsor	る。 承認取得者の役割
1.16. For the manufacturer to be able to comply with GMP,	<u> </u>
cooperation between the manufacturer and the marketing authorisation	得者(或いは、治験用ATMPの場合、製造業者と治験依頼者)の協力が
holder (or, in the case of investigational ATMPs, the manufacturer and	必要である。
the sponsor) is necessary.	
1.17. The manufacturer should comply with the specifications and	1.17. 製造業者は治験依頼者/販売承認取得者から供給された規格及
instructions provided by the sponsor/marketing authorisation holder. It	ひ指図に従っこと。製造業者に供給された規格/指図が冶験承認/販売 承認の要件に従っていることを保証することは治験依頼者/販売承認取
is the responsibility of the sponsor/marketing authorisation holder to ensure that the specifications/instructions submitted to the	得者の責任である。それに対する変更は直ちに通知すること。
manufacturer are in accordance with the terms of the clinical trial	
authorisation/marketing authorisation. Variations thereto should be	
1.18. It is important that marketing authorisation holders/sponsors	1.18.販売承認取得者/治験承認取得者が医薬品の品質、安全性、及
communicate swiftly to the manufacturer any information that is	び有効性に影響がある可能性がある如何なる情報についても、また製
relevant to the manufacturing process, as well as any information that	造工程に関する如何なる情報も(例えばセルラインの履歴)製造業者と 速やかに交信することが重要である。関連する情報の交信は徹底的に
may have an impact on the quality, safety and efficacy of the medicinal product (e.g. history of cell-line). The communication of the relevant	迷やかに交信9ることが里安でのる。 関連9る情報の交信は徹底的に
information should be exhaustive.	
1.19. In turn, manufacturers should inform the marketing authorisation	一方、製造業者は販売承認取得者/治験承認取得者に対し、製造活動
holder/sponsor of any information that is gathered in the context of	に関連して収集され、医薬品の品質、安全性、或いは有効性に関連する
	如何なる情報も報告すること。
the manufacturing activities and that is relevant for the quality, safety or efficacy of the medicinal product.	

1.20. The obligations of the marketing authorisation/sponsor holder	1.20. 販売承認取得者/治験承認取得者及び製造業者、及びそれら相
and the manufacturer and vis-à-vis each other should be defined in	互間の責務は文書化して規定すること。治験薬の場合、治験依頼者と
writing. In the case of investigational products, the agreement between	製造業者間の取り決めは査察報告の共有と品質問題に関する情報の
the sponsor and the manufacturer should specifically provide for the	交換につき特に規定すること。
sharing of inspection reports and exchange of information on quality	
1.2. General principles	1.2. 一般原則
1.21. Quality plays a major role in the safety and efficacy profile of	1.21. 品質はATMPの安全性及び有効性のプロファイルにおいて主要な
ATMPs. It is the responsibility of the ATMP manufacturer to ensure	役割を占める。製品品質を担保するために適切な対策(いわゆる医薬
that appropriate measures are put in place to safeguard the quality of	品質システム)が講じられていることを保証することはATMP製造業者の
the product (so-called "pharmaceutical quality system").	<u> 青務である。</u>
Pharmaceutical Quality System	医薬品質システム
1.22. 'Pharmaceutical quality system' means the total sum of the	1.22. 医薬品質システムは、医薬品がその意図する用途に対して要求さ
arrangements made with the objective of ensuring that medicinal	れる品質であることを保証する目的でなされた仕組みを統合したもので
products are of the quality required for their intended use.	あることを意味する。
1.23. The size of the company and complexity of the activities should	1.23. 医薬品質システムを設計する際には企業の規模と活動の複雑さ
be taken into consideration when designing a pharmaceutical quality	を考慮すること。上級経営者は医薬品質システムの有効性を保証する
system. Senior management should be actively involved to ensure the	ため積極的に関与すること。或る面では全社的であるが、医薬品質シス
effectiveness of the pharmaceutical quality system. While some	テムの有効性は通常製造所単位で示される。
aspects may be company-wide, the effectiveness of the	
pharmaceutical quality system is normally demonstrated at site level.	
1.24. Compliance with Good Manufacturing Practice ("GMP") is an	1.24. GMP適合は医薬品質システムの本質的な部分である。特に、医
essential part of the pharmaceutical quality system. In particular,	薬品質システムを通じて以下を保証すること:
through the pharmaceutical quality system it should be ensured that:	
(i) the personnel are adequately trained and there is clear allocation of	(i) 従業員は適切にトレーニングされ、責任体制が明確に割り振られてい
responsibilities;	ること;
(ii) the premises and equipment are suitable for the intended use and	(ii) 構造設備が適切であり、それらの維持管理が適切であること:
that there is appropriate maintenance thereof;	
(iii) there is an adequate documentation system that ensures that	(iii) 出発物質および原材料、中間製品、バルク製品、最終製品等に対し
appropriate specifications are laid down for materials, intermediates,	て適切な規格を制定し、製造工程が明確に理解され、記録が適切に取
	に過めな況俗を利定し、設造工程が明確に理解され、記録が過めに取 られることを保証する良好な文書化システムがあること;
bulk products and the finished product, that the production process is	られることを休証する反対な义者化システムがめること。
clearly understood, and that appropriate records are kept;	
(iv) the manufacturing process is adequate to ensure consistent	(iv) 製造工程が(その開発段階に対して適切に)一貫した製造、製品品
production (appropriate to the relevant stage of development), the	質、及び関連する規格への適合を保証するために適切であること;
quality of the product, and the compliance thereof with the relevant	
specifications;	
(v) there is a quality control system which is operationally independent	(v) 製造から独立した品質管理システムがあること;
from production;	
(vi) arrangements are in place for the prospective evaluation of planned	(vi)計画された変更の予測的評価と、規制上の要求事項(即ち承認され)
	たATMPの場合の変更手続き、或いは治験用ATMPの場合の実質的変
changes and their approval prior to implementation taking into account	
regulatory requirements (i.e. variations procedure in the case of	更の承認手続き)を考慮した実施前の承認、及び実施された変更の評
authorised ATMPs, or authorisation procedure of a substantial	価 のための仕組みがあること;
modification of a clinical trial in the case of investigational ATMPs), and	
for the evaluation of changes implemented;	
(vii) quality defects and process deviations are identified as soon as	(vii)品質異常及び工程逸脱ができる限り速やかに確認され、原因究明
possible, the causes investigated, and appropriate corrective and/or	がされ、適切な是正及び/又は予防措置が取られる:そして
preventive measures are taken; and	
(viii) adequate systems are implemented to ensure traceability of the	(viii) ATMP及びそれらの出発物質および重要原料のトレーサビリティを
ATMPs and of their starting and critical raw materials.	保証するために適切なシステムが実施される。
1.25. A continuous assessment of the effectiveness of the quality	1.25. 品質保証システムの有効性の継続的評価が重要である。品質特
assurance system is important. Results of parameters identified as a	性或いは重要であると特定されたパラメータの結果について傾向分析
quality attribute or as critical should be trended and checked to make	がされ、それらが互いに一貫している事を確認するためにチェックされる
sure that they are consistent with each other. The manufacturer	こと。製造業者は、医薬品質システムの一部として、GMPの実施と尊重
should conduct self-inspections as part of the pharmaceutical quality	をモニターし、必要な是正及び/又は予防措置を提案するために自己点
system in order to monitor the implementation and respect of good	検を実施すること。そのような自己点検の記録と、その後に取られた是
manufacturing practice and to propose any necessary corrective	正処置の記録を維持すること。
measures and/or preventive actions. Records should be maintained of	
such self-inspections and any corrective actions subsequently taken.	
1.26. In the case of authorised ATMPs, guality reviews should be	1.26. 承認されたATMPの場合、現行の工程の適切性と一貫性を検証
	し、何らかの傾向があれば明らかにし、製品及び/又は工程の改善の機
conducted annually to verify the adequacy and consistency of the	会を特定するために、品質照査を年次で実施すること。品質照査の程度
existing processes, and to highlight any trends and to identify	
opportunities for product and/or process improvements. The extent of	
the quality reviews should be determined by the volume of the	より決定すること(即ち、少数のロット/少量の製品が製造される場合より
manufactured products and whether there have been changes	も、数多くのロット/多量の製品が製造される場合品質照査はより大規
introduced to the manufacturing process (i.e. the quality review needs	模に行う必要があり、当該年に製造工程に変更があった場合は無かっ
to be more extensive when a high number of lots/ high product	た年に比べてより大規模に行うこと)。品質照査は科学的に妥当性を示
quantity has been produced than in case of low number of lots/ low	されるならば製品タイプごとにグループ化して実施してもよい。
product quantity; the quality review should also be more extensive	
when changes in the manufacturing process have been introduced	
during a given year than when no changes have been made). Quality	
reviews may be grouped by product type where scientifically justified.	
1.27. The manufacturer and -when it is a different legal entity- the	1.27. 製造業者及び-別法人である場合-販売承認取得者は照査の結果
	ナ証(年) はてれが(カはる吐地學ぶ)があれていた証(年七7~)。
marketing authorisation holder should evaluate the results of the	を評価し、是正及び/又は予防措置が必要か否かを評価すること。
marketing authorisation holder should evaluate the results of the review and assess whether corrective and/or preventive actions are	を評価し、定止及び/又は予防措直が必要が沿かを評価すること。
	を評価し、走正及び/又はア防宿直が必要が沿かを評価すること。 2. リスクベースのアプローチ
review and assess whether corrective and/or preventive actions are	

2.10. ATMPs are complex products and risks may differ according to the type of product, nature/characteristics of the starting materials and level of complexity of the manufacturing process. It is also acknowledged that the finished product may entail some degree of variability due to the use of biological materials and/or complex manipulation steps (e.g. cultivation of cells, manipulations that alter the function of the cells, etc.). In addition, the manufacture and testing of autologous ATMPs (and allogeneic products in a donor-matched scenario) poses specific challenges and the strategies implemented to ensure a high level of quality must be tailored to the constraints of the manufacturing process, limited batch sizes and the inherent variability	2.10. ATMPは複雑な製品であり、リスクは製品のタイプ、出発物質の性 質/特性及び製造工程の複雑さのレベルにより異なる。最終製品の品質 は、生物学的原料の使用及び/又は複雑な操作(即ち細胞の培養、細 胞の機能を変更する操作、等)によりある程度のばらつきを伴うという事 が認識されている。更に、自家ATMP(及びドナー適合の同種異系の製 品)の製造と試験は特別なチャレンジを提起し、高い水準の品質を保証 するために実施される戦略は製造工程と限定されたバッチサイズ及び 出発物質に内在する変動性等の制約に対応して立てられなければなら ない。
2.11. ATMPs are at the forefront of scientific innovation and the field is experiencing rapid technological change that also impacts on the manufacturing processes. For instance, new manufacturing models are emerging to address the specific challenges of ATMPs (e.g. decentralised manufacturing for autologous products). Additionally, ATMPs are also often developed in an academic or hospital setting operating under quality systems different to those typically required for the manufacture of conventional medicinal products.	2.11. ATMPは科学的なイノベーションの先端にあり、この分野は急速な 技術的変革を経験しているため、それが製造工程にも影響を与える。例 えば、新規製造モデルがATMPの特定のチャレンジに焦点を当てるため に出現してくる(例えば、自家製品の非集中製造)。更に、ATMPは一般 的な医薬品の製造に典型的に要求されるものとは異なった品質システ ムの下で稼働しているアカデミック或いは病院の設定環境下で開発され ることがある。
2.12. It follows that, in laying down the GMP requirements applicable to ATMPs, it is necessary to recognise a certain level of flexibility so that the ATMP manufacturer can implement the measures that are most appropriate having regard to specific characteristics of the manufacturing process and of the product. This is particularly important in the case of investigational ATMPs, especially in early phases of clinical trials (phase I and phase I/II), due to the often incomplete knowledge about the product (e.g. potency) as well as the evolving nature of the routines (in order to adjust the manufacturing process to the increased knowledge of the product).	2.12. これに伴い、ATMPIに適用されるGMPの要求事項を作成するにあ たり、ATMP製造業者が製造工程と製品の特定の特性を考慮して最も適 切な対策を実施することが出来るよう一定の水準のフレキシビリティを 認めることが必要である。これは、初期段階の臨床研究(第1相及びI/II 相)の治験用ATMPの場合、日常実施していることが新たな展開をして ゆくという状況(増加した製品知識に製造工程を適応させるため)と共 に、しばしば製品知識が不完全であることから、特に重要である。
2.2. Application of the risk-based approach by ATMP manufacturers 2.13. The risk-based approach ("RBA") is applicable to all type of ATMPS. It applies in an equal fashion to all type of settings. The quality, safety and efficacy attributes of the ATMPs and compliance with GMP should be ensured for all ATMPs, regardless of whether they are developed in a hospital, academic or industrial setting.	2.2. ATMP製造業者によるリスクベースのアブローチの適用 2.13. リスクベースのアブローチ(RBA)は全てのタイプのATMPに適用出 来る。RBAは全てのタイプの設定に同様に適用する。ATMPの品質、安 全性、及び有効性面での特性とGMP適合は、それらが病院、学術研究、 或いは産業のいずれの環境で開発されたかに拘わらず全てのATMPに ついて保証されること。
2.14. Manufacturers are responsible for the quality of the ATMPs they produce. The riskbased approach permits the manufacturer to design the organisational, technical and structural measures that are put in place to comply with GMP –and thus to ensure quality– according to the specific risks of the product and the manufacturing process. While the risk-based approach brings flexibility, it also implies that the manufacturer is responsible to put in place the control/mitigation measures that are necessary to address the specific risks of the product and of the manufacturing process.	2.14. 製造業者は自身が製造するATMPの品質に責任がある。リスク ベースのアプローチは製造業者がGMPに適合するため-それにより品質 を保証するため-確立し、製品及び製造工程の特定のリスクに応じて品 質を保証する組織的、技術的、及び構造上の対応を設計することを許容 する。リスクベースのアプローチはフレキシビリティをもたらすが、それは また製造業者が製品及び製造工程の特定のリスクに焦点をあてた管理 /低減策を確立する責任があることを意味する。
2.15. The quality risks associated with an ATMP are highly dependent on the biological characteristics and origin of the cells/tissues, the	2.15. ATMPに付随する品質リスクは細胞/組織の生物学的特性と起源、ベクターと導入遺伝子の生物学的特性(例えば複製能、逆転写)発現した蛋白のレベルと特性(遺伝子治療製品に関して)、他の非細胞性成分(原料、マトリックス等)の性質、及び製造工程に高度に依存している。
2.16. When identifying the control/mitigation measures that are most appropriate in each case, the ATMP manufacturer should consider all the potential risks related to the product or the manufacturing process on the basis of all information available, including an assessment of the potential implications for the quality, safety and efficacy profile of the product, as well as other related risks to human health or to the environment. When new information emerges which may affect the	2.16. それぞれの場合に最も適切な管理/低減策を決める際には、 ATMP製造業者は製品或いは製造工程に関連して考えられる全てのリ スクについて、その他ヒトの健康或いは環境への関連するリスクと共に、 製品の品質、安全性、及び有効性のプロファイルに関して可能性がある 影響の評価を含め、得られる全ての情報に基づいて考慮すること。リス クに影響する可能性がある新たな情報が出てきた際には管理戦略(即 ち適用されている管理及び低減策の総合)が引き続き適切か否かにつ いて評価を行うこと。
2.17. The evaluation of the risks and the effectiveness of the control/mitigation measures should be based on current scientific knowledge and the accumulated experience. Ultimately, this evaluation is linked to the protection of patients.	2.17. リスクと管理/低減策の有効性についての評価は現行の科学知識 と蓄積された経験に基づくものであること。最終的にはこの評価は患者 の保護に結び付いている。
2.18. The level of effort and documentation should be commensurate with the level of risk. It is neither always appropriate nor always necessary to use a formal risk management process (using recognized tools and/ or internal procedures e.g., standard operating procedures). The use of informal risk management processes (using empirical tools and/or internal procedures) can also be considered acceptable.	2.18. 実施する内容と文書化のレベルはリスクのレベルに相応したもの であること。(認知された手法及び/又は標準操作手順書等の内部的な 手順を用いた)形式に従ったリスクマネジメントプロセスを用いる事が常 に適切とは限らず、常に必要であるとは限らない。形式にとらわれないリ スクマネジメントプロセス(経験的な手法及び/又は内部的な手順を用い た)もまた許容可能と考えられる。
2.19. The application of a risk-based approach can facilitate compliance but does not obviate the manufacturer's obligation to comply with relevant regulatory requirements and to demonstrate that it is able to adequately manage the risks of the product/manufacturing process. It likewise does not replace appropriate communications with Investigational ATMPs	2.19. リスクベースのアプローチの適用は適合性を促進し得るが、関連 する規制上の要求事項を遵守し、製品/製造工程のリスクを適切に管理 することが出来るという事を証明するという製造業者の義務を取り除くも のではない。同様にそれは当局との適切な連絡を代替するものではな い。 治験用ATMP

2.20. The application of GMP to investigational ATMPs is intended to	2.20. 治験用ATMPへのGMPの適用は臨床試験の被験者を保護するこ
protect the clinical trial subjects and it is also important for the	とを意図しており、又、臨床試験の結果の信頼性のためにも重要であ
reliability of the results of the clinical trial, in particular by ensuring	る、特に臨床試験の結果が、用いられた製造工程が不充分であることに
consistency of the product, that the results of the clinical trial are not	より影響をうけたという事がなかった事と、開発中の製品の変更が適切
affected by unsatisfactory manufacturing used and that changes of the	に文書化されている事によって製品の一貫性が保証されている事によ
product throughout the development are adequately documented.	る信頼性である。
2.21. It is important to ensure that data obtained from the early phases	2.21. 臨床試験の早い段階から得られたデータがそれに次ぐ開発段階
	で用いることが出来ることを保証することが重要である。従って治験用
of a clinical trial can be used in subsequent phases of development.	
Therefore, a functional quality system should be in place for the	ATMPの製造においては機能している品質システムが存在するべきであ
manufacturing of investigational ATMPs.	る。
2.22. The quality and safety of the product needs to be ensured from	2.22. 製品の品質と安全性は開発の初めの段階から保証する必要があ
the first stages of development. Nevertheless, it is acknowledged that	る。しかし、製品知識は徐々に増加し、品質を保証するための戦略の設
there is a gradual increase in the knowledge of the product and that	計と実施のための努力の水準は徐々にステップアップしてゆくことが認
the level of effort in the design and implementation of the strategy to	識されている。さらに、製造工程と管理方法は臨床試験のより進んだ段
ensure quality will step up gradually. It follows that the manufacturing	階においてより詳細となり改良されることが期待される。
procedures and control methods are expected to become more detailed	
and refined during the more advanced phases of the clinical trial.	
	2.23. リスクベースのアプローチの適用の責任は製造業者にあるが、特
2.23. While the responsibility for the application of the risk-based	
approach lies with the manufacturer, it is encouraged that the advice of	
the competent authorities is sought in connection with the	アプローチの適用に関しては管轄当局の指導を求める事が推奨され
implementation of the risk-based approach for investigational ATMPs	る。リスクベースのアプローチの適用は、治験承認の条件と一貫してい
and, in particular, regarding early phases of clinical trials. The	ること。リスクベースのアプローチを適用する際には、治験承認申請にお
application of the risk-based approach should be consistent with the	ける製造工程と工程管理の記述は、適宜、製造業者の品質戦略を述べ
terms of the clinical trial authorisation. The description of the	ること。
manufacturing process and process controls in the clinical trial	
authorisation application should explain, as appropriate, the quality	
strategy of the manufacturer when the risk-based approach is applied.	
	204 公験承認で特にカバーされていたことについてき 史佐 インス
2.24. For aspects that are not specifically covered by the clinical trial	2.24. 治験承認で特にカバーされていない点については、実施している
authorisation, it is incumbent upon the manufacturer to document the	アプローチの理由を文書化し、適用された対策の全体が製品品質を保
reasons for the approach implemented and to justify that the totality of	証するために適切であることを示す事が製造業者の責任である。これに
the measures applied are adequate to ensure the quality of the	関して、本ガイドラインに記載されている要求事項への代替アプローチ
product. In this regard, it is recalled that alternative approaches to the	はそれらが同じ目的に適合することが出来る場合においてのみ許容で
requirements explained in these Guidelines are only acceptable if they	きるという事を再認識すべきである。
are capable of meeting the same objective.	
Authorised ATMPs	承認されたATMP
2.25. For authorised ATMPs, the application of the risk-based	2.25. 承認されたATMPに関しては、リスクベースのアプローチの適用は
approach should be consistent with the terms of the marketing	販売承認の条件と齟齬がないこと。販売承認申請(或いは、一変申請の
	提出の場合)において製造工程と工程管理の記述を提出する際には、
authorisation. When providing the description of the manufacturing	
process and process controls in the marketing authorisation application	標準的に期待される内容の適用/それからの逸脱の妥当性を示すため
(or, as appropriate, in the context of the submission of a variation),	に製品/製造工程の特定の特性について考慮することが出来る。この様
account can be taken of the specific characteristics of the	に、原料及び出発物質の管理、製造用の構造設備、試験及び合格基
product/manufacturing process to justify adaptation/deviation from	準、プロセスバリデーション、出荷規格、或いは安定性データを含めた製
standard expectations. Thus, the strategy to address specific	造工程に関連して存在するであろう特定の限度に焦点を当てた戦略が
limitations that may exist in connection with the manufacturing	販売承認の一部として合意されるべきである。
process, including controls of raw materials and starting materials, the	
manufacturing facilities and equipment, tests and acceptance criteria,	
process validation, release specifications, or stability data should be	
2.26. For aspects that are not specifically covered by the marketing	2.26. 販売承認で特にカバーされていない部分についてはリスクベース
authorisation, it is incumbent upon the manufacturer to document the	のアプローチが適用された場合は実施したアプローチの理由を文書化
reasons for the approach implemented when the risk-based approach is	
applied, and to justify that the totality of the measures applied are	ることの妥当性を示すことが製造業者の義務である。これに関して、本
adequate to ensure the quality of the product. In this regard, it is	ガイドラインにおいて述べられている要求事項への代替アプローチは、
recalled that alternative approaches to the requirements explained in	それらが同じ目標に適合することが出来る場合のみ受け入れ可能であ
these Guidelines are only acceptable if they are capable of meeting the	る。
same objective.	
same objective. 2.3. Examples of the application of the risk-based approach	2.3. リスクベースのアプローチの適用例
-	2.3.リスクベースのアプローチの適用例 2.27. この章の内容は、リスクベースのアプローチの可能性と限界のいく
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233. In these cases, an adequate control strategy should be designed. 2.33. こたらの場合、適切な管理戦略を設計すること、例えば、以下のみ、 などませないため、 などまなせいため、 などまなせいため、 などまなせいため、 などまなせいため、 などまなせいため、 などまなせいため、 などまなせいため、 などまなせいため、 などまなせいため、 などまなせいため、 などまなせいため、 などまなせいため、 などまなせいたか。 などまなせいたかかいたか。 などまなせいたか。 などまなせいたかかいたかか。 ないたいたか。 ないたいたか。 などまなせいたか。 などまなせいたかかいたかかいたか。 などまなせいたか。 などまなせいたかかいたかかいたかかいたかかいたかかいたかかいたかかいたかか。 などまなせいたかかいたかかいたかかいたかかいたかかいたかかいたかかいたかかいたかかいたか	be administered immediately after completion of manufacturing), or	
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 Past time testing in case of short shelf-life materials/nonucta 328. Transformed enlance on process validation. Mhen the scarely of materials or the very short shelf-life limits the possibilities for release controls, the limitston should be compensated by a reinforced by BRD (31, V2CL2, V1)(V22, V2CR4C) (52, CR4, CL4, VII)(V22, V2CR4C) (52, CL4	of the results from these tests to the critical quality attributes of the	相関があることが証明されるならば、重要中間体試験或いは工程管理
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provided that alternative measures are put in place, such as controls of particles from materials (e.g. filtration of raw material solutions) and equipment used during manufacturing, or the verification of the ability of the manufacturing process to produce low particle products with simulated samples (without cells). 2.43. 1t may be justified to waive the on-going stability program for oroducts with shorter shelf-life. 2.33. Additional considerations relevant for ATMPs that are not subject to substantial manipulation 2.44. Manufacturing processes of ATMPs not involving substantial manipulation of the cells/tissues are typically associated with lower risks than the manufacturing of ATMPs not involving substantial manipulations. However, it cannot be inferred that processes that not qualified as "substantial long exposure of the resles/tissues to the guivements. Accordingly, an analysis of the risks of the specific manufacturing process should be performed in order to identify the measures that are necessary to ensure the quality of the product. 245. With a view to reduce administrative burden, in the specific manufacturing process should be performed in order to identify the equivalent standards that are applied by ATMP manufacturing process of which dees not involve substantial manipulation, account may be taken of equivalent standards that are applied by ATMP manufacturers in compliance with other legislative frameworks. For instance, the premises and equipment that have been duly validated to process cells/tissues for transplantation purposes in accordance with standareds that can be deemed comparable to those laid down in these Guidelines	2.42. \cdot As cells in suspension are not clear solutions, it is acceptable to replace the particulate matter test by an appearance test (e.g. colour).	
equipment used during manufacturing, or the verification of the ability of the manufacturing process to produce low particle products with simulated samples (without cells). 2.43. It may be justified to waive the on-going stability program for products with shorter shelf-life. 2.33. Additional considerations relevant for ATMPs that are not subject to substantial manipulation 2.44. Manufacturing processes of ATMPs not involving substantial manipulation of the cells/tissues are typically associated with lower risks than the manufacturing of ATMPs involving complex substantial manipulations. However, it cannot be inferred that processes that are not qualified as "substantial long exposure of the cells/tissues to the processing of the cells entails long exposure of the cells/tissues to the environment. Accordingly, an analysis of the risks of the specific manufacturing process that are necessary to ensure the quality of the product. 2.45. With a view to reduce administrative burden, in the application of the GMP requirements to ATMPs the manufacturing process of which does not involve substantial manipulation. account may be taken of equivalent standards that are applied by ATMP manufacturers in compliance with other legislative frameworks. For instance, the premises and equipment that have been duly valided to process that can be deemed comparable to those laid down in these Guidelines	provided that alternative measures are put in place, such as controls of	て微粒子を管理すること(例えば原料溶液のろ過)或いは、細胞抜きの
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risks than the manufacturing of ATMPs involving complex substantial manipulations. However, it cannot be inferred that processes that are not qualified as "substantial manipulation" are risk-free, notably if the processing of the cells entails long exposure of the cells/tissues to the environment. Accordingly, an analysis of the risks of the specific manufacturing process should be performed in order to identify the measures that are necessary to ensure the quality of the product. 2.45. With a view to reduce administrative burden, in the application of the GMP requirements to ATMPs the manufacturing process of which does not involve substantial manipulation, account may be taken of equivalent standards that are applied by ATMP manufacturers in compliance with other legislative frameworks. For instance, the premises and equipment that have been duly validated to process cells/tissues for transplantation purposes in accordance with standards that can be deemed comparable to those laid down in these Guidelines	2.44. Manufacturing processes of ATMPs not involving substantial	2.44. 細胞/組織の実質的な操作を伴わないATMPの製造工程は、複雑
not qualified as "substantial manipulation" are risk-free, notably if the processing of the cells entails long exposure of the cells/tissues to the environment. Accordingly, an analysis of the risks of the specific manufacturing process should be performed in order to identify the measures that are necessary to ensure the quality of the product. 2.45. With a view to reduce administrative burden, in the application of the GMP requirements to ATMPs the manufacturing process of which does not involve substantial manipulation, account may be taken of equivalent standards that are applied by ATMP manufacturers in compliance with other legislative frameworks. For instance, the premises and equipment that have been duly validated to process cells/tissues for transplantation purposes in accordance with standards that can be deemed comparable to those laid down in these Guidelines	manipulation of the cells/tissues are typically associated with lower risks than the manufacturing of ATMPs involving complex substantial	
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the GMP requirements to ATMPs the manufacturing process of which does not involve substantial manipulation, account may be taken of equivalent standards that are applied by ATMP manufacturers in compliance with other legislative frameworks. For instance, the premises and equipment that have been duly validated to process cells/tissues for transplantation purposes in accordance with standards that can be deemed comparable to those laid down in these Guidelines	measures that are necessary to ensure the quality of the product. 2.45. With a view to reduce administrative burden, in the application of	2.45. 管理の負相を低減する観点から、GMPの要求事項をATMPに適
equivalent standards that are applied by ATMP manufacturers in compliance with other legislative frameworks. For instance, the premises and equipment that have been duly validated to process cells/tissues for transplantation purposes in accordance with standards that can be deemed comparable to those laid down in these Guidelines	the GMP requirements to ATMPs the manufacturing process of which	用することにおいて、実質的な操作を伴わない製造工程においては、他
premises and equipment that have been duly validated to process cells/tissues for transplantation purposes in accordance with standards い。 that can be deemed comparable to those laid down in these Guidelines	does not involve substantial manipulation, account may be taken of equivalent standards that are applied by ATMP manufacturers in	同等の基準を考慮して良い。例えば、本ガイドラインと同様とみなし得る
cells/tissues for transplantation purposes in accordance with standards $ u_\circ$ that can be deemed comparable to those laid down in these Guidelines	compliance with other legislative frameworks. For instance, the premises and equipment that have been duly validated to process	
	cells/tissues for transplantation purposes in accordance with standards	
	need not being validated again (for the same type of manufacturing	

specifically addressed under other legislative frameworks and which, therefore, should follow the requirements in these Guidelines, also when the manufacturing process does not involve substantial manipulation. In particular, the requirements on product characterisation (through the setting of adequate specifications), \overline{p}	MPの品質、安全性、及び有効性を保証することを意図したGMPの有る 種の要素がある、そしてそれは本ガイドラインの要求に従うべきで、製造 工程が実質的な操作を伴わない場合においてもである。特に、製品の 特性説明(適切な規格の設定を通じた)、工程バリデーション(治験用AT MPに関して期待される項目は10.3章に記載されている)、品質管理(販 売/治験承認の条件に従った)、及びQPによる証明が従うべき要求事 項である。
therefore, should follow the requirements in these Guidelines, also when the manufacturing process does not involve substantial manipulation. In particular, the requirements on product characterisation (through the setting of adequate specifications), process validation (the expectations for investigational ATMPs are	工程が実質的な操作を伴わない場合においてもである。特に、製品の 特性説明(適切な規格の設定を通じた)、工程バリデーション(治験用AT MPに関して期待される項目は10.3章に記載されている)、品質管理(販 売/治験承認の条件に従った)、及びQPによる証明が従うべき要求事
when the manufacturing process does not involve substantial#manipulation. In particular, the requirements on productMcharacterisation (through the setting of adequate specifications),#process validation (the expectations for investigational ATMPs areI	特性説明(適切な規格の設定を通じた)、工程バリデーション(治験用AT MPに関して期待される項目は10.3章に記載されている)、品質管理(販 売/治験承認の条件に従った)、及びQPによる証明が従うべき要求事
manipulation. In particular, the requirements on product characterisation (through the setting of adequate specifications), process validation (the expectations for investigational ATMPs are	MPに関して期待される項目は10.3章に記載されている)、品質管理(販 売/治験承認の条件に従った)、及びQPによる証明が従うべき要求事
characterisation (through the setting of adequate specifications), process validation (the expectations for investigational ATMPs are	売/治験承認の条件に従った)、及びQPによる証明が従うべき要求事
	項である。
described in Section 10.3) quality controls (in accordance with the	
terms of the marketing/clinical trial authorisation), and QP certification	2.47. 同じ手術の処置の間に製造行為があって投与されるATMPは、A
	2.47. 向し手術の処直の间に要這行為かめって投与されるATMPは、A TMP規制から除外されない(従ってGMPへの適合も含めて)。
therefore GMP compliance).	TWF 洗前がら床がられない(使うてGWF*、の)過日の日のです。
	2.3.4. 治験用ATMPに関連して更に考慮する事項
2.48. While additional adaptations in the application of GMP may be 2	2.48. 治験用ATMPの場合GMPの適用において更なる適応を妥当とす
	ることが出来るが、製品の品質、安全性及びトレーサビィティーは治験の
	場合でも保証されなければならない。
a clinical trial setting.	
2.49. The following are examples of additional possible adaptations that 2	2.49. 以下は、冶映用ATMPの場合に許容できるかもしれない更なる週 応の例である:
	2.50.
	 ・治験用ATMPは4.3.2及び9.5章に規定されている要求事項に従った空
	気の質の施設において製造されるべきであるが、非常に初期/コンセプ
Sections 4.3.2 and 9.5, in case of investigational ATMPs in very early	トの証明のための治験用ATMPの場合、以下の条件(の総合)が適合し
	ているなら、グレードCのバックグラウンドの中のグレードAの重要区域
	にあるオープンシステムにおいて製品を製造することを例外的に認めて
	も良い。
(cumulative) conditions are met: (i) A risk-assessment has been performed and demonstrated that the	(i) リスク評価が実施され、実施されている管理対策が適切な品質の製
	品の製造を保証するために適切であることが示されている。それに加
	れの表達を休益するために過めてのることが小されてている。 てれていれていた。
should be described in the investigational medicinal product dossier.	
	(ii) 製品が、他の代替の治療法が無い生命にかかわる状態を治療する
	ことを意図している。
	(iii) 管轄当局が同意している(審査官と当該施設の査察官の双方が同 金、
	意)。 051.加期の販店試験/第111販店試験及び第1/0日試験)においては
	2.51.・初期の臨床試験(第1相臨床試験及び第1/2相試験)においては 製造活動が非常に低い場合、キャリブレーション、メンテナンス作業、構
	表記には、「ないない」では、「ないない」として、「ないない」では、「ないない」では、「ないない」では、「ないない」では、「ないない」では、「ないない」では、「ないない」では、「ないない」では、「ないない」では、
	施すること。全ての設備の使用適合性について使用前に検証すること。
analysis. The suitability for use of all equipment should be verified	
	2.52.・文書化のレベルと正式さの度合いは開発の段階に応じてで良
	い。トレーサビリティの要求事項については全面的に実施すること。
should however be implemented in full.	
	2.53.・初期の臨床試験(第1相臨床試験及び第1/2相試験)の間は、規 格はその時点のリスクについての知識を然るべく考慮し、治験を承認し
	格はての時点のリスクにういての知識をぶるへく考慮し、冶験を承認した管轄当局の承認に従って、より広い許容基準に基づくことが可能であ
	る。
2.54. • Possible adaptations regarding qualification of premises and 2	2.54. ・構造設備の妥当性確認、洗浄バリデーション、プロセスバリデー
	ション、及び分析法バリデーションにリスクベースのアプローチをどのよう
· · ·	に適用するかについて考えられる点は10章に記載されている。
	3. 従業員
	3.1. 一般原則 2.10 ATMD制造業者は適切な適格性に 音図する作業に関する適切な
	3.10. ATMP製造業者は適切な適格性と、意図する作業に関する適切な 実務経験を有する、適切な数の従業員を擁していなければならない。
experience relevant to the intended operations.	へコリリロニッヘビトリ ブロヘルニーツリなタメゾルに木只とリカヒレ い 'よいれいみなびない'。
	3.11. ATMPの製造及び試験に従事する全ての従業員は、担当職務に
	対して適切な製品知識を含めてその責務と責任について明確に理解し
	ていなければならない。
	3.12. 全ての従業員は彼らに影響があるGMPの原則についての教育
	訓練を受けること、また、導入時及び定期的に彼らの職務に関連する教 育訓練を受けること。
	月訓練を受けること。 3.13. 製品の製造、試験、及びトレーサビリティに関して特定の要求事項
	についての適切な(及び定期的な)教育訓練があること。
the product.	
3.14. Personnel working in clean areas should be given specific training 3	3.14. 清浄区域で働く従業員には微生物学の基礎的な面を含む無菌製
	造についての特定の教育訓練を行うこと。
	3.15. ルーチンの無菌製造作業に参加するに先立って、従業員は結果が
	適合であった培地充填試験に参加すること(9.5.2章参照)。3.3章に規定
	された更衣の要求事項に関する教育訓練も必要である。グレードA/B区 域で働く従業員の、更衣の要求事項に適合する職務能力を、少なくとも
	域で動く促素員の、更なの安水争項に適合する戦務能力を、少なくとも 年次で再評価すること。
reassessed at least annually.	
	3.16. A/B区域で作業を行う従業員の微生物モニタリングを重要作業の
performed after critical operations and when leaving the A/B area. A	後、及びA/B区域から退出する際に実施すること。関連するであろう他
	のパラメータと共に、モニタリングプログラムの結果次第で従業員を不適
	格とするシステムを確立すること。不適格とされた場合、その作業員が
	無菌操作に従事することが可能となる前に再教育/再適格性確認が必
	要である。再教育/再適格性確認は結果が適合であった培地充填への 参加を含む。
process simulation test.	<i>ש ח</i> יי מי ש ט ס

3.17. In addition, there should be appropriate training to prevent the transfer of communicable diseases from biological raw and starting materials to the operators and vice versa. Personnel handling genetically modified organisms ("GMOs") require additional training to prevent cross-contamination risks and potential environmental impacts.	3.17. 更に、原料及び出発物質から作業員へ、及びその逆の感染性疾 患の伝染を防止するための適切な教育訓練を行うこと。遺伝子操作を 行った微生物(GMO)を取り扱う従業員はクロスコンタミのリスクと環境 への影響の可能性を防止するため追加の教育訓練を必要とする。
3.18. Cleaning and maintenance personnel should also receive training relevant to the tasks performed, in particular on measures to avoid risks to the product, to the environment, and health risks.	3.18. 清掃及びメンテナンスを行う従業員は、特に製品、環境、及び健康に及ぼすリスクを避けるための対応について、担当職務に関連した教育訓練を受けること。 3.19. 教育訓練は社内で行うことができる。教育訓練の効果は定期的に評価すること。教育訓練記録を保管すること。 3.3. 衛生
	3.20. 高い水準の従業員の衛生と清潔さが必須である。衛生管理プログ
Hygiene programs should be established.	ラムを確立すること。
3.21. Eating, drinking, chewing or smoking, as well as the storage of food or personal medication should be prohibited in the production and storage area.	3.21. 食品或いは個人用医薬品の保管と共に、飲食、ガムをかむこと、 或いは喫煙は製造及び保管区域では禁止する事。
3.22. Direct contact should be avoided between the operator's hands and the exposed product as well as with any part of the equipment that comes into contact with the products.	3.22. 露出した製品、また製品と接触する設備の如何なる部分も同様 に、作業員の手と直接接触することを避けること。
3.23. Every person entering the manufacturing areas should wear clean clothing suitable for the manufacturing activity with which they are involved and this clothing should be changed when appropriate. Additional protective garments appropriate to the operations to be carried out (e.g. head, face, hand and/or arm coverings) should be worn	3.23. 製造区域に入る各従業員は彼らが従事する製造作業に適した清 潔な作業衣を着用すること、この作業衣は適宜交換すること。必要な場 合、実施する操作に適した追加の保護衣(例えば頭、顔、手及び/又は 腕カパー)を着用すること。
	3.24. 更衣及びその質は工程及び作業区域のグレードに適したもので あること。作業員と製品を汚染リスクから保護すべく着用すること。
3.25. The description of clothing required for clean areas is as follows: • Grade D: Hair and, where relevant, beard and moustache should be covered. A general protective suit and appropriate shoes or overshoes should be worn. Appropriate measures should be taken to avoid any contamination coming from outside the clean area.	3.25. 清浄区域で必要とされる更衣についての記述は以下の通りであ ・グレードD:髪の毛及び該当する場合あごひげ及びロひげをカバーする こと。一般的な保護衣及び適切な靴或いはオーバーシューズを着用す ること。清浄区域外からもたらされる如何なる汚染も避けるために適切 な対策を取ること。
 Grade C: Hair and where relevant beard and moustache should be covered. A single or two-piece trouser suit, gathered at the wrists and with high neck and appropriate shoes or overshoes should be worn. They should shed virtually no fiber or particulate matter. Grade A/B: Sterile headgear should totally enclose hair and, where relevant, beard and moustache; it should be tucked into the neck of the suit; a sterile face mask and sterile eye coverings should be worn to prevent the shedding of droplets and particles. Appropriate sterilised, non-powdered rubber or plastic gloves and steriles or disinfected footwear should be worn. Trouser-legs should be tucked inside the footwear and garment sleeves into the gloves. The protective clothing 	 ・グレードC: 髪の毛及び該当する場合あごひげ及び口ひげをカバーすること。つなぎ或いは上下のツーピースの、袖口を絞った、ハイネックの作業衣と適切な靴或いはオーバーシューズを着用すること。それらは実質的に繊維或いは微粒子を放出しないものであること。 ・グレードA/B:滅菌した頭巾が全体的に頭髪及び該当する場合あごひ
the activity. Gloves should be regularly disinfected during operations. Upon exit from a clean area there should be a visual check of the 3.27. Clean area clothing should be cleaned and handled in such a way that it does not gather additional contaminants which can later be	3.26. 屋外の衣服はグレードB及びCの部屋に連絡している更衣室に持ち込まないこと。グレードA/B区域での作業員全員に清浄な(滅菌した)保護衣(マスク及び眼カバーを含めて)を清浄区域に入室する都度提供すること:別の製造工程/別のバッチの為の清浄区域からの退出及び再入室の必要性は作業のリスクにより決定すること。手袋は作業中に規則的に消毒すること。清浄区域から退出すると同時に保護衣の完全性について目視でチェックすること。 3.27. 清浄区域の更衣は付着後に放出されるような汚染物質を取り込まないような方法で洗浄し、取り扱うこと。封じ込め区域で作業を行った場
shed. When working in a contained area, protective clothing should be discarded before leaving the contained area. 3.28. Wristwatches, make-up and jewellery should not be worn in clean	合、保護衣は封じ込め区域から退出する前に廃棄すること。 3.28. 腕時計、化粧品、宝飾品は清浄区域においては着用しないこと。
areas.	
3.29. Where required to minimise the risk for cross-contamination, restrictions on the movement of all personnel should be applied. In general, personnel (or any other person) should not pass directly from areas where there is exposure to live microorganisms, GMOs, toxins or animals to areas where other products, inactivated products or different organisms are handled. If such passage is unavoidable, appropriate control measures (having regard to the risks) should be applied. When a person moves from one clean room to another clean room (higher to lower grade, or lower to higher grade) appropriate disinfection measures should be applied. The garment requirements required for the relevant grade should be respected.	3.29. クロスコンタミのリスクを最小限にすることが求められる場所におい ては、全ての従業員の動きを緩徐にさせること。通常、従業員は(或いは 他のいかなる人員も)生存微生物、遺伝子組換え生物、毒素、或いは動 物に暴露される区域から他の製品、不活化された製品、或いは別の微 生物が取り扱われている区域に直接通過しないこと。そのような通過が 避けられない場合、(リスクを考慮した)適切な管理対策を適用すること。 人が或るクリーンルームから他のクリーンルームに移動する場合(高い グレードから低いグレードへ、或いは低いグレードから高いグレードへ)、 適切な消毒対策を適用すること。対応するグレードについて必要な着衣 の要求事項を配慮すること。
3.30. Activities in clean areas, especially when aseptic operations are in progress, should be kept to a minimum. Excessive shedding of particles and organisms due to over-vigorous activity should be avoided.	3.30. 清浄区域での活動は、特に無菌操作進行中は、最小限にとどめること。過度の動きによる微粒子及び微生物の過剰な放出を避けること。
3.31. Only the minimum number of personnel should be present in clean areas. Inspections and controls should be conducted outside the clean areas as far as possible.	3.31. 清浄区域の中は最小限の人員に限定すること。検査及び管理は できる限り清浄区域の外部から行うこと。

3.32. Steps should be taken to ensure that health conditions of the	3.32. ATMPの品質に係る健康状態について従業員が申告することを確
personnel that may be relevant to the quality of the ATMP are declared	
and that no person affected by an infectious disease which could	ぼす可能性のある感染症の影響がある従業員或いは露出された体表
adversely affect the quality of the product, or having open lesions on	面に開放創傷を持つ従業員は製品の製造に係わらないようにすること。
the exposed surface of the body, is involved in the manufacture of	2.22 スカッフの健康学能のエニカい、グけリスカに広じたものでもてこ
3.33. Health monitoring of staff should be proportional to the risks.	3.33. スタッフの健康状態のモニタリングはリスクに応じたものであるこ
Where necessary having regard to the specific risks of the product,	と。必要な場合、製品の特定のリスクを考慮して、製造、メンテナンス、
personnel engaged in production, maintenance, testing and internal	試験・工程管理、及び動物管理に従事する従業員はワクチン接種を受
controls, and animal care should be vaccinated. Other measures may	けること。製品及びそれらの製造に用いられている原材料について知られている。製品及びそれらの製造に用いられている原材料について知られている。
need to be put in place to protect the personnel according to the	れているリスクに応じて従業員を保護するためのその他の対策を講じる
known risks of the product and of the materials used in the	必要がある場合がある。
3.4. Key personnel	3.4. 主要責任者
3.34. Because of their essential role in the quality system, the person	3.34. 品質システムにおける必須の役割があるため、製造の責任者、品 質管理の責任者及びQPは上級管理者により任命されなければならな
responsible for production, the person responsible for quality control	
and the Qualified Person ("QP") should be appointed by senior	い。遺伝子組換え生物を含むか遺伝子組換え生物で構成されるATMP の場合バイオセーフティ責任者も又上級管理者により任命されなければ
	の場合ハイオセーンノイ員に自も文工版管理自により仕叩されないれば ならない。
person responsible for biosafety should also be appointed by senior 3.35. The roles and responsibilities of key personnel should be clearly	3.35. 主要責任者の役割と責任は明確に規定し、組織内で周知されな
defined and communicated within the organisation.	いる。工会員に省の反割と員には防止に尻足し、危険的で周知されなければならない。
3.36. As a minimum, the person responsible for production should take	3.36. 最低限、製造の責任者は製造が関連する規格/指図に従って行
	われることを保証するための責任、製造作業に使用する構造設備の適
responsibility for ensuring that manufacturing is done in accordance with the relevant specifications/instructions, for the qualification and	将進設備の過格性確認とメンテナンスについての責任を果たし、適切なバリデーション
	が実施されることを保証する責任を果たすこと。品質管理の責任者の責
maintenance of the premises and equipment used in manufacturing operations, and to ensure that appropriate validations are done. The	が実施されることを床証する員任を未たすこと。 品員管理の員任者の員 任については12.1章に詳細が記載されており、QPの責任については
responsibilities of the person responsible for quality control are detailed	
in Section 12.1 and the responsibilities of the QP are explained in	
Section 11.2.	
3.37. Additionally, depending on the size and organisational structure of	
the company, a separate unit responsible for quality assurance may be	の部門を設立してもよい。この場合製造の責任者と品質管理の責任者
established. In this case, the responsibilities of the person responsible	の責任は品質保証の責任者と共有する。
for production and the person responsible for guality control are shared	T THE REAL AND THE TRANSPORT
with the person responsible for quality assurance.	
3.38. The person responsible for production, the person responsible for	3.38. 製造の責任者、品質管理の責任者、そして該当する場合品質保
quality control, and where applicable- the person responsible for quality	証の責任者は、医薬品質システムの設計と実施、そして特に教育訓練、
assurance, share some responsibilities regarding the design and	文書化の責務、工程バリデーション、輸送条件及び(該当する場合)再
implementation of the pharmaceutical quality system and in particular	溶解手順のバリデーション、製造環境の管理、外注業務の管理、及び品
concerning training, documentation obligations, process validation,	質問題に関する究明について責任を共有している。
validation of the transport conditions and of the reconstitution process	
(where applicable), control of the manufacturing environment, control of	
outsourced activities, and quality investigations.	
3.39. While the duties of key personnel may be delegated to persons	3.39. 主要責任者の責務は適切な適格性をもつ従業員に代理をさせて
with appropriate qualification, there should be no gaps or unexplained	も良いが、主要責任者の責任に欠損や説明できない重複が無いこと。
overlaps in the responsibilities of key personnel.	
3.40. The same person can perform the role of person responsible for	3.40. 同一人物が品質管理の責任者とQPの役職を遂行してもよい。
quality control and QP. It is also possible for the QP to be responsible	又、QPが製造の責任者となることも可能である。しかし、製造の責任者
for production. However, responsibility for production and for quality	と品質管理の責任者は同一人物を任ずることはできない。小さな組織に
control cannot be assumed by the same person. In small organisations,	おいて、チームが多方面の技能を有し品質管理作業と製造作業の両方
where teams are multi-skilled and trained in both quality control and	の教育訓練を受けている場合、同一人物が異なったバッチについては
production activities, it is acceptable that the same person is	両方の役割(製造及び品質管理)の責任を持つことは許容できる。個別
responsible for both roles (production and quality control) with respect	のバッチについては製造と品質管理の責任は2名の別々の人員に割り
to different batches. For any given batch, the responsibility for	当てなければならない。従って、同一バッチについては品質管理作業の
production and quality control of the batch must be vested on two	製造からの独立が適切に文書化された手順によって明確に確立されて
different persons. Accordingly, it becomes particularly important that	いることが特に重要となる。
the independency of the quality control activities from the production	
activities for the same batch is clearly established through appropriate	
4. Premises	4. 施設
4.1. General principles	4.1. 一般原則
4.10. Premises must be suitable for the operations to be carried out.	4.10. 施設は実施する作業に適したものであること。特に、外的な汚染、
In particular, they should be designed to minimise the opportunity for	クロスコンタミ、エラーのリスク及び、一般的に、製品品質に対するいか
extraneous contamination, crosscontamination, the risk of errors and, in	なる好ましくない影響の機会をも最小限とすべく設計されること
general, any adverse effect on the quality of products.	444 いてる 師匠叫とたとしてこしがチェッシュ
4.11. It is important that the following general principles are	4.11.以下の一般原則を実施することが重要である:
(i) Premises should be kept clean (disinfection to be applied as	(i) 施設は清潔に維持しなければならない(除染を適切に適用する)
appropriate).	
(ii) Premises should be carefully maintained, ensuring that repair and	(ii) 施設は、修理及びメンテナンス作業が製品品質を害さないように注
maintenance operations do not present any hazard to the quality of	意深く維持管理しなければならない
products.	
(iii) Lighting, temperature, humidity and ventilation should be	(iii)照明、温度、湿度及び換気は実施する作業の為に適切で、ATMP或 しいは機器の動作に要影響をみぼさないこと
appropriate for the activities performed and should not adversely affect	いる液動の剤TFI~芯影音を及ばらないこと。
the ATMPs or the functioning of equipment.	(iv) 主要な環境パラメータをモニターするための適切な対策を実施する
(iv) Appropriate measures to monitor key environmental parameters	
should be applied.	こと。 (v) 施設は、昆虫或いは他の動物の侵入から最大限の防御が出来るよ
(v) Premises should be designed and equipped so as to afford maximum	
protection against the entry of insects or other animals.	う設計し、設置しなければならない。 (vi) 許可されていない人が入ることを防止するための対策を取らなけれ
(vi) Steps should be taken to prevent the entry of unauthorised people.	(い)許可されていない人が入ることを防止するにのの対策を取らなけれ ばならない。製造、保管、品質管理区域はそれらの区域内で作業を行わ
Production, storage and quality control areas should not be used as a transit area by personnel who do not work in them. When such passage	はならない。要垣、床官、血員官理区域はそれらの区域内で作業を打力 ない従業員の通過区域として使用してはならない。そのような通過が避
transit area by personnel who do not work in them. When such passage	はい従来員の通過区域として使用してはならない。そのような通過が避けられない場合、適切な管理対策を適用すること。
is unavoidable, appropriate control measures should be applied.	1754ない場合、通りな管理対象を適用すること。 (vii)殺虫剤、除草剤等の毒性物質の製造はATMPの製造に使用する施
(vii) The manufacture of technical poisons, such as pesticides and	
herbicides should not be allowed in premises used for the manufacture	
herbicides, should not be allowed in premises used for the manufacture	設内では許容されない。
herbicides, should not be allowed in premises used for the manufacture of ATMPs.	設内では計谷されない。

42. Multi-product facility 42. 複数型品の型温施設でのATMPの型温は、リスクに用たた運 When appropriate riskmitigation measures commensurate with the risk are implementation of to prevent mixings and that so containing on the risk explanations can be found in Section 94. 41.3 Manufacture of ATMPs in a multi-product facility is accentable with appropriate manufacture in a term of the adequately controlled by operational and/or technical measures. Where there are separate production areas should be used for the oseparate production subced area of the facility. 41.8 基礎市がATMPの製造は総営の専用区域において実施すると思い SocTo-So-5. 41.5 Special operational and/or technical measures. Where there are to separate production subced fer the oseparate production subced fer the manufacture of ATMPs by acit tight and the gale before any subsequent manufacturing in the same are and concount activities should take place in a segregated area. 41.6 Big Light All Light Light All Light All Light All Light All Light All Li		4.12. ATMPの製造については、施設は適格性確認されること。(10.1章 を参照)
413. Manufacture of ATMPs in a multi-product fielity is acceptate when appropriate inskinitigation measures commensates with the risk are implemented to provent mix-ups and cross-contamination. Further are implemented to provent mix-ups and const-contamination. Further A14. If the manufacturing site produces medicinal products other than A14. Use mix-there is a dedicated on 9.4. 414. Elements and the formality is a const-contamination. Further and formation is a dedicated area of the formality controlled by operational and/or technical measures. Where there are no separate production autes and and/or technical measures. Where there are accontamination procedure of validated effectiveness should take place biotics and the place in a sequence of the constrained of the controlled by operational and/or technical measures. Where there are accontamination procedure of validated effectiveness action occur. 416. Exployed (C)		
when appropriate risknitization measures commensures with the risk an implemented to preven thin-ups and cross-containation. Further dataST 626.3. BMD SQB HEL 2012.2.34.4. dataStrong 5.4. dataStrong		
sepanations can be found in Section 9.4. 14.1 HT manufacturing is produces medicinal products other ML 14.2 製造所がATMPUM ong 素品を装造しているならば、リスク部 ATMPS, based on a risk assessment, the manufacture of ATMPS may 14.3 製造所がATMPUM ong 素品を装造しているならば、リスク部 ATIM Segregated production arces should be used for the 14.3 15.5 55.5 71.0000 装置しまり通道の口管理できないシスク ATIM Segregated production arces should be used for the 15.5 14.6 14.8 14.2 14.5 14.6 14.7		なリスク軽減措置が混同及びクロスコンタミ防止のために実施される場
41.4.1 If the manufacturing site produes medicinal products other han AIA. 製造前がAIME以外の原葉品を発起しているならば、リスク判 med to take place in a dedicated area of the facility. 14.1. 製造前がAIME以外の原葉品を発起しているならば、リスク判 AIAE Site Sareaged products manases should be used for the manufacturing of AIME presenting a risk that conto te adequately controlled by operational and or technical measures. Where there are controlled by operational and or technical measures. Where there are controlled by operational and or technical measures. Where there are controlled by operational and or technical measures. Where there are controlled by operational and or technical measures are can occur at the special procession should be taken in the case of manufacturing of different starting materials and/or finished products should be taken in a bagregated area. Concurrent manufacturing of different batchs/resolutes 14.1. Sign Case 2007/07/-(例えば葦屋高原開性ウイルス)が助 and		合は許容できる。追加の説明はセクション9.4。
ATMPs, based on a risk sessesment, the manufacture of ATMPs may read to take place in a decinated area of the fairby. 415. Segregated production areas should be used for the segarate production areas through cleaning and decontamination procedure of validated effectiveness should take place decontamination procedure of validated effectiveness should take place decontamination procedure of validated effectiveness should take place decontamination procedure of validated effectiveness should take place activities should be place in a segregated area concurrent manufacturing of different batches/products and/or finished products should be segarated, either in place or in time. 417. Manufacturing activities concerning different tatting materials and/or finished products and be segarated, either in place or in time. 421. Segaration in place: 421. Segaration in segarate activities as foldows: 422. Segaration in segarate activities as foldows: 423. Segaration in segarate activities as foldows: 423. Segaration in segarate activities as foldows: 424. Segaration in segarate activities as foldows: 425. Segaration in place: 426. Segaration in place: 427. Segaration in place: 427. Segaration in segarate activities asegarate		
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415. Segregated production areas should be used for the manufacturing of ATMPs presenting a risk that cannot be adequate controlled by operational and/or technical messures. Where there are decontamination procedure of validated frectiveness should take place before any subsequent manufacturing in this same area can occur activities involution subset. A through cleaning and decontamination procedure of validated frectiveness should take place activities involut take place in a segregated area. Concurrent manufacturing in this same area can occur activities involut take place in a segregated area. Concurrent manufacturing a different batchess area can occur activities involut take place in a segregated area. Concurrent manufacturing a different starting materials and/or finande products should be separated. Here in place on in the all or finande products should be separated. Here in place on in the all or finande neo closed instart (or other closes in the and creat in more isolation of two different ATMPs/ batches in the exampted in from the isolators and regular integrity ophexes in the exampted in from the isolator (or other close and the facility (i.e. on recirculation). In other cases, a fiftration runal water handling. 110. Skite Tot. Diskite Tot. Disk		
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1.20. When two isolators are used to process different viral vectors within the same room there should be 100% air exhaustion from the room and the facility (i.e. no recirculation). In other cases, air filtration may be acceptable. In addition, in case of concurrent production of viral vectors, it is necessary to provide for closed, separate and unidrectional waste handling. 420. 2:0074/ULX-054g&cb 5a#@3g&cb		
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production to take place in areas connected in a logical order		
		作業環境及び設備、材質は、異なった製品或いはその成分間の混同の
		リスクを最小限とし、クロスコンタミを避け、如何なる製造或いは管理の 段階についても、抜け或いは誤った適用のリスクを最小限とするために
of confusion between different products or their components, to avoid 適切であること。		
cross-contamination, and to minimise the risk of omission or wrong		
application of any of the manufacturing or control steps.	_	
		4.28. 施設のレイアウトは、非無菌で使用済みの物と設備のフローを滅
		菌された物のフローと分離できるものであること。これが不可能な場合、
		非無菌で使用済みの物/設備の取り扱いは時間で区分し、適切な洗浄
materials/equipment should be separated in time and appropriate 対策を適用すること。		対策を適用すること。
cleaning measures should be applied.	cleaning measures should be applied.	

				pe effectively ventilated, wit						その中で行われる操作、そして	
-		. –		and, where necessary, hum						温度及び必要な場合湿度、そ	して空
			•	n to the products handled, t		気のろ	過を含め	りて)によ	って効果的	に換気すること。	
				em, and to the external env				4			
				be designed, constructed, a						なった区域間のクロスコンタ	
		-		of cross-contamination bet						の特定な必要性がある場合、	
				uring site and may need to l						こと。製品の特定なリスクに応し	レーシ
		-		ific risks of the product, the	e use of	シウル	ハスの当	ミマンイ	テムの使用を	を考慮すること。	
				pe considered.	h. 1	4.01 5	主治反対	ホルト レ	マの重山	ちまあけ 微粒スポいけ微け	香う
			-		-					た表面は、微粒子或いは微生 ・剤及び消毒剤を使用する場合	
				ze the shedding or accumu Id to permit the repeated ap						「別及び消毎別を使用する場」で不浸透性であり耐久性があ	
				ts where used.	plication of	である		HEC 9 0		に行後過住ての分前大住がの	000
				ion of dust and to facilitate	the cleaning			を抑制	清掃を図	易とするため清掃できない凹る	みが毎
				recesses and a minimum of	-					備は最小限とすること。ドアは	
				equipment. Doors should b						計すること;引き戸はこの理由	
-				esses; sliding doors may be	-	好まし		ц., с.			11-01 /
	is reas			····, ·····g ·····, ···, ···,							
			should be s	ealed to prevent contamina	tion from the	4.33. ł	おり天井	はその	Lの空間から	の汚染を防止するために密閉	月する
	e above	-	-			こと。					
			ts and othe	r utilities should be installe	d so that	4.34. /	パイプ、	ダクト及び	びその他のコ	Lーティリティーは、凹み、密閉	されて
	•									を生じないよう設置すること。	
	ult to cl			-							
4.35.	Clean/	/contain	ed areas sh	ould be accessed through a	an air lock					-ロックされたドア或いは両方の	
				propriate procedural control						めの適切な手順上の管理を行	
that b	ooth do	ors are	not opened	simultaneously. The final s	stage of the					。最終段階のエアロックは非代	F業時
			e at-rest st	tate, be the same grade as [•]	the area into	の状態	でそれた	が通じる	区域と同じグ	[、] レードであること。	
	n it lead										
	-	-		e designed as airlocks and ι						し、更衣の異なった段階を物	
				he different stages of chan						び微粒子による汚染を最小	
			-	te contamination of protect	-					ーを通した空気で効果的にフラ	
-				ely with filtered air. The us						の入室と退室に別の更衣室を	
				tering and leaving clean are				。一版的	川ー、十元いり	施設は更衣室の第一段階のみ	れー設
				hand washing facilities sho of the changing rooms.		置する					
		c enviro				4.3.2.	無菌環境	音			
				ole for the intended operation	ons and they				最作に 滴した	ものであり、無菌環境を保証す	よるた-
				l to ensure an aseptic envir	-					を保証するために実施される	
		-	-	re an aseptic environment s						全て考慮して適切なものであ	
				e specific risks of the prod						別の注意を払うこと。	-
manu	facturir	ng proce	ess. Special	attention should be paid wh	nen there is						
no te	rminal s	sterilisat	tion of the f	inished product.							
Clear	areas					清浄区	<u>域</u>				
4.38.	A criti	cal clea	n area is an	area where the product is	exposed to	4.38. 重	重要清浄	区域は、	製品が環境	条件に暴露される区域である	、その
				ne design thereof should the						するものであること。重要区域	
										≤域)の空気もまた適切に管理	
				be adequately controlled a						ターを通した空気を供給する	
	0			areas should be supplied w						品と製造工程の特性、特に加またのは	
has p	assed t	hrough	filters of an	appropriate efficiency. The	appropriate					われるかを考慮した特定のリ	人力を
				be determined having regard		方慮し	し次める	o(9.5	5.1章を参照)	0	
		-		nt the nature of the product							
				cular whether processing ta Section 9.5.1).	res hiace in						
				n rooms/clean air devices s	hould be	430		L = 1.77	クリー・シェマン	装置のクラス分類はISO14644	-1/-
				. For qualification, the airbo						表置のアクス分類は13014044 ては0.5µm以上の浮遊塵を測定	
				should be measured. This						時に測定すること。各グレードで	
			•	ned at rest and in operation	. The					の通りである。	
				rticle concentration for eac							
					<u> </u>						
r					1			1			-
		Maximum 0.5 μm	permitted numb	per of particles equal or greater than				0.5 (m CI ⊨	の微粒子の最大調	许容数	
		0.0 µm									
		At rest	In operation	ISO classification	1			非作業時	作業時	ISO によるクラス分類	
		$({\bf per}\;{\bf m}^{3)}$	(per m ³⁾	(At rest/in operation)				(per m ³⁾	$(per m^{3)}$	(非作業時/作業時)	
					J						
	Grade]		Grade	1			1
	A	3 520	3 520	5/5			Δ	3 520	3 520	5/5	1

3 520

3 520

3 520 000

352 000

А

В

C D 3 520

352 000

3 520 000

Not defined

5/5

5/7

7/8 8

4.40. クリーンルームの適格性確認の一部としてクリーンルームの作業時の微生物量を測定すること。各グレードの微生物汚染の限度は以下の通りである(推奨値)

3 520

3 520

3 520 000

352 000

Α

в

C D 3 520

352 000

3 520 000

Not defined

5/5

5/7

7/8

4.40. As part of the qualification of clean rooms, the microbial load of the clean room in operation should be measured. The limits for microbial contamination for each grade are as follows (recommended

8

		1									
	Grade	Air sai cfu/m3	dian 90mr	neter m) cfu/4	Contact plates (diameter 55 mm)		グレー	ド 浮遊菌 cfu/m3	落下菌 (diamet 90mm)	cfu/4 mm)	
	4.00		hours		cfu/plate		A**	<1	+ours*	cfu/plat <1	;e
	A**	<1	<1		<1		B	10	5	5	
	B	10	5		5		C	100	50	25	
	С	100	50		25		D	200	100	50	
	D	200	100		50						
ett ho f c	le plate: uld still ritical o	s are exposed be used. Set perations and	d for less than tle plates sho changed as i	n 4 hours t ould be exp required at		e table ば uration と に	定用プレー と。落下菌源 こ交換する。	トを4時間以内 則定用プレート こと。	の暴露とした場 は重要操作の	らでも表中の 間暴露し、必要	良い。 落下
fu		ed; any recov	-	-	cted result sho should result ir	nan 柞	検出された:	場合は如何な	る場合も究明す	「ること。	ある;1cfu以上
art	icles sh	ould be minim	nised in the cl	ean areas	als liable to ge reas is essenti	5	させることは	は最小限とする	こと。		青浄区域に存在 毒剤の除去を含
nclu Tum nac shoi o a rang	uding th nigation cessible uld be c void the ge of bio	e removal of i may be usefu e places. Whe hecked. It is e development odecontaminat	residual clean I to reduce m are disinfecta also advisable t of resistant tion activity. I	ing agents iicrobiologi nts are us e that mor strains an Disinfectar	A and B should be a should be a should be a should be a should be	ion in 存 / thereof 性 e is used 万 broader 月 and	めて必須で 有用であろ 生種の増殖 プより多い利	ある。届かない う。消毒剤を使 を避け、より広	、箇所の微生物 用する場合、 範な微生物除 方が良い。グレ	Ŋ汚染を抑制す その効果をチェ 染活性を達成 ノードA及びBC	「るために燻蒸れ 、ックすること。而 「するために1タ の清浄区域で使
.3.3	3. Enviro	onmental mon	itoring			4	<u>.3.3. 環境</u> -	Eニタリング	っガニノ・キモジ	いの日本	め果が評価でき
					important too I measures ca						り来か評価でさ ノールである。環
					ne products be						と:微粒子/微生
				-	m should includ	le the 特	物汚染、差	圧、そして工程	について適切	な管理が要求	される場合一温
ollo	wing pa	rameters: nor	n−viable∕viabl	e contami	nation, air pres	sure 扂		、そして結果に			· · · ·
					quired for the						
					ts should be tr		144 T - 4	ᇄᇧᇏᆆᆂᆂ	フカ/加ニル	汗沈についる	ション
					nined having re						〔最大のリスクを 果を考慮して決
		.g. at location obtained duri					にらす部位。 すること。	~心衣の道格	土畑 認 ~わし、	こすりれんに結:	木で方思しし次
					y of monitoring			リングのサン	プル数、量、頻	度、アラート及	びアクション限
			• • •		to account the						であること。サ
					mpling method			よ製造作業に対	すして汚染のリ	スクをもたらさ	ないものである
				e manufac	turing operatio		<u>と。</u> 新州マテー				
		particulate m		tome cl-	ld bo ant-List		<u> </u>		シフティナエッ	リリフクのコー	性の討体でない
					Ild be establish n risks and to (性の評価とクリ っこと。アイソレー
		-	-		ronmental mon						ニタリングを行う
		ed for isolato					とが望ましし				
					n-viable partic				環境管理の程度	きとモニタリング	ブシステムの選
					Id be adapted						のリスクに沿った
•		•			turing process	-		こと。頻度、サン			
_					duration, alert						き慮して確立する いたものと同じて
					se by case hav ample volume t		_と。テノノ ある必要は		- ルームの通俗		いこついと回し(
		at used for qu									
					l be defined. W						こと。工程に有る
					etrimental to t						らDのアラート
			0		d be lower tha					よりも低いもの)であること、そ
					<u>n the area perf</u> : when alert lim			<u>の能力に基づ</u> コリングシステノ		もち越った 燃け	その事象が迅
					rm settings). I						を保証するもの
				-	ons should be t	aken. ð	あること。も	し、アクション	艮度値を超過し		切な是正措置を
		Ild be docume						らは文書化され		711	
.50	. The r	ecommended	action limits	are as foll	ows:	4	.50. 推奨る	されるアクション	1個は以下の通	<u> しいである:</u>	
	Grade	Recommended	maximum limits	Recomme	nded maximum lim	its	Grade	≧ 0.5 um の満ち	子のm³当たりの	≧5 um の微約-	子の m ³ 当たりの最
		for particles	i≧ 0.5 μm/m³	for pa	articles≧5µm/m ³				我度値		設度値
		in operation	at rest	in operation	n at rest			作業時	非作業時	作業時	非作業時
	А	3 520	3 520	20*	20*						
		352 000	3 520	2 900	29		A	3 520	3 520	20*	20*
	В	352 000				\neg	В	352 000	3 520	2 900	29
	В		352 000	29 000	2 900						
	B C	3 520 000	352 000	29 000 Set a limit	2 900		C	3 520 000	352 000	29 000	2 900
	В		352 000 3 520 000	29 000 Set a limit based on th	29 000		C D	3 520 000 リスク評価に	352 000 3 520 000	29 000 リスク評価に	2 900 29 000
	B C	3 520 000 Set a limit		Set a limit	29 000		-	The second second		and a subscription of	- Connectorization

* Due		·	· · ·			x = b + b + b	社界の四日の	+ 4000 + 4	旧共されてい	フーがはレイ古		
					f 20 has been Ilue should also			75802000個か れる場合も究明		る。継続して高 と。		
	er an investig											
the fi exce	ull duration o pt where dul	of critical pr y justified (ocessing, incl e.g. contamina	uding equipm ants in the pr		4.51. グレードA区域については、適切に妥当性を示した場合を除いて (例えば工程における汚染物質がパーティクルカウンターにダメージを与 える、或いはそれが危険性を示すもの、例えば生きている病原性微生物 の場合) 微粒子モニタリングは設備の組み立てを含めて重要な加工の						
				-	nt a hazard, e.g. Iuring equipment			は設備の組み :。例外の場合				
			ke place (i.e. p	. –				即ち製品が危				
			itoring should					り間も実施する				
			e should be pa monitoring d		oring during I to cover the			にはモニタリンク が、重要作業中		業の全作業時		
	-		-		area should be					ような適切な頻		
monit	tored at an a	appropriate	frequency and	d with suitabl	e sample size to		· -	タリングを行う				
			of contamina		should be set	453 グレード(こみびり区域の	モニタリング戦	略はリスクとま	に特に実施す		
havin	ng regard to t				of the operations		を考慮して設定					
	ucted. When there	is no critica	al operations	on-going (i e	at rest)	454 重亜作業	きが行われて	いない時(即ちま	作業時)け	商切た問隔の		
					While at rest,			・ない時(即ら) F業時の間、H\				
					ay trigger the			るため、停止し				
			the event of a			1				対応(例えば追		
			icted to deter ne activities p	-	tions that may be the affected	加りモータリュ	77)を決止す	る/この//こり へ クi	許恤を夫他9~	ຈຼະເ		
	s (e.g. additio											
		• •	•		monitoring of the			いのまた しんしょう いんしん しんしょう しんしん しんしん しんしん しんしん しんしん しんしん				
	•		ion in grade A as it is an imp		s is required for			モニタリングは Eニタリングの)検出の重要な		
					ion of ≥5.0 μ m			ることは擬陽性				
partic	cle counts m	ay be false	counts, cons	ecutive or re	gular counting of	が、継続或い	は定常的な低	レベルのカウン	トは汚染の可	能性を示すも		
					nd it should be			のような事象し				
			ay, for examp ventilation a		ive of early ioning system),			の状態である。 業を未熟に実施		、 或い は 彼 奋 を 示 し て い る 場		
			ay also be dia			合がある。						
	-		outine operat	on.								
	<u>e particle mo</u>		recence of or	ocific mieror	organisms in the	<u>微生物モニタ</u>		医空炎生物(面	ライモ ちょうしょう	・ 笙)の方女		
			ls, etc.) shoul			4.56. クリーンルーム内での特定微生物(例えば酵母、カビ、等)の存在 を検出するためのチェックを適宜実施すること。微生物モニタリングはア						
					d for isolators	イソレータ及びバイオセーフティキャビネットについても実施することがす められる。 4.57 無菌操作が行われている場合、モニタリングは落下菌測定用プレート、エアサンプラー及び付着菌サンプリング(例えば、スワブ及びコ レタクトプレート)等の方法を用いて頻繁に行うこと。迅速微生物モニタリ						
	piosafety cab											
			ns are perforn n as settle pla									
	-		and contact									
	-		e considered	and may be	adopted after	ング法を考慮	し、建物のバリ	デーション後に	適用しても良	い。		
	ation of the p		ام المعارية	wine a with a a l	operations where	4 50 制 ロ - がま	目前に 早 雪 ナ ち	る場合、重要な	い品作の問け	声結エーカル、		
		-	e environmen	-	•			「の後は設備及				
					al microbiological	ターすること。	その他、リスク	に応じて製造化		いても微生物モ		
			red outside p			ニタリングが	<u> X要な場合がままの ***********************************</u>	<u>5る。</u> ニタリングにつし		生活百十四年		
	toring of clea	0		n limits for m	nicrobiological	4.59. 肩戸区 値が適用され		-97291236	・(の以下の)	主义取入限度		
		1		1			•			1 1		
	Grade	Air sample	Settle plates	Contact plates		Grade	浮遊菌	落下菌	コンタクトプ	作業者の手		
		cfu/m3	(diameter 90mm) cfu/4	(diameter 55 mm)	õfingers		cfu/m3	(プレート径	V	5指		
1 I					cfu/glove			90mm) cfu/4	(プレート径 55	cfu/glove		
			hours*	cfu/plate				herr-*	mm) ofu/plata			
	A**	< 1			< 1	Δ**	~ 1	hours*	mm) cfu/plate	< 1		
I 1	A** B	< 1 10	hours*	cfu/plate	< 1 5	A**	< 1	< 1	<1	<1		
			hours* <1	cfu/plate < 1	<u> </u>	В	10	< 1 5	<1 õ	< 1 5		
-	В	10	hours* < 1 5	cfu/plate < 1 5	<u> </u>	B C	10 100	< 1 5 50	< 1 5 25			
-	B C	10 100	hours* < 1 5 50	cfu/plate < 1 5 25	<u> </u>	В	10	< 1 5	< 1 õ			
	B C D	10 100 200	hours* < 1 5 50 100	cfu/plate < 1 5 25 50	5	B C D	10 100 200	< 1 5 50 100	< 1 5 25 50	ō		
* Ind	B C D	10 100 200	hours* < 1 50 100 y be exposed	cfu/plate < 1 5 25 50	5 4 hours. Where	B C D * 個々の落下	10 100 200 菌測定用プレ	<1 5 50 100 一トは4時間未	<1 5 25 50 満の暴露でも」	<u>5</u> - - - 良い。落下菌測		
* Ind	B C D ividual settle e plates are o	10 100 200 e plates may exposed for	hours* < 1 50 100 7 be exposed r less than 4 h	cfu/plate < 1 5 25 50 for less than nours the limit	5 . . 4 hours. Where its in the table	B C D * 個々の落下 定用プレート	10 100 200 菌測定用プレ を4時間未満暴	<1 5 50 100 ートは4時間未 露する場合でも	<1 5 25 50 満の暴露でも」	 5 - -		
* Ind settle	B C D ividual settle e plates are Id still be use	10 100 200 e plates may exposed for ed. Settle p	hours* < 1 50 100 7 be exposed r less than 4 h	cfu/plate < 1 5 25 50 for less than nours the limit be exposed f	5 . . . 4 hours. Where its in the table for the duration	B C D を用プレート? と。落下菌測 以降交換する	10 100 200 を4時間未満暴 定用プレートは こと。	<1 5 50 100 ートは4時間未 露する場合です 重要作業の間	<1 5 25 50 満の暴露でも 5 表中の限度 信 暴露し、必要に	5 - - - - - - - - - - - - -		
* Ind settle shoul of cri ** It	B C D ividual settle e plates are o ld still be use itical operationshould be not	10 100 200 e plates may exposed for ed. Settle p ons and cha bted that fo	hours* <1 5 50 100 / be exposed / less than 4 h blates should anged as requir r grade A the	cfu/plate < 1 5 25 50 for less than nours the limit be exposed f ired after 4 h expected re	4 hours. Where its in the table or the duration nours. sult should be 0	B C D E 用プレート? と。落下菌測 以降交換する ** グレードA	10 100 200 菌測定用プレートはこと。 医域については	<1 5 50 100 ートは4時間未 露する場合です 重要作業の間 は、期待される新	<1 5 25 50 満の暴露でも 5 表中の限度 信 暴露し、必要に	5 - - - - - - - - - - - - -		
* Ind settle shoul of cri ** It cfu re	B C D iividual settle e plates are o ld still be use itical operations should be no ecovered; an	10 100 200 e plates may exposed for ed. Settle p ons and cha bted that fo	hours* <1 5 50 100 / be exposed less than 4 h plates should anged as requ	cfu/plate < 1 5 25 50 for less than nours the limit be exposed f ired after 4 h expected re	4 hours. Where its in the table or the duration nours. sult should be 0	B C D E 用プレート? と。落下菌測 以降交換する ** グレードA	10 100 200 菌測定用プレートはこと。 医域については	<1 5 50 100 ートは4時間未 露する場合です 重要作業の間	<1 5 25 50 満の暴露でも 5 表中の限度 信 暴露し、必要に	5 - - - - - - - - - - - - -		
* Ind settle shoul of cri ** It cfu re inves	B C D ividual settle e plates are of ld still be use itical operations should be no ecovered; an stigation.	10 100 200 e plates may exposed for ed. Settle p ons and cha oted that fo y recovery	hours* <1 5 50 100 / be exposed / less than 4 blates should anged as requ r grade A the of 1 cfu or gr	cfu/plate < 1 5 25 50 for less than hours the limit be exposed for ired after 4 h expected re eater should	4 hours. Where its in the table for the duration hours. sult should be 0 result in an	B C D を た ア た の 落 下 南 プレート き と。落 下 菌 ガレート き と。落 下 菌 ガレート き と。 落 下 黄 測 こ し ート れ た て た の ろ い で ト れ こ の ち で た い こ れ ち で し し ート れ た る 下 気 両 式 し ート れ こ る 下 て 南 す る て ら れ う こ の ち に う し し ト れ こ ろ 下 う し し ト れ こ ろ 下 う し し ート れ こ ろ 下 ち 朝 す る て ら れ う こ の ろ 下 ら れ う こ ろ 下 う し ート ろ こ ろ 下 う し 一ト ろ こ ろ 下 う し 一ト ろ こ ろ ち い し 一ト ろ こ ろ ち い う こ ろ こ ろ こ ろ ち い し し ート ろ こ ろ ち い こ ろ こ ろ こ ろ ち い こ ろ こ ろ ち い し 一 ち ら 「 ら こ ろ こ こ ろ こ こ こ ろ こ こ ろ こ こ ろ こ こ こ ろ こ ろ こ ろ こ ろ こ こ ろ こ こ こ ろ こ こ ろ こ ろ こ こ ろ ろ こ こ ろ こ ろ こ ろ こ ろ こ ろ こ こ こ ろ こ ろ こ ろ こ ろ こ ろ ろ ろ こ こ ろ こ ろ こ ろ ろ こ ろ ろ こ こ こ ろ こ ろ こ ろ ろ こ こ ろ こ ろ こ ろ こ こ ろ ろ こ こ こ ろ こ こ ろ こ ろ こ ろ こ ろ こ こ ろ こ ろ こ こ ろ こ ろ こ ろ こ ろ こ ろ こ ろ こ ろ こ ろ こ ろ ろ こ ろ ろ ろ こ ろ ろ ろ こ ろ ろ ろ こ ろ ろ ろ ろ ろ ろ ろ ろ ろ ろ ろ ろ ろ	10 100 200 菌測定用プレートは 定用プレートは こと。 区域についてに された場合は穿	<1 5 50 100 -トは4時間未 露する場合で 重要作業の間 は、期待される統 の間を行うこと。	<1 5 25 50 満の暴露でも 5表中の限度 結果は検出が(5 - - - - - - - - - - - - -		
* Ind settle shoul of cri ** It cfu re inves 4.60.	B C D ividual settle e plates are of ld still be use tical operations should be no ecovered; an stigation.	10 100 200 e plates may exposed for ed. Settle p ons and cha boted that for y recovery e alert and a	hours* <1 5 50 100 / be exposed / less than 4 h blates should anged as requir r grade A the	cfu/plate < 1 5 25 50 for less than hours the limit be exposed for ired after 4 hours expected re eater should should be de	4 hours. Where its in the table for the duration hours. Sult should be 0 result in an	B C D を 超々の落下 定用プレートな と。落下菌測 以降交換する ** グレードAI cfu以上検出す 4.60. 適切な	10 100 200 菌測定用プレ を4時間未満暴 定用プレートは こと。 区域については された場合は穿 アラート及びア	<1 5 50 100 ートは4時間未 露する場合です 重要作業の間 は、期待される約	<1 5 25 50 満の暴露でも 5表中の限度値 暴露し、必要に 結果は検出が(定すること。エ	 5 . .		
* Ind settle shoul of cri ** It cfu re inves 4.60. view proce	B C D D ividual settle e plates are o ld still be use itical operation should be no ecovered; an stigation. Appropriate to identify p ess, the alert	10 100 200 e plates may exposed for ed. Settle p ons and cha boted that fo ny recovery e alert and a otential cha t limits for g	hours* <1 5 50 100 / be exposed r less than 4 h blates should anged as requ r grade A the of 1 cfu or gr actions limits anges that ma grades B to D	cfu/plate < 1 5 25 50 for less than ours the limit be exposed f ired after 4 h expected re eater should should be de y be detrime should be low	4 hours. Where its in the table for the duration hours. sult should be 0 result in an fined. With a ntal to the wer than those	B C D D で た 用プレート を と。落下 意測 り 以 に 下 意 周プレート る と。落下 意 測 の 落下 た ま の 落下 た る 、 下 で し の ろ 下 で ま の ろ で の ろ 下 で る 、 下 で ま の ろ で の ろ 下 で あ で の ろ で し ート る さ る の ろ で し 一ト ろ こ の 下 ろ に 一 ド ろ し し 一ト ろ こ の ろ 下 ろ て し 一 ト ろ こ の ろ 下 ろ て し 一 ト ろ こ の ろ 下 ろ て し 一 ト ろ こ の ろ 下 ろ て し ろ 下 ろ ろ て ろ ろ て の ろ 下 ろ ろ て ろ の ろ て ろ ろ で ろ ろ て の ろ て の ろ て の ろ て の ろ て の ろ ろ の ろ ろ の ろ ろ ろ ろ	10 100 200 菌測定用プレートはこと。 室域については された場合は穿 アラート及びア 観点から、グレ た値よりも低い	<1 5 50 100 ートは4時間未 露する場合でも 重要作業の間 は、期待される緒 37 にの たた見から Dの 値であること、	<1 5 25 50 満の暴露でも」 5表中の限度値 暴露し、必要に 結果は検出が(定すること。エ アラート値は、 そしてその区域	 5 . .		
* Ind settle shoul of cri ** It cfu ro inves 4.60. view proce speci	B C D ividual settle e plates are o ld still be use itical operation should be no ecovered; an stigation. Appropriate to identify p ess, the alert ified as action	10 100 200 e plates may exposed for ed. Settle p ons and cha oted that for y recovery e alert and a otential cha t limits for g on limits and	hours* <1 5 50 100 / be exposed less than 4 h plates should anged as required r grade A the of 1 cfu or gr actions limits anges that ma grades B to D I should be ba	cfu/plate < 1 5 25 50 for less than ours the limit be exposed f ired after 4 H expected re eater should should be de y be detrime should be low sed on the a	4 hours. Where its in the table for the duration nours. sult should be 0 result in an fined. With a ntal to the wer than those rea performance.	B C D 個々の落下 プレートない と。落交換する ** グレードAI cfu以上検出さる 4.60.適切なご 4.62 次アクション くこと。アクション	10 100 200 菌測定用プレ を4時間未満暴 定用プレートは こと。 区域については タート及びアした 観点から、グレ た値を越えた	<1 5 50 100 ートは4時間未 露する場合で 重要作業の間 は、期待される お に明を行うこと。 クション値を規 レードBからDの	<1 5 25 50 満の暴露でも」 5表中の限度値 暴露し、必要に 結果は検出が(定すること。エ アラート値は、 そしてその区域	 5 . .		
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4.62. An essential part of contamination prevention is the adequate	4.62. 汚染防止の為に不可欠な部分は作業区域の適切な分離である。
separation of areas of operation. To maintain air quality, it is important	空気の質を維持するためには、清浄度の高い区域から隣接する清浄度
to achieve a proper airflow from areas of higher cleanliness to adjacent	のより低い区域への適切な気流を達成することが重要である。空気の清
less clean areas. It is fundamental for rooms of higher air cleanliness	浄度のより高い部屋が、隣接する清浄度のより低い部屋に対して実質
to have a substantial positive pressure differential relative to adjacent	的な陽圧の差圧であることが基本である。このような段階的な差圧を明
	確に規定し、適切な方法で連続的にモニターすること(例えばアラームを
clearly defined and continuously monitored with appropriate methods	設定して)。異なったグレードの隣接する部屋間は差圧を10-15Pa(ガイ
(e.g. alarm settings). Adjacent rooms of different grades should have a	ダンス値である)とすること。
pressure differential of 10-15 Pa (guidance values).	
4.63. However, negative pressure in specific areas may be required in	しかし、特定の区域では封じ込めの理由で陰圧が必要な場合がある(例
containment reasons (e.g. when replication competent vectors or	えば複製能力のあるベクター或いは病原性バクテリアを用いている場
pathogenic bacteria are used). In such cases, the negative pressure	合)。そのような場合、陰圧区域は適切なグレードの陽圧区域により囲ま
areas should be surrounded by a positive pressure clean area of	れていること。
appropriate grade.	
4.3.4. Drains	4.3.4. 排水設備
4.64. Drains should be of adequate size, and have trapped gullies.	4.64. 排水設備は適切なサイズで、トラップを設置したものであること。
Drainage systems must be designed so that effluents can be effectively	
neutralised or decontaminated to minimise the risk of cross-	的に中和或いは汚染除去し得るよう設計されなければならない。開放溝
contamination. Open channels should be avoided where possible, but if	は可能な場合は避けること、しかし必要な場合それらは清掃と消毒を行
necessary, they should be shallow to facilitate cleaning and disinfection.	いやすくするため浅いものであること。製造業者はバイオハザードの有
Manufacturers are reminded that, for risks relating to biohazard waste,	る廃水に関連するリスクに関して地元の規制に従う事を忘れないこと。
local regulations should be followed.	
4.65. Clean areas of grade A and B should not have sinks or drains	4.65. グレードA及びBの清浄区域は、流し或いは排水口を設置しないこ
installed.	と 。
4.4. Storage areas	4.4. 保管区域
4.66. Storage areas should be of sufficient capacity to allow orderly	4.66. 保管区域は種々の領域の原材料及び製品:出発物質及び原料、
storage of the various categories of materials and products: starting	包装資材、中間製品、バルク及び最終製品、判定待ち中の製品、出荷
and raw materials, packaging materials, intermediate, bulk and finished	可の判定がされた製品、不合格品、返品或いは回収品、の整然とした
products, products in quarantine, released, rejected, returned or	保管を可能とするために十分な収容容量があること。
4.67. Storage areas should be clean and dry and maintained within	4.67. 保管区域は清潔で乾燥しており、許容できる温度範囲内に維持す
acceptable temperature limits. Where special storage conditions are	ること。特別の保管条件が必要な場合(例えば温度、湿度)これらを規定
required (e.g. temperature, humidity) these should be specified and	しモニターすること。
monitored.	
4.68. Where quarantine status is ensured by storage in separate areas,	4.68. 判定待ちの状態が区分された区域に保管することにより保証され
these areas should be clearly marked and their access restricted to	る場合、これらの区域は明確にマークし、そこへのアクセスは許可され
authorised personnel. Any system replacing the physical quarantine	た者に制限すること。物理的な判定待ちの状態管理を代替する如何な
should give equivalent security.	るシステムも同等の安全性を提供するものであること。
Separated areas should be provided for the storage of recalled and	4.69. 回収及び返品された原材料/製品の管理が電子的な手段を通じて
returned materials/products, unless control of these	保証されるのではない限り、これらの保管の為に区分された区域が提供
materials/products is ensured through electronic means. Rejected	されること。不合格原材料/製品は規制された区域(例えば施錠)に保管
materials/products should be stored in restricted areas (e.g. locked).	すること。
4.70. Highly reactive materials/products should be stored in safe and	9.0000。 4.70.反応性が高い原料/製品は安全で保安された区域に保管するこ
secure areas.	
4.5. Quality control areas	
4.71. Quality control laboratories should be designed to suit the	4.71. 品質管理試験室はその中で実施される作業に適するよう設計され
operations to be carried out in them. Sufficient space should be given	たものであること。試験の過程での混同及びクロスコンタミを避けるため
to avoid mix-ups and cross-contamination during testing. There should	に十分なスペースを与えること。サンプル及び記録の保管の為に適切な
be adequate suitable storage space for samples and records.	スペースがあること。
4.72. Quality control laboratories should normally be separated from	
	4.72. 品質管理試験室は通常製造区域から分離されていること。しか
production areas. However, in-process controls may be carried out	し、工程内管理は製品に如何なるリスクももたらさない限り製造区域内
production areas. However, in-process controls may be carried out within the production area provided that they do not carry any risk for	
production areas. However, in-process controls may be carried out within the production area provided that they do not carry any risk for the products. Further details are available in Section 12.1.	し、工程内管理は製品に如何なるリスクももたらさない限り製造区域内 で実施しても良い。更なる詳細は12.1.章にて見ることが可能である。
production areas. However, in-process controls may be carried out within the production area provided that they do not carry any risk for the products. Further details are available in Section 12.1. 4.6. Ancillary areas	し、工程内管理は製品に如何なるリスクももたらさない限り製造区域内 で実施しても良い。更なる詳細は12.1.章にて見ることが可能である。 4.6. 補助区域
production areas. However, in-process controls may be carried out within the production area provided that they do not carry any risk for the products. Further details are available in Section 12.1. 4.6. Ancillary areas 4.73. Rest and refreshment rooms should be separate from production,	し、工程内管理は製品に如何なるリスクももたらさない限り製造区域内 で実施しても良い。更なる詳細は12.1.章にて見ることが可能である。 4.6. 補助区域 4.73. 休憩室は製造、保管及び品質管理区域から区分されていること。
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5.13. The location and installation of the equipment should be	5.13. 設備の配置と設置はエラー或いは汚染のリスクを最小限とするた
adequate to minimise risks of errors or contamination. Connections	めに適切であること。その後SIPによる滅菌を行わない限り、或いは接続
that are to be made in aseptic conditions should be performed in a	をバリデートされた無菌システムにより行うのでない限り(例えばチュー
critical clean area of grade A with a background clean area of grade B,	ブの無菌溶接機、滅菌したセプタム)無菌条件で行うべき接続はグレー
unless there is subsequent sterilisation by steam-in-place or the	ドBのバックグラウンド清浄区域を持つグレードAの重要清浄区域で実施
connection is made by means of a validated sterile system (e.g. sterile	すること。
tube welders, aseptic connection with a sterile septum).	
5.14. Balances and measurement equipment should be of appropriate	5.14. 秤及び計測設備は計測操作の精度を保証するため適切な計測範
range and precision to ensure the accuracy of weighing operations.	囲と精度のものであること。
5.15. Qualification of relevant equipment should be done in accordance	
with the principles in Section 10.1.	
5.16. Defective equipment should, if possible, be removed from	」こ。 15.16. 欠陥のある設備は可能であれば製造及び品質管理区域から撤去
production and quality control areas, or at least be clearly labelled as	するか、最低限、欠陥がある旨明確に表示すること。
5.2. Maintenance, cleaning, repair	5.2. メンテナンス、清掃、修理
5.17. Equipment should be adequately maintained:	5.17. 設備は適切に維持管理すること:
(i) Equipment should be calibrated, inspected or checked (as	(i) 設備は適切な能力を保証するため、決められた間隔で適宜キャリブ
appropriate) at defined intervals to ensure adequate performance. In	レートし、検査或いはチェックを行うこと。コンピュータ化システムの場
the case of computerised systems, the checks should include an	合、チェックはデータの完全性を保証するためのシステムの能力の評価
evaluation of the ability of the system to ensure data integrity.	を含むこと。これらのチェックの適切な記録を保存すること。
Appropriate records of those checks should be maintained.	
(ii) Air vent filters should be adequately qualified and maintained and	(ii) エアベントフィルターは適切に適格性確認し、メンテナンスすること、
should be changed at appropriate intervals (to be set according to the	そして(フィルターの重要度に応じて設定した)適切な間隔で交換するこ
criticality of the filter). Qualification can be done by the manufacturer,	と。適格性確認はフィルターの製造業者或いは供給業者/製造業者によ
or by the supplier/manufacturer of the filter. When replaced, the filter	るものでも良い。交換した際には、フィルターは完全性試験の対象とする
should be subject to an integrity test.	
5.18. Adequate cleaning and storage of the equipment is essential in	5.18. 設備の適切な清掃と保管は、製品の汚染のリスクを避けるため必
order to avoid the risk of contamination for the products. Whenever	須である。可能な限り、シングルユースの清掃用品を使用すること。製
possible, single-use cleaning materials should be used. The	品と接触する兼用設備に適用される清掃/除染工程は10.2章に述べら
cleaning/decontamination procedures applied to multi-use equipment	れているようにバリデートされること。
coming into contact with the product should be validated as explained	
in Section 10.2.	
5.19. Repair and maintenance operations should not present any hazard	5.19. 修理及びメンテナンス作業は製品品質に如何なる危害ももたらさ
to the quality of the products. As far as possible, maintenance and	ないものであること。可能な限り、メンテナンス及び修理作業は清浄区域
repair operations should be done outside the clean area. When repair or	外で行うこと。修理及び清掃作業が清浄区域内で行われた場合、製造
cleaning operations occur in a clean area, production should not be	はその区域が適切に清掃され、必要とされる環境状態が再確立された
restarted until it has been verified that the area has been adequately	ことが検証されるまで再開しないこと。
	ことが、彼血どれのなく、中間しない、こと。
cleaned and that the required environmental status has been re-	
5.20. Where required to minimise the risk of cross-contamination,	5.20. クロスコンタミのリスクを最小限とするために必要な場合設備の移
restrictions on the movement of equipment should be applied. In	動制限を適用すること。一般に設備はハイリスク区域から他の区域に、
general, equipment should not be moved from high risk areas to other	或いはハイリスク区域間で移動すべきでない(例えば、感染症のドナー
areas, or between high risk areas (e.g. equipment used for the handling	からの細胞の取り扱いに使用される設備或いは腫瘍溶解性ウイルスを
of cells from infected donors or the handling of oncolytic viruses).	取り扱う設備)。これを行う場合、クロスコンタミのリスクを避けるために
When this happens, appropriate measures need to be applied to avoid	適切な対策を適用する必要がある。移動した設備の適格性確認の状態
the risk of crosscontamination. The qualification status of the	を再度考慮すること。
equipment moved should also be reconsidered.	
6. Documentation	6. 文書化
6.1. General principles	6.1. 一般原則
6.10. Good documentation is an essential part of the quality system	6.10. 適切な文書化は品質保証システムに不可欠な部分であり、GMP
and is a key element of GMP. The main objective of the system of	の重要な要素である。適用する文書化のシステムの主要な目的は、医
documentation utilized must be to establish, control, monitor and	薬製品の品質に直接或いは間接に影響する全ての活動を確立し、管理
record all activities which directly or indirectly may affect the quality of	
the medicinal products. Records required to ensure traceability should	に必要な記録もまた残さなければならない。
6.11. There are two primary types of documentation relevant for the	6.11. 品質保証システムに関連した文書化には基本的に2つのタイプの
quality assurance system:	
specifications/instructions (including -as appropriate- technical	規格/指図(必要に応じて-技術的要求事項、手順書(SOP)、及び契約
requirements, standard operating procedures ("SOPs"), and contracts)	書を含む)及び記録/報告である。
and records/reports.	
6.12. Documentation may exist in a variety of forms, including paper-	6.12. 文書化は、紙ベース、電子的、写真媒体或いはビデオ録画を含め
based, electronic, photographic media or video recording.	て種々の形態がある。
6.13. Irrespective of the form in which data is kept, suitable controls	6.13. データを保管する形態に拘わらず、以下を含めてデータの完全性
should be implemented to ensure data integrity, including:	を保証するため適切な管理を実施すること
(i) Implementation of measures to protect data against accidental loss	(i) データを偶然のロス或いはダメージから保護するための対策の実施、
or damage, e.g. by methods such as duplication or back-up and transfer	
to another storage system.	間には、シェンク或にはハウシアリン、反び別の保留システムへの移置
(ii) Implementation of measures to protect the data against tampering	・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・
· · · · -	の対策の実施。コンピュータ化システムへのアクセスを、権限を有する者
in place to limit access to computerised system to authorised persons.	に限定するための物理的及び/又は論理的アクセス制限があること。シ
Suitable methods of preventing unauthorised entry to the system may	ステムへの権限無しのエントリーを防止するための適切な方法は、例え
include e.g. the use of keys, pass cards, personal codes with passwords,	
biometrics, or restricted access to computer equipment and data	ピュータ設備及びデータ保管区域への立ち入り制限等を用いることを含
storage areas. The extent of security controls depends on the	む。セキュリティ管理の程度はコンピュータ化システムの重要度に依存
criticality of the computerised system	する。
(iii) Implementation of measures to ensure the accuracy, completeness,	(iii) 文書の正確さ、完全性、利用可能性、及び判読性について、保管期
availability and legibility of documents throughout the retention period.	間を通して保証する対策を実施。
and regionery of documento en eugnout the recontion period.	
The content of documents should be unambiguous.	6.14. 文書の内容が曖昧でないこと。
The content of documents should be unambiguous. 6.15. Where different manufacturing steps are carried out at different	6.14. 文書の内容が曖昧でないこと。 6.15. 異なった製造工程が別の場所で別のQP(権限を有する者)の責任
The content of documents should be unambiguous. 6.15. Where different manufacturing steps are carried out at different locations under the responsibility of different QPs, it is acceptable to	6.14. 文書の内容が曖昧でないこと。 6.15. 異なった製造工程が別の場所で別のQP(権限を有する者)の責任の下で実施される場合、当該場所で行われる作業に関連する情報に限
The content of documents should be unambiguous. 6.15. Where different manufacturing steps are carried out at different locations under the responsibility of different QPs, it is acceptable to maintain separate files limited to information of relevance to the	6.14. 文書の内容が曖昧でないこと。 6.15. 異なった製造工程が別の場所で別のQP(権限を有する者)の責任
The content of documents should be unambiguous. 6.15. Where different manufacturing steps are carried out at different locations under the responsibility of different QPs, it is acceptable to	6.14. 文書の内容が曖昧でないこと。 6.15. 異なった製造工程が別の場所で別のQP(権限を有する者)の責任の下で実施される場合、当該場所で行われる作業に関連する情報に限

6.16. The specifications for the materials and the finished product and the manufacturing instructions are intended to ensure compliance with the terms of the marketing authorisation/clinical trial authorisation, product consistency (appropriate to the relevant stage of development), and the required level of quality. Therefore, it is important that specifications and instructions are documented appropriately and that they are clear and detailed enough.	6.16. 原材料及び最終製品の規格及び製造指図は販売承認/治験承認 の要件、製品の一貫性(開発の段階に対して適切な)、及び品質の要求 される水準、に適合することを保証することを意図している。従って、規 格及び指図は適切に文書化され、明確で充分に詳細であることが重要 である。
6.17. Documents containing specifications and instructions (including changes thereto) should be approved, signed and dated by authorised persons and the date of entry into operation should be defined. Steps should be taken to ensure that only the current version of a document is used.	6.17. 規格及び指図を含む文書は(それらに対する変更を含めて)権限 のある者により承認され、署名され、日付を入れること、そしてその発効 日を規定すること。その文書の最新版のみが使用されることを保証する ための手段を講じること。
6.18. Specifications and instructions should be periodically re- assessed during development and post-authorisation and be updated as necessary. Each new version should take into account the latest data, current technology used, as well as the terms of the marketing authorisation/clinical trial authorisation. It should also allow traceability to the previous document.	6.18. 規格と指図は開発中及び承認後に定期的に再評価し、必要に応 じてアップデートすること。各々の新版は販売承認/治験承認の要件と共 に最新のデータ、用いられている最新技術を考慮すること。また、旧版 の文書に対するトレーサビリティを与えるものであること。
6.19. Rationales for changes should be recorded and the consequences of a change on product quality, safety or efficacy and, where applicable, on any on-going non-clinical study or clinical trials should be investigated and documented. It is noted that changes to the manufacturing requirements approved as part of the marketing authorisation must be submitted to the competent authorities (variation procedure) ¹ , and that substantial modifications in the manufacturing process of an investigational ATMP also require approval by the	6.19. 変更についての理論的根拠を記録し、変更が製品品質、安全性 或いは有効性、又、該当する場合進行中の非臨床試験及び臨床試験に 対してどのような結果となったかを調査し、文書化すること。販売承認の 一部として承認された製造要件に対する変更は管轄当局に提出しなけ ればならず(変更手続き)、治験用ATMPの製造工程に対する実質的変 更も又管轄当局の承認を要することを留意すること。
6.20. As a minimum, the following should be documented:	6.20. 最低限以下を文書化すること:
(i) Specifications for raw materials, including: —Description of the raw materials, including reference to designated name and any other information required to avoid risks of error (e.g. use of internal codes). In addition, for raw materials of biological origin, the identification of the species and anatomical environment from which materials originate should also be described.	(i) 以下を含む原料の規格: 一所定の名称と間違い防止に必要なその他の情報(例えば、社内の
—For critical raw materials (e.g. sera, growth factors, enzymes (e.g. trypsin), cytokines), quality requirements to ensure suitability for intended use, as well as acceptance criteria (see Section 7.2). Quality requirements agreed with suppliers should be kept (expectations in the case of investigational ATMPs are explained in Section 7.2).	一重要原料については(例えば、血清、成長因子、酵素(例えばトリプシン)、サイトカイン)合格基準(7.2章参照)と共に、意図する用途に対する 適合性を保証するための品質要求事項。供給業者と合意した品質要求 事項を守ること(治験用ATMPの場合に期待される事項は7.2章に記述されている)。
—Instructions for sampling and testing, as appropriate (see Section 7.2, 12.2 and 12.3).	
	保管条件及び最大保管期間。
—Transport conditions and precautions.	ー運搬条件及び運搬上の注意事項。
(ii) Specifications for starting materials, including: —Description of the starting materials, including any relevant information required to avoid risks of error (e.g. use of internal codes). For starting materials of human origin, the identification of the supplier and the anatomical environment from which the cells/tissues/virus originate (or, as appropriate, the identification of the cell-line, master cell bank, seed lot) should also be described.	(iii) 以下を含む出発物質の規格 —エラーのリスクを避けるために必要な何らかの関連する情報(例えば 社内コードの使用)を含む出発物質の記述。ヒト起源の出発物質につい ては、供給業者及び細胞/組織/ウイルスが解剖学的環境のどこ由来か (或いは該当する場合セルライン、マスターセルバンク、シードロット)の 特定も記載すること。
 Quality requirements to ensure suitability for intended use, as well as acceptance criteria (see Section 7.3). Contracts and quality requirements agreed with the suppliers should be kept. 	—受け入れ基準(7.3章参照)と共に意図する用途への適合性を保証す るための品質要求事項。
 Instructions for sampling and testing (see Sections 7.3, 12.2 and —Storage conditions and maximum period of storage. 	―サンプリング及び試験の指図(7.3、12.2、12.3章参照)。 ―保管条件及び最大保管期間。
Transport conditions and precautions. (iii) Specifications for intermediate and bulk products should be available where applicable, including release criteria and maximum	 — 運搬条件及び運搬上の注意事項。
 (iv) Specifications for primary packaging materials, including release (v) Where applicable, specifications for other materials that are used in 	(iv) 一次包装資材についての使用可否判定基準を含めた規格。 (v) 該当する場合、製造工程で用いられ、品質に重大な影響を持つと考
the manufacturing process and that can have a critical impact on quality (e.g. medical devices used in a combined ATMP, materials and account of the second	えられるその他の原材料(例えば、併用ATMP中で用いられる医療機器、モノクローナル抗体でコーティングした皿或いはビーズのように細胞しい影響)得るた物活性を中たする原材料及び消耗日)の規格
consumables that have an inherent biological activity through which they can impact cells, such as mAb coated dishes or beads). (vi) Batch definition. Products generated from different starting	に影響し得る生物活性を内在する原材料及び消耗品)の規格。 (vi) バッチの定義。異なった出発物質から製造された製品は別個のバッ
(vii) Manufacturing instructions (including description of principal	(vii) 製造指図(使用する主要な設備の記述を含む)及び工程内管理。
equipment to be used) and in-process controls. (viii) Specifications for finished products, in particular:	(viii) 以下を含む最終製品の規格
-Name/identification of the product.	
—Description of the pharmaceutical form.	一剤形の記述
 Instructions for sampling and testing (see Sections 12.2 and 12.3). Qualitative and quantitative requirements with acceptance limits. Storage and transport conditions and precautions. Where applicable, particular attention should be paid to the requirements at cryopreservation stage (e.g. rate of temperature change during freezing or thawing) to ensure the quality of the product. The shelf-life. 	 サンプリング及び試験の指図(12.2及び12.3章参照) 許容限界を伴った定性的及び定量的要求事項。 一保管及び運搬条件及び注意事項。該当する場合、製品品質を保証する為、凍結保存の段階において要求事項(例えば、凍結中或いは解凍中の温度変化率)に特に注意を払うこと。 一有効期間
	(ix)該当する場合、製品の出荷可否判定の前に出発物質、中間製品、

(x) Packaging instructions for each product. Particular attention should be paid to ensuring the traceability of the product. It is noted that, for authorised ATMPs, the donation identification code received from the tissue establishment/blood establishment should be included in the outer packaging or, where there is no outer packaging, on the immediate packaging. Other labelling requirements are laid down in	(x)各製品についての包装指図。製品のトレーサビリティを保証する為に 特に注意を払うこと。承認されたATMPについて、組織施設/血液施設か ら受領した提供識別コードを外側包装或いは外側包装が無い場合直接 包装に含めること。その他の表示要求項目はRegulation (EC)No 1394/2007の第11条及び12条に規定されている。(その他現地の法規 制の表示要求項目に従う事)
Articles 11 and 12 of Regulation (EC) No 1394/2007.	
Investigational ATMPs: the Product Specification File	<u>治験用ATMP:製品規格ファイル</u>
6.21. In the case of investigational ATMPs, the level of detail of the specifications and instructions should be adapted to the type of product and to the stage of development. Given the evolution/refinement of the manufacturing process and quality controls that is typical of investigational products, it is important that the level of documentation is sufficient to enable the identification of the specific characteristics of each batch. It is also noted that a deficient characterisation of the product may hinder the acceptability of the results of the clinical trial for the purposes of obtaining a marketing	6.21. 治験用ATMPの場合、規格及び指図の詳細さの水準は製品のタイ プと開発の段階に適合させること。治験用製品において典型的である製 造工程の進展/改良を考慮に入れて、文書化の水準は各バッチの特性 を特定することを可能とするために十分であることが重要である。製品 の特性の記述に欠陥があるならば販売承認を得る目的の臨床試験の 結果の受け入れを阻害することに留意すること。
6.22. In addition to the specifications and instructions, where products	6.22. 製品が盲検試験用の場合、規格及び指図に加え、製品規格ファイ
are blinded, the Product Specification File should contain appropriate documentation of the system used to ensure the blinding. Such system should ensure that the blinding is achieved and maintained, while allowing for identification of the product when necessary. The effectiveness of the blinding procedures should be verified.	ルは盲検を保証する為に用いられたシステムの適切な文書化を含むこと。そのようなシステムは、必要な場合に製品の被検薬か対照薬かの確認を可能とするが、盲検を達成し維持することを保証すること。盲検の手順の有効性を検証すること。
6.23. A copy of the manufacturing order and a copy of the approved	6.23. 製造指示及び承認されたラベルのコピーも又製品規格ファイルの
label should also be kept as part of the Product Specification File. As the Product Specification File is typically subject to changes, particular attention should be paid in the manufacturing order to the identification of the version that the manufacturer should adhere to.	ー部として保管すること。製品規格ファイルは、典型的には変更されるものであるため、製造指示において製造業者が従うべき版の特定に特段の注意を払うこと。
6.24. The information contained in the Product Specification File should	6.24. 製品規格ファイルに含まれる情報は特定のバッチのQPによる証明
form the basis for assessment of the suitability for certification and	と出荷可否判定のための適合性評価の根拠となるべきものであり、その
release of a particular batch by the QP and should therefore be	ために彼/彼女にとってアクセス可能であるべきものである。
accessible to him/her.	
6.3. Records/reports	6.3. 記録/報告
6.25. Records provide evidence that the relevant	6.25. 記録は該当する規格/指図が遵守されたことを示すエビデンスを 提供する。記録は各作業を行った時に作成或いは記入を済ませること。
specifications/instructions have been complied with. Records should be	症状9 る。記録は谷作来を打つた時に作成或いな記入を済ませること。 記録への如何なる変更も権限を持った者により承認・署名を受け日付を
made or completed at the time each action is taken. Any change to a	記録への如何なる変更も権限を持つに有により承認・者名を受けて下を 記載すること。
record should be approved, signed and dated by authorised persons. 6.26. The level of documentation will vary depending on the product	記載9つここ。 6.26. 文書化の水準は製品及び開発の段階によって異なる。記録は一
and stage of development. The records should enable the entire history	0.20. 文書化の小竿は装品及び開光の段階によりて異なる。記録は一つのバッチについての全履歴をトレースできるものであること。更に、記
of a batch to be traced. Additionally, the records/reports should form	録/報告は或るバッチの証明及び出荷判定についての適合性を評価す
the basis for assessment of the suitability for certification and release	るための基となるものである。最低限以下を文書化すること:
of a particular batch. As a minimum, the following should be	
(i) Receipt records for each delivery of raw materials, starting material,	(i) 直接包装材料と共に原料、出発物質、バルク製品、中間製品、の配
bulk, intermediate as well as primary packaging materials. The receipt	送毎の受領記録。受領記録は以下を含むこと:
records should include:	
-name of the material on the delivery note and the containers as well	—何らかの社内名称及び社内コードと共にその物質の配送票及び包装
as any "inhouse name" and or internal code if appropriate;	容器に記載されている物質名
—supplier's name and manufacturer's name;	供給業者名及び製造業者名
—supplier's batch or reference number;	供給業者のバッチ或いは参照番号
	<u></u>
— date of receipt;	
—unique receipt number assigned after receipt; and any relevant comment.	—受領後に指定した固有の受領番号;及び何らかの関連するコメント。
	(ii) バッチ加工記録は加工された各バッチについて保持すること;それは 以下の情報を含むこと:
—name of the product and batch number;	―製品名及びバッチナンバー
-dates and times of commencement, of critical intermediate stages,	―製造開始、重要な中間段階、及び完了の日付及び時間;
and of completion of production;	
-quantities and batch number of each starting material;	―各出発原料の量及びバッチナンバー; 素素な原料の量及びバッチナンバー;
-quantities and batch number of critical raw materials;	<u>一重要な原料の量及びバッチナンバー;</u> 該当まる場合、制造工程で使用され、日質に重要な影響がある他の
—where applicable, quantities and batch number of other materials that are used in the manufacturing process and that can have a critical	該当する場合、製造工程で使用され、品質に重要な影響がある他の 原材料の量とバッチナンバー(例えば併用ATMPで使用される医療機
impact on quality, (e.g. medical devices used in a combined ATMP,	器、モノクローナル抗体でコーティングした皿或いはビーズのような細胞
materials and consumables that have an inherent biological activity	に影響を与え得る内在する生物活性を持つ原料或いは消耗品);
through which they can impact cells, such as mAb coated dishes or	
-confirmation that line-clearance has been performed prior to starting	―製造作業開始に先立ってラインクリアランスを実施したことの確認;
some matine of a and the order and the been performed prior to starting	一表迫作未開始にルエラ(ノインクリアノンへを失心したことの確認。
manufacturing operations;	
manufacturing operations; —identification (e.g. by means of initials or another suitable system) of	
manufacturing operations; —identification (e.g. by means of initials or another suitable system) of the operator who performed each significant step and, where	
manufacturing operations; —identification (e.g. by means of initials or another suitable system) of the operator who performed each significant step and, where appropriate, of the person that checked these operations;	—各重要段階を実施した作業員が誰であるかの確認(例えばイニシャ ル或いは他の適切なシステムによる)及び必要に応じてこれらの作業を チェックした者が誰であるかの確認
manufacturing operations; —identification (e.g. by means of initials or another suitable system) of the operator who performed each significant step and, where appropriate, of the person that checked these operations; —a record of the in-process controls;	一各重要段階を実施した作業員が誰であるかの確認(例えばイニシャル或いは他の適切なシステムによる)及び必要に応じてこれらの作業を チェックした者が誰であるかの確認 ー工程管理の記録;
manufacturing operations; —identification (e.g. by means of initials or another suitable system) of the operator who performed each significant step and, where appropriate, of the person that checked these operations; —a record of the in-process controls; —identification of clean room and major equipment used;	 一各重要段階を実施した作業員が誰であるかの確認(例えばイニシャル或いは他の適切なシステムによる)及び必要に応じてこれらの作業を チェックした者が誰であるかの確認 一工程管理の記録; 一使用したクリーンルーム及び主要な設備がどれであるかの確認;
manufacturing operations; —identification (e.g. by means of initials or another suitable system) of the operator who performed each significant step and, where appropriate, of the person that checked these operations; —a record of the in-process controls; —identification of clean room and major equipment used; — the product yield obtained at relevant stages of manufacture; and	 一各重要段階を実施した作業員が誰であるかの確認(例えばイニシャル或いは他の適切なシステムによる)及び必要に応じてこれらの作業をチェックした者が誰であるかの確認 一工程管理の記録: 一使用したクリーンルーム及び主要な設備がどれであるかの確認: 一製造の適切な段階での製品収量;及び
manufacturing operations; —identification (e.g. by means of initials or another suitable system) of the operator who performed each significant step and, where appropriate, of the person that checked these operations; —a record of the in-process controls; —identification of clean room and major equipment used; — the product yield obtained at relevant stages of manufacture; and —notes on special problems including details, with signed authorisation	 一各重要段階を実施した作業員が誰であるかの確認(例えばイニシャル或いは他の適切なシステムによる)及び必要に応じてこれらの作業を チェックした者が誰であるかの確認 一工程管理の記録: 一使用したクリーンルーム及び主要な設備がどれであるかの確認: 一製造の適切な段階での製品収量:及び 一製造指図からの如何なる逸脱に関しても署名入りの承認と共に詳細
manufacturing operations; —identification (e.g. by means of initials or another suitable system) of the operator who performed each significant step and, where appropriate, of the person that checked these operations; —a record of the in-process controls; —identification of clean room and major equipment used; — the product yield obtained at relevant stages of manufacture; and —notes on special problems including details, with signed authorisation for any deviation from the manufacturing instructions.	 一各重要段階を実施した作業員が誰であるかの確認(例えばイニシャル或いは他の適切なシステムによる)及び必要に応じてこれらの作業を チェックした者が誰であるかの確認 一工程管理の記録: 一使用したクリーンルーム及び主要な設備がどれであるかの確認: 一製造の適切な段階での製品収量:及び 一製造指図からの如何なる逸脱に関しても署名入りの承認と共に詳細を含めて特別な問題点についての注記。
 manufacturing operations; identification (e.g. by means of initials or another suitable system) of the operator who performed each significant step and, where appropriate, of the person that checked these operations; a record of the in-process controls; identification of clean room and major equipment used; the product yield obtained at relevant stages of manufacture; and motes on special problems including details, with signed authorisation for any deviation from the manufacturing instructions. (iii) Results of release testing. 	 一各重要段階を実施した作業員が誰であるかの確認(例えばイニシャル或いは他の適切なシステムによる)及び必要に応じてこれらの作業を チェックした者が誰であるかの確認 一工程管理の記録: 一使用したクリーンルーム及び主要な設備がどれであるかの確認: 一製造の適切な段階での製品収量:及び 一製造指図からの如何なる逸脱に関しても署名入りの承認と共に詳細 を含めて特別な問題点についての注記。 (iii) 出荷試験の結果
 manufacturing operations; identification (e.g. by means of initials or another suitable system) of the operator who performed each significant step and, where appropriate, of the person that checked these operations; a record of the in-process controls; identification of clean room and major equipment used; the product yield obtained at relevant stages of manufacture; and motors on special problems including details, with signed authorisation for any deviation from the manufacturing instructions. (iii) Results of release testing. (iv) Environmental monitoring records. 	 一各重要段階を実施した作業員が誰であるかの確認(例えばイニシャル或いは他の適切なシステムによる)及び必要に応じてこれらの作業をチェックした者が誰であるかの確認 一工程管理の記録: 一使用したクリーンルーム及び主要な設備がどれであるかの確認: 一製造の適切な段階での製品収量:及び 一製造指図からの如何なる逸脱に関しても署名入りの承認と共に詳細を含めて特別な問題点についての注記。 (iii) 出荷試験の結果 (iv) 環境モニタリング記録
manufacturing operations; —identification (e.g. by means of initials or another suitable system) of the operator who performed each significant step and, where appropriate, of the person that checked these operations; —a record of the in-process controls; —identification of clean room and major equipment used; — the product yield obtained at relevant stages of manufacture; and —notes on special problems including details, with signed authorisation for any deviation from the manufacturing instructions. (iii) Results of release testing.	 一各重要段階を実施した作業員が誰であるかの確認(例えばイニシャル或いは他の適切なシステムによる)及び必要に応じてこれらの作業を チェックした者が誰であるかの確認 一工程管理の記録: 一使用したクリーンルーム及び主要な設備がどれであるかの確認: 一製造の適切な段階での製品収量:及び 一製造指図からの如何なる逸脱に関しても署名入りの承認と共に詳細 を含めて特別な問題点についての注記。 (iii) 出荷試験の結果

(vi) Outcome of self-inspections should be recorded. Reports should	(vi)自己点検の結果を記録すること。報告書は点検中に行われた全て
contain all the observations made during the inspections and, where	の指摘及び、該当する場合、全ての是正処置の提案を含むこと。その後
applicable, proposals for corrective measures. Statements on the	取られた対策についての記述も又記録すること。
actions subsequently taken should also be recorded.	
6.27. Any deviations should be recorded and investigated, and	6.27. 如何なる逸脱も記録し、究明されること、又適切な是正処置をとる
appropriate corrective measures should be taken.	こと。
6.4. Other documentation	6.4. 他の文書化
6.28. There should be appropriate documentation of policies and	6.28. 製品品質を守る観点から製造業者により適用されるべき方針及
procedures to be applied by the manufacturer with a view to safeguard	び手順について以下を含む適切な文書化を行うこと:
the quality of the product, including:	
(i) Qualification of premises and equipment.	(i) 構造設備の適格性確認・
	(ii) 製造工程バリデーション(治験用ATMPに関して期待される事項は
(ii) Validation of manufacturing process (the expectations for	
investigational ATMPs are described in Section 10.3).	10.3章に記載されている)。
(iii) Validation of relevant analytical methods.	(iii) 関連する分析法のバリデーション
(iv) Maintenance and calibration of equipment.	(iv)設備の維持管理及びキャリブレーション。
(v) Cleaning procedures.	<u>(v)洗浄手順。</u>
(vi) Environmental monitoring.	(vi) 環境モニタリング。
(vii) Investigations into deviations and non-conformances.	(vii) 逸脱及び不適合への究明。
(viii) Procedures for handling of quality complaints and recall of	(viii)品質に関する苦情及び製品回収の取り扱い手順。
6.29. Logbooks should be kept for equipment used for critical	6.29. 重要な製造及び試験操作に使用する設備のログブックを保持する
manufacturing and testing operations.	
	。 6.30. 上記の方針及び手順の文書化は開発の段階により調整すること。
be adjusted to the stage of development. The documentation for phase	
I and I/II clinical trials can be more limited but it is expected that it	得るが、より後期の開発段階ではより包括的になることが期待される。
becomes more comprehensive in later phases of development.	
6.31. A site master file should be prepared for every site involved in	6.31. 承認されたATMPの製造に関与する製造所毎にサイトマスターファ
manufacturing of authorised ATMPs. The site master file should provide	
a high level description of the premises, activities conducted at the site	される業務及び実施している品質システムについての高いレベルの記
and of the quality system implemented.	述を提供するものであること。
6.5. Retention of documents	6.5. 文書の保管
6.32. Without prejudice to Section 6.6, batch documentation (i.e.	6.32.6.6章の規定を損なう事なしに、バッチ文書(即ち、該当する場合製
documents in the batch processing record, results of release testing,	品に関連する逸脱についての何らかのデータと共に、バッチ加工記録、
	出荷試験の結果の文書)は当該バッチが関連するバッチの有効期限後
as well as -where applicable- any data on product related deviations)	
should be kept for one year after expiry of the batch to which it relates	
or at least five years after certification of the batch by the QP,	の期間保管すること。治験薬に関しては、バッチ文書は当該バッチが使
whichever is the longest. For investigational medicinal products, the	用された最後の臨床試験の完了あるいは正式な中止から最低5年保管
batch documentation must be kept for at least five years after the	しなければならない。
completion or formal discontinuation of the last clinical trial in which	
6.33. It is acceptable that some of the data pertaining to the batch	6.33. バッチ文書に付属するデータの或るものについては、それらが容
documentation is kept in a separate file, provided that they are readily	易に入手可能で明確に関連するバッチに連結しているならば、別ファイ
available and are unequivocally linked to the relevant batch.	ルで保管することが許容される。
6.34. Critical documentation, including raw data (for example relating to	
validation or stability) that supports information in the marketing	(例えばバリデーション或いは安定性に関連するデータ)は承認が有効
authorisation, should be retained whilst the authorization remains in	な間保持すること。しかし、データが新たなフルセットのデータにより置き
force. However, it is acceptable to retire certain documentation (e.g.	換えられたある種の文書化(例えばバリデーション報告或いは安定性報
raw data supporting validation reports or stability reports) where the	告を裏付ける生データ)を保存文書から除くことは許容される。これに関
data has been superseded by a full set of new data. Justification for	する妥当性の説明を文書化し、バッチ文書の保持に関する要求事項を
this should be documented and should take into account the	考慮すること。
requirements for retention of batch documentation.	
6.6. Traceability data	6.6. トレーサビリティに関するデータ
	6.35. ATMPに含まれる細胞/組織の提供の時点から製造を経て最終製
contained in ATMPs from the point of donation, through manufacturing,	品の投与を受ける人への配送までについて双方向からの追跡を可能と
to the delivery of the finished product to the recipient should be	するシステムを作り上げること。そのようなシステムはマニュアルでも電
created. Such system, which can be manual or electronic, should be	子的でも良いが、臨床使用の為のバッチの製造の開始時点から確立す
	一日の一日の一日の一日の一日の一日の一日の一日の一日の一日の一日の一日の一日の一
established since the beginning of the manufacture of batches for	
6.36. In accordance with Article 15 of Regulation 1394/2007,	6.36. 欧州Regulation1394/2007の第15条(製造所及び製品の市場の現)
traceability information should also cover raw materials and all	地の法規制)に従って、トレーサビリティの情報は細胞或いは組織と接
-	触する原料及び全ての物質もカバーするものであること。本章はATMP
describes the type and amount of data that must be generated and	の製造業者により作成し保持されなければならないデータのタイプと量
kept by manufacturers of ATMPs.	を記載する。
6.37. The manufacturer should ensure that the following data is	製造業者は以下のデータについて、より長い期間が販売承認で規定さ
retained for a minimum of 30 years after the expiry date of the product,	
unless a longer period is provided for in the marketing authorisation:	証すること:
(i) Donation identification code received from the tissue	(i) 組織施設/血液施設から受領した提供の確認コード。例えばEU圏外
establishment/blood establishment. For cells and tissues that are not	で確立されたセルライン或いはセルバンクのような、
	C確立されたビルションスはなどかパンシのような、 Directive2004/23/EC或いはDirective2002/98/ECではカバーされてい
e.g. cell-lines or cell-banks established outside the EU, information	ない細胞及び組織に関しては、ドナーの確認に関する情報を保持する
permitting the identification of the donor should be kept.	
(ii) Internal code (or other identification system) that is generated by	(ii) 出発物質として用いられた組織/細胞をバッチの出荷可否判定の時
(ii) Internal code (or other identification system) that is generated by the manufacturer to unequivocally identify the tissues/cells used as	(ii) 出発物質として用いられた組織/細胞をバッチの出荷可否判定の時 点までの製造工程の全体を通じて明確に確認するために製造業者によ
	(ii) 出発物質として用いられた組織/細胞をバッチの出荷可否判定の時
the manufacturer to unequivocally identify the tissues/cells used as	(ii) 出発物質として用いられた組織/細胞をバッチの出荷可否判定の時 点までの製造工程の全体を通じて明確に確認するために製造業者によ り付けられた社内コード(或いは他の確認システム)。製造業者は社内
the manufacturer to unequivocally identify the tissues/cells used as starting materials throughout the entire manufacturing process up to the point of batch release. The manufacturer must ensure that the link	(ii) 出発物質として用いられた組織/細胞をバッチの出荷可否判定の時 点までの製造工程の全体を通じて明確に確認するために製造業者によ り付けられた社内コード(或いは他の確認システム)。製造業者は社内 コードと提供確認コードとの連結が常に確立されていることを保証しなけ
the manufacturer to unequivocally identify the tissues/cells used as starting materials throughout the entire manufacturing process up to the point of batch release. The manufacturer must ensure that the link between the internal code and the donation identification code can	(ii) 出発物質として用いられた組織/細胞をバッチの出荷可否判定の時 点までの製造工程の全体を通じて明確に確認するために製造業者によ り付けられた社内コード(或いは他の確認システム)。製造業者は社内 コードと提供確認コードとの連結が常に確立されていることを保証しなけ ればならない。Directive2004/23/EC或いはDirective2002/98/ECではカ
the manufacturer to unequivocally identify the tissues/cells used as starting materials throughout the entire manufacturing process up to the point of batch release. The manufacturer must ensure that the link between the internal code and the donation identification code can always be established. For starting materials not covered by Directive	(ii) 出発物質として用いられた組織/細胞をバッチの出荷可否判定の時 点までの製造工程の全体を通じて明確に確認するために製造業者によ り付けられた社内コード(或いは他の確認システム)。製造業者は社内 コードと提供確認コードとの連結が常に確立されていることを保証しなけ ればならない。Directive2004/23/EC或いはDirective2002/98/ECではカ バーされていない出発物質に関しては、社内コードとドナー確認コードと
the manufacturer to unequivocally identify the tissues/cells used as starting materials throughout the entire manufacturing process up to the point of batch release. The manufacturer must ensure that the link between the internal code and the donation identification code can	(ii) 出発物質として用いられた組織/細胞をバッチの出荷可否判定の時 点までの製造工程の全体を通じて明確に確認するために製造業者によ り付けられた社内コード(或いは他の確認システム)。製造業者は社内 コードと提供確認コードとの連結が常に確立されていることを保証しなけ ればならない。Directive2004/23/EC或いはDirective2002/98/ECではカ

(iii) Identification (including batch number) of critical raw materials and other substances that come into contact with the cells or tissues used as starting materials that may have a significant impact on the safety of the finished ATMP (e.g. reagents of biological origin, scaffolds, matrixes). For biological materials, the identification of the supplier, species and anatomical environment from which materials originate should also be described.	(iii) 重要原料及び最終製品のATMPの安全性に有意な影響がある可能 性のある、出発物質として用いられた細胞或いは組織と接触する、他の 物質(例えば生物由来の試薬、足場となる担体、マトリックス)の確認 (バッチナンバーを含む)。生物学的物質に関しては、供給業者の確認、 その物質の起源となった種及び解剖学的環境も又記載すること。
 (iv) Where applicable, identification (including batch number) of all other active substances that are contained in the ATMPs. 6.38. When xenogeneic cells are used as starting materials for ATMPs, information permitting the identification of the donor animal should be 	 (iv)該当する場合、ATMPに含有されている他の全ての活性物質の確認 (バッチナンバーを含めて)。 6.38. 異種動物の細胞がATMPの出発物質として用いられている場合、 ドナー動物の確認を含む情報を30年間保持すること。
kept for 30 years. 6.39. Traceability data should be kept as auditable documents. It is acceptable that it is kept outside the batch processing record, provided that they are readily available and are unequivocally linked to the relevant medicinal product. The storage system should ensure that traceability data may be accessed rapidly in case of an adverse	6.39. トレーサビリティデータは監査可能な文書として保持すること。それ をバッチ加工記録と別に保持することは、容易に見ることが出来、該当 する医薬品と明確に連結しているならば許容できる。保管システムは患 者に副作用があった場合トレーサビリティデータが速やかにアクセスで きることを保証するものであること。
6.40. By means of a written agreement, the responsibility for the retention of the traceability data may be transferred to the marketing authorisation holder/sponsor.	6.40. 文書化した契約によって、トレーサビリティデータの保管の責任を 販売承認保持者/治験のスポンサーに移管しても良い。
7. Starting and raw materials 7.1 General principles	<u>7. 出発物質及び原料</u> 7.1 一般原則
7.10. The quality of starting and raw materials is a key factor to consider in the production of ATMPs. Particular attention should be paid to avoiding contamination and to minimising as much as possible the variability of the starting and raw materials. Specifications related to the product (such as those in Pharmacopoeia monographs, marketing/clinical trial authorisation), will dictate whether and to what stage substances and materials can have a defined level of bioburden or need to be sterile. Prior to introduction in the manufacturing	7.10.出発物質及び原料の品質はATMPの製造において考慮すべき主要な要因である。出発物質及び原料の汚染を避け、変動をできる限り最 小限とするために特別の注意を払うこと。製品に関連する規格(例えば 局方のモノグラフ、販売/治験承認、におけるもの)は、使用する物質及 び原料が規定されたバイオバーデンの水準にあるか否か、無菌である 必要があるか否か、又どの段階までにそうなるべきかを示している。製 造工程に投入する前に関連する要求事項への適合性をチェックするこ と。
process, the conformity to the relevant requirements should be 7.11. The use of antimicrobials may be necessary to reduce bioburden associated with the procurement of living tissues and cells. However, it is stressed that the use of antimicrobials does not replace the requirement for aseptic manufacturing. When antimicrobials are used, they should be removed as soon as possible, unless the presence thereof in the finished product is specifically foreseen in the marketing authorisation/clinical trials authorisation (e.g. antibiotics that are part of the matrix of the finished product). Additionally, it is important to ensure that antibiotics or antimicrobials do not interfere with the sterility testing, and that they are not present in the finished product	7.11. 生きている組織及び細胞の調達に伴うバイオバーデンを低減す るために抗生物質の使用が必要な場合がある。しかし、抗生物質の使 用は無菌製造の必要性を代替するものでないことが強調される。抗生 物質が用いられた場合、最終製品中に存在する事が販売承認/治験承 認において特に予見される(例えば最終製品の母材の一部である抗生 物質)のでない限り、可能な限り速やかに除去されるべきである。更に、 抗生物質或いは抗菌剤は無菌試験を阻害しないことと、(販売承認/治 験承認において特に予見されるのでない限り)最終製品に存在しないこ とを保証することが重要である。
(unless specifically foreseen in the marketing authorisation/clinical trial	
7.2. Raw Materials 7.12. Raw materials should be of suitable quality having regard to the intended use. In particular, the growth promoting properties of culture media should be demonstrated to be suitable for its intended use.	7.2. 原料 7.12. 原料は意図する用途を考慮して適切な品質であること。特に、培 地の生育促進作用は意図した用途に適したものであることを示すこと。
7.13. As far as possible, raw materials used in the manufacturing of ATMPs should take into consideration the Ph. Eur 5.2.12 general chapter on raw materials of biological origin for the production of cell based and gene therapy medicinal products. While raw materials should	7.13. 可能な限り、ATMPの製造に用いられる原料はPh. Eur 5.2.12 general chapter on raw materials of biological origin for the production of cell based and gene therapy medicinal productsを考慮すること。原料 は医薬品のグレードであるべきであるが、或る場合には研究用のグレー ドしか入手できない場合があることは認められる。研究グレードの原料を 使用することのリスクを理解すること(より多くの量の製品が製造される 際の供給の継続性に対するリスクを含めて)。更に、そのような原料の 意図した用途に対する適切性を、該当する場合は試験することにより (例えば機能試験、安全性試験)保証すること。
7.14. Specifications for raw materials should be set as explained in Section 6.2. In the case of critical raw materials, the specifications should include quality requirements to ensure suitability for the intended use, as well as the acceptance criteria. For authorised ATMPs, these quality requirements should be agreed with the supplier(s) ("agreed specifications"). For investigational ATMPs, the technical specifications for the critical raw materials should be agreed with the suppliers whenever possible. The assessment whether a specific raw materials is critical should be done by the manufacturer (or, as appropriate, the sponsor or marketing authorisation holder) having regard to the specifications should cover aspects of the production, testing and control, and other aspects of handling and distribution as appropriate. The specifications set should be in compliance with the terms of the marketing authorisation or clinical	7.14. 原料の規格を6.2章で述べられているように設定すること。重要原 料の場合、規格は受け入れ基準と共に意図した用途への適合性を保証 する品質要求事項を含むこと。承認されたATMPの場合これらの品質要 求事項は供給業者と合意されたものであること(合意規格)。治験用 ATMPに関しては、重要原料の技術的規格は可能な限り供給業者と合 意されたものであること。特定の原料が重要であるか否かの評価はその 物のリスクを考慮して製造業者(或いは、場合により治験のスポンサー 或いは販売承認保持者)により行われること。行われた決定は文書化す ること。合意規格は製造の特徴、試験管理の特徴、その他、適切な流通 や取扱いの特徴等をすべてカバーすること。これら規格は販売承認・治 験承認に適合していること。

7.15. The ATMP manufacturer should verify compliance of the supplier's materials with the agreed specifications. The level of supervision and further testing by the ATMP manufacturer should be proportionate to the risks posed by the individual materials. Reliance on the certificate of analysis of the supplier is acceptable if all the risks are duly understood and measures are put in place to eliminate the risks or mitigate them to an acceptable level (e.g. qualification of suppliers). For raw materials that are authorised as medicinal products in the EU (e.g. cytokines, human serum albumin, recombinant proteins)	7.15. ATMP製造業者は供給業者の原材料の、合意した規格への適合 性を検証すること。ATMP製造業者による管理及び更なる試験の水準は 個々の原材料によりもたらされるリスクに比例するものであること。供給 業者の試験成績表に依存することは、全てのリスクが然るべく理解さ れ、全てのリスクを除去するか許容できる水準まで低減するための対策 (例えば、供給業者の適格性確認)が立てられているならば許容できる。 EUにおいて医薬品として承認されている原料(例えば、サイトカイン、ヒト 血清アルブミン、遺伝子組み換えタンパク)に関しては供給業者の試験 成績表は必要とされない。入手可能な場合は承認された医薬品の使用
the certificate of analysis of the supplier is not required. Where	が勧められる。
available, the use of authorised medicinal products is encouraged. 7.16. The risk of contamination of raw materials of biological origin during their passage along the supply chain must be assessed, with particular emphasis on viral and microbial safety and Transmissible Spongiform Encephalopathy ("TSE"). Compliance with the latest version of the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy (TSE) Agents via Human and Veterinary Medicinal Products is required. Where there is a potential mycoplasma contamination risk associated with a raw material, the ATMP manufacturer should filter the material prior to use (0.1 μ m filter), unless the supplier of the raw material has certified that the raw	製品の市場、治験施設の現地のウイルス、微生物、TSE安全性に関す る法規制)の最新版の遵守が必要である。原料に伴うマイコプラズマ汚 染のリスクの可能性がある場合、ATMP製造業者は、その原料は試験さ れておりマイコプラズマが存在しないということを原料の供給業者が証 明しない限り、その原料を使用前に(0.1 μ m filterで)ろ過すること。
7.17. The risk of contamination from other materials that come into direct contact with manufacturing equipment or the product (such as media used for process simulation tests and lubricants that may contact the product) should also be taken into account.	7.17. 製造設備或いは製品と直接接触する他の原料(例えば培地充填 試験に使用される培地及び製品と接触する可能性がある潤滑剤)から の汚染のリスクも考慮すること。
7.18. Raw materials in the storage area should be appropriately labelled. Labels for critical raw materials should bear at least the following information:	7.18. 保管区域にある原料は適切に表示すること。重要原料の表示は 少なくとも以下の情報を含むこと:
(i) the designated name of the product and the internal code reference (if applicable);	(i) 製品の名称及び(該当する場合) 社内のコード;
(ii) a batch number given at receipt;	(ii) 受領時付けられたバッチナンバー;
 (iii) storage conditions; (iv) the status of the contents (e.g. in quarantine, on test, released, rejected); 	(iii) 保管条件; (iv) 内容物の状態(例えば、判定待ち、試験中、合格、不合格)
(v) an expiry date or a date beyond which retesting is necessary.	(v) 有効期限、或いはその日以降は再試験が必要になる日。
7.19. When fully computerised storage systems are used, all the above	7.19. 完全にコンピュータ化された保管システムが用いられている場合、
information need not necessarily be in a legible form on the label. The use of automated systems (e.g. use of barcodes) is permissible.	上記の情報が全て表示上に読み取れるようになっている必要はない。 自動化されたシステム(例えば、バーコード)の使用は許容され得る。
7.20. Only raw materials that have been released by the person responsible for quality control should be used.	7.20. 品質管理の責任者により使用許可判定された原料のみ使用する こと。
7.21. The ATMP manufacturer should put in place appropriate measures to ensure that critical raw materials can be traced in order to facilitate recall of products if necessary.	<u>と</u> 。
7.3. Starting Materials	7.3. 出発物質
7.22. The donation, procurement and testing of human tissues and cells used as starting materials should be in accordance with Directive 2004/23/EC. For blood-derived cells, compliance with Directive 2002/98/EC regarding donation, procurement and testing is likewise acceptable. The accreditation, designation, authorisation or licensing of the supplier of starting materials as provided for under the legislation above-referred should be verified.	7.22. 出発物質として用いられるヒト組織および細胞の提供、調達及び 試験はDirective 2004/23/ECに従って行うこと。血液由来の細胞に関し ては、提供、調達及び試験についてはDirective 2002/98/ECを遵守する ことで同様に受け入れられる。出発物質の供給業者が、上記で参照され た法規制の下で規定された認定、指定、承認或いは許可を受けている ことを確認しておくこと。
7.23. When the cells/tissues used are outside the scope of the Directive 2004/23/EC or- as appropriate- Directive 2002/98/EC (e.g. cell-lines/cell banks established outside the EU, or cells procured before the entry into force thereof), the ATMP manufacturer (or, as appropriate, the sponsor or marketing authorisation holder) should take appropriate steps to ensure the quality, safety and traceability thereof, in accordance with the terms of the marketing authorization/clinical	7.23. 使用される細胞/組織がDirective 2004/23/EC或いは場合により Directive 2002/98/ECの適用範囲外である場合(例えば、EU圏外で確 立されたセルライン/セルバンク、或いは当該法規制が発効する前に作 成された細胞)、ATMP製造業者(或いは、場合により治験スポンサー或 いは販売承認保持者)は、販売承認/治験承認の要件に従って、それら の品質、安全性、トレーサビリティを保証するために適切な対策をとるこ と。
7.24. The ATMP manufacturer (or, as appropriate, the sponsor or marketing authorisation holder) should establish quality requirements for the starting materials (specifications) which should be agreed with the supplier(s). These agreed specifications should cover aspects of the production, testing and control, storage, and other aspects of handling and distribution as appropriate. Depending on the product's characteristics, testing in addition to that foreseen in the Directive 2004/23/EC (or- as appropriate- Directive 2002/98/EC) may be required. The agreed specifications should be in compliance with the terms of the marketing authorisation or clinical trial authorisation.	こ。 7.24. ATMP製造業者(或いは該当する場合、治験スポンサー或いは販売承認保持者)は、供給業者と合意した出発物質の品質要件(規格)を確立すること。これらの合意された規格は製造、試験及び管理、保管及び取り扱い、配送等の他の面についても包含すること。Directive 2004/23/EC(或いは場合によりDirective 2002/98/EC)にある項目に加え、製品特性に応じた試験が必要であろう。合意された規格は販売承認或いは治験承認の要件に適合したものであること。
7.25. The ATMP manufacturer should verify compliance of the supplier's materials with the agreed specifications. The level of supervision and further testing by the ATMP manufacturer should be proportionate to the risks posed by the individual materials.	7.25. ATMP製造業者は、供給業者の原料が合意された規格に適合していることを検証すること。ATMP製造業者による監督及び更なる試験の水準は個々の原料によりもたらされるリスクに比例したものであること。

7.26. Blood establishments and tissue establishments authorised and supervised in accordance with Directive 2002/98/EC or Directive 2004/23/EC do not require additional audits by the ATMP manufacturer regarding compliance with the requirements on donation, procurement and testing provided for under the national law of the Member State where the blood/tissue establishment is located. It is, however, recommended that the agreement between the ATMP manufacturer and the blood/tissue establishment foresees the possibility for the ATMP manufacturer to audit the blood/tissue establishment. Moreover, if the agreed specifications foresee requirements which imply that the blood/tissue establishment should carry out activities in addition to those authorised and supervised by the competent authority in accordance with Directive 2002/98/EC or Directive 2004/23/EC (e.g. additional testing), adequate supervision in	7.26. Directive 2002/98/EC 或いは Directive 2004/23/ECにより承認 を受け監督を受けている血液施設及び組織施設は、それらが存在して いる地域の国の法律の下で規制を受ける提供、調達及び試験の要件へ の適合性に関してATMP製造業者による更なる監査を受ける必要は無 い。しかし、ATMP製造業者と血液/組織施設との間の取決めにおいて ATMP製造業者による監査が出来るようにしておくことを推奨する。更に 合意された規格が、Directive 2002/98/EC 或いは Directive 2004/23/ECに従って管轄当局により承認され、監督される業務に加え て実施すべき血液/組織施設の業務を包含する要求事項を含んでいる ならば、追加の要求事項に関する適切な監督を行うこと。
7.27. In addition to the specifications for the starting materials, the agreement between the ATMP manufacturer (or, as appropriate, the sponsor or marketing authorisation holder) and the supplier (including blood and tissue establishments) should contain clear provisions about the transfer of information regarding the starting materials, in particular, on tests results performed by the supplier, traceability data, and transmission of health donor information that may become available after the supply of the starting material and which may have an impact on the quality or safety of the ATMPs manufactured therefrom.	7.27. ATMP製造業者(或いは場合により治験スポンサー或いは販売承 認保持者)と供給業者(血液及び組織施設を含めて)との間の取決め は、出発物質の規格に加えて、出発物質に関する情報の伝達、とりわけ 供給業者が実施した試験の結果、トレーサビリティデータ、出発物質の 受け渡し後に入手可能となったところのそれらの出発物質から製造され たATMPの品質及び安全性に影響があり得るドナーの健康に関する情 報の伝達について明確な規定を含むこと。
7.28. The risk of contamination of the starting materials during their passage along the supply chain must be assessed, with particular emphasis on viral and microbial safety and Transmissible Spongiform Encephalopathy ("TSE"). Compliance with the latest version of the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy (TSE) Agents via Human and Veterinary	7.28. 出発物質のサプライチェーンを通過する間の汚染のリスクについ て、ウイルス及び微生物の安全性及び伝染性海綿状脳症(TSE)に特に 注意して評価すること。Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy (TSE) Agents via Human and Veterinary Medicinal Productsの最新版への適合が必要で ある。
 7.29. Only starting materials that have been released by the person responsible for quality control should be used. 7.30. Where the results from the test(s) required to release the starting materials take a long time (e.g. sterility test), it may be permissible to process the starting materials before the results of the test(s) are available. The risk of using a potentially failed material and its potential impact on other batches should be clearly assessed and understood. In such cases, the finished product should only be released if the results of these tests are satisfactory, unless appropriate risk mitigation measures are implemented (see also Section 	7.29. 品質管理の責任者により使用許可判定された出発物質のみ使用 すること。 7.30. 出発物質の使用可否判定に必要な試験の結果が出るまで長時間 を要する場合(例えば無菌試験)、その出発物質を試験結果が入手可能 となる前に加工することが許容できる。不合格となる可能性がある原料 を使うリスクと他のパッチへの影響を明確に評価し、理解すること。その ような場合、最終製品は適切なリスク低減策が実施されない限り(11.3.2 章参照)これらの試験結果が満足すべきものであった場合のみ出荷可 の判定を行うこと。
 7.31. Starting materials in the storage area should be appropriately labelled. Labels should bear at least the following information: (i) the designated name of the product and the internal code reference (if applicable); 	 7.31. 保管区域での出発物質は適切に表示を行うこと。表示は少なくとも以下の情報を含むこと: (i) 製品の名称及び社内コードの参照(該当する場合);
(ii) a batch number given at receipt;	(ii) 受領時に付けられたバッチナンバー;
 (iii) storage conditions; (iv) the status of the contents (e.g. in quarantine, on test, released, rejected); 	(iii) <u>保管条件;</u> (iv) 内容物の状態(例えば、判定待ち、試験中、合格、不合格)
 (v) an expiry date or a date beyond which retesting is necessary. 7.32. When fully computerised storage systems are used, all the above information need not necessarily be in a legible form on the label. The use of automated systems (e.g. use of barcodes) is permissible. 	(√) 有効期限或いはその日以降再試験が必要な日付。 7.32. 全自動化された保管システムが用いられている場合、上記全ての 情報が表示上に判読できるようになっている必要はない。自動システム (例えばパーコード)の使用も許容できる。
Processing of starting materials 7.33. The quality of ATMPs is dependent on the quality of the starting materials. Cells and tissues of human origin must comply with the donation, procurement and testing requirements provided for under Directive 2004/23/EC or -as appropriate- Directive 2002/98/EC. The further processing/manufacturing thereof should take place in a GMP environment.	<u>出発物質の加工</u> 7.33. ATMPの品質は出発物質の品質に依存する。ヒト由来の細胞及び 組織はDirective 2004/23/EC 或いは該当する場合Directive 2002/98/ECに規定されている提供、調達、及び試験の要求事項に適合 しなければならない。その後の加工/製造はGMPの環境(体制)の下で 実施すること。
7.34. However, where steps like washing or preservation are needed to make the cells/tissues available, this can also take place at the tissue/blood establishment under the requirements of Directive 2004/23/EC or -as appropriate- Directive 2002/98/EC.	7.34. しかし、細胞/組織を入手可能とするために洗浄或いは保存のよう な工程が必要な場合、これをDirective 2004/23/EC 或いは該当する場 合Directive 2002/98/ECの要求事項に従う組織/血液施設で実施するこ とがあり得る。
7.35. In exceptional cases, it may be acceptable that the manufacture of an ATMP starts from already available cells or tissues where some initial processing/manufacturing steps have been performed outside of the GMP environment, provided it is impossible to replace such material with GMP-compliant material. The use of cells that have been separated/isolated and preserved outside a GMP environment for the manufacture of an ATMP should remain exceptional and it is only possible if a risk analysis is performed to identify the testing requirements necessary to ensure the quality of the starting material. The overall responsibility for the quality – as well as the impact thereof on the safety and efficacy profile of the product– lies with the ATMP manufacturer (and/or, as appropriate, the sponsor or marketing authorisation holder), even if the activities have been outsourced. The release of such cells/tissues for use in the manufacturing process should be done by the person responsible for quality control after verifying the quality and safety thereof. Additionally, the competent authorities should agree to the control strategy in the context of the assessment of the marketing authorisation application/clinical trial	7.35. 例外的に、GMP適合の原料に置き換えることが不可能な場合、 ATMPの製造をいくつかの初期の加工/製造工程をGMP環境外で実施さ れた既存の細胞或いは組織から開始することが許容される。GMP環境 外で分離/単離及び保存された細胞のATMP製造の為の使用は例外で あり、出発物質の品質を保証するために必要な試験の要求事項を特定 する為にリスク評価が実施された場合においてのみ可能である。製品の 安全性及び有効性のプロファイルへの影響と共に品質への全般責任 は、作業が外注されたとしてもATMP製造業者(及び該当する場合、治 験依頼者或いは販売承認保持者)にある。そのような細胞/組織の製造 工程での使用可否判定はそれらの品質及び安全性を検証した後に品 質管理に責任を有する者により行われること。更に、管轄当局は販売承 認申請/治験承認申請の審査に関連してその管理戦略に同意すること。

7.36. In the case of vectors and naked plasmids used as starting	7.36. 遺伝子治療用医薬品の製造の出発物質として使用されるベクター
materials for the manufacturing of gene therapy medicinal products, the	や裸のプラスミドの場合、GMPの原則は遺伝子導入に用いられるベク
principles of GMP apply from the bank system used to manufacture the	ター或いはプラスミドを製造するために用いられるバンクシステムから適
vector or plasmid used for gene transfer. Additional considerations for xenogeneic cells and tissues:	用される。 異種細胞及び組織に関して更に考慮すべき事項
7.37. The use of xenogeneic cells/tissues in the manufacture of	7.37. ATMPの製造における異種細胞/組織の使用は新たな感染症を持
ATMPs poses additional risks of transmitting known and unknown	ち込むリスクの可能性を含め、既知及び未知の病原体をヒトに伝播する
pathogens to humans, including the potential risk of introducing new	という更なるリスクをもたらす。そのために、提供動物の選定は厳格に管
infectious diseases. The selection of donor animals must therefore be	理しなければならない。由来/提供動物は健康であること、特定病原体
strictly controlled. Source/donor animals should be healthy and should	を持たない(SPF)こと、そして健康状態のモニタリングを含むSPF状態で
be specific pathogen free (SPF) and be raised in SPF conditions,	飼育されたものであること。由来/提供動物はこの目的の為に特に設計
including health monitoring. The donor/source animal should have been	
bred in captivity (barrier facility) specifically designed for this purpose.	ATMPの製造においては野生動物或いは屠畜場からの異種細胞及び組
In the manufacture of ATMPs, it is not acceptable to use xenogeneic	織を使用することは許容されない。同様の意味で遺伝子導入した初代
cells and tissues from wild animals or from abattoirs. Cells and tissues	動物の細胞及び組織は使用しないこと。
of founder animals similarly should not be used.	200 中本/担供動版の独店に招生したい影響を及ぼせ声例 ざいけ
7.38. Appropriate measures should be implemented to identify and prevent incidents that negatively affect the health of the source/donor	7.38. 由来/提供動物の健康に好ましくない影響を及ぼす事例、或いは 由来/提供動物のバリア施設或いはSPF状態に好ましくない影響を及ぼ
animals or that could negatively impact on the barrier facility or the	す事例を発見し、防止するための適切な対策を実施すること。TSE規制
SPF status of the source/donor animals. In addition to compliance with	の遵守に加え、懸念される他の病原体(ヒトに伝染する動物疾患、由来
TSE regulations, other adventitious agents that are of concern	動物の疾患)についてもモニターし、記録すること。モニタリングプログラ
(zoonotic diseases, diseases of source animals) should be monitored	ムの確立においては専門家のアドバイスを得ること。
and recorded. Specialist advice should be obtained in establishing the	
7.39. Instances of ill-health occurring in the herd should be investigated	7.39. 動物群で発生した不健康の状況は接触している動物の継続した使
with respect to the suitability of in-contact animals for continued use	用(製造においては出発物質及び原料としての使用、品質管理及び安
(in manufacture, as sources of starting and raw materials, in quality	全性試験においての使用)の適切性に関して究明すること。行われた決
control and safety testing). The decisions taken must be documented.	定について文書化しなければならない。動物由来の細胞/組織が使用さ
A look-back procedure should be in place which informs the decision making process on the continued suitability of the biological active	れたか或いは含まれている生物学的活性を有する物質或いは生物学 的製剤が引き続き適切であると決定した過程を知らせるルックバック手
substance or medicinal product in which the animal sourced	間袋剤がらる続き過してめると決定した過程を知らせるルックパックチー 順がなければならない。この決定手順には、提供動物がいつまで陰性で
cells/tissues have been used or incorporated. This decision-making	順がなりればならない。この次定于順には、提供動物がいうまで属住であったかを確認するための同一提供動物からの以前の採取での保存サ
process may include the re-testing of retained samples from previous	ンプル(該当する場合)の再試験を含んでも良い。
collections from the same donor animal (where applicable) to establish	
7.40. The withdrawal period of therapeutic agents used to treat	7.40. 由来/提供動物の治療に用いられた治療剤の投与終了後の期間
source/donor animals must be documented and used to determine the	を文書化し、これら動物の一定期間のドナープログラムからの除外を決
removal of those animals from the programme for defined periods.	定するために用いなければならない。
8. Seed lot and cell bank system	8. シードロット及びセルバンクシステム
8.10. It is recommended that the system of master and working seed	8.10.ドナーと患者のマッチングを必要としない同種製品に関しては、マ
lots/cell banks is used for allogeneic products which do not require a	スター及びワーキングシードロット/セルバンクのシステムを使用すること
match between the donor and the patient. However, the establishment of seed lots/cell banks is not mandatory.	が推奨される。しかし、シードロット/セルバンクの確立は強制ではない。
8.11. When seed lots and cell banks, including master and working	8.11. シードロット及びセルバンクがマスター及びワーキングの代を含め
generations are used, they should be established under appropriate	
	て使用された場合、それらはこのカイトラインで現定されているように
	て使用された場合、それらはこのガイドラインで規定されているように GMPに適合することを含めて、適切な条件の下で確立されたものである
conditions, including compliance with GMP as provided for in these Guidelines. This should include an appropriately controlled environment	て使用された場合、それらはこのカイトラインで規定されているように GMPに適合することを含めて、適切な条件の下で確立されたものである こと。これにはシードロット、セルバンク、そしてそれを扱う従業員を保護
conditions, including compliance with GMP as provided for in these	GMPに適合することを含めて、適切な条件の下で確立されたものである こと。これにはシードロット、セルバンク、そしてそれを扱う従業員を保護 するための適切に管理された環境を含むこと。シードロット及びセルバン
conditions, including compliance with GMP as provided for in these Guidelines. This should include an appropriately controlled environment	GMPに適合することを含めて、適切な条件の下で確立されたものである こと。これにはシードロット、セルバンク、そしてそれを扱う従業員を保護 するための適切に管理された環境を含むこと。シードロット及びセルバン クの確立の間は他の生物或いは感染性物質(例えばウイルス、セルライ
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appropriate. Deviations should be investigated with a view to identify	処置及び予防措置を実施すること。
quality, safety and efficacy), with the involvement of the QP as	ること。逸脱は根本原因を特定する観点から究明し、必要に応じて是正
as far as possible. If a deviation occurs, it should be approved in writing by a responsible person (after having assessed the impact thereof on	脱が発生した場合、場合によりQPが関与して、責任者による(逸脱の品 質、安全性及び有効性への影響を評価した後の)書面による承認を得
9.14. Any deviation from instructions or procedures should be avoided	9.14. 指図或いは手順からの如何なる逸脱も可能な限り避けること。逸し
should be managed in accordance with the principles set out in Section	
Any change to the manufacturing formula or manufacturing method	
finished product and consistent production (appropriate to the relevant stage of development) should be considered prior to implementation.	考察すること。製造手順或いは製造方法への如何なる変更も6.2章に述 べられた原則に従って管理すること。
effects of changes in the production in relation to the quality of the	発の段階に対応した)品質及び一貫した製造に関する影響を実施前に
adopted, steps should be taken to demonstrate its suitability. The	性を示すための対応を行うこと。製造における変更の、最終製品の(開
9.13. When any new manufacturing formula or manufacturing process is	9.13. 新たな製造手順或いは製造工程が適用される場合にはその適切
also important to consider steps necessary to reduce process variability and to enhance reproducibility at the different stages of the	動を低減し再現性を高めるために必要な対策を考えることは重要である。
this is especially relevant during the early phases of clinical trials, it is	いて該当するが、製品ライフサイクルのその他の段階においても工程変
reviewed regularly, and they should be improved as appropriate. While	必要に応じて改善すること。この事は特に初期の臨床試験の段階にお
9.12. Manufacturing processes and their control strategies should be	9.12. 製造工程及びその管理戦略は定期的に見直しを行うこと、そして
the manufacturing process. It is expected that the manufacturing process and quality controls become more refined as development	
phases of development, it is critical to carefully control and document	につれてより高度になることが求められる。
be adapted as the knowledge of the process increases. In the early	して文書化することが重要である。製造工程と品質管理は開発が進む
that the manufacturing process (including quality controls) may need to	
phases of clinical trials (phase I and I/II). It is therefore acknowledged	工程(品質管理を含めて)は工程知識が増加するに従って調整する必要
understanding of the product may be limited, particularly for early	関しては、製品知識および理解は限定されているであろう。従って、製造
the requirements set in the relevant manufacturing and 9.11. In case of investigational ATMPs, the knowledge and	 9.11. 治験用ATMPの場合、特に初期の臨床試験(第1相及びI/II相)に
(appropriate to the relevant stage of development), and to comply with	売承認/治験承認で設定された要求事項を遵守すること。
designed to ensure the quality of the product, consistent production	る為に設計された明確に規定された手順に従うこと、そして関連する販
applicable- cryopreservation should follow clearly defined procedures	品品質と一貫した製造(関連した開発の段階に対して適切な)を保証す
9.10. Production operations, including filling, packaging and -as	9.10. 充填、包装、及び該当する場合、凍結保存を含む製造作業は製
9.1. General principles	9. 表垣 9.1. 一般原則
marketing authorisation application/clinical trial authorisation 9. Production	9. 製造
competent authorities in the context of the assessment of the	認されたものであること。
1394/2007 outside of GMP conditions should be approved by the	用は、販売承認申請/治験承認申請の審査において管轄当局により承
seed stocks generated prior to the entry into force of Regulation	胞ストック/セルバンク及びウイルスシードストックからの出発物質の使
8.24. The use of starting materials from cell stocks/cell banks and viral	
sponsor or marketing authorisation holder.	
product- lies with the ATMP manufacturer and/or -as appropriate- the	
as well as the impact thereof on the safety and efficacy profile of the	ポンサー或いは販売承認保持者にある。
starting material. In all cases, the overall responsibility for the quality –	への全般的責任はATMP製造業者、及び/又は該当する場合治験のス
identify the testing requirements necessary to ensure the quality of the	
compliance. In these cases, a risk analysis should be conducted to	な試験の要求事項を特定する為にリスク評価を行うこと。全ての場合、
the entry into force of Regulation 1394/2007 without full GMP	能な場合がある。このような場合、出発物質の品質を保証する為に必要
justified cases, it might be possible to accept the use of cell stocks/cell banks and viral seed stocks that were generated prior to	1394/2007の発効前にGMPに元至には適合せずに作成された細胞ス トック/セルバンク及びウイルスシードを使用することを許容することが可
stocks should be done in accordance with GMP. In exceptional and justified cases, it might be possible to accept the use of cell	て行うこと。例外的で妥当性を示した場合において、Regulation 1394/2007の発効前にGMPに完全には適合せずに作成された細胞ス
8.23. The establishment of new cell stocks/banks and viral seed	8.23. 新たな細胞ストック/セルバンク及びウイルスシードはGMPに従っ このティート 個別的で平当性を示した場合におして Pergulation
conditions prior to the entry into force of Regulation 1394/2007	/セルバンク及びウイルスシードストック 222 新たた細胞ストック/セルバンク及びウィルスシードはCMDに従っ
Cell stocks/banks and viral seed stocks established outside of GMP	<u>Regulation 1394/2007発効前にGMPの条件外で確立された細胞ストック</u>
for cell banks.	
cells should be done in accordance with the principles outlined above	否判定を上記のセルバンクについて述べた原則に従って行うこと。
8.22. When cell stocks are used, the handling, storage and release of	8.22. 細胞ストックを用いた場合は、細胞の取り扱い、保管、及び使用可
the preceding paragraphs.	
controls at such locations should provide the assurances outlined in	の管理は前の節で述べた保証を提供するものであること。
different locations so as to minimize the risks of total loss. The	たものを異なった場所に保管しておくことが望ましい。そのような場所で
8.21. It is desirable to split stocks and to store the split stocks at	8.21. ストックを分割し、全体を失うリスクを最小限とする為に、分割され
authorisation and the conditions therein should be complied with.	
donors) should be addressed in the marketing authorisation/clinical trial	
obtained after expansion and does not cover the entire life cycle of the product. Cell stock changes (including introduction of cells from new	トックの変更(新たなトナーからの細胞の導入を含めて)は販売承認/ 冶 験承認において焦点をあてること、そしてその条件を遵守すること。
production runs from a cell stock is limited by the number of aliquots	は限定され、製品のライフサイクル全体をカバーすることはない。細胞ス トックの変更(新たなドナーからの細胞の導入を含めて)は販売承認/治
tiered system of master and working cell banks, the number of	対して、増殖後に得られる回分数によって細胞ストックからの製造回数 け限定され 創品のライフサイクル全体をカバーすることけない、細胞ス
obtained from a limited number of passages. In contrast with the two	ら作られる。マスター及びワーキングセルバンクの2段構えのシステムに 対して 増殖後に得られる回分数によって細胞ストックからの製造回数
8.20. Cell-based products are often generated from a cell stock	8.20. 細胞に基づく製品はしばしば限定された継代数の細胞ストックか
Cell Stock	
8.19. Access to cell banks should be limited to authorised personnel.	8.19. セルバンクへのアクセスは許可された従業員に限定すること。
have been maintained.	
returned to storage if it can be documented that adequate conditions	維持されたことが文書化できる場合にのみ戻すことが出来る。
8.18. Containers removed from the cryostorage unit, can only be	8.18. 凍結保存設備から取り出した(シードの)容器は、適切な状態が
built-up with real-life data as the clinical trial progresses.	
the product is used in a clinical trial, and the stability data should be	と。
development or from suitable cell models) should be available before	て同時並行の安定性データを臨床試験の進行と共に積み上げてゆくこ
evaluation. In the case of investigational ATMPs, a gradual approach is acceptable. Thus, preliminary stability data (e.g. from earlier phases of	期のデータから、或いは適切な細胞モデルから)が入手可能なこと、そし
documented and records should be kept in a manner permitting trend	と。治験用のATMPの場合段階的なアプローチが許容される。即ち、製 品が臨床試験に使用される前に初期の安定性データ(例えば、開発初
Evidence of the stability and recovery of seeds and banks should be	及び復元について文書化し記録を傾向評価が出来るように保管するこ
seed lots, quarantine and release procedures should be followed.	果待ち及び使用可否判定の手順に従うこと。シード及びバンクの安定性
8.17. Following the establishment of cell banks and master and viral	8.17. セルバンク、マスター及びウイルスシードロットの確立に次いで、結

9.15. All handling of materials and products (such as receipt and	9.15. 原材料及び製品の全ての取り扱い(受け入れ、判定待ち、サンプ
quarantine, sampling, storage, labelling and packaging) should be done in accordance with written procedures or instructions and recorded as	リング、保管、表示、及び包装)は、文書化された手順或いは指図に従って実施し、適宜記録すること。管理戦略はリスクを考慮して適切なもので
appropriate. The control strategy should be adequate having regard to	て天地し、過生記録すること。自生我唱はリスノを考慮して過めなりのであること。
the risks.	w w 0
9.16. All incoming materials should be checked to ensure that the	9.16. すべての入荷原材料について配送されたものが発注と対応してい
consignment corresponds to the order. The specific requirements for	るかを確認するためにチェックすること。原料及び出発物質に関する特
raw and starting materials are described in Section 7. For other	定の要求事項は7章に記載されている。その他の原材料については、全 てのリスクが適切に理解され、リスクを除去するか或いは許容可能なレ
materials, reliance on the documentation provided by third parties (e.g. supplier) is acceptable provided that all risks are duly understood and	ベルに低減するための適切な対策がなされているならば(例えば供給業
that appropriate measures are put in place to eliminate the risks or	者の適格性確認)第3者(例えば供給業者)から供給された文書への依
mitigate them to an acceptable level (e.g. qualification of suppliers).	存も許容される。必要な場合、同一性の検証(表示の確認)及び/又は
Where necessary, identity verification and/or testing should be	試験を考慮すること。
9.17. Incoming materials and finished products should be physically or	9.17. 入荷原材料及び最終製品は受け入れ直後或いは加工終了直後 に使用可或いは出荷可の判定が出るまで物理的或いは管理手段により
administratively quarantined immediately after receipt or processing, until they have been released for use or distribution.	旧に使用可以いな山前可の利定が山るまで初陸的以いな管理于投により 判定待ちの状態に留め置くこと。
9.18. Intermediate and bulk products purchased as such should be	9.18. 中間製品及びバルク製品として購入した製品は、製造に使用可能
released by the person responsible for quality control before they can	となる前に、該当する規格に適合していることを検証した後、品質管理に
	責任を有する者により使用可の判定を受けること。
specifications.	9.19. 全ての原材料及び製品は品質を保証する為に適切な条件で、
9.19. All materials and products should be stored under appropriate conditions to ensure the quality and in an orderly fashion to permit	バッチの隔離と在庫の回転が出来るよう整然と保管すること。自家製品
batch segregation and stock rotation. Particular attention should be	及びその他の専用製品(即ち特定の患者向けの製品)の混同を防止す
paid to implementing appropriate measures to prevent mixups of	るための適切な対策を実施するために特別に留意すること。
autologous products and other dedicated products (i.e. products	
intended for specific patients).	0.20 加工由け労に 今ての店社料 バルカ家聖 キーかいみ フェイ
9.20. At all times during processing, all materials, bulk containers, major items of equipment and, where appropriate, rooms used should be	9.20. 加工中は常に、全ての原材料、ハルク谷岙、土要な設備、そして 場合により加工に使用している部屋に表示を行うか他の方法で加工中
labelled or otherwise identified with an indication of the product or	の製品或いは原材料、その力価(該当する場合)、及びバッチナンバー
material being processed, its strength (where applicable) and batch	を識別しておくこと。該当する場合、この表示は製造の段階についても
number. Where applicable, this indication should also mention the stage	示すこと。
9.21. Labels applied to containers, equipment or premises should be	9.21. 容器、設備或いは建物に付けられている表示は明確であいまいで
clear and unambiguous. It is often helpful, in addition to the wording on the labels, to use colours to indicate status (for example, quarantined,	ないこと。表示の文字に加えて状態(例えば、判定待ち、合格、不合格、 清掃済み)を示す色を使用することが有効である。ラベルの保管条件或
accepted, rejected, clean). The compatibility of labels with storage or	いは加工条件(例えば極低温の保管条件、ウオーターバス)への適合性
processing conditions (e.g. ultra-low storage temperatures, waterbath)	を検証すること。
should be verified.	
9.22. Containers should be cleaned where necessary. Damage to	9.22. 容器は必要に応じて洗浄すること。容器の破損及び原材料の品
containers and any other problem which might adversely affect the quality of a material should be investigated, recorded and reported to	質に好ましくない影響を及ぼす可能性があるその他の問題については 究明し、記録し、品質管理に責任を有する者に報告すること。
	九切し、山峡し、山貞自生に夏にと伯子の伯に取自子のここ。
The person responsible for quality control.	
the person responsible for quality control. 9.3. Utilities	9.3. ユーティリティ
9.3. Utilities 9.3.1. Water	9.3.1. 水
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9.4. Prevention of cross-contamination in production	9.4. 製造における交差汚染の防止 9.31. どの様な製造作業を開始するについてもその前に、作業区域と設
9.31. Before any manufacturing operation starts, steps should be taken to ensure that the work area and equipment are clean and free from	間が清浄で、当該作業に必要がない如何なる出発物質、製品、製品の
any starting materials, products, product residues or documents not	構が消滞で、当該作業に必要がない如何なる山光物員、表品、表品の 残渣、或いは文書も無いことを保証する為の処置をとること。原材料の
required for the current operation. Mix-ups of materials should be	混同を防止すること;自家用の原材料、その他患者専用原材料の混同
prevented; special precautions should be taken to avoid the mixing of	を避けるための特別な予防措置をとること。
autologous materials or other dedicated materials.	
9.32. At every stage of production, products and materials should be	9.32. 製造の各段階において製品と原材料は微生物および他の汚染物
protected from microbial and other contamination (e.g.	質(例えば粒子状物質(ガラスおよびその他目視可能およびそれ以下の
pyrogens/endotoxins as well as particulate matter (glass and other	微粒子)と共にパイロジェン/エンドトキシン)から保護されていること。溶
visible and sub-visible particles)). Appropriate measures should also be	液、緩衝液の調製およびその他の添加操作を汚染のリスクから保護す
put in place to protect the preparation of solutions, buffers and other	ること(或いは販売/治験承認で予見される許容バイオバーデンレベル
additions from the risk of contamination (or within the accepted	以内とすること)。
bioburden level foreseen in the marketing authorisation/clinical trial	
9.33. The risks of cross-contamination should be assessed having	9.33. 交差汚染のリスクを製品の特性(例えば出発物質の生物学的特
regard to the characteristics of the product (e.g. biological	性、精製技術への抵抗性)と製造工程の特性(例えば、外部からの微生
characteristics of the starting materials, possibility to withstand	物汚染が増殖する機会がある工程の使用)を考慮して評価すること。最
purification techniques) and manufacturing process (e.g. the use of	終製品の滅菌が不可能な場合、環境に暴露される製造工程(例えば充
processes that provide extraneous microbial contaminants the	填)に対して特別の注意を払うこと。
opportunity to grow). If sterilisation of the finished product is not	
possible, particular attention should be paid to the manufacturing steps	
where there is exposure to the environment (e.g. filling).	
	9.34. 望まないエアロゾルの生成につながる可能性がある全ての製造
aerosols (e.g. centrifugation, working under vacuum, homogenisation,	段階においては(例えば、遠心分離、減圧下での作業、ホモジナイザー
sonication) appropriate mitigation measures should be implemented to	作業、超音波処理)、交差汚染を避けるための適切な低減策をとること。
avoid cross-contamination. Special precautions should be taken when	感染性物質を取り扱う作業の際は特別の注意を払うこと。
working with infectious materials.	0.25 株字されたリフカに対して海辺かさ美に効果で強まってていた。
9.35. Measures to prevent cross-contamination appropriate to the	9.35. 特定されたリスクに対して適切な交差汚染防止策を立てること。交
risks identified should be put in place. Measures that can be	差汚染防止の為に考慮し得る対策として種々あるが以下のようなもの
considered to prevent cross-contamination include, among others:	が含まれる: (i) 区分された建屋
(i) Segregated premises. (ii) Dedicating the whole manufacturing facility or a self-contained	(1) 区分されに建産 (ii) 製造施設全体の専用化或いは封じ込めの製造区域でのバリデートさ
	(11) 装置施設主体の専用化或いな到し込めの装置区域でのハリアートで れた洗浄工程を伴うキャンペーン生産(時間の区分)。
production area on a campaign basis (separation in time) followed by a	れに流浄工程を伴うキャンペーン生産(時间の区方)。
cleaning process of validated effectiveness. (iii) Use of "closed systems" for processing and material/product	(前)加工及び設備間の原料/製品の移送にクローズドシステムの使用
transfer between equipment.	(加)加工及び設備間の原料後面の物区にクロースドンスプムの使用
(iv) Use of air-locks and pressure cascade to confine potential airborne	(iv)所定の区域内に浮遊汚染の可能性がある物質を封じ込めるための
contaminant within a specified area.	エアロック及び段階的差圧の使用
(v) Utilisation of single use disposable technologies.	エアロジア及び段間的差圧の使用 (v) シングルユースの使い捨て設備の技術の適用
(vi) Adequate cleaning procedures. The cleaning procedure (technique,	(vi) 適切な洗浄工程。洗浄手順(技術、消毒工程の回数、等)を製品と
number of sanitation steps, etc.) should be adapted to the specific	製造工程の個別の特性に対応させること。必要な洗浄/消毒工程につい
characteristics of the product and of the manufacturing process. A	て、その頻度を含めて決定するためにリスク評価結果を用いること。最
risk-assessment should be used to determine the	低限、バッチ間で適切な洗浄/除染を行うこと。洗浄/除染工程は10.2章
cleaning/decontamination procedures that are necessary, including the	で述べられたようにバリデートすること。
frequency thereof. As a minimum, there should be appropriate	
cleaning/decontamination between each batch. The	
cleaning/decontamination procedures should be validated as explained	
(vii) Other suitable technical measures, such as the dedication of	(vii) ある部分の設備(例えば、フィルター)を特定のリスクプロファイルを
certain parts of equipment (e.g. filters) to a given type of product with a	
specific risk profile.	的対策
(viii) Other suitable organizational measures, such as keeping specific	(viii)特定の保護衣を汚染の高リスク製品を加工している区域の中に留
protective clothing inside areas where products with high-risk of	めること、廃棄物、汚染された洗浄水及び汚れた作業着の取り扱いにつ
contamination are processed, implementing adequate measures to	いて適切な対策を実施すること、或いは作業者の動きに制限を加える、
handling waste, contaminated rinsing water and soiled gowning, or	というような他の適切な組織的対策。
imposing restrictions on the movement of personnel.	
9.36. The control strategy is multifaceted and should address all the	9.36. 管理戦略は多面的で、施設、設備及び作業員のレベルでの対策、
potential risks, including therefore measures at the level of the	出発物質及び原料の管理、効果的な滅菌及び消毒手順の実施、及び
facilities, equipment and personnel, controls on starting and raw	適切なモニタリングシステムを含めて可能性がある全てのリスクについ
materials, implementation of effective sterilisation and sanitisations	て焦点をあてること。適用された対策を総合したものが、その製造所内
procedures, and adequate monitoring systems. The totality of the	で製造された製品に汚染が無いことを保証するものであるべきである。
measures applied should assure the absence of contamination of the	如何なる最終工程或いは最終製品の試験に対しても依存し切らないこ
products manufactured within the manufacturing site. Sole reliance	と 。
should not be placed on any terminal process or finished product test.	
9.37. The effectiveness of the measures implemented should be	9.37. 実施した対策の効果を決められた手順に従って定期的に見直すこ
reviewed periodically according to set procedures. This assessment	と。この評価を、必要な場合に是正処置及び予防措置につなげること。
should lead to corrective and preventive actions being taken as	
9.38. Accidental spillages, especially of live organisms, must be dealt	9.38.事故による漏えい、特に生きている微生物の漏えいは迅速にかつ
with quickly and safely. Qualified decontamination measures should be	安全に対処すること。製造で使用されている微生物に付随するリスクと
available taking into consideration the organism used in production, as	共に、その微生物について考慮した適格性確認された除染処置が使え
well as the risks attached to the relevant biological materials.	るようになっていること。
9.5. Aseptic manufacturing	9.5. 無菌製造
9.5.1. General principles	
0.00 The metaline of ATMD	
9.39. The majority of ATMPs cannot be terminally sterilised. In such	9.39. ATMPの大多数は最終滅菌が出来ない。そのような場合、製造工
cases, the manufacturing process should be conducted aseptically (i.e.	程は無菌的に実施すること(即ち微生物汚染を防止する条件下で)。特
cases, the manufacturing process should be conducted aseptically (i.e. under conditions which prevent microbial contamination). In particular,	程は無菌的に実施すること(即ち微生物汚染を防止する条件下で)。特に、これには製品を汚染に暴露する可能性がある製造作業については
cases, the manufacturing process should be conducted aseptically (i.e. under conditions which prevent microbial contamination). In particular, this requires that, for any manufacturing activity that may expose the	程は無菌的に実施すること(即ち微生物汚染を防止する条件下で)。特
cases, the manufacturing process should be conducted aseptically (i.e. under conditions which prevent microbial contamination). In particular, this requires that, for any manufacturing activity that may expose the product to a risk of contamination, the following measures should be	程は無菌的に実施すること(即ち微生物汚染を防止する条件下で)。特に、これには製品を汚染に暴露する可能性がある製造作業については 以下の対策を実施することが求められる。
cases, the manufacturing process should be conducted aseptically (i.e. under conditions which prevent microbial contamination). In particular, this requires that, for any manufacturing activity that may expose the product to a risk of contamination, the following measures should be 9.40. (a) Manufacturing should take place in clean areas of appropriate	程は無菌的に実施すること(即ち微生物汚染を防止する条件下で)。特に、これには製品を汚染に暴露する可能性がある製造作業については以下の対策を実施することが求められる。 9.40. (a) 製造は適切な清浄度レベルの環境の清浄区域で行うこと。具
cases, the manufacturing process should be conducted aseptically (i.e. under conditions which prevent microbial contamination). In particular, this requires that, for any manufacturing activity that may expose the product to a risk of contamination, the following measures should be 9.40. (a) Manufacturing should take place in clean areas of appropriate environmental cleanliness level. Specifically:	程は無菌的に実施すること(即ち微生物汚染を防止する条件下で)。特に、これには製品を汚染に暴露する可能性がある製造作業については以下の対策を実施することが求められる。 9.40. (a) 製造は適切な清浄度レベルの環境の清浄区域で行うこと。具体的には以下のような点である:
cases, the manufacturing process should be conducted aseptically (i.e. under conditions which prevent microbial contamination). In particular, this requires that, for any manufacturing activity that may expose the product to a risk of contamination, the following measures should be 9.40. (a) Manufacturing should take place in clean areas of appropriate	程は無菌的に実施すること(即ち微生物汚染を防止する条件下で)。特に、これには製品を汚染に暴露する可能性がある製造作業については以下の対策を実施することが求められる。 9.40. (a) 製造は適切な清浄度レベルの環境の清浄区域で行うこと。具

Validation should take into account all critical factors of isolator technology, for sample the quality of the air inside and outside (background) the isolator, disinfection regime of the isolator, the transfer process, and the isolator is integrity. Sola 94.3 Monitoring should be carried out routinely and should include frequent leak testing of the isolator is one of the greates should be put in place. 94.4 For additional disperpoints convolution and appropriate convolution. 94.4 Sola 94.4 The analysis of conventional and appropriate convolution. 94.4 Without an aseptic connection (e.g. use of sterile connectors), used influency, the system can no longer bordication to an outside clean mouth without an aseptic connection (e.g. use of sterile connectors), used is an otherable to move the considered cload used without an exceptional circumstances and provided that it thus husterion bocause the time between the donation and administration of the and is not possible to move the particip tasks that it is also in the conditions of the product is very what and the patient is also in the conditions of the advaute and write is also in the conditions of the advaute and write is also in the conditions of the advaute and write is also in the conditions of the advaute and write is also in the conditions of the advaute and write is also in the conditions of the advaute and write is also in the conditions of the advaute and write out is also in the conditions of the advaute and advinication mount assift of the product is very adval adval the testing and pressure check is required for aspecie paragrant and filling. Sola Sola Sola Sola Sola Sola Sola Sola		
technology, for example the quality of the air inside and outside transfer process, and the isolator is integer. All Sectors and the isolator isolator is integer. All Sectors and the isolator isolator isolator isolator isolator isolator isolators and the isolator isol	9.42. Isolators should be introduced only after appropriate validation.	9.42. アイソレータは適切なバリデーションを実施した後にのみ導入す
blockground the isolator, its instary. マ、アイレータの除発地方、搬送設理、及びアイリレータの完全たつ、 94.3. Montoring should be carried out routinely and should includ マ、アイレータの除発地方、搬送設理、及びアイリレータのたまたつ、 94.3. Montoring should be carried out routinely and should includ マス・マンクシンクシンクシンクシンクシンクシンクシンクシンクシンクシンクシンクシンクシン		
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without an aseptic connection (ag. use of sterile connectors, use of fiber), the system can no longer do considered closed APAL StateVerQueTX-EXACX_US_BETEX-Status, Status, Exact Status, CS, EtaBUSE, CS, AtaWAS, CS, STATUS, S	9.44. When materials are added/withdrawn from the closed system	9.44. 原材料がクローズドシステムから無菌接続(例えば滅菌済みコネ
Titleral: the system can no longer be considered closed CF-Lift ic Vp-U-CK-bx dota. 94.5 In exceptional circumstances and provided that is duiy_justified 9.45. Web System 2017 by the system of the system		クターの使用、フィルターの使用)無しに出し入れされたならば、そのシ
9.45 In exceptional circumstances and provided that it is dury justified 9.45 My 約2本状にて、それが熟って実習性を示えれるららに (W) (1.2.1MPの設立が)を示えたいた。 9.45 In top possible to move the production on the product is very short and the patient is also in the operating theatre in a more indicable in more classified environment. The conditions of the possible to more classified environment. The conditions of the product should not be single environment. The conditions of the possible to more classified environment. The conditions of the product should not be single exposed at any moment to the environment (see, susporting data from leak testing and pressure check of the equipment. 14 <u>BU 2.2.7.4.7.0.92</u> (BU 2.2.7.1.0.2.8.8.1.8.8.8.1.8.8.1.8.8.8.1.8.8.1.8.8.1.8.8.8.1.8.8.1.8.8.1.8.8.1.8.8.		
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recommended that media is sterilised in situ. 9.52. When sterilisation of articles, materials or equipment is not possible, a strictly controlled process should be implemented to minimise the risks (e.g. treatment of biopsy with antibiotics, sterile filtration of raw materials, appropriate disinfection of materials). The effectiveness of the process should be checked at appropriate 9.53. (c) Addition of materials or cultures to fermenters and other vessels and sampling should be carried out under carefully controlled conditions to prevent contamination. Care should be taken to ensure that vessels are correctly connected when addition or sampling takes place. In-line sterilising filters for routine addition of gases, media, acid or alkalis, anti-foaming agents, etc. to bioreactors should be used 9.54. The conditions for sample collection, additions and transfers involving replication competent vectors or materials from infected donors should prevent the release of viral/infected material.	is delivered ready-to-use (i.e. already sterilised by the supplier), it is	奨される。
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		142、添加及(1)物达のための余件は'74ルス/感染を受けた物質の放出
9.5.2. Aseptic processing validation 19.5.2. 無風加工のハリナーション		
	donors should prevent the release of viral/infected material.	を防止するものであること。

9.55. The validation of aseptic processing should include a process simulation test. The aseptic process simulation test is the performance of the manufacturing process using a sterile microbiological growth medium and/or placebo (e.g. culture media of cells which is demonstrated to support the growth of bacteria) to test whether the manufacturing procedures are adequate to prevent contamination during production. Results and conclusions should be recorded. The process simulation test should follow as closely as possible the routine manufacturing process and it should be conducted in the same locations where the production occurs. The process simulation should focus on all operations carried out by operators involving open process steps. All potential interventions and challenges	9.55. 無菌加工のパリデーションは培地充填試験を含むこと。無菌工程 の培地充填試験は、製造手順が製造中の汚染を防止するために適切 であるか試験する為に無菌の培地及び/又はプラセボ(例えばパクテリ アの生育を促進することが示されている細胞培養の培地)を用いた製造 工程の実演である。結果と結論を記録すること。培地充填試験はルーチ ンの製造工程にできる限り忠実に従い、製造を行う場所と同一の場所で 実施すること。培地充填試験は開放工程を含めて作業員によって行わ れる全ての操作に焦点を当てること。工程への全ての可能性がある介 入及びチャレンジ(例えば徹夜作業)を考慮すること。
9.56. An appropriate simulated model (e.g. use of alternative tools to the manufacturing kit ("mock materials") may be acceptable provided that this is duly justified.	9.56. 適切な模擬のモデル(例えば製造キットに対する代替ツール(模擬 品))の使用が、適切に妥当性を示せば許容されるであろう。
9.57. Alternative approaches may also be developed for steps that take a long time. The simulation of reduced times for certain activities (e.g. centrifugation, incubation) should be justified having regard to the risks. In some cases, it may also be acceptable to split the process into key stages which are simulated separately provided that the transitions between each stage are also evaluated. When a closed system is used	9.57. 長時間を要する工程に関しては代替アプローチを開発してもよい。 ある種の作業(例えば遠心分離、培養)について時間を短縮したシミュ レーションを行う場合はリスクを考慮して妥当性を示すこと。ある場合に は、工程を主要な段階に分けて別々にシミュレートすることが、各段階の 移行についても評価されるならば許容されるであろう。クローズドシステ ムがATMPの製造に用いられる場合、培地充填はクローズドシステムの 接続に関連する工程に焦点を当てること。
9.58. In case of manufacturing of various types of ATMPs, consideration can be given to the matrix and/or bracketing approach. Under a bracketing approach, only samples on the extremes of certain design factors would undergo a full process simulation. This approach can be accepted if the handling of different products is similar (same equipment and processing steps). Under a matrix approach, it may be possible to combine media fills for different ATMPs sharing similar processing steps, provided that the worst case is covered by the matrix approach. The use of bracketing and matrixing together should	9.58. 種々のタイプのATMPを製造する場合には、マトリックス及び/又は ブラケティングアプローチを考慮することが可能である。ブラケティングア プローチにおいては、或る工程設計要素の最極端の条件のサンプルの みで全工程のシミュレーションを行うであろう。このアプローチは異なった 製品の取り扱いが似ている(同じ設備及び工程)ならば許容されるであ ろう。マトリックスアプローチにおいては、ワーストケースがマトリックスア プローチにより包含されるならば、同様な加工工程を共有する異なった ATMPについて培地充填をまとめて行うことが可能であろう。ブラケティン グ及びマトリキシングを共に用いるためには、適切に妥当性を示すこと。 9.59. 充填済みの容器は容器・栓の全ての部分が培地/プラセボに接触 することを保証するために反転して培養すること。培養時間と温度の選 定は、シミュレートした工程と選定した培地/プラセボに対して適切で、妥 当であることを示すこと。
9.60. All contaminants from the filled containers should be identified. The results should be assessed, in particular in relation to the overall quality of the product and the suitability of the production process. The target should be zero growth. Any growth detected should be investigated. If the growth detected is indicative of potential systemic failure, the potential impact on batches manufactured since the last successful media fill simulation test should be taken.	9.60. 充填した容器から検出された汚染は全て同定すること。結果は特に製品の全般的品質と製造工程の適切性に関して評価すること。目標は微生物の生育がゼロであることである。検出された如何なる微生物の 生育も究明すること。検出された生育がシステムのほころびを示しているならば、前回培地充填で問題なかった時以降に製造されたバッチに対する影響を評価し、適切な是正処置及び予防措置を取ること。
9.61. Process simulation test to support initial validation should be performed with three consecutive satisfactory simulation tests per production process.	9.61. 初期バリデーションを裏付ける培地充填は製造工程毎に3回連続 して問題なく実施出来たものであること。
9.62. Process simulation (one run) should be repeated periodically to	9.62. 培地充填(1回)は無菌製造の保証の為に工程と作業員の能力の 継続的保証を提供する為に定期的に反復すること。頻度はリスク評価に 基づいて決定するが、一般的に(製造工程毎に)6か月に1回より少なく ないこと。
9.63. However, in the case of infrequent production (i.e. if the interval	9.63.しかし、まれな製造の場合(即ち2つのバッチの間隔が6か月より長 い場合)、培地充填の結果が製造の開始前に得られるならば、培地充 填を次のバッチの製造の直前に実施することが許容される。しかし、休 止期間がより長い場合(即ち1年以上)製造開始前のバリデーションは3 回で実施すること。
9.64. When considering the frequency of the simulation test, the manufacturer is required to consider also the relevance of the media fill test for the training of operators and their ability to operate in an aseptic environment (see Section 3.2).	9.64. 培地充填の頻度を考慮する際に、製造業者は作業者の訓練と無 菌環境での作業能力との関連も考慮することが求められる。(3.2章を参 照)
9.65. A process simulation should also be conducted in cases when there is any significant change to the process (e.g. modification of HVAC system, equipment, etc). In this case, three runs are required. 9.5.3. Sterilisation	9.65. 培地充填は工程に対して有意の変更(例えばHVACシステム、設備、等の変更)が行われた際にも実施すること。この場合3回の実施が 必要である。 9.5.3. 滅菌
9.66. The sterilisation processes applied should be suitable having regard to the specific characteristics of the product. In particular, where the sterilisation of the starting materials (e.g. chemical matrixes) and raw materials and excipients is required, it should be ensured that the sterilisation process applied (e.g. heat, irradiation, filtration, or chemical inactivation) is effective in terms of removing the contaminants while preserving the activity of starting/raw materials	9.66. 適用される滅菌工程は、製品特有の特性を考慮して適切なもので あること。特に、出発物質(例えば化学的マトリックス)、原料および添加 剤の滅菌が必要な場合、適用される滅菌工程(例えば、熱、照射、ろ 過、或いは化学的不活化)が、汚染物質を除去する点で有効であるが、 一方では出発物質/原料及び添加剤の活性を損なわないことを保証す ること。
9.67. The sterilisation process(es) applied should be validated. Particular attention should be paid when the adopted sterilisation method is not in accordance with the European Pharmacopoeia. Additional guidance on sterilisation methods can be found in Annex 1 of the Part I of the Good Manufacturing Practice Guidelines published in	9.67. 適用される滅菌工程はバリデートされたものであること。適用され る滅菌工程が欧州薬局方従っていない場合特に注意を払うこと。滅菌 法に関する更なるガイダンスはEudralex ボリューム4において発行され たGMPガイドラインのパート1のアネックス1において見ることができる。

9.68. Solutions or liquids that cannot be sterilised in the final container	9.68. 最終容器中で滅菌できない溶液或いは液体は、公称孔径0.22ミク
should be filtered through a sterile filter of nominal pore size of 0.22	ロン(或いはそれ以下)、或いは少なくとも同等の微生物阻止特性の滅
micron (or less), or with at least equivalent micro-organism retaining	菌用フィルターでろ過し、予め滅菌した容器に入れること。
properties, into a previously sterilised container.	9.69. フィルターは製品に好ましくない影響を及ぼさないものであること
9.69. The filter should not have a negative impact on the product (e.g. by removing components or by releasing substances into it). The	9.09. クイルターは装品に好ましてない影響を及ばさないものでのること (例えば、成分を(吸着して)除去したり、物質を製品に放出する)。滅菌
integrity of the sterilising filter should be verified before use, in case it	用フィルターの完全性を使用前に検証し、加工においてフィルターが破
is suspected that the filter may have been damaged by processing, and	損の可能性が疑われる場合は、使用直後にもオンライン試験で適切な
should also be confirmed by on-line testing immediately after use by an	方法により確認すること(例えばバブルポイント、ディフュージョンフロー、
appropriate method (e.g. bubble point, diffusive flow, water intrusion or	水侵入或いはプレッシャーホールド試験)。フィルター完全性を試験する
pressure hold test). If filter integrity cannot be tested (e.g. small size	ことが出来ない場合(例えばバッチサイズが小さい場合)リスク評価に基
batches), an alternative approach may be applied, which should be	づいた代替アプローチを適用しても良い。同じフィルターを異なったバッ
based on a risk-assessment. The same filter should not be used for	チに使用しないこと。更に、同じフィルターを1作業日を越えて使用するこ
different batches. Additionally, the same filter should not be used for	とがバリデートされていない限り、そのような使用を行わないこと。
more than one working day, unless such use has been validate.	
9.6. Other operating principles	
9.70. Critical quality parameters (as identified in the marketing	9.70. (販売承認/治験承認において特定されている)重要品質パラメー
authorisation/clinical trial authorisation) should be monitored at appropriate intervals. When technically possible, continuous monitoring	タは適切な間隔でモニターすること。技術的に可能な場合、主要な工程 パラメータの連続モニタリングを行うことが望ましい(例えばバイオリアク
of key process parameters is expected (e.g. in bioreactors). Any	ター)。如何なる逸脱も記録し究明すること、そして取られた処置も記録
deviations should be recorded and investigated, and the measures	すること。
taken should also be documented.	, <u>, , , , , , , , , , , , , , , , , , </u>
9.71. Any necessary environmental controls (see Section 4.3.3) should	9.71. 必要な環境管理(4.3.3章を参照)はいずれも実施し、記録するこ
be carried out and recorded.	
9.72. Where chromatography equipment is used, a suitable control	9.72. クロマト設備が用いられている場合で、キャンペーン生産で複数製
strategy for matrices, the housings and associated equipment (adapted	品を扱う状況においては、カラムの充填剤、ハウジング、及び付随設備
to the risks) should be implemented when used in campaign	に関して(リスクに対応して)適切な管理戦略を実施すること。同じ充填
manufacture and in multi-product environments. The re-use of the	剤を異なった加工段階で使用することは望ましくない。そのような再使用
same matrix at different stages of processing is discouraged. Any such	は如何なる場合もバリデーションデータによる裏付けがあること。クロマ
re-usage should be supported by appropriate validation data.	トカラムの合格基準、操作条件、再生方法、可使時間、及び消毒或いは
Acceptance criteria, operating conditions, regeneration methods, life	滅菌法を規定すること。
span, and sanitization or sterilization methods of chromatography 9.73. Where ionizing radiation is used in the manufacturing of ATMPs,	9.73. ATMPの製造にイオン化放射線が使用される場合、更なるガイダ
Annex 12 of the Part I of the Good Manufacturing Practice Guidelines	ンスとしてGMPガイドラインのPart IのAnnex12を参照すること。
published in Volume 4 of Eudralex should be consulted for further	
guidance.	
9.7. Packaging	9.7. 包装
9.74. The suitability of primary packaging materials should be ensured	9.74. 一次包装材料の適切性を製品特性と保存条件を考慮して保証す
having regard to the characteristics of the product and the storage	ること(例えば極低温で保存すべき製品)。販売承認或いは治験承認に
conditions (e.g. products that should be stored at ultra-low	おいて規定されている規格を遵守すること。
temperature). The specifications provided for in the marketing	
authorisation or the clinical trial authorisation should be complied with.	
9.75. The level of documentation regarding the demonstration of	9.75. 一次包装材料の適切性を示すための文書化の水準は開発の段
suitability of the primary packaging material should be adapted to the	階に対応させること。承認されたATMPの製造に関しては、一次包装材 料の供給業者の選定、適格性確認、承認及び適格性確認の維持管理
phase of development. For production of authorised ATMPs, selection, qualification, approval and maintenance of suppliers of primary	科の供給来有の迭定、適格性確認、承認及び適格性確認の維持管理について文書化すること。
packaging materials should be documented.	について又言化すること。
9.76. ATMPs should be suitably packaged to maintain the quality of the	976. ATMPは、保存、取り扱い、輸送中に製品品質を保持するために
product during storage, handling, and shipping. Particular attention	適切に包装すること。製品の完全性及び品質を保証する為に容器の栓
should be paid to the closure of containers so as to ensure the	に特別の注意を払うこと。承認されたATMPに関しては、施栓工程をバリ
integrity and quality of the product. For authorised ATMPs, the closure	
procedures should be validated and the effectiveness should be verified	少な場合、代用品を用いたバリデーションが許容される。
at appropriate intervals. Validation with surrogate materials is	
acceptable when materials are scarce.	
9.77. Checks should be made to ensure that any electronic code	9.77. 何らかの電子的コード読み取り装置、ラベル計数機或いは同様な
readers, label counters or similar devices are operating correctly.	機器が正しく動作していることを保証する為にチェックを行うこと。ラベル は輸送取び保存条件(例えば振作泪)に適応するキのであること
Labels should be compatible with transport and storage conditions (e.g. ultra-low temperatures).	は輸送及び保存条件(例えば極低温)に適応するものであること。
9.78. Prior to product labelling operations, the work area and any	9.78. 製品の表示作業に先立って、作業区域及び使用する如何なる設
equipment used should be clean and free from any product, material or	19.76. 袰田の衣が作業に光立って、作業区域及び使用9 る如何なる設備 備も清潔で、その時の作業に必要がない如何なる製品、原材料、或い
document that is not required for the current operation. Precautions	は文書も存在しないこと。製品の混同を防止し、製品を汚染のリスクから
should be taken to avoid mix-ups of products and to protect the	保護するための予防措置を取ること。
product from the risk of contamination.	
Additional requirements for investigational	ATMPs 治験用ATMPに関する追加の要求事項
9.79. Packaging and labelling of investigational ATMPs are likely to be	9.79. 治験用のATMPの包装及び表示は販売承認された医薬品に対し
more complex and more liable to errors which are also harder to detect	て、特に外観が似ている盲検用製品が使用される場合に、より複雑でよ
than for authorised medicinal products, particularly when "blinded"	り検出し難いエラーを犯し易い。従って、特別の注意を払うこと。
products with similar appearance are used. Therefore, special	
precautions should be taken.	
9.80. During packaging of investigational ATMPs, it may be necessary	9.80. 治験用のATMPの包装中は、異なった製品を同じ包装ラインで同時に取り扱う必要がある可能性がある。制品の混同のリスクを適切な手
to handle different products on the same packaging line at the same	時に取り扱う必要がある可能性がある。製品の混同のリスクを適切な手 順及び/又は必要に応じて特別の設備を用い、関連するスタッフの教育
time. The risk of product mix-up must be minimised by using appropriate procedures and/or specialised equipment as appropriate	順及び/又は必要に応して特別の設備を用い、関連するスタッフの教育 訓練により最小限としなければならない。
appropriate procedures and/or specialised equipment as appropriate and relevant staff training.	ロソリリルト \ 〜 ∽ フ 邦2 1 'PX ∟ し'み \ 1 / いみ'み 'D'みい '₀
9.81. Labelling of investigational ATMPs should comply with the	9.81. 治験用のATMPの表示は、Regulation (EU) No 536/2014(治験実
requirements of Regulation (EU) No 536/2014. If it becomes necessary	施国、地域の法規制)の要求事項を遵守すること。使用期限を変更する
to change the expiry date, an additional label should be affixed to the	必要がある場合は、追加表示を治験用のATMPに貼付すること。追加
investigational ATMP. This additional label should state the new expiry	表示には、新しい使用期限を表示し、再度バッチナンバーを表示するこ
	と。古い使用期限の上に表示を貼り重ねることがあるかもしれないが、
date and repeat the batch number. It may be superimposed on the old	
date and repeat the batch number. It may be superimposed on the old expiry date, but for quality control reasons, not on the original batch	品質管理の観点から、もとのバッチナンバーの上に貼り重ねないこと。

9.82. Re-packaging and re-labelling operation should be performed by appropriately trained staff in accordance specific standard operating procedures and should be checked by a second person.	9.82. 再包装、再表示の作業はそのためのSOPに従って適切に教育訓 練されたスタッフにより実施し、二人目の者によるチェックを受けること。
9.83. Where products are blinded, the blinding system should be described in the Product Specification File (see Section 6.2). Where the manufacturer has been delegated the responsibility for generation of randomisation codes, the manufacturer should enable that unblinding information is available to the appropriate responsible investigator site personnel before investigational medicinal products are supplied.	9.83. 製品が盲検用の場合、盲検システムを製品規格ファイル(6.2章参 照)に記載すること。製造業者が無作為化コードの作成の権限を与えら れた場合、その製造業者は治験用医薬品を供給する前に治験施設の 適切な責任者に盲検解除の情報を提供可能にしておくこと。包装材料の バッチ間で外観が変更されたことによって意図せずに盲検解除してしま う事を避けるため特別の注意を払うこと。
Special precautions should be taken to avoid unintentional unblinding due to changes in appearance between different batches of packaging	
9.8. Finished products 9.84. As a general principle, finished products should be held in quarantine until their release under conditions established by the manufacturer in accordance with the terms of the marketing authorization or the clinical trial authorisation. It is acknowledged, however, that due to the short shelf-life, physical or administrative quarantine of ATMPs may not always be possible. The release of products before completion of all quality control tests is addressed	9.8. 最終製品 9.8. 一般原則として、最終製品は、販売承認あるいは治験承認の要件 に従って製造業者により確立された条件で出荷可否判定がされるまで、 判定待ちの状態に保たなければならない。しかし、有効期間が短いこと により、物理的或いは管理手段によるATMPの判定待ちは常に可能で あるとは限らないことが認められている。全ての品質管理試験が完了す る前に製品の出荷可否判定を行うことについては11.3.2章で焦点を当て られている。
individually for extraneous contamination or other defects. When the inspection is done visually, it should be done under suitable conditions of illumination and background.	9.85. 注射用製品の充填された容器は異物の汚染或いは他の欠陥に ついて個々に検査すること。目視で検査する際には照度と背景について 適切な条件下で実施すること。
requirements laid down in Section 14.1 are also applicable in case of defects detected at this stage.	9.86. 検出された如何なる欠陥についても記録し究明すること。この段 階で検出された欠陥の場合、14.1章で規定された要求事項もまた適用さ れる。
preserve the quality of the product and to prevent mix-ups. Particular attention should be paid to implementing appropriate measures to prevent mix-ups of autologous products and other dedicated products (i.e. products intended for specific patients).	9.87. 最終製品は製品品質を保持し混同を防止するために適切な条件の下で保管すること。自家製品及び他の専用製品(即ち特定の患者向けの製品)の混同を防止するための適切な対策を実施する為に特別な注意を払うこと。
	9.9. 不合格品、再加工品、及び返品
	9.88. 不合格品はその旨明確に印をつけ、分別して制限された区域(例 えば施錠した区域)に保管すること。不合格の出発物質及び原料は供給 業者に返却するか、製造環境から除去するかのいずれかとすること。ど のような対応が取られたとしても、権限を有する者に承認を得るとともに 記録すること。
9.89. The reprocessing of rejected products should be exceptional. For authorised ATMPs, reprocessing is only permissible if this possibility is foreseen in the marketing authorisation. In the case of investigational ATMPs, the competent authorities should be informed when, exceptionally, there is reprocessing.	9.89. 不合格品の再加工は例外とすること。承認されたATMPに関して は、再加工はこの可能性が販売承認において予見された場合のみ許容 できる。治験用ATMPの場合、例外的に再加工があった場合、管轄当局 に報告すること。
	9.90. 更に、再加工した物の使用は最終製品の品質が影響されず、規 格に適合している場合のみ可能である。再加工されたか或いは再加工 された製品が含まれる最終製品の追加の試験の必要性は品質管理に 責任を有する者により評価されること。再加工の記録を保存すること。製 品が出荷判定される前にQPIこよる証明が必要である。
manufacturer, should be marked as such and be segregated so that	9.91. 製造業者の管理下にある返品はその旨印を付け、品質管理に責任を有する者により批判的に評価された後に疑いもなく品質に問題ないのでない限り更なる臨床使用に使用可能としないよう隔離すること。
10. Qualification and validation 10.1. Qualification of premises and equipment	<u>10. 適格性確認及びパリデーション</u> 10.1. 構造設備の適格性確認
10.1.1. General principles 10.10. Premises and equipment used in the manufacture of ATMPs should be qualified. Through the qualification of premises and equipment, it is established that the premises and equipment are adequate for the intended operations.	10.1.1. 一般原則 10.10. ATMPの製造に使用される構造設備は適格性確認を行うこと。構 造設備の適格性確認を通じて構造設備が意図した作業に適切であるこ とが確認される。
10.11. Decisions on the scope and extent of the qualification should be	10.11. 適格性確認の範囲と程度について決定するにあたっては、文書 化されたリスク評価に基づくこと。構造設備の適格性確認の戦略を決定 する際には以下の点を考慮すること:
10.12. (a) Clean areas should be qualified in accordance with ISO 14644-1 and re-qualified at appropriate intervals in accordance with ISO 14644-2. In particular, periodic classification testing (in accordance with ISO 14664-1) is expected annually but the frequency can be extended based on risk assessment, the extent of the monitoring system and data that are consistently in compliance with acceptance limits or levels defined in the monitoring plan.	10.12. (a) 清浄区域はISO 14644-1に従って適格性確認を行い、再確認 をISO 14644-2に従って適切な間隔で実施すること。特に、(ISO 14644- 1に従った)定期的な清浄度クラス確認の試験は年次で実施することが 求められる、しかし、頻度はリスク評価及び、モニタリングシステムとその データがモニタリング計画に規定された限度或いは基準に一貫して適合 している程度に基づき延長することが可能である。
10.13. (b) If computerized systems are used, their validation should be proportionate to the impact thereof on the quality of the product. For computerised systems supporting critical processes, provisions should be made to ensure continuity in the event of a system breakdown (e.g.	10.13. (b)コンピュータ化システムが用いられている場合、それらのバリ デーションは製品品質への影響に比例したものであること。重要工程を サポートしているコンピュータ化システムに関しては、システムがダウン した場合の継続性(例えば手動或いは代替システム)を保証する規定を 作成しておくこと。

10.14. (c) For investigational ATMPs, it is expected that at least the suitability of the air quality system (in accordance with ISO 14644–1 and ISO 14664–2) and the suitability of the premises to adequately control the risk of microbial and nonviable particle contamination is verified. Any other aspect of the premises that is critical having regard to the specific risks of the intended manufacturing process should be qualified (e.g. containment measures when viral replicating vectors are used). Critical equipment should be qualified also.	10.14. (c) 治験用ATMPについては、少なくとも空気の品質に関するシス テムの適切性(ISO 14644-1及びISO 14644-2に従って)及び微生物およ び微粒子汚染のリスクを適切に管理する事に関する建物の適切性につ いて検証することが求められる。意図する製造工程の特定のリスクを考 慮して重要な施設のその他の如何なる側面(例えば、ウイルスの複製用 のベクターが用いられている場合の封じ込め対策)についても適格性確 認を行うこと。重要設備についても適格性確認を行うこと。
10.15. Before starting the manufacturing of a new type of ATMP in premises that have already been qualified, the manufacturer should assess if there is a need for re-qualification having regard to the specific risks and characteristics of the new manufacturing process/new product. For example, if the premises have been qualified for open processing and a closed system is introduced, it can be assumed that the (existing) qualification of the premises covers a worst case scenario and therefore no requalification is needed. In contrast, when the premises have been qualified for a simple manufacturing process and a more complex process is introduced that e.g. may require an additional level of containment, requalification is required. Likewise, if there is a significant change in the lay out of the premises,	カバーしているとみなすことができ、従って適格性の再確認は必要ない。
there should be an assessment whether requalification is required. 10.16. Facilities and equipment should be re-evaluated at appropriate intervals to confirm that they remain suitable for the intended	10.16. 構造設備は、意図する作業に引き続き適切であるか確認するため、適切な間隔で再評価を行うこと。
10.1.2. Steps of the qualification process	10.1.2. 適格性確認を進める段階
Setting the user requirement specifications:	ユーザー要求規格の設定
10.17. The manufacturer, or- as appropriate- the sponsor or marketing authorisation holder should define the specifications for the premises and equipment. The user requirement specifications should ensure that the critical quality attributes of the product and the identified risks linked to the manufacturing processes are adequately addressed (e.g. measures to avoid cross-contamination in a multi-product facility). The suitability of the materials of the parts of the equipment that come into contact with the product should be also addressed as part of the user requirement specifications.	10.17. 製造業者、或いは該当する場合、治験依頼者或いは販売承認保 持者は構造設備の規格を明確にすること。ユーザー要求規格は製品の 重要品質特性と特定された製造工程関連のリスクが適切に焦点を当て られていること(例えば、複数製品製造施設における交差汚染防止対 策)を保証するものであること。製品と接触する設備の部品の材質の適 切性も又、ユーザー要求規格の一部として焦点を当てること。
Design qualification (DQ):	設計時適格性確認(DQ)
10.18. The compliance of the user requirement specifications with GMP	10.18. ユーザー要求規格のGMP適合性を明示し、文書化すること。
should be demonstrated and documented.	
Verifying compliance with the user requirement specifications:	<u>ユーザー要求規格への適合性検証:</u>
10.19. The manufacturer or- as appropriate- the sponsor or marketing authorisation holder should verify that the premises/equipment comply with the user specifications and are in line with GMP requirements. Typically, this involves the following steps:	10.19. 製造業者、或いは該当する場合、治験依頼者或いは販売承認保 持者は、建物/設備がユーザー要求規格に適合しており、GMP要求事項 に従っていることを検証すること。典型的にはこれは以下の段階を含む:
Installation Qualification (IQ): As a minimum, it should be verified that: (i) components, equipment, pipe work and other installations have been installed in conformity with the user specifications,	10.20. (a) 据え付け適格性確認(IQ):最低限以下を検証すること: (i) 構成部分、設備、配管及び他の装置がユーザー規格に適合して据え 付けられていること
(ii) operating and maintenance instructions are provided (as appropriate), and	(ii)操作及びメンテナンス説明書が(適宜)提供されている、そして
(iii) instruments are appropriately calibrated and -where applicable- associated alarms are functional.	(iii) 計器が適切にキャリブレートされており、-該当する場合-付属のア ラームが機能する。
10.21. (b) Operational Qualification (OQ): The suitability of the	10.21. (b) 運転適格性確認(OQ):構造設備が設計通り(ワーストケース
premises and equipment to operate as designed (including under "worst case" conditions) should be tested.	
10.22. (c) Performance Qualification (PQ): The suitability of the premises and equipment to operate consistently in accordance with the requirements of the intended manufacturing process (assuming worst case conditions) should be tested. A test with surrogate materials or simulated product is acceptable.	10.22. (c) 稼働性能の確認(PQ):構造設備が意図する製造工程の要 求事項(ワーストケースの条件を想定して)に従って一貫して稼働するこ とを試験すること。代用品或いは模擬製品による試験が許容される。
10.23. Any deviations identified should be addressed before moving to the next qualification step. However, it is acknowledged that, in some	10.23. 特定された如何なる逸脱も次の適格性確認の段階に進む前に焦 点を当てること。ある場合にはIQ,OQ,PQを同時に実施することが適切で ある場合もある。工程バリデーションをPQと同時に実施することも許容さ れ得る。
10.24. Where functionality of the equipment is not affected by transport and installation, the documentation review and some tests could be performed at the vendor's site (e.g. through factory acceptance testing), without the need to repeat the relevant elements of IQ/OQ at the manufacturer's site.	10.24. 設備の機能が輸送や据付により影響されない場合、IQ/OQの該 当する要素を製造業者の製造所で繰り返し行う必要なしに、納入業者の 報告書の照査を行い、或る試験を納入業者の製造所で(例えば、工場
10.25. Likewise, when validating several identical pieces of equipment, it is acceptable for the manufacturer to establish a suitable testing strategy based on an evaluation of the risks.	価に基づいて適切な試験戦略を立てることが許容される。
Documentation:	<u>文書化</u>
10.26. A report should be written summarizing the results and conclusions reached. When qualification documentation is supplied by a third party (e.g. vendor, installers), the ATMP manufacturer or -as appropriate- the sponsor or marketing authorisation holder should assess whether the documentation provided is sufficient, or if additional tests should be performed at the site to confirm suitability of the equipment (e.g. when information gaps exist having regard to the intended manufacturing process, if the equipment is to be used differently than as intended by the manufacturer of the equipment,	10.26. 結果と達した結論をまとめた報告書を作成すること。適格性確認 の文書が第3者(例えば、供給業者、設置業者)から供給される場合は、 ATMP製造業者或いは-該当する場合-治験依頼者或いは販売承認保 持者は供給された文書が充分か、又、設備の適切性を確認するため追 加の試験をその製造所で行うべきかについて評価すること。(例えば、 意図した製造工程に関して情報が欠けている部分がある場合、設備の 製造業者が意図していたのとは異なる使い方をする場合、等)
10.27. Where the qualification of the premises/equipment is outsourced	10.27.建物/設備の適格性確認を第3者に委託する場合、13章に規定さ
to a third party, the principles laid down in Section 13 also apply.	れている原則もまた適用される。
10.2. Cleaning validation	10.2. 洗浄バリデーション

10.28. The cleaning procedures applied to re-usable tools and parts of	10.28. 繰り返し使用する製品接触の道具類及び設備の部品に適用す
equipment that enter into contact with the product should be validated.	る洗浄手順はバリデートすること。 10.29. 洗浄バリデーションはある洗浄手順が効果的且つ再現性をもって
10.29. Cleaning validation is the documented evidence that a given cleaning procedure effectively and reproducibly removes contaminants,	10.29. 元序ハリアーションはのる元序手順が効果的且シー境にともうで 汚染物質、前の製品からの残留物、及び洗浄剤の残留を除去すること
residues from previous product, and cleaning agents below a pre-	の文書化されたエビデンスである。洗浄バリデーションを実施するため
defined threshold. There may be more than one way to perform	の方法は1つ以上あるであろう。目的は、洗浄工程が一貫して予め規定
cleaning validation. The objective is to demonstrate that the cleaning	された許容基準に適合することである。微生物及びエンドトキシン汚染
process consistently meets the predefined acceptance criteria. The	のリスクも適切に評価すること。
risk of microbial and endotoxin contamination should be duly assessed.	
10.30. The following considerations apply when designing the cleaning	10.30. 以下の点が洗浄バリデーションの戦略を設計する際に適用され
validation strategy:	<u>ລະ</u>
-Factors that influence the effectiveness of the cleaning process (e.g.	一洗浄工程の効果に影響する要因(例えば、作業者、洗浄時間、洗浄
operators, rinsing times, cleaning equipment and amounts of cleaning	器具、及び使用する洗浄剤の量)を特定すること。若し変動要因が特定
agents used) should be identified. If variable factors have been	されたならば、ワーストケースの状況を洗浄バリデーション評価の基本と
identified, the worst case situations should be used as the basis for	して用いること。
cleaning validation studies. —The influence of the time between manufacture and cleaning, and	
between cleaning and use should be taken into account to define dirty	の時間の影響を、洗浄工程のダーティーホールドタイムとクリーンホール
and clean hold times for the cleaning process.	ドタイムを規定するために考慮すること。
-When justified due to the scarcity of the starting materials,	一出発物質が希少であることにより、妥当性を示した場合、シミュレート
simulating agents may be used.	した試薬を使用してもよい。
10.31. Cleaning procedures for closely related ATMPs do not need to	10.31. 近似したATMPの洗浄手順は個別にバリデートする必要はない。
be individually validated. A single validation study which considers the	ワーストケースと考えられる1つのバリデーション試験で許容できる。
worst case scenario is acceptable.	
10.32. Cleaning validation should be described in a document, which	10.32. 洗浄バリデーションは以下をカバーする文書に記載すること:
should cover:	
(i) Detailed cleaning procedure for each piece of equipment: Grouping	(i) 個々の設備ごとの詳細な洗浄手順:適切に妥当性を示した場合グ
approaches are acceptable if appropriately justified (e.g. cleaning of	ループ化のアプローチが許容される(例えば、同じ設計の容量違いの加
processing vessels of the same design but with different capacity).	工用設備の洗浄)。同様なタイプの設備を互いにグループ化した場合、
Where similar types of equipment are grouped together, a justification	洗浄バリデーションのために選定した特定の設備が妥当であることの説
of the specific equipment selected for cleaning validation is expected.	明が求められる。設備の選定はワーストケース(例えば最大容量の容 器)を代表するものであること。
The selection of the equipment should be representative of the worst case scenario (for example, the higher capacity vessel).	hf/でこうな y るひひ CのるにC。
(ii) Sampling procedures: Sampling may be carried out by swabbing	 (ii) サンプリング手順:サンプリングは、製造設備によってスワブ法及び/
and/or rinsing or by other means depending on the production	マはリンス液の採取或いはその他の手段で行って良い。サンプリング用
equipment. The sampling materials and method should not influence the	
result. For swabs, sampling should be from locations identified as	プリングはワーストケースであると特定された部位から行うこと。設備内
"worst case". Recovery should be shown to be possible from all	のすべての製品接触材料に関して、用いた全てのサンプリング法につい
product contact materials sampled in the equipment with all the	て回収率を提示できること。
(iii) Validated analytical methods to be used.	(ⅲ) 用いる分析法はバリデートされたものであること。
(iv) Acceptance criteria, including the scientific rationale for setting the	(iv) 個々の限度を設定するための科学的妥当性を含む許容基準。
specific limits.	
10.33. The cleaning procedure should be performed an appropriate	10.33. 洗浄方法がバリデートされたことを証明するためにリスク評価に
number of times based on a risk assessment and meet the acceptance	基づき適切な回数洗浄手順を実施すること(通常少なくとも連続した3
criteria in order to prove that the cleaning method is validated (usually	バッチ)。製造工程にディスポーザブル設備のみが使用されている場合
three consecutive batches as a minimum). Cleaning validation may be	は洗浄バリデーションは減らすか不要としても良い。
reduced or not required if only disposables are used in the 10.34. A visual check for cleanliness is an important part of the	 10.34. 清浄度の目視チェックは洗浄バリデーションの許容基準の重要な
acceptance criteria for cleaning validation. However, it is not generally	部分である。しかし、一般的にこの基準のみを用いることは許容されな
acceptable for this criterion alone to be used. Repeated cleaning and	い。残留チェックの結果が合格となるまで洗浄と試験を繰り返すこともま
retesting until acceptable residue results are obtained is not	に許容されるアプローチとはみなされない。
considered an acceptable approach either.	
Approach for investigational ATMPs	治験用ATMPについてのアプローチ
10.35. For investigational ATMPs, cleaning verification is acceptable. In	
such cases, there should be sufficient data from the verification to	その場合、設備が清浄で、その後使用するために利用可能であるという
support a conclusion that the equipment is clean and available for	結論を裏付けるための充分なベリフィケーションからのデータがあるこ
further use.	<u>E</u> .
10.3. Process validation	10.3. 工程バリデーション
10.36. Process validation is the documented evidence that the	10.36. 工程バリデーションは、製造工程が一貫して特定のパラメータの
manufacturing process can consistently produce a result within specific	
parameters. While it is acknowledged that some degree of variability of	特性に基づく最終製品のある程度の変動はATMPに内在する特性であ
the finished product due to the characteristics of the starting materials	
is intrinsic to ATMPs, the aim of the process validation for ATMPs is to	
demonstrate that the finished product characteristics are within a	ことを証明することである。
given range (in compliance with the terms of the marketing	 10.37. エ程バリデーションの戦略は文書に定めること(バリデーションプ
10.37. The strategy to process validation should be laid down in a document ("validation protocol"). The protocol should define (and	10.37. 工程ハリテーションの戦略は又書に定めること(ハリテーションノ ロトコール)。そのプロトコールは、開発データ或いは文書化された工程
justify as appropriate) the critical process parameters, critical quality	ロトコール)。 てのノロトコールは、開発ナータ或いは又書れされた工程 知識に基づいた重要工程パラメータ、重要品質特性、及びそれらに伴う
attributes and the associated acceptance criteria based on	許容基準(及び必要に応じて妥当性の説明)を明確にすること。則ったア
development data or documented process knowledge. The approach	プローチの妥当性を示すこと。場合により、プロトコールにはバリデー
retained should be justified. As appropriate, the protocol should	ション時に検討するか、モニターすべきその他の(重要でない)特性およ
identify other (non-critical) attributes and parameters which should be	びパラメータについても特定し、それらを入れた理由を示すこと。
investigated or monitored during the validation activity, and the reasons	
10.38. The following should also be specified in the protocol:	10.38. 以下も又プロトコールに示すこと:
(i) List of the equipment/facilities to be used (including	(i) (測定/モニタリング/記録 機器を含めて)使用する設備/施設のキャ
measuring/monitoring/recording equipment) together with the	リブレーション状態を伴ったリスト。
calibration status.	
(ii) List of analytical methods and how they are to be validated, as	(ii) 分析法のリスト及び該当する場合それらがどのようにバリデートされ
	るのか。
appropriate.	
appropriate. (iii) Proposed in-process controls with acceptance criteria and the reason(s) why each in-process control is selected.	(前)許容基準を含めた、予定している工程内管理、及びそれぞれの工程 内管理を選定した理由。

 (iv) Where required, additional testing to be carried out with acceptance criteria. (v) Sampling plan and the rationale behind it. (vi) Methods for recording and evaluating results. (viii) Process for release and certification of batches (if applicable). (viii) Specifications for the finished product (as provided for in the marketing authorisation). 10.39. It is generally accepted that, as a minimum, three consecutive batches manufactured under routine conditions constitute a validation of the process. An alternative number of batches may be justified taking into account whether standard methods of manufacture are used, whether similar products or processes are already used at the site, the variability of starting material (autologous v. allogenic), clinical 	 (v) サンプリング計画及びその裏付けとなる根拠。 (vi) 記録法及び結果の評価法。 (vii) (該当する場合) バッチの出荷可否判定および証明の手順。 (viii) 最終製品の規格(販売承認において規定されている通り)。 10.39. ルーチンの条件下で製造した最低連続した3バッチが工程のバリデーションを構成する事が一般的に認められている。標準の製造法を用いるか否か、当該製造所で類似の製品或いは工程が既に使用されてい
 (v) Sampling plan and the rationale behind it. (vi) Methods for recording and evaluating results. (vii) Process for release and certification of batches (if applicable). (viii) Specifications for the finished product (as provided for in the marketing authorisation). 10.39. It is generally accepted that, as a minimum, three consecutive batches manufactured under routine conditions constitute a validation of the process. An alternative number of batches may be justified taking into account whether standard methods of manufacture are used, whether similar products or processes are already used at the 	 (vi) 記録法及び結果の評価法。 (vii) (該当する場合)バッチの出荷可否判定および証明の手順。 (viii) 最終製品の規格(販売承認において規定されている通り)。 10.39. ルーチンの条件下で製造した最低連続した3バッチが工程のバリデーションを構成する事が一般的に認められている。標準の製造法を用いるか否か、当該製造所で類似の製品或いは工程が既に使用されてい
 (vii) Process for release and certification of batches (if applicable). (viii) Specifications for the finished product (as provided for in the marketing authorisation). 10.39. It is generally accepted that, as a minimum, three consecutive batches manufactured under routine conditions constitute a validation of the process. An alternative number of batches may be justified taking into account whether standard methods of manufacture are used, whether similar products or processes are already used at the 	 (vii)(該当する場合)バッチの出荷可否判定および証明の手順。 (viii)最終製品の規格(販売承認において規定されている通り)。 10.39. ルーチンの条件下で製造した最低連続した3バッチが工程のバリデーションを構成する事が一般的に認められている。標準の製造法を用いるか否か、当該製造所で類似の製品或いは工程が既に使用されてい
 (viii) Specifications for the finished product (as provided for in the marketing authorisation). 10.39. It is generally accepted that, as a minimum, three consecutive batches manufactured under routine conditions constitute a validation of the process. An alternative number of batches may be justified taking into account whether standard methods of manufacture are used, whether similar products or processes are already used at the 	 (viii) 最終製品の規格(販売承認において規定されている通り)。 10.39. ルーチンの条件下で製造した最低連続した3バッチが工程のバリデーションを構成する事が一般的に認められている。標準の製造法を用いるか否か、当該製造所で類似の製品或いは工程が既に使用されてい
10.39. It is generally accepted that, as a minimum, three consecutive batches manufactured under routine conditions constitute a validation of the process. An alternative number of batches may be justified taking into account whether standard methods of manufacture are used, whether similar products or processes are already used at the	デーションを構成する事が一般的に認められている。標準の製造法を用いるか否か、当該製造所で類似の製品或いは工程が既に使用されてい
batches manufactured under routine conditions constitute a validation of the process. An alternative number of batches may be justified taking into account whether standard methods of manufacture are used, whether similar products or processes are already used at the	デーションを構成する事が一般的に認められている。標準の製造法を用いるか否か、当該製造所で類似の製品或いは工程が既に使用されてい
indication (rare disease: only few batches will be produced).	るか否か、出発物質の変動性(自家対同種)、臨床適応(希少疾患:少数バッチのみ製造される)を考慮して代替バッチ数でバリデーションを実施することの妥当性を示しても良い。
10.40. The limited availability of the cells/tissues which is typical for	10.40. 多くのATMPにおいて細胞/組織の入手可能性が限定されている
most ATMPs requires the development of pragmatic approaches. The approach to process validation should take into account the quantities of tissue/cells available and should focus on gaining maximum experience of the process from each batch processed. Reduced process validation should, where possible, be offset by additional in-process testing to demonstrate consistency of production:	ことが典型的であることにより、現実的アプローチを開発することを必要 とする。工程バリデーションのアプローチは入手可能な組織/細胞の量 を考慮し、加工した各バッチから最大の経験を得ることに焦点を当てるこ と。縮小した工程バリデーションにおいては可能な場合は製造の一貫性 を示すための追加の工程内試験により埋め合わせること。
Validation with surrogate materials	代用品を用いたバリデーション
10.41. The use of surrogate material may be acceptable when there is shortage of the starting materials (e.g. autologous ATMPs, allogeneic in a matched-donor scenario, allogeneic where there is no expansion of cells to MCB). The representativeness of surrogate starting material should be evaluated, including -for example- donor age, use of materials from healthy donors, anatomical source (e.g. femur vs. iliac crest) or other different characteristics (e.g. use of representative cell-types or use of cells at a higher passage number than that foreseen in the product specifications).	10.41. 出発物質が不足している場合代用品の使用が許容される(例え ば、自家ATMP、適合ドナーによる同種品、MCBへの拡大培養を伴わな い同種品)。代用出発物質が代表していることの妥当性を、例えばド ナーの年齢、健康なドナーからの出発物質の使用、解剖学的供給源(例 えば大腿骨に対して腸骨稜)或いは他の異なった特性(例えば、代表す るタイプの細胞の使用或いは製品規格において予見されるよりも継代数 の多い細胞の使用)を含めて評価すること。
10.42. Where possible, consideration should be given to complementing the use of surrogate materials with samples from the actual starting materials for key aspects of the manufacturing process. For instance, in the case of an ATMP based on modification of autologous cells to treat a genetic disorder, process validation using the autologous cells (affected by the condition) may be limited to those parts of the process that focus on the genetic modification itself. Other aspects could be	10.42. 可能な場合、製造工程の主要な面に関して実際の出発物質のサンプルを含む代用品を用いることにより補足することも考慮すること。例えば、遺伝疾患治療用の自家細胞の改変に基づいたATMPの場合、自家細胞(病状に影響を受けた細胞)を用いたパリデーションは遺伝子の改変そのものに焦点を当てた工程の部分に限定して良い。工程のその他の部分は代用のタイプの細胞を用いてバリデートすることが出来る。
validated using a representative surrogate cell type. Concurrent validation approaches	ー コンカレントバリデーションのアプローチ
10.43. Due to the limited availability of the starting materials and/or where there is a strong benefit-risk ratio for the patient, a concurrent validation may be acceptable. The decision to carry out concurrent validation should be justified and a protocol should be defined. Regular reviews of data from the manufacture of batches should be subsequently used to confirm that the manufacturing process is able to ensure that the specifications in the marketing authorization are	10.43. 出発物質の入手が限定されている事及び/又は患者にとって強い ベネフィット/リスク比がある場合、コンカレントバリデーションが許容され うる。コンカレントバリデーションを実施するための決定については妥当 性を示し、プロトコールで規定すること。バリデーション後のルーチンの バッチの製造からのデータの定例の照査を、製造工程が販売承認の規 格が遵守されていることを保証し得るものであることを確認するために 用いること。
10.44. Where a concurrent validation approach has been adopted, there should be sufficient data to support the conclusion that the batch meets the defined criteria. The results and conclusion should be formally documented and available to the QP prior to the certification	10.44. コンカレントバリデーションのアプローチを適用した場合、バッチが 規定した基準に適合したという結論を裏付ける十分なデータがあること。 結果と結論は正式に文書化し、バッチ証明を行うにあたってQPに入手 可能となっていること。
Validation Strategy for closely related products 10.45. Where the same manufacturing platform is used for a number of closely related products (e.g. genetically modified cells where viral vectors are manufactured according to the same manufacturing process), the extent of validation work for each new product should be based on a justified and documented risk assessment of the process. This should take into account the extent of process knowledge, including existing relevant process validation work, for each significant step in the process. Thus, in so far as the other manufacturing steps remain the same, it may be possible to limit the validation to only the steps that are new to the process.	密接に関連した製品のパリデーション戦略 10.45.同じ製造基盤が複数の密接に関連した製品に用いられている場 合(例えば同じ製造工程に従ってウイルスベクターが製造された遺伝子 改変細胞)、各新製品についてのバリデーション作業の程度は、妥当性 を示し文書化された工程のリスク評価に基づくこと。これには工程の重 要な段階毎の既存の関連する工程パリデーションを含めた工程知識の 程度を考慮すること。他の製造工程が同じである限り、パリデーションを その工程にとって新たな部分のみに限定して実施することが可能であ る。
Investigational ATMPs	
10.46. The manufacturing process for investigational ATMPs is not expected to be validated but appropriate monitoring and control measures should be implemented to ensure compliance with the requirements in the clinical trial authorisation. Additionally, it is expected that the aseptic processes (and, where applicable, sterilising processes) have been validated.	10.46. 治験用ATMPの製造工程はバリデートされていることは求められ ないが、治験承認での要求事項に適合していることを保証する為の適切 なモニタリング及び管理対策を実施すること。更に、無菌操作(及び該当 する場合、滅菌工程)はバリデートされていることが求められる。
10.47. Process validation/evaluation data should be collected throughout the development. It is noted that for the clinical trial to be used in support of a marketing authorisation application it is important to demonstrate that the manufacturing process of the investigational ATMP ensures consistent production.	10.47. 工程バリデーション/評価のデータを開発を通じて収集すること。 販売承認申請を裏付ける為に用いられる臨床試験に関しては、治験用 ATMPの製造工程は一貫した製造を保証することを示すことが重要であ る。
10.4. Validation of test methods	10.4. 試験方法のバリデーション 10.48 公共方法のバリデーションは、公共方法の音図にも日的に対する。
10.48. The validation of analytical methods is intended to ensure the suitability of the analytical methods for the intended purpose. Analytical procedures, which are either described in the European Pharmacopoeia, the pharmacopoeia of a Member State, or are linked to a product specific monograph, and are performed according to the monograph, are normally considered as validated. In such cases, the suitability of the validated test for the intended purpose should be	10.48. 分析方法のバリデーションは、分析方法の意図した目的に対する 適切性を保証することを意図している。欧州薬局方、EUのメンバー国の 薬局方に記載されているか、或いは製品特定のモノグラフに連結してい るかのいずれかであり、モノグラフに従って実施される分析手順は通常 パリデートされていると考えられる。そのような場合、バリデートされてい る試験の意図した目的への適切性を検証すること。

10.49. All analytical methods should be validated at the stage of	10.49. 全ての分析方法は販売承認申請の段階ではバリデートされてい
marketing authorisation application.	ること。
Investigational ATMPs	<u>治験用ATMP</u>
10.50. During clinical development a gradual approach can be applied:	10.50. 臨床開発の間は漸進アプローチを適用することが出来る:
•First-in-man and exploratory clinical trials: Sterility and microbial assays should be validated. In addition, other assays that are intended	・ヒトに初めて使用する臨床試験及び探査的臨床試験:無菌試験及び微 生物アッセイをバリデートすること。更に、他の患者の安全性を保証する
to ensure patient's safety should also be validated (e.g. when retroviral	ことを意図した他のアッセイも又バリデートすること(例えばレトロウイル
vectors are used, the analytical methods for testing for replication	スのベクターが用いられる場合、複製能があるレトロウイルスの試験の
competent retrovirus should be validated).	ための分析法をバリデートすること)。
Throughout the clinical development, the suitability of analytical	・臨床開発を通じて重要品質特性を測定する為に使用する分析方法の
methods used to measure critical quality attributes (e.g.	適切性(例えば、ウイルス及び/又は生物由来の他の不純物の不活化/
inactivation/removal of virus and/or other impurities of biological origin) should be established but full validation is not required. Potency assays	除去)を確立すること、しかしフルバリデーションは要求されない。カ価の アッセイは有効性安全性を示すためのピボタル試験より前にバリデート
are expected to be validated prior to pivotal clinical trials.	うりとれば有効性女生性を示すためのと不多が試験より前にハウノート されること。
• Pivotal clinical trials: Validation of analytical methods for batch	・有効性安全性を示すためのピボタル試験:バッチの出荷可否判定およ
release and stability testing is expected.	び安定性試験用の分析方法のバリデーションが求められる。
10.5. Validation of transport conditions	10.5. 輸送条件のバリデーション
10.51. Transport conditions may have a crucial impact on the quality of	10.51. 輸送条件はATMPの品質に決定的な影響を与える可能性があ
ATMPs. The transport conditions should be defined in writing.	る。輸送条件は文書で規定すること。 10.52. 規定された輸送条件(例えば、温度、容器のタイプ、等)の適切性
10.52. The adequacy of the defined transport conditions (e.g. temperature, type of container, etc.) should be demonstrated.	でした、 成定で102期区末件(防たは、 温度、 谷協の タイン、 寺)の 過 の 住 を示すこと。
10.53. Compliance with the defined transport conditions falls outside	10.53. 規定された輸送条件の遵守は製造業者の責任の範囲外になる
the responsibility of the manufacturer (unless such responsibility is	(そのような責任が契約によって製造業者に帰せられない限り)。そのよ
assumed by means of contract). Such compliance is outside the scope	うな遵守はGMPの範囲外である。
11. Qualified person and batch release	11. QP及びバッチの出荷可否判定
11.1. General principles 11.10. Each manufacturing site of ATMPs in the EEA must have at	<u>一般原則</u>
least one Qualified Person ("QP"). It is not excluded that two or more	11.10. EEA内の各ATMP製造所は少なくとも1名のQPがいること。2以上の製造
sites may have the same QP, provided that this does not impair the	所が同一のQPを置くことは、それがQPの業務を各製造所において継続
ability of the QP to provide his services to each of the sites in a	して行うことに支障を来たさないならば排除されない。
continuous fashion.	
11.11. Without prejudice to Section 11.5, batches of ATMPs should only	11.11.11.5章に影響を与えることなしに、ATMPのバッチはQPにより証明
be released for sale, supply to the market, or for use in clinical trial	された後にのみ販売、市場への供給、臨床試験での使用のために出荷
after certification by a QP. Until a batch is released, it should remain at the site of manufacture or be shipped under quarantine to another	可の判定を行うこと。バッチが出荷可の判定をされる迄は、製造所に留めるか、他の承認された事業場に判定待ちの状態で輸送すること。証明
authorised site. Safeguards to ensure that uncertified batches are not	されていないバッチが出荷可の判定をされないことを保証する安全措置
released should be in place. These safeguards may be physical (via the	があること。これらの安全措置は物理的(隔離と表示の使用による)或い
use of segregation and labelling) or electronic (via the use of	は電子的(コンピュータ化システムによる)なもので良い。証明されてい
computerized systems). When uncertified batches are moved from one	ないバッチが或る承認された事業場から他に移される際には手順が完
authorised site to another, the safeguards to prevent premature	了する前に出荷判定されることを防止する安全措置が機能しているこ
11.2. Qualified person 11.12. In addition to having the qualification requirements provided for	<u>11.2. QP</u> 11.12.Directive 2001/83の第49条に規定されている適格性に関する要
under Article 49 of Directive 2001/83, QPs responsible for ATMPs	求事項を満たしていることに加えて、ATMPに責任を有するQPは細胞及
should have training and experience relevant to the specific	び組織の生物学、バイオテクノロジーの技術、細胞の加工、特性解析、
characteristics of these products, including cell and tissue biology,	及び力価試験を含むATMP製品の特定の特性に関する教育訓練と経験
biotechnological techniques, cell processing, characterization and	を有すること。QPは彼らが責任を有しているATMPのタイプと製造工程
potency testing. QPs should have detailed knowledge of the type of	に関する詳細な知識を有していること。
ATMP and manufacturing steps for which they are taking responsibility. 11.13. The QP's main responsibility is to verify and certify that each	 11.13. QPの主要な責務は、EU内で製造された各バッチが以下に従って
batch produced in the EU has been manufactured and checked in	製造され、チェックされたことを検証し、証明することである
accordance with:	表達してい、アエッアというこことで決証し、証券17 8000 CB58
(i) the requirements of the marketing authorisation/clinical trial	(i) 販売承認/臨床試験承認の要求事項
authorisation,	
(ii) relevant regulations governing the manufacture of medicinal	(ii) GMPを含めて医薬品の製造を規制している関連法規制
products, including GMP, and (iii) relevant product specifications in the destination country (in the	(ⅲ) (輸出の場合)仕向け先国での関連する製品規格
case of exports).	
11.14. QPs should have access to:	11.14. QPは以下にアクセス可能であること:
(i) the necessary details of the marketing authorisation/clinical trial	(i) 関連する要求事項が遵守されているかを評価するための、販売/治
authorisation to assess if the relevant requirements have been	験承認の内容についての評価に必要なだけの詳細、そして
complied with, and (ii) relevant data about the entire manufacturing process of the ATMP,	(ii) 輸入がある場合はそれに関する業務も含めて、ATMPの製造工程全
including importation activities if any.	体に関するデータ
Imported ATMPs	解に関するアプレー 輸入ATMP
11.15. In case of imports of investigational ATMPs from third countries,	11.15. 第3国からの治験用ATMPの輸入の場合、QPはそのバッチの品
the QP should ensure that the quality of the batch is in accordance	質が治験承認の条件に従っており(製品規格ファイルの条件の遵守を
with the terms of the clinical trial authorisation (including compliance	含めて)、それがEUにおいて適用されるGMPの要求事項と少なくとも同
with the terms of the Product Specification File) and that it has been	等の品質基準に従って製造されたことを保証すること。
manufactured in accordance with quality standards at least equivalent to the GMP requirements applied in the EU.	
11.16. In case of imports of authorised ATMPs from third countries, the	11.16. 承認されたATMPを第3国から輸入する場合、QPはバッチの品質
QP should ensure that the quality of the batch is in accordance with	が、他に必要な何らかのチェックと共に活性物質の全項目の定性的及
the terms of the marketing authorisation, including by means of a full	び定量的分析によることを含めて、販売承認の条件に従っていることを
qualitative and quantitative analysis of the active substance(s) as well	保証すること。しかし、ATMPに関しては、最終製品から活性物質を分離
as any other necessary checks.21 However, it is acknowledged that for	することは必ずしも可能とは限らないことが認められている。再試験戦略
ATMPs it is not always possible to separate the active substance from	は販売承認の条件に従ったものであること。
the finished product. The re-testing strategy should be in accordance with the terms of the marketing authorisation.	
and the terms of the marketing authorisation.	1

11.17. Additionally, it may be justified to rely on testing performed in the third country in cases where the limited amount of material available (e.g. autologous products) or the short shelf-life impedes double release testing. In such cases, the testing in the third country should be conducted in GMP-certified facilities (in the case of authorised ATMPs) or under GMP conditions equivalent to those particular is the same of impacting of the same of the sam	11.17. 更に、物が限られた量しか得られない場合(例えば自家製品)或 いは有効期間が短く2重の出荷試験を行うことに障害がある場合、第3 国で実施された試験に依存することを正当化して良いであろう。そのよう な場合、第3国での試験はGMP証明を受けた施設(承認されたATMPの 場合)或いはEUで適用されるものと同等のGMP条件の下で(治験用 ATMPの場合)実施されること。
applicable in the EU (in the case of investigational ATMPs). 11.18. When the QP wishes to rely on testing of samples taken in a third country, transport and storage conditions should be adequate, so as to ensure the samples taken in the third country are still representative of the batch.	11.18. QPが第3国で採取されたサンプルについて行った試験に依存す ることを望んだ場合、輸送及び保管条件は、第3国で採取されたサンプ ルがバッチを代表している事を保証する為に適切であること。
11.19. In all cases, the conditions of storage and transport should be checked before certifying any batch; these conditions must be in accordance with the terms of the marketing authorisation/clinical trials authorisation.	11.19. 全ての場合において、バッチの証明を行う前に保管及び輸送条件をチェックすること;これらの条件は販売承認/治験承認の条件に従うこと。
Relying on GMP assessments by third parties e.g. audits	
11.20. In some cases the QP may rely on audits conducted by third parties attesting the general compliance with GMP in sites involved in the manufacture of the product. In these cases, there should be a clear delimitation of responsibilities and the general requirements in Section 13 also apply.	11.20. ある場合にはQPは、第3者が実施し、製品製造に関与した製造所のGMPへの全般的適合を証明した監査に依存しても良い。この場合、責任範囲を明確に定めること、そして13章の要求事項もまた適用される。
11.21. The QP should have access to all documentation which facilitates review of the audit outcome and continued reliance on the outsourced activity.	11.21. QPは監査の結果を照査するため、及び外注した業務に対して継続して信頼するために有用な全ての文書にアクセスできること。
Involvement of more than one QP	ー名以上のQPの関与
11.22. The QP who performs certification of the finished product batch may assume full responsibility for all stages of manufacture of the batch, or this responsibility may be shared with other QPs who have confirmed compliance of specific steps in the manufacture and control	11.22. 最終製品バッチの証明を行ったQPはそのバッチの製造の全段階 に全責任を負っても良い、又、この責任はバッチの製造及び管理の特定 の段階の適合性を確認した他の(複数の)QPと分担してもよい。
11.23. If a site only undertakes partial manufacturing operations, the QP at that site must (as a minimum) confirm that the operations undertaken by the site have been performed in accordance with GMP and the terms of the written agreement detailing the operations for which the site is responsible.	11.23. 或る製造所が製造作業の一部のみ実施した場合、当該製造所の QPは(最低限)その製造所で実施した作業がGMPと当該製造所が責任 を有する作業について詳細を記載した文書化された契約の条件に適合 して実施されたことを確認しなければならない。
11.24. Where more than one QP is involved in the assessment of one batch, the division of responsibilities amongst QPs in relation to compliance of the finished batch (including details on the responsibility for assessment of any deviations) should be clearly laid down in writing.	11.24. ーバッチの評価に1名より多いQPが関与した場合、それらのQP 間の最終製品バッチの適合性に関する責任の分担(何らかの逸脱が あった場合の評価の責任についての詳細を含めて)を文書にて明確に 規定しておくこと。
11.25. The QP should have access to any documentation relevant to	11.25. QPは彼らが責任を負っている責務に関連したどのような文書にも
the task for which they are talking responsibility. 11.3. Batch release	アクセスできること。 11.3. バッチの出荷可否判定
11.3.1. Batch release process	11.3.1. バッチの出荷可否判定の手順
11.26. The process of batch release includes the following steps:	11.26. バッチの出荷可否判定の手順は以下の段階を含む:
11.27. (a) Checking that the manufacture and testing of the batch has	そのバッチの製造及び試験が以下を含む該当する要求に従って行なわ
been done in accordance with applicable requirements, including that: (i) all manufacturing steps (including controls and testing) have been done in accordance with the marketing authorisation/clinical trial	<u>れたことをチェックする:</u> (i) 全ての製造工程(管理及び試験を含めて)が販売承認/治験承認に
3	従って行なわれた、
authorisation, (ii) the specifications for the raw materials, starting materials (including matrixes or devices that are a component of the ATMP) and packaging materials comply with the terms of the marketing authorisation/clinical	従って行なわれた、 (ii) 原料,出発物質(ATMPのコンポーネントであるマトリックス或いは医療 機器を含めて)及び包装材料が販売承認/臨床試験承認の要件に適合 している、
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reach to patients across the EU ("decentralised manufacturing"). This scenario may occur both in the context of authorised ATMPs as	starting materials/finished product, etc.). In such cases, manufacturing	
This scenario may occur both in the context of authorised ATMPs as		
	-	AIMPICおいてと共に、承認されたAIMPICおいても起こる。
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	wen as in the context of investigational ATWPS.	

11.45. The batch certification and release process becomes particularly	11.45. 複数の製造所での製造は製品のバラツキのリスクを増すため、
important in the case of ATMPs manufactured under a decentralised	分散システムで製造されたATMPの場合バッチ証明及び出荷可否判定
system as manufacturing in multiple sites increases the risk of	の手順が特に重要となる。特にどの製造所で製造されたバッチでも各
variability for the product. In particular, through the batch certification	バッチが販売承認/治験承認及びGMPへの適合を含めて他の関連する
and release process it must be ensured that each batch released at	法規制の要求事項に従って製造され、チェックされていることを、バッチ
any of the sites has been manufactured and checked in accordance	証明と出荷可否判定手順を通じて保証しなければならない。この為に以
with the requirements of the marketing authorisation/clinical trial	下の面につて考慮すること:
authorisation and other relevant regulatory requirements including	
compliance with GMP. To this effect, the following aspects should be	
11.46. (a) A "central site", which should be established in the EU,	11.46. (a) EU内に設立された中央製造所を特定すること。中央製造所
should be identified. The central site is responsible for the oversight of	は分散製造所の監視責任がある。この点で、中央製造所は少なくとも以
the decentralised sites. To this end, the central site assumes, as a	下の責務が課せられている:
minimum, the following tasks:	
(i) ensuring that those involved in the batch certification and release	(i) バッチ証明と出荷可否判定に従事する者が彼らの責務に関して適切
process are adequately qualified and trained for their tasks, and	に適格性確認され教育訓練されていることを保証すること、及び
(ii) performing audits to confirm that the batch certification and release	(ii) バッチ証明と出荷可否判定の手順が(SOPに記述された通りに)遵守
process (as descripted in SOP) is complied with.	されていることを確認するために監査を実施する。
11.47. The marketing authorisation holder/sponsor may be the central	11.47.販売承認保持者/治験依頼者が製造業者の役割を担っている場
site in cases when the marketing authorisation holder/sponsor also	合は販売承認保持者/治験依頼者が中央製造所であろう。
assumes the role of manufacturer.	
11.48. (b) There should be a written contract/technical agreement	11.48.(b) 中央製造所と分散製造所の間に、QPの責任を含めて、それ
between the central site and the decentralised sites establishing the	ぞれの製造所の責任を定めた文書化された契約/技術取決めがあるこ
responsibilities of each party, including the responsibility of the QP.	
11.49. (c) The steps of the batch certification and release process	
should be laid down in writing (SOP). The responsibilities of each of	と。関与する各製造所/関連する職務を果たす者の各々の責任を明確
the sites/actors involved should be clearly explained. There should be	に記載すること。該当する者の責任に隙間或いは説明できない重複が
	に記載すること。該当する自の員任に隙間或いは説明できない重後が 無いこと。手順は適宜販売承認/治験承認に関連して記載すること。
no gaps or unexplained overlaps in the responsibilities of the personnel	<u> </u>
concerned. The process should also be explained, as appropriate, in the	
context of the marketing authorisation application/clinical trial	
11.50. (d) A QP established in the EU should have ultimately	11.50. (d) EU内で指名されたQPがバッチ証明に最終責任を有すること。
responsibility for the batch certification. However, it should be possible	
for the QP of the central site to rely on data/information that is	れた者から彼/彼女に送られたデータ/情報に依って責任を果たすことが
transmitted to him by qualified and trained personnel at the	可能である。
11.51. (e) If a deviation occurs at the decentralised sites, it should be	11.51. (e) 分散製造所で逸脱が発生した場合、適宜QPが関与し、責任
approved in writing by a responsible person (after having assessed the	者により書面で承認を得ること(それが品質、安全性、有効性に及ぼす
impact thereof on quality, safety and efficacy), with the involvement of	影響を評価した後に)。逸脱は根本原因を特定する観点から究明し、必
the QP as appropriate. Deviations should be investigated with a view	要に応じて是正処置及び予防措置を実施すること。何らかの品質の欠
to identify the root cause and to implement corrective and preventive	陥が発生した場合は、逸脱、不適合を直ちに中央製造所に報告するこ
measures as appropriate. Any instances of quality defects, deviations	Ł
or non-conformity should be immediately reported to the central site.	
11.4. Handling of unplanned deviations	11.4. 計画外の逸脱の処理
As long as the specifications for the finished product are met, a QP	最終製品が規格に適合している限りQPは、以下の場合は製造工程及
may confirm compliance/certify a batch where an unexpected deviation	
related to the manufacturing process and/or the analytical control	の適合/証明を承認しても良い:
methods has occurred provided that:	
(i) there is an in-depth assessment of the impact of the deviation	(i) 逸脱の発生が製品の品質、安全性、或いは有効性に好ましくない影
	響を与えないことを裏付ける結論について掘り下げた評価がされてい
which supports a conclusion that the occurrence does not have a	
negative effect on quality, safety or efficacy of the product, and	
(ii) the need for inclusion of the affected batch/batches in the on-going	
stability programme has been evaluated, where appropriate.	リンクフロクラムに入れる必要性について評価されている
11.5. Administration of out of specification products	11.5. 規格外製品の管理
11.53. Exceptionally, the administration of the cells/tissues that are	11.53. 例外的に、細胞/組織を基にしたATMPに含まれる細胞/組織で規
contained in a cell/tissue based ATMP that is out of specification may	格外のものの投与が患者に必要な場合がある。当面の有意の危険性を
be necessary for the patient. Where the administration of the product	避けるためと、患者に対する代替の選択肢、そしてその製品に含まれる
is necessary to avoid an immediate significant hazard to the patient	細胞/組織を投与しない場合の帰結を考慮してその製品の投与が必要
and taking into account the alternative options for the patient and the	な場合、製品の主治医への供給は妥当とされる。
consequences of not receiving the cells/tissues contained in the	
product, the supply of the product to the treating physician is justified.	
11.54. When the request of the treating physician is received, the	11.54. 主治医の要望を受けた際に、製造業者は主治医にリスクの評価
manufacturer should provide the treating physician with its evaluation	結果を知らせ、規格外の製品を主治医の要望に依って供給しようとして
of the risks and notify the physician that the out of specification	いることを通知すること。主治医がその製品を受け入れることの確認を
product is being supplied to the physician at his/her request. The	製造業者は記録すること。臨床試験の中での治療という状況において
confirmation of the treating physician to accept the product should be	は、製造業者は直ちに治験依頼者にその件を通知すること。一方、治験
recorded by the manufacturer. In a clinical trial setting, the	依頼者は管轄当局に報告すること。市販されている製品に関しては、販
manufacturer should immediately notify the sponsor of such events. In	一、一、一、一、一、一、一、一、一、一、一、一、一、一、一、一、一、一、一、
turn, the sponsor should inform the relevant competent authority. For	に報告すること。
marketed products, the marketing authorisation holder and the	
manactor producto, the marketing authorisation holder and the	
supervisory authority for the site of the batch release should be	19 日哲告理
supervisory authority for the site of the batch release should be 12. Quality control	12. 品質管理
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12.12. The person responsible for quality control supervises all quality control procedures. In particular, it assumes responsibility for the following tasks:	12.12. 品質管理の責任者は全ての品質管理手順を監督する。特に以 下の責務を負う:
(i) Approval of specifications, sampling instructions, test methods and other quality control procedures.	(i) 規格、サンプリング指図、試験法及び他の品質管理手順の承認。
(ii) Approval of conditions for outsourced testing.	(ii) 外注試験の条件の承認。
(iii) Control of raw materials, starting materials, medical devices that	(iii)原料、出発物質、併用ATMPに使用されている医療機器、包装材
are used in combined ATMPs, packaging materials, intermediate, bulk	料、中間製品、バルク及び最終製品の管理(それらの事項の承認及び
and finished products (including approval or rejection thereof). In case	却下を含む)。自家製品或いはドナー適合の同種製品の場合、出発物
of autologous products or allogeneic products in a donor-match	質の起源と投与を受ける患者との適合を検証すること(細胞/組織の起
scenario, the match between the origin of the starting material and the	源に関する情報をチェックすること)。
recipient should be verified (information on the origin of the	
cells/tissues should be checked).	
Where, exceptionally, there is release of expired materials for use in	例外的に、期限切れの原材料を製造工程で使用する為に使用可の判
the manufacturing process, the person responsible for quality control	定をする場合、品質管理の責任者はそれらの品質を適切な再試験によ
should ensure the quality thereof through appropriate retesting.	り保証すること。
(iv) Supervision of the control of the reference and/or retention	(iv) 原材料及び製品について参考品及び/又は保存サンプルが必要な
samples of materials and products, as appropriate.	場合それらの管理の監督
(v) Ensuring that all necessary testing is carried out and the associated	
records are evaluated.	保証する。
(vi) Ensuring the monitoring of the stability of the products.	(vi) 製品の安定性モニタリングを保証する。
(vii) Participation in investigations related to the quality of the product.	(vii) 製品品質に関係する究明に参加する。
12.13. Appropriate records in connection with the above-referred	12.13. 上記の業務に関連する適切な記録を保管すること。(iii)~(vi)に
activities should be kept. Written procedures should be put in place in	列挙されている業務に関する文書化された手順があること。
connection with the activities listed in (iii) to (vi).	
12.14. Quality control personnel should have access to production	12.14. 品質管理の担当者は場合によりサンプリング及び究明の為に製
areas for sampling and investigation as appropriate. All documents that	造区域にアクセスできるようになっていること。品質管理の評価の為に
are needed for the assessment of quality control (e.g. description of	必要な全ての文書(例えば製造工程及び試験についての手順或いは記
procedures or records from the manufacturing process and testing)	録について記載したもの)についてもアクセス可能であること。
should also be accessible.	
12.2. Sampling	12.2. サンプリング
12.2.1. General principles	12.2.1. 一般原則
12.15. Samples should be representative of the batch of materials or	12.15. サンプルは採取した原材料及び製品のバッチを代表するもので
products from which they are taken. Bulk containers from which	あること。サンプルを抜き取ったバルク容器を特定すること。無菌原料或
samples have been drawn should be identified. In case of samples of	いは加工中に採取したサンプルの場合、サンプルの識別は他の適切な
sterile materials or samples that are taken during processing activities,	手段によること。
identification of the sample should be done by other appropriate means.	
12.16. The sample taking should be done and recorded in accordance	12.16. サンプル採取は、採取すべきサンプル量を含めたサンプリング方
with written procedures that describe the method of sampling, including	法、留意すべき注意事項、保管条件、等を記載した文書化された手順に
the amount of sample to be taken, precautions to be observed, storage	従って行ない、記録すること。サンプル容器は最低、内容物、バッチナン
conditions, etc. Containers should bear a label indicating, as a minimum,	バー、及びサンプリング日を示したラベルを付すこと。容器が小さすぎる
the content, batch number and date of sampling. When containers are	場合、バーコード或いは他にこの情報にアクセスできる手段を考慮する
too small, the use of bar-codes or other means that permit access to	こと。
this information should be considered.	
12.2.2. Retention of samples	12.2.2. サンプルの保存
12.17. Samples are generally retained for analytical purposes should the	12.17. 一般的に、サンプルを該当するバッチの有効期間中に必要が生
need arise during the shelf life of the batch concerned (reference	じた場合の分析用の目的(参考品)と、確認の目的(最終製品からの完
samples) and for identification purposes (retention sample of a fully	全に包装された単位製剤の保存サンプル)で保存する。場合によって
packaged unit from a batch of finished product). The reference sample	(即ち、完全に包装された単位製剤の場合)参考品と保存サンプルは同
and the retention sample may be identical in some cases (i.e. a fully	じで良い。
packaged unit).	
12.18. As a general principle, a reference sample should be of sufficient	12.18. 原則的に、参考品は販売承認/治験承認での全項目試験を少な
size to permit the carrying out on at least two occasions of the full	くとも2回実施するために十分な量であること。しかし、原材料が少量で
analytical controls on the batch foreseen in the marketing	あることや、バッチサイズが限定されているためにこれが常に可能であ
authorisation/clinical trial authorisation. However, it is acknowledged	るとは限らないことが認められている(例えば、自家製品、適合ドナーに
that this may not always be feasible due to scarcity of the materials or	よる同種製品、超希少疾患のための製品、非常に小スケールでの製造
limited size of the batches (e.g. autologous products, allogeneic	によるヒトに初めて使用する臨床試験のための製造)。
products in a matched donor scenario, products for ultra-rare diseases,	
products for use in first-in-man clinical trial with a very small scale	
12.19. The retention sample should be contained in its finished primary	12.19. 保存サンプルは最終製品の一次包装あるいは市販製品の一次
packaging or in packaging composed of the same material as the	容器と同じ材質から成る包装に入れられていること。
primary container in which the product is marketed.	
12.20. Samples should normally be stored under the conditions	12.20. サンプルは通常製品情報に見られる条件で保存すること。しかし
foreseen in the product information. However, for products/materials	有効期間が短い製品/原材料に関しては、安定性を最大限に出来る条
with a short shelf-life, it should be carefully considered if other storage	件を用いることが可能であるか注意深く検討すること(下記を参照)。
conditions that maximise stability can be used (see below).	
12.21. The sampling plan should be documented. The sampling plan	12.21. サンプリング計画は文書化すること。サンプリング計画は製品の
should be adapted to the specific characteristics of the product. In	特性に適応させること。サンプリング戦略を設計する際には製造業者は
designing the sampling strategy, the manufacturer should take into	リスク、存在する可能性がある実際上の制約、そして可能性がある軽減
account the risks, the practical limitations that may exist, and possible	策(例えば、工程内試験への依存度を高める)を考慮すること。製造業
mitigation measures (e.g. increased reliance on in-process testing).	者のサンプリング戦略は適切に妥当性を示すこと。
The sampling strategy of the manufacturer should be duly justified.	
12.22. In particular, the following considerations apply:	12.22. 特に、以下の配慮が適用される:
12.23. • Samples of raw materials: Reference samples of critical raw	12.23. <u>原料のサンプル</u> :重要原料の参考品(例えば、サイトカイン、成長
materials (e.g. cytokines, growth factors, enzymes, sera) are important	因子、酵素、血清)は製品で品質問題が発生した場合に究明のため重
to investigate possible quality problems with the product. The	要である。特定の原料が重要であるか否かの評価は製造業者(或い
assessment whether a specific raw materials is critical should be done	は、場合により、治験依頼者或いは販売承認保持者)により特定のリス
by the manufacturer (or, as appropriate, by the sponsor or marketing	クおよび取り得る軽減策(例えば、QC管理の強化)を考慮に入れて行わ
authorisation holder) having regard to the specific risks and possible	れること。行われた決定については文書化すること。重要原料のサンプ
mitigation measures (e.g. increased QC controls). The decisions taken	ルは当該原料の有効期間の間保存すること。
should be documented. Samples of critical raw materials should be	
retained during the shelflife of the relevant raw materials.	

12.24. • <u>Samples of the starting materials</u> should generally be kept for	12.24. 出発物質のサンプルは、通常バッチの出荷可否判定の後2年間
two years after the batch release. However, it is acknowledged that the	保存すること。しかし、その物質が希少であることからサンプルの保存は
retention of samples may be challenging due to scarcity of the	難問であることが認められている。この内在する制約のため、自家
materials. Due to this intrinsic limitation, it is justified not to keep	ATMPおよびある種の同種ATMP(適合ドナーの場合)の場合、出発物質
reference samples of the cells/tissues used as starting materials in the	として使用された細胞/組織の参考品を保存しないことが正当化される。
case of autologous ATMPs and certain allogeneic ATMPs (matched	原料の希少性が懸念されるその他の場合、サンプリング戦略は、これが
donor scenario). In other cases where the scarcity of the materials is	正当化され、適切な低減策が実施されるならばそのサンプリング戦略を
also a concern, the sampling strategy may be adapted provided that	希少性に適応させても良い。
this is justified and appropriate mitigation measures are implemented.	
12.25. <u>Samples of active substances and intermediate products</u> should	12.25. 活性物質及び中間製品のサンプルは通常バッチの出荷可否判
generally be kept for two years after the batch release. However, it is	定の後2年間保存すること。しかしATMPに関しては出発物質、活性物
acknowledged that for ATMPs it is not always possible to separate the	質、中間製品および最終製品のサンプリングを別々に行うことが常に可
sampling of the starting materials, active substance, intermediate and	能とは限らないことが認められている。出発物質が希少であることにつ
finished product. The considerations regarding scarcity of starting	いて配慮された内容が一必要に応じて修正を加えて一活性物質と中間製
materials apply -adapted as necessary- to the expectations on the	品のサンプルの保存に関して求められる内容に適用される。
retention of samples of active substances and intermediate products.	
12.26. <u>Samples of primary packaging material</u> : Samples of primary	12.26. 1次包装材料のサンプル:1次包装材料のサンプルは通常関連す
packaging material should generally be retained for the duration of the	る最終製品の有効期間の間保存すること。ある場合は、その材料のリス
shelf-life of the finished product concerned. The retention of samples	ク及び/又は他の関連する点(例えば、QCの管理が強化されている事、
of primary packaging material may not be necessary in certain cases,	1次容器が医療機器として証明されている)を考慮して1次包装材料のサ
having regard to the risks of the materials and/or other relevant	ンプルは必要ないであろう。1次包装材料のサンブルを保存しないという
	決定は適切に妥当であることを示し、文書化すること。
certified as a medical device). A decision not to keep samples of	
primary packaging materials should be duly justified and documented.	
12.27. <u>A sample of a fully packaged unit (retention sample)</u> should be	12.27. 完全に包装された単位製剤のサンプル(保存サンプル)をバッチ
kept per batch for at least one year after the expiry date. A retention	毎に有効期限後少なくとも1年保存すること。保存サンプルは、しかし、
sample is, however, not expected in the case of autologous products or	自家製品或いはドナー適合の同種製品の場合は患者の組織/細胞の
allogeneic products in a matched donor scenario as the unit produced	構成物から製造された単位が患者に投与されるため求められない。保
with the patient's tissues/cells constitutes should be administered to	存サンプルを保存することが出来ない場合、ラベルの写真或いはコピー
the patient. When it is not possible to keep a retention sample,	をバッチレコードに含めることが許容される。
photographs or copies of the label are acceptable for inclusion in the	
12.28. The retention period of samples of starting materials, active	12.28. 出発物質、活性物質、及び中間製品のサンプルの保存期間は製
substance and intermediate product should be adapted to the stability	品の安定性及び有効期間に合わせるべきであり、従ってより短い期間も
and shelf-life of the product and, therefore, shorter periods may be	正当化して良い。有効期間が短い場合、製造業者はサンプルの保存を
justified. In cases of short shelf-life, the manufacturer should consider	有効期間を延長する条件下(凍結保存のような)で保存することが意図
if the retention of the sample under conditions that prolong the shelf-	する目的を代表するか考慮すること。例えば、新鮮な細胞の凍結保存は
life (such as cryoprervation) is representative for the intended purpose.	サンプルを特性解析の目的に対しては不適としてしまうが、そのサンプ
For instance, cryoprervation of fresh-cells may render the sample	ルは無菌試験或いはウイルス安全性の管理のためには適切であろう
inadequate for characterisation purposes but the sample may be	(サンプル量は意図する目的によって減らすことが出来る)。サンプルの
adequate for sterility or viral safety controls (the volume of the	凍結保存が意図する目的に対して不適と考えられる場合、製造業者は
samples can be reduced according to the intended purpose). When the	代替アプローチを考慮すること(例えば、分化細胞のような中間製品の
cryostorage of a sample is considered inadequate for the intended	サンプル)。
purpose, the manufacturer should consider alternative approaches (e.g.	
sample of intermediate product such as differentiated cells).	
12.3. Testing	12.3. 試験
12.29. Testing is important to ensure that each batch meets the	12.29. 試験は各バッチが関連する規格に適合していることを保証するた
relevant specifications. Inprocess controls testing should be performed	めに重要である。工程内管理試験を、製造の適切な段階において、製
at appropriate stages of production to control those conditions that are	品品質に重要な条件を管理する為に実施すること。
important for the quality of the product.	
12.30. Testing of critical raw materials, starting materials, active	12.30. 重要原料、出発物質、活性物質/中間製品/最終製品の試験、及
	び安定性試験を販売承認/治験承認で規定された条件に従って実施す
be performed in accordance with the terms defined in the marketing	ること。
authorisation/clinical trial authorisation.	
12.31. Testing methods should be validated and reference materials	12.31. 試験法をバリデートし、適格性確認及び日常試験のための標準
should be established (where available) for qualification and routine	品(入手可能な場合)を確立すること。治験用ATMPに関しては、バリ
testing. For investigational ATMPs, the level of validation should be	デーションのレベルは開発の段階と患者のリスクを考慮した試験結果の
commensurate with the development phase and the criticality of the	重要性に相応したものであること。(10.4章を参照)
test results considering the risks for the patient (see Section 10.4).	
12.32. The following records should be kept in connection with the	12.32.実施した試験に関して以下の記録を保存すること:
tests performed:	
(i) Name of the material or product and, where applicable, dosage form.	(i) 原材料或いは製品の名称、該当する場合剤形。
(ii) Batch number and, where appropriate, the manufacturer and/or	(ii) バッチナンバー及び、該当する場合、製造業者及び/又は供給業者。
supplier.	
(iii) References to the relevant specifications and testing procedures.	(iii) 関連する規格及び試験手順への参照。
(iv) Test results, including observations and calculations, and reference	(iv) 観察した事項及び計算を含めた試験結果、及び試験成績書への参
to any certificates of analysis.	
	////。 (v) 試験日。
(v) Dates of testing.	
(v) Dates of testing. (vi) Initials of the persons who performed the testing (or another	(vi) 試験実施者のイニシャル(或いは他の適切な識別システム)。
 (v) Dates of testing. (vi) Initials of the persons who performed the testing (or another suitable identification system). 	(vi) 試験実施者のイニシャル(或いは他の適切な識別システム)。
 (v) Dates of testing. (vi) Initials of the persons who performed the testing (or another suitable identification system). (vii) Initials of the persons who verified the testing and the calculations, 	(vi) 試験実施者のイニシャル(或いは他の適切な識別システム)。(vii) 該当する場合、試験及び計算を検証した者のイニシャル(又は他の)
 (v) Dates of testing. (vi) Initials of the persons who performed the testing (or another suitable identification system). (vii) Initials of the persons who verified the testing and the calculations, where appropriate (or another suitable identification system). 	 (vi) 試験実施者のイニシャル(或いは他の適切な識別システム)。 (vii) 該当する場合、試験及び計算を検証した者のイニシャル(又は他の 適切な識別システム)
 (v) Dates of testing. (vi) Initials of the persons who performed the testing (or another suitable identification system). (vii) Initials of the persons who verified the testing and the calculations, where appropriate (or another suitable identification system). (viii) A clear statement of approval or rejection (or other status 	 (vi) 試験実施者のイニシャル(或いは他の適切な識別システム)。 (vii) 該当する場合、試験及び計算を検証した者のイニシャル(又は他の 適切な識別システム) (viii) 合格或いは不合格の明確な記述(或いは他の状態の決定)及び責
 (v) Dates of testing. (vi) Initials of the persons who performed the testing (or another suitable identification system). (vii) Initials of the persons who verified the testing and the calculations, where appropriate (or another suitable identification system). (viii) A clear statement of approval or rejection (or other status decision) and the dated signature of the responsible person. 	 (vi) 試験実施者のイニシャル(或いは他の適切な識別システム)。 (vii) 該当する場合、試験及び計算を検証した者のイニシャル(又は他の 適切な識別システム) (viii) 合格或いは不合格の明確な記述(或いは他の状態の決定)及び責 任者の日付入りの署名。
 (v) Dates of testing. (vi) Initials of the persons who performed the testing (or another suitable identification system). (vii) Initials of the persons who verified the testing and the calculations, where appropriate (or another suitable identification system). (viii) A clear statement of approval or rejection (or other status decision) and the dated signature of the responsible person. (ix) Reference to the equipment used. 	 (vi) 試験実施者のイニシャル(或いは他の適切な識別システム)。 (vii) 該当する場合、試験及び計算を検証した者のイニシャル(又は他の 適切な識別システム) (viii) 合格或いは不合格の明確な記述(或いは他の状態の決定)及び責 任者の日付入りの署名。 (ix) 使用した設備への参照。
 (v) Dates of testing. (vi) Initials of the persons who performed the testing (or another suitable identification system). (vii) Initials of the persons who verified the testing and the calculations, where appropriate (or another suitable identification system). (viii) A clear statement of approval or rejection (or other status decision) and the dated signature of the responsible person. (ix) Reference to the equipment used. 12.33. Materials, reagents, culture media and reference standards used 	 (vi) 試験実施者のイニシャル(或いは他の適切な識別システム)。 (vii) 該当する場合、試験及び計算を検証した者のイニシャル(又は他の 適切な識別システム) (viii) 合格或いは不合格の明確な記述(或いは他の状態の決定)及び責任者の日付入りの署名。 (ix) 使用した設備への参照。 12.33. 品質管理試験に使用した物質、試薬、培地、及び標準品は適切
 (v) Dates of testing. (vi) Initials of the persons who performed the testing (or another suitable identification system). (vii) Initials of the persons who verified the testing and the calculations, where appropriate (or another suitable identification system). (viii) A clear statement of approval or rejection (or other status decision) and the dated signature of the responsible person. (ix) Reference to the equipment used. 12.33. Materials, reagents, culture media and reference standards used for QC tests should be of appropriate quality and used according to 	 (vi) 試験実施者のイニシャル(或いは他の適切な識別システム)。 (vii) 該当する場合、試験及び計算を検証した者のイニシャル(又は他の 適切な識別システム) (viii) 合格或いは不合格の明確な記述(或いは他の状態の決定)及び責任者の日付入りの署名。 (ix) 使用した設備への参照。 12.33. 品質管理試験に使用した物質、試薬、培地、及び標準品は適切な品質であること、そして指図に従って使用すること。必要な場合、受領
 (v) Dates of testing. (vi) Initials of the persons who performed the testing (or another suitable identification system). (vii) Initials of the persons who verified the testing and the calculations, where appropriate (or another suitable identification system). (viii) A clear statement of approval or rejection (or other status decision) and the dated signature of the responsible person. (ix) Reference to the equipment used. 12.33. Materials, reagents, culture media and reference standards used for QC tests should be of appropriate quality and used according to instructions. Where necessary, identity verification and/or testing 	 (vi) 試験実施者のイニシャル(或いは他の適切な識別システム)。 (vii) 該当する場合、試験及び計算を検証した者のイニシャル(又は他の 適切な識別システム) (viii) 合格或いは不合格の明確な記述(或いは他の状態の決定)及び責任者の日付入りの署名。 (ix) 使用した設備への参照。 12.33. 品質管理試験に使用した物質、試薬、培地、及び標準品は適切
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 (v) Dates of testing. (vi) Initials of the persons who performed the testing (or another suitable identification system). (vii) Initials of the persons who verified the testing and the calculations, where appropriate (or another suitable identification system). (viii) A clear statement of approval or rejection (or other status decision) and the dated signature of the responsible person. (ix) Reference to the equipment used. 12.33. Materials, reagents, culture media and reference standards used for QC tests should be of appropriate quality and used according to instructions. Where necessary, identity verification and/or testing should be considered upon receipt or before use. Technical transfer of testing methods 	 (vi) 試験実施者のイニシャル(或いは他の適切な識別システム)。 (vii) 該当する場合、試験及び計算を検証した者のイニシャル(又は他の 適切な識別システム) (viii) 合格或いは不合格の明確な記述(或いは他の状態の決定)及び責 任者の日付入りの署名。 (ix) 使用した設備への参照。 12.33. 品質管理試験に使用した物質、試薬、培地、及び標準品は適切 な品質であること、そして指図に従って使用すること。必要な場合、受領 時或いは使用前に同定の検証及び/又は試験を考慮すること。 試験法の技術移管
 (v) Dates of testing. (vi) Initials of the persons who performed the testing (or another suitable identification system). (vii) Initials of the persons who verified the testing and the calculations, where appropriate (or another suitable identification system). (viii) A clear statement of approval or rejection (or other status decision) and the dated signature of the responsible person. (ix) Reference to the equipment used. 12.33. Materials, reagents, culture media and reference standards used for QC tests should be of appropriate quality and used according to instructions. Where necessary, identity verification and/or testing should be considered upon receipt or before use. Technical transfer of testing methods 12.34. The transfer of testing methods from one laboratory (transferring 	 (vi) 試験実施者のイニシャル(或いは他の適切な識別システム)。 (vii) 該当する場合、試験及び計算を検証した者のイニシャル(又は他の 適切な識別システム) (viii) 合格或いは不合格の明確な記述(或いは他の状態の決定)及び責 任者の日付入りの署名。 (ix) 使用した設備への参照。 12.33. 品質管理試験に使用した物質、試薬、培地、及び標準品は適切 な品質であること、そして指図に従って使用すること。必要な場合、受領 時或いは使用前に同定の検証及び/又は試験を考慮すること。 試験法の技術移管 12.34. 試験法の、或る試験室(移管試験室)から他の試験室(受領試験
 (v) Dates of testing. (vi) Initials of the persons who performed the testing (or another suitable identification system). (vii) Initials of the persons who verified the testing and the calculations, where appropriate (or another suitable identification system). (viii) A clear statement of approval or rejection (or other status decision) and the dated signature of the responsible person. (ix) Reference to the equipment used. 12.33. Materials, reagents, culture media and reference standards used for QC tests should be of appropriate quality and used according to instructions. Where necessary, identity verification and/or testing should be considered upon receipt or before use. Technical transfer of testing methods 	 (vi) 試験実施者のイニシャル(或いは他の適切な識別システム)。 (vii) 該当する場合、試験及び計算を検証した者のイニシャル(又は他の 適切な識別システム) (viii) 合格或いは不合格の明確な記述(或いは他の状態の決定)及び責 任者の日付入りの署名。 (ix) 使用した設備への参照。 12.33. 品質管理試験に使用した物質、試薬、培地、及び標準品は適切 な品質であること、そして指図に従って使用すること。必要な場合、受領 時或いは使用前に同定の検証及び/又は試験を考慮すること。 試験法の技術移管

 12.35. The transfer protocol should include, among others, the following parameters: (i) Identification of the testing to be performed and the relevant test method(s) undergoing transfer. (ii) Identification of any additional training requirements. (iii) Identification of standards and samples to be tested. (iv) Identification of any special transport and storage conditions of test items. (v) The acceptance criteria. 	 含むこと: (i) 移管を行なおうとしている試験及び関連する試験法の特定。 (ii) 何らかの追加の教育訓練の必要性についての特定。 (iii) 試験すべき標準品及びサンプルの特定。
 (i) Identification of the testing to be performed and the relevant test method(s) undergoing transfer. (ii) Identification of any additional training requirements. (iii) Identification of standards and samples to be tested. (iv) Identification of any special transport and storage conditions of test items. 	 (i) 移管を行なおうとしている試験及び関連する試験法の特定。 (ii) 何らかの追加の教育訓練の必要性についての特定。 (iii) 試験すべき標準品及びサンプルの特定。
method(s) undergoing transfer. (ii) Identification of any additional training requirements. (iii) Identification of standards and samples to be tested. (iv) Identification of any special transport and storage conditions of test items.	 (ii) 何らかの追加の教育訓練の必要性についての特定。 (iii) 試験すべき標準品及びサンプルの特定。
 (iii) Identification of standards and samples to be tested. (iv) Identification of any special transport and storage conditions of test items. 	(iii) 試験すべき標準品及びサンプルの特定。
(iv) Identification of any special transport and storage conditions of test items.	
items.	(10) 試験面について何らかの特別な軸送及び休官朱什の特定。
	(v)許容基準。
	12.36. プロトコールからの逸脱は技術移管のプロセスが完了する前に究
12.36. Deviations from the protocol should be investigated prior to	明すること。技術移管報告はそのプロセスの比較結果を文書化し、該当
closure of the technical transfer process. The technical transfer report	する場合更なる試験法再バリデーションが必要な分野を特定すること。
should document the comparative outcome of the process and should identify areas requiring further test method revalidation, if applicable.	
12.4. On-going stability program	12.4. 継続的安定性プログラム
12.37. After the marketing authorisation is granted, a program should be	12.37. 販売承認が得られた後、該当する保存条件(販売承認において
implemented to verify that, under the relevant storage conditions (as	見ることが出来る)の下で製品が有効期間を通じて規格内に留まること
foreseen in the marketing authorisation), the product remains within the specifications during the shelf-life (so called- "on-going stability	を検証するためのプログラム(いわゆる「継続的安定性プログラム」)を 実施すること。継続的安定性プログラムの方法は、妥当性を示した場
program"). The methodology in the on-going stability programme can	合、販売承認申請において提出した安定性データを取得するために
differ from the approach followed to obtain the stability data submitted	従ったアプローチと異なる(例えば試験頻度が異なる)ことは可能であ
in the marketing authorisation application (e.g. different frequency of	る。
testing), provided that it is justified.	10.00 健结的史中世計除止逐步目の制고について中华ナスニレ/四本
12.38. The on-going stability studies should generally be performed on the finished product (i.e. as released by the manufacturer). When	12.38. 継続的安定性試験は通常最終製品について実施すること(即ち、 製造業者により出荷可の判定をされたものとして)。中間製品の保存期
intermediates can be stored for extended periods of time, consideration	
should be given to include in the stability program those batches that	を安定性プログラムに入れることを考慮すること。再調製された製品の
have been manufactured from materials stored for longer periods of	安定性試験は製品開発の間に実施され、継続的プログラムにおいてモ
time. Stability studies on the reconstituted product are performed	ニターする必要はない。代用品(即ち健常ボランティアから製造された物)
during product development and need not be monitored on an on-going basis. The use of surrogate materials (i.e. material derived from healthy	質)を使用することは、バッチ全体を患者に投与する必要がある自家製 品(或いけ適合ドナーからの製品)の場合許容可能である
volunteers) is acceptable in case of autologous products (or matched	
donor scenario) where the batch needs to be administered in its	
12.39. The number of batches and frequency of testing should be	12.39. バッチ数及び試験頻度は傾向分析を行えるよう適切であること。
adequate to allow for trend analysis. It is generally expected that at	通常、その年に製造が無かったか、他の頻度が別途正当化されること
least one batch of the product is included per year in the stability	がない限り、少なくとも年1バッチの製品を含めることが求められる。規格 外及び有意な非定常の傾向は究明し、それらが市場にある製品に及ぼ
program, unless none are produced in a given year or a different frequency is otherwise justified. Out of specifications and significant	す可能性がある影響について評価し、必要な場合管轄当局に報告する
atypical trends should be investigated and their possible impact on the	
batches on the market should be assessed and reported to the	
competent authorities as appropriate.	
13. Outsourced activities 13.1. General principles	<u>13. 外注した業務</u> 13.1. 一般原則
13.10. Activities that are outsourced to a third party (including	13.10. 第3者に外注した業務(コンサルタントへの依頼を含め)はそれぞ
consultancy work) should be governed by a written contract that	れの側の責任を定めた文書化した契約により管理すること。該当する場
establishes the responsibilities of each party. As appropriate, the role	合、トレーサビリティに関するそれぞれの側の責務と共に、場合により品
and responsibilities in the event of detection of quality defects should	質異常を検出した際の役割と義務を契約に明確に規定すること。
be clearly established in the contract, as well as -where applicable- the obligations of each party regarding traceability.	
13.2. Obligations of the contract giver	13.2. 委託者の義務
13.11. Prior to outsourcing any activity, the manufacturer, or - as	13.11. 如何なる業務についても外注する前に製造業者或いは-該当す
appropriate- the sponsor or marketing authorisation holder ("contract	る場合-治験依頼者或いは販売承認保持者(委託者)は販売承認/治験
giver") should assess the suitability of the contractor ("contract	承認及びGMP適合を含めた他の適用される法規制の条件に従って外注
acceptor") to carry out the outsourced activities in accordance with the terms of the marketing authorisation/clinical trial authorisation and	された業務を遂行する外注業者(受託者)の適切性を評価すること。
other applicable regulations, including compliance with GMP.	
13.12. Exceptionally, when the outsourced activity is a highly	13.12. 例外的に、外注された業務が高度に専門化された試験の場合
specialised test (e.g. karyotype test), it is acceptable that the contract	(例えば核形試験)受託者が外注された業務に関連した適切な品質基
acceptor is not GMP-certified, provided that it complies with suitable	準(例えばISO)に適合しており、これが適切に妥当性を示されるならば、
quality standards relevant to the outsourced activity (e.g. ISO) and that 13.13. The contract giver should provide the contract acceptor with	GMP証明を受けていないことは計谷される。 13.13. 委託者は受託者に外注された業務を正しく実施する為に必要な
detailed information on the product/manufacturing process, as well as	他の如何なるデータも、それと共に製品/製造工程に関する詳細な情報
any other data that is necessary to carry out the contracted	を供給すること。
operations correctly.	
13.14. The contract giver should review and assess the records and the	
results related to the outsourced activities. 13.3. Obligations of the contract acceptor	<u>ること。</u> 13.3. 受託者の義務
13.15. The contract acceptor should take all necessary measures (e.g.	13.15. 受託者は外注された業務を実施する為に必要な全ての対策を取
adequate premises, equipment, trained personnel, etc.) to carry out	ること(例えば、適切な建物、設備、教育訓練された従業員、等)。交差
	汚染の防止とトレーサビリティの維持に特別の配慮をすること。
given to the prevention of cross-contamination and to maintaining	
traceability.	1316 受託者は工程 建物 設備 試験法 相格おいけん注された業務
traceability. 13.16. The contract acceptor should not introduce changes in the	13.16. 受託者は工程、建物、設備、試験法、規格或いは外注された業務 に関する他の如何なる要素についても事前の委託者の承認無しに変更
traceability.	13.16. 受託者は工程、建物、設備、試験法、規格或いは外注された業務 に関する他の如何なる要素についても事前の委託者の承認無しに変更 を行わないこと。
traceability. 13.16. The contract acceptor should not introduce changes in the process, premises, equipment, test methods, specifications or any other element related to the outsourced activity without the prior approval of the contract giver.	に関する他の如何なる要素についても事前の委託者の承認無しに変更 を行わないこと。
traceability. 13.16. The contract acceptor should not introduce changes in the process, premises, equipment, test methods, specifications or any other element related to the outsourced activity without the prior approval of the contract giver. 13.17. All records related to the outsourced activities as well as	に関する他の如何なる要素についても事前の委託者の承認無しに変更 を行わないこと。 13.17.参考品とともに外注された業務に関する全ての記録は委託者に
traceability. 13.16. The contract acceptor should not introduce changes in the process, premises, equipment, test methods, specifications or any other element related to the outsourced activity without the prior approval of the contract giver. 13.17. All records related to the outsourced activities as well as reference samples should either be transferred to the contract giver or,	に関する他の如何なる要素についても事前の委託者の承認無しに変更 を行わないこと。 13.17. 参考品とともに外注された業務に関する全ての記録は委託者に 渡すか或いはその代わりとして委託者がそれらにアクセス出来るように
traceability. 13.16. The contract acceptor should not introduce changes in the process, premises, equipment, test methods, specifications or any other element related to the outsourced activity without the prior approval of the contract giver. 13.17. All records related to the outsourced activities as well as	に関する他の如何なる要素についても事前の委託者の承認無しに変更 を行わないこと。 13.17.参考品とともに外注された業務に関する全ての記録は委託者に

13.19. The contract acceptor should permit audits/inspections by the	13.19. 受託者は外注された業務に関して委託者及び管轄当局による監
contract giver and the competent authorities in connection with the	査/査察を許諾すること。
outsourced activities.	
14. Quality defects and product recalls 14.1. Quality defects	<u>14. 品質異常及び製品回収</u> 14.1. 品質異常
14.10. A system should be put in place to ensure that all quality related	14.10. 全ての品質に関する苦情が、口頭で受けたか文書で受けたかに
complaints, whether received orally or in writing, are recorded and that	拘わらず、記録され、それらが徹底的に究明されることを保証するシス
they are thoroughly investigated. Personnel responsible for managing	テムがなければならない。苦情および品質異常の究明を管理することに
complaint and quality defect investigations should be independent from	責任を有する従業員は他に正当性を示さない限り、販売及び営業部門
marketing and sales departments unless otherwise justified. If the QP	から独立していること。若し問題のバッチの証明に関与しているQPが究
involved in the certification of the concerned batch(es) does not	明に参加していないならば、タイムリーに報告を受けるようになっている
participate in the investigation, it should be informed in a timely	こと。
14.11. Operating procedures should be developed describing the	14.11. 苦情を受けた際に取るべき対応、特に、品質異常について可能
actions to be taken upon the receipt of a complaint, addressing in	性がある根本原因の特定、品質異常によりもたらされるリスクの評価、
particular the identification of the potential root cause(s) of the quality	適切な是正処置及び予防措置の必要性、回収の実行が患者に対する
defect, the assessment of the risk(s) posed by the quality defect, the	医薬品の入手可能性に及ぼす影響の評価、及び行うべき内部及び外部
need for appropriate corrective or preventive measures, the	との連絡、に焦点を当てて記載した処理手順を作成すること。根本原因 を確認できなかった場合、最も可能性がある原因を特定すること。
assessment of the impact that any recall action may have on the availability of the medicinal product to patients, and the internal and	と推認してなが、フに物白、取むり化圧がのる原因を特定すること。
external communications that should be made. Where the root cause	
cannot be ascertained, the most probable reasons should be identified.	
14.12. If additional donor (human or animal) health information becomes	14.12.調達後に製品品質に影響する追加のドナー(ヒト或いは動物)健
available after procurement, which affects product quality, an analysis	康情報が入手可能となった場合、リスク分析と是正処置及び予防措置
of the risk(s) and of the need for corrective or prevented measures is	の必要性の分析が要求される。
also required.	
14.13. When a quality defect is discovered or suspected in a batch,	14.13. あるバッチに品質異常が発見されるか或いは疑われる場合、他
consideration should be given to the need of checking other batches	のバッチ(或いは場合により他の製品)についても影響を受けてないか
(or, as appropriate, other products) in order to determine if they are	判断する為のチェックの必要性を考慮すること。
also affected.	
14.14. Quality defect investigations should include a review of previous	14.14. 品質基準の究明には以前の品質異常報告の照査或いは単発の
quality defect reports or any other relevant information for any	問題なのか反復する問題なのかを何らかの形で示す他の関連する情報
indication of specific or recurring problems.	の照査を含むこと。 14.15. 究明における優先順位は患者の安全性を保証する為に適切なリ
14.15. The priority during an investigation should be to ensure that appropriate risk management measures are taken to ensure patients	スク管理対策が取られることを保証するものであること。適用された全て
safety. All decisions and measures adopted should be documented.	の決定及び対策は文書化すること。実施された是正処置及び予防措置
The effectiveness of the corrective and/or preventive measures	の有効性をモニターすること。
implemented should be monitored.	
14.16. Quality defect records should be retained and used to evaluate	14.16. 品質異常の記録を保存し、反復する問題の存在の可能性につい
the possible existence of recurring problems. Competent authorities	て評価するために用いること。結果として製品回収或いは供給の異常な
should be informed in a timely manner in case of a confirmed quality	制限となり得るATMPの品質異常が確認された場合(製造の失敗、製品
defect (faulty manufacture, product deterioration, detection of	の劣化、虚偽の検出、販売承認或いは製品規格書に違反、或いは他の
falsification, non-compliance with the marketing authorisation or	何らかの重篤な品質問題)管轄当局にタイムリーに通知すること。11.4
Product Specification File, or any other serious quality problems) with	章に記載されているような計画外の逸脱は通知しないこと。
an ATMP which may result in the recall of the product or an abnormal	
restriction in the supply. Unplanned deviations as described in Section 14.17. Where the ATMP is manufactured by an entity that is not the	
marketing authorisation holder/sponsor, the role and responsibilities of	る場合、製造業者、販売承認保持者/治験依頼者及び評価、決定、情報
the manufacturer, the marketing authorisation holder/sponsor and any	の配布、及びリスク低減策の実施に関係する如何なる他の第3者につい
other relevant third parties in relation to assessment, decision-making,	てもその役割と責任を文書で制定しておくこと。
dissemination of information, and implementation of risk reducing	
actions should be laid down in writing.	
Additional considerations for investigational	ATMPs 治験用ATMPに関し追加で考慮すべき点
14.18. Where blinding of investigational medicinal products is required	14.18. 臨床試験のプロトコールにより治験薬の盲検化が必要な場合、製
by the protocol of a clinical trial, the manufacturer should implement a	造業者は迅速な回収が必要な場合に盲検化された製品の迅速な盲検
procedure for the rapid unblinding of blinded products where this is	用キーの開示のための手順を実施すること。製造業者は盲検化された
necessary for a prompt recall. The manufacturer should ensure that the	
procedure discloses the identity of the blinded product only in so far as	保証すること。
it is necessary. 14.2. Product recalls and other risk-reducing actions	
14.19. Measures to address guality defects should be proportionate to	14.19. 品質異常に焦点を当てた対応はリスクに比例したものであり、優
the risks and the priority should be the protection of patients.	先するのは患者の保護である。可能な限り、取るべき対策は事前に管
Whenever possible, the actions to be taken should be discussed with	語当局と議論すること。
the concerned competent authorities in advance.	
14.20. There should be established written procedures for the recall of	14.20. 回収をどのように開始すべきか、回収の際に誰に報告するべきか
products, including how a recall should be initiated, who should be	(関連する当局及び臨床機関を含めて)、そして回収した製品をどの様
informed in the event of a recall (including relevant authorities and	に扱うかを含めた製品回収の文書化された手順を確立すること。その手
clinical sites), and how the recalled material should be treated. The	順は出荷量と回収された量の収支計算がされ、終結するまでの進行が
procedure should foresee the reconciliation between the delivered and	記録されるものでなければならない。臨床機関で不良品の破棄を行い
the recovered quantities and the recording of the progress until	文書化することは製品の返却に対する許容できる代替である。回収され
closure. The documented destruction of a defective product at the	た製品は明確に識別し隔離すること。
clinical site is an acceptable alternative to the return of the product.	
Recalled products should be clearly identified and segregated.	
14.21. It should be ensured that recall operations can be initiated	14.21. 回収作業を迅速かつ何時でも開始出来ることを保証すること。或る場合は、そして公共の健康を守るためという観点から、根本原因或い
promptly and at any time. In certain cases and with a view to protect public health, it may be necessary to recall products prior to	る場合は、そして公共の健康を守るためという観点から、低本原因或い は品質異常の程度の全体像を確認する前に製品を回収する必要があ
establishing the root cause or the full extent of the quality defect.	は加貝共常の程度の主体隊を確認する前に設加を回収する必要がの るであろう。
recussioning the root budge of the full extent of the quality delect.	

case of authorised ATMP: consideration should be given to the possibility of performing mode. recall actions. However, it is advonsideged that a moder-recall action may not be appropriate in manufacturing and administration. However, it is advonsidered parts actions may not be appropriate in the instance of authorises should be informed prior to the instance of authorises should be informed prior to the instance of authorises induce in first performance prior in the instance of anone to recalle phote-same to the parts and advonsite of a recall operation unless urgent action is required to the instance of authorises induce in first performance prior in the instance of anony be recalled be caused: the already been administered to the autointition. 14.23 Eligible actions the autointition of a recall phote-same the parts and advonsite of a many be reliable of the cause in the autointition of a recall, there are other ink-reducing actions the autointition with the manufacturer, where different. The manufacturer investing of the thinpents may be the information of the advance and the interview of the advance and the advance and the interview of advance and the interview of the advance and advance and the interview of advance and the interview of the advance and advance and the interview of advance advance and the interview of advance and the interview		
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116.16. the case of authorised ATMPo, the manufacturer should validate the reconstitution process is to afficiently robust and consistent is through appropriate studies is thould be demonstrated that the specified reconstitution process is sufficiently robust and consistent so that the product can be administration at with the definited reconstitution process is sufficiently robust and consistent so that the product can be administration at with the definited reconstitution process file socied of the ATMP. 16.17. Naccomatic can be administration at with the definited reconstitution process file socied of the ATMP. 16.17. Naccomatic can be administration at with the definited reconstitution process file socied of the ATMP. 16.17. Naccomatic can be administration at with the definited reconstitution process file socied of the ATMP. 16.17. Naccomatic can be administration at write the administration at write the definition of ATMP. 16.17. Naccomatic can be administration at write the referred to as "automated quipment" meets the definition of ATMP. 17.1. Tak@BII 17.1. Tak@BIII	and/or other materials these should be specified or, as appropriate,	る場合、これらを特定し、場合により供給すること。
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ueviations/instances of malfunctioning is essential. じめる。	deviations/instances of malfunctioning is essential.	である。

17.20. A program of services/calibration at regular intervals required to	
ensure the good performance of the automated equipment should be	隔での点検/キャリブレーションのプログラムをその製造業者が記述す
described by the manufacturer thereof. In turn, the ATMP	ること。一方、ATMP製造業者はメンテナンスプログラムが実施されるこ
manufacturer should ensure that the maintenance program is	とを保証すること。場合により、自動化された設備の製造業者とATMPの
performed. As appropriate, the split of responsibilities between the	製造業者の責任分担を文書で規定すること。
manufacturer of the automated equipment and the manufacturer of	
17.21 Aseptic processing: The automated equipment should only be	17.21 無菌操作: 自動化された設備は無菌操作を保証する条件下での
used under conditions that ensure aseptic processing (e.g. validation of	み使用すること(例えば、洗浄工程のバリデーション、製品と接触する繰
cleaning processes, sterilisation of multiple-use materials that are in	り返し使用の部材の滅菌、例えばプレッシャーホールド試験或いはリー
contact with the product, adequate checks of the integrity of the	ク試験等による設備の完全性についての適切なチェック)。
equipment, for example, by means of pressure-hold test or leak testing,	
etc.).	
17.22 Batch and traceability records should be kept.	17.22 <u>ハウテレコート及びトレーリヒウティーの記録を休留すること。</u> 17.3. 従業員
17.3. Personnel	
17.23. Personnel involved in production should be adequately trained	17.23. 製造に関わる従業員は適切に教育訓練を受け、工程に伴うリスク
and the associated risks of the process should be duly understood	を適切に理解していること(製品の有効性に対するリスクを含めて)。
(including risks to the efficacy of the product).	
17.4. 建物	17.4. 建物
17.24. As explained in Section 9.5.1, the room where a closed system is	17.24.9.5.1章において述べられたように、クローズドシステムが使用され
used should be of at least grade D. The transfer of the material	ている部屋は最低限グレードDであること。原材料の設備への出し入れ
into/from the equipment is a critical step and a validated procedure	は重要工程であり、製品を汚染のリスクから守るためにバリデートされ
should be put in place to preserve the product from the risk of	た手順があること。
17.25. Section 9.5.1 also explains the conditions under which,	17.25.9.5.1章はまた、例外的にクローズドシステムを、管理されてはいる
exceptionally, closed systems may be placed in a controlled but non-	がクラス管理ではない環境に設置しても良いことを述べている。
classified environment.	
17.5. Production and process validation	17.5. 製造及び工程バリデーション
17.26. The definition of the moment when the manufacturing process	17.26. 製造工程がどの時点で開始され、終了するのかを明確にし、種々
starts and finishes should be defined and the role and responsibilities of	の時点で関与する全ての作業者の役割と責任を明確に確立すること。
all actors involved at the different time points should be clearly	
17.27. Possibilities for in-process controls may be limited by the	17.27. 工程内管理の可能性は連続したクローズドシステムによる加工に
	17.27. 工程内管理の可能性は運続したクローストシステムによる加工に おいては限定されている。そのような場合、技術的に可能であれば、重
continuous closed processing. In such cases, continuous monitoring of	
critical process parameters and other input parameters that affect	要工程パラメータ及び(販売承認/治験承認で特定されている)他の製
product quality (as identified in the marketing authorisation/clinical trial	品品質に影響する入力パラメータの連続モニタリングを実施すること。連
authorisation) should be performed if technically possible. When	続モニタリングが技術的に可能でない場合、パラメータの重要度とリスク
continuous monitoring is not technically possible, monitoring at	の重篤度を考慮した上で適切な間隔でモニタリングすることが求められ
appropriate intervals having regard to the criticality of the parameter	る。エ程パラメータのデータはバッチレコードの一部として保存すること。
and the risks is required. Data on process parameters should be kept	
as part of the batch records.	
17.28. Validation of aseptic processing by media fill simulation should	17.28. 無菌操作の培地充填によるバリデーションも実施すること。年2回
also be performed. The bi-annual frequency is recommended but it	の頃南杉士はこれてお リフクナキ虎 て調整士フェレビゴ化ホセス
also be performed. The bill annual frequency is recommended but it	の頻度が求められるが、リスクを考慮して調整することが可能である。
could be adapted having regard to the risks (see Section 9.5.2).	の頻度が氷められるが、リスクを考慮して調発することが可能である。 (9.5.2章を参照)
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- Segregated area: a segregated area within a manufacturing site	- 隔離区域:製造所内の隔離区域は、区分された凍結保存設備、区分
requires separate cryostorage, separate production suite with separate	されたHVACを持つ区分された一続きの製造室、従業員及び設備の(適
HVAC, restrictions on the movement of personnel and equipment (without appropriate decontamination measures) and dedicated	切な除染対策無しの)移動制限、及び或る特定のリスクプロファイルを 持った一つのタイプの製品の製造の為に専用化された設備を必要とす
equipment reserved solely for the production of one type of product	は、シリントンの表面の表色の為には用心とないた設備を必要とする。
5. <i>Bulk Product</i> : any product which has completed all processing	©。 5. バルク製品 :最終包装の直前までの全ての加工段階を完了し、最終
stages up to, but not including, final packaging.	包装されていない製品。
6. <i>Campaigned manufacture</i> : The manufacture of a series of batches	6. キャンペーン製造:同一製品の一連のバッチを連続で一定の期間製
of the same product in sequence in a given period of time followed by	造し、次いで他の製品に移行する前に事前に確立した管理対策に厳密
strict adherence to preestablished control measures before transfer to	に従うこと。適切な管理対策が適用されるならば、同じ設備を異なった製
another product. Use of the same equipment for distinct products is	品に使用することは可能である。
possible provided that appropriate control measures are applied.	9 L. H. A. M.
7. Cell bank	7. セルバンク <i>セルバンクシステム</i> :セルバンクシステムは、製品の一連のバッチが
— <i>Cell bank system</i> : A cell bank system is a system whereby successive batches of a product are manufactured by culture in cells	一 <i>モルハンシンステム</i> :セルハンシシステムは、要由の一連のハッテが 同一のマスターセルバンクに由来する細胞の培養により製造されるシス
derived from the same master cell bank. A number of containers from	テムである。マスターセルバンクからの或る数の容器がワーキングセル
the master cell bank are used to prepare a working cell bank. The cell	バンクを調製する為に用いられる。セルバンクシステムは継代のレベル
bank system should be validated for a passage level or number of	或いは倍加数がルーチンの製造において達成されるレベル或いは数を
population doublings beyond that achieved during routine production.	越えた水準までバリデートされること。
— <i>Master cell bank</i> : A culture of (fully characterised) cells distributed	— マスターセルバンク:単一の操作で複数容器に分配され、均一性を
into containers in a single operation, processed together in such a	保証する方法で加工され、安定性を保証する方法で保存された(十分に
manner as to ensure uniformity and stored in such a manner as to	特性解析された) 培養細胞。マスターセルバンクは全てのワーキングセ
ensure stability. The master cell back is used to derive all working cell	ルバンクを得るために用いられる。 ローキングタリッグ・ク ・ファターキリッジンクに中来し、制造田培養細
 Working cell bank: A culture of cells derived from the master cell bank and intended for use in the preparation of production cell cultures. 	─ ワーキングセルバンク:マスターセルバンクに由来し、製造用培養細胞の調製に用いられる培養細胞。
 Bank and intended for use in the preparation of production cell cultures. Cell stock: primary cells expanded to a given number of cells to be 	18. 細胞ストック:分割して細胞に基づくATMPの限定したロット数の製造
aliquoted and used as starting material for production of a limited	の出発物質として使用するための、一定の細胞数まで増殖させた一次
number of lots of a cell-based ATMP.	細胞。
9. Clean room : A room designed, maintained, and controlled to prevent	9. クリーンルーム:製品の微粒子及び微生物汚染を防止する為に設計
particle and microbiological contamination of the products. Such a room	され、維持され、管理されている部屋。部屋は清浄度が設定され、常に
is assigned and reproducibly meets an appropriate air cleanliness	適切な規格値を満足する。
classification.	
10. Cleaning validation: See Section 10.2	10. 洗浄バリデーション:10.2章を参照。
11. Cleaning verification : the gathering of evidence through appropriate	11. 洗浄ベリフィケーション:各バッチ/キャンペーン後に汚染物質、前の制用式いけば剤の環体が予めた時にあってした。
analysis after each batch/campaign to show that contaminants, residues of the previous product or cleaning agents have been reduced	製品或いは洗剤の残渣が予め決めた閾値以下に低減されている事を 示すための、適切な分析を通じたエビデンスの収集。
below a pre-defined threshold.	小りための、過めな力がを通じたエビアンへの収来。
12. Closed system : A process system designed and operated so as to	12. クローズドシステム :製品或いは原料の部屋の環境への暴露を避け
avoid exposure of the product or material to the room environment.	る為に設計され、稼働される加エシステム。原料はクローズドシステムに
Materials may be introduced to a closed system, but the addition must	投入される、しかし追加は製品を部屋の環境に暴露することを避けるよ
be done in such a way so as to avoid exposure of the product to the	うな方法で行わなければならない(例えば、無菌接続或いは熔融システ
room environment (e.g. by means of sterile connectors or fusion	ムによって)。クローズドシステムは開放する必要が生ずるであろう(例
systems). A closed system may need to be opened (e.g., to install a	えば、フィルターの設置、或いは接続を行う際)、しかし工程に使用する
filter or make a connection), but it is returned to a closed state through	前に殺菌或いは滅菌工程によりクローズドな状態に戻される。
a sanitization or sterilization step prior to process use. 13. Isolator : A decontaminated unit supplied with grade A (ISO 5) or	13. アイソレータ :グレードA(ISO5)或いはより高い質の空気を供給され
higher air quality that provides uncompromised, continuous isolation of	る除染されたユニットで、その内部を外部の環境(即ち、周辺のクリーン
its interior from the external environment (i.e., surrounding cleanroom	ルーム及び作業者)から障害を受けることなく継続して分離することを提
air and personnel).	供する。
14. Intermediate: Partly processed material which must undergo further	14. 中間製品:中途まで加工された物質で、バルク製品となるまでに更
manufacturing steps before it becomes a bulk product.	なる製造段階を経なければならないもの。
15. Manufacturing order : document that contains the request of the	15. 製造指示:治験依頼者の特定の製品を製造することの要求を含む
sponsor to manufacture a given product. The document should be	文書。その文書は明確で製品規格書及び必要に応じて関連する臨床試
unambiguous and it should refer to the Product Specification File and	験プロトコールを参照すること。
the relevant clinical trial protocol as appropriate. 16. Product Specification File : a file containing, or referring to files	
containing, the specifications, instructions and other information	ために必要なその他の情報を含むか或いは参照するファイル。それに
necessary for the manufacturing of an investigational medicinal product	
and to perform batch certification. The specific content thereof is	
explained in Section 6.2.	
17. Qualification of premises and equipment: see Section 10.1.	17. 建物及び設備の適格性確認: 10.1章を参照
18. Qualification of suppliers: Process designed to ensure the	18. 供給業者の適格性確認:供給業者の適切性を保証する為に設計さ
suitability of suppliers. Qualification of suppliers may be done through	れた過程。供給業者の適格性確認は種々の手段で実施して良い、例え ば日間に開まる原則で、新たなにより
various means, <i>e.g.</i> by means of quality questionnaires, audits, etc). 19. Raw materials : The definition of "raw materials" is provided for in	<u>ば品質に関する質問票、監査、等により。</u> 19. 原料 :原料の定義はAnnex to Directive 2001/83/EC on the
Part IV of the Annex to Directive 2001/83/EC on the Community code	19. 原科 : 原科の定義はAnnex to Directive 2001/83/EC on the Community code relating to medicinal products for human useのパート
relating to medicinal products for human use.	IVに規定されている。
20. Room status:	20. 部屋の状態:
— At rest : "At rest" state is the condition where all HVAC systems	— 非稼働時:「非稼働時」の状態は、全てのHVACのシステム及び装置
and installations are functioning but without personnel and with	が稼働しているが作業者が居らず製造設備が停止している状態。作業
equipment static. The particle limits should be achieved after a short	終了後約15-20分の短いクリーンアップ時間で微粒子の限度値を達成
"clean up period" of approximately 15-20 minutes after completion of	
- In operation : "in operation" state is the condition when all	- 稼働時:「稼働時」の状態は全ての製造設備及び空調装置が稼働
equipment and installations are functioning and personnel are working	し、作業者が製造手順に従って作業している状態である。
in accordance with the manufacturing procedure. 21. Seed lot	21. シードロット

-Seed lot system: A seed lot system is a system according to which successive batches of a product are derived from the same master seed lot at a given passage level. For routine production, a working seed lot is prepared from the master seed lot. The final product is derived from the working seed lot and has not undergone more passages from the master seed lot than what has been shown in	- シードロットシステム:シードロットシステムは、それに従って連続した バッチの製品が同じマスターシードロットから特定の継代レベルで製造さ れるシステムである。ルーチンの製造の為にはマスターシードロットから ワーキングシードロットが調製される。最終製品はワーキングシードロッ トから得られ、マスターシードロットから臨床試験において安全性及び有 効性に関して良好であると示されたもの以上の継代を行わない。マス ターシードロット及びワーキングシードロットの起源と継代履歴は記録さ
clinical studies to be satisfactory with respect to safety and efficacy. The origin and the passage history of the master seed lot and the	スーンードロッド及びソーキンソンードロッドの起源と経て履歴は記録で
-Master seed lot: A culture of a micro-organism (virus or bacteria) distributed from a single bulk into containers in a single operation in such a manner as to ensure uniformity, to prevent contamination and to ensure stability.	マスターシードロット:単一のバルクから単一操作で均一性を保証し、 汚染を防止し、安定性を保証するする方法で(複数)容器に分配された 微生物(ウイルス或いはバクテリア)の培養物。
-Working seed lot: A culture of a micro-organism (virus or bacteria)	— ワーキングシードロット :マスターシードロットから導かれ、製造におい て使用することを意図した微生物(ウイルス或いはバクテリア)の培養
derived from the master seed lot and intended for use in production. 22. Substantial manipulation : The criterion of substantial manipulation is laid down in Article 2(1) of Regulation (EC) No 1394/2007. Additional	(19日) ることを息因した版生物(191ルス以いはハウナリア)の店食 22. 実質的操作:実質的操作の基準はRegulation (EC) No 1394/2007の 第2条(1)に制定されている。その適用に関する更なるガイダンスはCAT
guidance on the application thereof can be found in the CAT Reflection paper on classification of advanced therapy medicinal products	
(http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/gener al/general_cont ent_000296.jsp).	<pre>(http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/gener al/general_cont ent_000296.jsp).</pre>
23. Starting materials: The definition of "starting materials" is provided for in Part IV of the Annex to Directive 2001/83/EC on the Community code relating to medicinal products for human use.	23. 出発物質:出発物質の定義はAnnex to Directive 2001/83/EC on