Non-Conformance 不適合			
All non-conformance should be investigated. Where applicable this includes the identification of the root cause, a risk analysis (including the risk to other lots and the impact to other test results) of the actions taken for correction of the problem, prevention of future occurrence and the formal conclusion by Supplier's Quality Assurance. If an investigation reveals that there is an impact to Excipients received by the Customer, Supplier shall inform Customer without unreasonable delay. 全ての不適合は調査されなければならない。 可能な場合においては、根本原因の特定、問題の解決の為に取られた対策のリスク分析(他のロットへのリスク、並びに他の試験結果へのインパクトを含む)、将来的な防止策、並びに正式な供給者の品質保証部による結論を含む。 もし調査で顧客の受け取った医薬品添加剤に影響があることが明らかになれば、供給者は遅滞なく顧客に知らせるものとする。	×		
Out of Specification (OOS) 規格外試験結果(OOS)			
Out-of-specification (OOS) test results should be investigated and documented according to a documented procedure. 規格外試験結果(OOS)は、調査されそして手順書に従い文書化されるべきである。	×		
Deviations 逸脱			
If significant deviations from an established process are recorded, there should be evidence of suitable investigations and a review of the quality of the Excipients. もし規定された工程からの著しい逸脱が記録された場合、適切な調査を行った証明、並びに添加剤の品質の確認を行われなければならない。	×		
Complaints 苦情			
Have a written procedure to investigate and document quality related complaints. A root cause analysis, actions taken for correction of the problem, prevention of future occurrence and the formal conclusion will be provided to the Customer within a reasonable time after receipt of the complaint. 苦情に関する品質を調査し記録するための手順書を	×		

有する。根本原因分析、問題の解決のために行った対応策、将来の予防及び正式な結論を、苦情を受けた後、適切な時間内に顧客に提供する。			
Complaints made shall at least indicate the Supplier's batch number of the excipient and complaint subject. The complaint shall be communicated to the Supplier within a reasonable time after receipt of the excipient. Samples will be provided where appropriate and available. 受け付けた苦情は、少なくともその医薬品添加剤の供給者のバッチ番号とクレーム内容を記載する。その苦情は医薬品添加物の受領後、適切な時間内に供給者に伝えるものとする。 必要に応じて可能な場合にはサンプルを提供する。		×	
The parties shall cooperate in the exchange of information required to effectively conduct an investigation. 関係者は効率的に調査を行うのに必要である情報交換に協力するものとする。	×	×	
Recalls 回収			
In the case of a recall of the Excipients, Supplier shall inform Customer without unreasonable delay of the planned recall. 添加剤の回収の場合、供給者は回収計画を遅滞なく顧客に知らせるものとする。	×		
Have a written recall procedure. 書面の回収手順書を有する。	×		

Customer shall notify Supplier of any finished product recall which has been investigated or is under investigation and has potential to be related to the quality of the Excipients, as soon as possible. 顧客は供給者に対し、添加剤の品質に関連する調査したか、調査中である最終製品の回収を速やかに通知する。		×	
The parties shall cooperate in the exchange of information required to effectively conduct a recall or recall investigation. 関係者は効率的に回収又は回収の調査を行うのに必要な情報交換に協力する。	×	×	
Auditing 査察			
Have the right to audit Supplier's facilities, systems and documentation, as they relate to the manufacture of Excipients, at mutually agreed upon times. お互いに合意した日程において、添加剤の製造に関連する、供給者の施設、システム及び文書を監査する権利を有する。		×	
Allow Customer to audit facilities, systems and documentation, as they relate to the manufacture of Excipients, at mutually agreed upon times. お互いに合意された日程において、医薬品添加剤の製造に関連する供給者の施設、システム及び文書を査察することを顧客に許可する。	×		
If required, a confidentiality agreement will be executed within a reasonable period of time prior to the audit. 要求された場合、適切な期間が設定された秘密保持契約を、査察に先立ち締結する。	×	×	
Customer shall issue a confidential written audit report to the Supplier, which will include audit observations, within X days (mutually agreed upon timeline). 顧客は供給者に対し書面にて指摘事項を含む査察報告書(confidential written audit report)を XX 日以内(相互に合意した期限内)に発行する。		×	
Supplier shall issue responses within X days (mutually agreed upon timeline) to all observations in writing to Customer Quality Assurance. Where the Supplier commits to a corrective action, a description and timeframe for completion will be included in the written response. 供給者はXX日以内(相互に合意した期間)に全ての	×		

指摘事項に関し、顧客の品質保証部門に対し書面にて対応書を発行する。 供給者が是正措置をとる場合、完了までの詳細及び期限を対応書に含む。			
Where applicable, agree upon requirements for auditing third parties used in association with excipients production, processing, warehousing, or testing. 可能な場合、添加剤の製造、加工、倉庫保管又は試験に関連して使用されるサードパーティーを査察するための要求事項を取り決める。	×	×	

Distributor's Quality Agreement Template

ﾃﾞｨｽﾄﾘﾋﾞｭｰﾀｰ品質協定書ﾃﾝﾌﾟﾚｰﾄ

1. Introduction/Purpose

1.序論/目的

Scope

適用範囲

Parties to the agreement

契約の当事者

Example wording:
This Quality Agreement is by and between <Supplier Name> with office at <address>, hereafter referred to as <Supplier> and <Customer Name> with office at <address>, hereafter referred to as <Customer>. Whereas, <Supplier> supplies excipients suitable for pharmaceutical use to <Customer>.

Note: Company name can be expanded to include further descriptive information about the company such as Company X, a distributor of pharmaceutical excipients duly organized and existing under the laws of <list appropriate jurisdiction>.

例文：
この品質協定書は<供給者名、所在地>(以下、ｻﾌﾟﾗｲﾔｰとする)と<顧客名、所在地>(以下、ｶｽﾀﾏｰとする)において取り交わされたものである。 <ｻﾌﾟﾗｲﾔｰ>は<ｶｽﾀﾏｰ>が使用する製薬にふさわしい医薬品添加剤を供給する。

Specify excipients covered by agreement

Example wording:
This agreement pertains to the following excipient(s) (or excipient processes/types/locations, etc), hereafter referred to as <Excipients>: <list or see attachment>.

本協定で対象となる医薬品添加剤
本協定は以下の医薬品添加剤(あるいは医薬品添加剤ﾌﾟﾛｾｽ、ﾀｲﾌﾟ、ﾛｹｰｼｮﾝ等)に関するものである。(以下、<医薬品添加剤>とする。)；<添付資料参照>。

Definition of the quality criteria
Example wording:
Supplier will conduct all activities concerning the Excipients in accordance with the following quality criteria:

品質基準の定義
例文
ｻﾌﾟﾗｲﾔｰは以下の品質基準に従い<医薬品添加剤>に関する全ての活動を運営する。

Examples of potential quality criteria:
IPEC Good Distribution Practices Guide for Pharmaceutical Excipients, current version **(Primary Reference)**

Others as applicable:
ISO-9001, current version
WHO Guideline Good Trade and Distribution Practices for Pharmaceutical Starting Materials, current version
NACD Code of Management Practice
Cefic/ FECC Safety and Quality Assessment Systems(SQAS)
Distributor/European Single Assessment Document (ESAD II) Assessment (Section F and G)
United States FD&C Act Misbranding and Adulteration Provisions
Other regional certification, as applicable

重要な品質基準の例
現行版　医薬品添加剤のためのIPEC GDP（Good Distribution Practices）ｶﾞｲﾄﾞ (もっとも重要な規定)

その他適用できる文献
現行版　ISO-9001
現行版　医薬品出発物質に関する貿易並びに販売WHOｶﾞｲﾄﾞﾗｲﾝ
NACDｺｰﾄﾞのﾏﾈｼﾞﾒﾝﾄ教書
Cefic/ FECC Safety and Quality Assessment Systems(SQAS)
Distributor/European Single Assessment Document (ESAD II) Assessment (Section F and G)
United States FD&C Act Misbranding and Adulteration
その他、適用できるものとしての地域の証明書

Responsibilities for quality activities

Example wording:
This Quality Agreement will outline the responsibilities of <Supplier> and <Customer> with regard to the quality activities described in the quality criteria listed above.

Site(s) involved
Note: Sites supplying <Excipients> should be mutually agreed upon. The supplier sites involved can be specified here if needed (may refer to an appendix). If the sites involved are not listed in this agreement, it should be indicated where the agreed sites are specified.

品質活動のための責任

例文
本品質協定は上記の品質基準で記された品質活動に関する<ｻﾌﾟﾗｲﾔｰ>と<ｶｽﾀﾏｰ>間の責任を概説したものである。

対象となる事業所(工場)
注釈：<医薬品添加剤>を供給する事業所(工場)は相互に同意されていなければならない。　対象となるｻﾌﾟﾗｲﾔｰの事業所は必要に応じて(、この項で特定することができる。(あるいは付記として参照にしてもよい。)
対象となる事業所が本協定書に記載されていない場合、同意された事業所がどこで特定されるのかを示さなければならない。

Manufacturer and Use of Other Third Parties

Example wording:
Agreed upon manufacturer, manufacturing site(s) and other third parties are disclosed in <attachment><EIP><other document>.
Changes in the use of third parties as set forth in this agreement will not be made without prior written notification to the <Customer>. Supplier shall, however, retain all obligations under this Agreement whether or not a third party manufactures, packages, labels, inspects, tests, releases or handles Excipients.
Note: If this information is considered confidential, specify how this information can be disclosed to the customer, for example under confidentiality agreement.

ﾒｰｶｰおよびｻｰﾄﾞﾊﾟｰﾃｨｰの使用

例文
ﾒｰｶｰとの合意において、製造所およびｻｰﾄﾞﾊﾟｰﾃｨｰの使用を<添付資料><EIP><その他の文書>の中で開示する。
<ｶｽﾀﾏｰ>への文書による通知無く本協定書に明記されたｻｰﾄﾞﾊﾟｰﾃｨｰの変更をすることができない。
本協定においてｻﾌﾟﾗｲﾔｰは、医薬品のｻｰﾄﾞﾊﾟｰﾃｨｰによる製造、包装、ﾗﾍﾞﾘﾝｸﾞ、調査、試験、販売ならびに取り扱いの如何に関わらず、全ての責任を負う。
注釈：この情報が非公開と判断されたとき、特にｶｽﾀﾏｰにこの情報を開示できない場合には、例えば、秘密保持契約を結ぶ必要がある。

Term of agreement
Example wording:
This Agreement shall become effective and binding upon the date of the final signature and shall remain in effect until 2 years after the last delivery of <Excipients> by <Supplier> to <Customer> unless <Customer> specifically requests an extension of the Agreement. Either party may terminate this Agreement by giving 6 months written notice to the other party. After such termination,
and if so requested by <Customer>, <Supplier> will negotiate with <Customer> in good faith a subsequent Quality Agreement.

協定の完了
例文：
本協定は<ｶｽﾀﾏｰ>が特に協定の延長を要求しない限り、<ｻﾌﾟﾗｲﾔｰ>から<ｶｽﾀﾏｰ>に<医薬品添加剤>の最後の供給から2年間有効である。 もし一方が本協定を完了したい場合には文書によって他方に6ヶ月前に通告する。 この様にして完了した後も、<ｶｽﾀﾏｰ>から要求があった場合には、<ｻﾌﾟﾗｲﾔｰ>は<ｶｽﾀﾏｰ>とそれ以降の品質協定について誠意を持って協議する。

Assignment
Example wording:
Neither party shall have the right to assign any or all of its rights or obligations under this agreement without the other party's prior written consent, which shall not unreasonably be withheld. The foregoing notwithstanding, prior written consent shall not be required in connection with a merger, consolidation, or a sale of all or substantially all of party's assets to a third party, except if such merger, consolidation or sale is with a competitor of the other party.

譲渡
例文
両社とも相手方の不当な承諾を除いて、同意文書なしに本協定における権利または義務を譲渡することはできない。　上記にも関わらず、競合会社を除いたサードパーティーへの企業合併、統合、売却で関係が続く場合には同意文書は必ずしも必要でない。

Confidentiality (optional)
Note: May define here according to <Supplier>'s policy or refer to other documents pertaining to confidentiality, e.g. confidentiality agreement (also referred to as a confidential disclosure agreement).

秘密保持(任意)
注釈：<ｻﾌﾟﾗｲﾔｰ>の方針によりここで定義することあるいは、その他の文書、例えば秘密保持契約などで守秘義務について関連する文書にて定義することもできる。(秘密開示協定書のような文書も関係する。)

Other agreements
Example wording:
If a supply agreement is in place between <Supplier> and <Customer>, and there are any inconsistencies between the supply agreement and the Quality Agreement, the supply agreement will take precedence over the Quality Agreement.

その他の協定
例文
<ｻﾌﾟﾗｲﾔｰ>と<ｶｽﾀﾏｰ>間に供給契約が存在し、その供給契約と品質協定になんら矛盾がない場合、供給契約がすべての品質協定よりも優先される。

Choice of Law
Note: If a choice of law is not specified in a supply agreement, a choice of law should be agreed to between the parties and designated here.

準拠法
供給契約で法律の選択が特定されていない場合、両者間での合意が必要であり、ここで明記する必要がある。

2. Compliance
See attached QA Responsibility Table.

2. 遵守事項
QA Responsibility Tableを参照のこと

3. Manufacturing, Packaging and Labeling
See attached QA Responsibility Table.

3.製造、包装およびﾗﾍﾞﾘﾝｸﾞ
QA Responsibility Tableを参照のこと

4. Documentation and Records
See attached QA Responsibility Table.

4.文書作成および記録
QA Responsibility Tableを参照のこと

5. Storage and Distribution
See attached QA Responsibility Table.

5.保管および販売
QA Responsibility Tableを参照のこと

6. Change Control
See attached QA Responsibility Table.

6.変更管理
QA Responsibility Tableを参照のこと

7. Non-Conformance
See attached QA Responsibility Table.

7.不適合
QA Responsibility Tableを参照のこと

8. Auditing
See attached QA Responsibility Table.

8.査察
QA Responsibility Tableを参照のこと

9. Quality Contacts
List the contact persons from each party that will be responsible for communications related to this agreement. This information can be provided in an attachment.

9.品質担当

本協定書に関するそれぞれの会社の担当者をﾘｽﾄ化すること。

付帯情報として付記することもできる。

10. Signatories

10.署名者

11. References

11.参照文献

12. List of Attachments

12.添付資料のﾘｽﾄ

Quality Agreement Responsibility Table

Responsibilities	Supplier	Customer	NA
Compliance **遵守事項**			
Conform to the *IPEC Good Distribution Practices Guide for Pharmaceutical Excipients* and/or other quality criteria defined in the scope of this agreement. The current versions of the defined quality criteria in effect at the time of this agreement are attached. (Attachment of quality criteria is optional.) 医薬品添加剤に関する、IPEC Good Distribution Practices Guide並びに・もしくは、この契約の目的に定義される他の品質基準に合致する。 その時点で施行される、この契約の定義される品質基準の現行バージョンを添付する。（品質基準の添付は任意である）	×	×	
Supplier will have a Quality Agreement(s) with the original manufacturer and/or any third parties used for production, packaging, testing or processing the Excipients in any manner that could be viewed during an audit of the Supplier. 供給者は査察の際、開示可能である品質契約を、製造業者並びに・もしくは、製造、梱包、試験もしくはその添加剤の製造工程に関わった第3者と何らかの方法で締結する。	×		
Mutually agreed upon specifications for the Excipients which are the subject of this agreement. Specifications in place at the time of this agreement are attached. (Attachment of specifications is optional.) この協定の対象である医薬品添加剤の規格に関する相互に同意する。この合意の際に決められた規格は添付する。(規格の添付は任意。)	×	×	
Changes to the agreed upon specifications must be mutually agreed upon and communicated in writing between the parties to this agreement, except for compendial changes which can be implemented without mutual agreement. Compendial changes must be implemented by the compendial implementation date. 相互の合意なしに実施することができる、公定書の変更を除き、同意した規格の変更は、当事者間で相互に合意し、書面により行われなければならない。	×	×	

公定書の変更は、公定書の施行日までに実施されなければならない。			
Ensure that the specifications for compendial excipients are in compliance with the current compendia. 公定書に記載されている医薬品添加剤規格は、最新の公定書に適合することを保証する。	×	×	
Supply Excipients that conform to the mutually agreed upon specifications. 相互に合意した規格に適合する医薬品添加剤を供給する。	×		
Upon request, disclose to the Customer recent regulatory agency inspections and findings pertaining to the Excipients. 要請があれば、その医薬品添加剤に関する最近の規制当局の査察及び指摘事項を顧客に対して開示する。	×		
Notify promptly if, in the course of a regulatory inspection, negative findings are made related to the quality of the Excipients supplied. もし、規制上の査察の過程で、医薬品添加剤の供給品質に関連するマイナスの指摘事項がされた場合、早急に通知する。	×	×	
Processing, Packaging and Labelling 加工、包装並びにラベリング			
Where applicable, appropriately document all processes related to the Excipients such as processing and packaging are fit for purpose. Demonstrate the commissioning of critical systems and equipment used. Demonstrate that cleaning procedures are appropriate, and their effectiveness has been demonstrated. 加工、包装等、添加剤に関連する全ての工程が目的に合致していることを、適用可能な場合には、適切に記録する。使用される重要なシステム並びに機器の試運転を行う。洗浄手順が適切であり、また、その効果が明らかであることを実証する。	×		

Responsibilities	Supplier	Customer	NA
If Excipients are repackaged, processed or packaged from bulk, samples will be retained for a period of _____ years from _____ (specify). もし添加剤が小分け、加工もしくはバルクより梱包される場合、サンプルは_____(規定する)より_____年間保存する。	×		
Agree upon special labelling requirements. 特別なラベリング要求に関し合意する。	×	×	
Documentation and Records **文書作成及び記録**			
Certificate of analysis will be supplied with each batch in accordance with the *IPEC Good Distribution Practices Guide for Pharmaceutical Excipients* or an agreed upon alternative that is defined in this agreement. IPEC Good Distribution Practice Guide for Pharmaceutical Excipients、もしくはこの契約に規定されている他の方法による取り決めに基づき、バッチ毎に分析表を提供する。	×		
Where applicable, the certificate of analysis will be prepared either according to the current IPEC-Americas *Certificate of Analysis Guide for Bulk Pharmaceutical Excipients* or an agreed upon alternative that is defined in this agreement (an example COA may be attached). 適用可能な場合には、分析表は、最新のIPEC-Americas Certificate of Analysis Guide for Bulk Pharmaceutical Excipients もしくはこの契約に規定された代替様式のどちらかに基づき作成される。(分析表例を添付してもよい)	×		
Agree upon special certificate of analysis requirements. 特別な分析表に関する要望事項を取り決める。	×	×	
Where applicable, electronic signatures used on the Certificates of Analysis must conform to the requirements of the IPEC-Americas *Certificate of Analysis Guide for Bulk Pharmaceutical Excipients* or an agreed upon alternative that is defined in this agreement.			

必要な場合には、分析表で使用される電子署名は、IPEC-Americas Certificate of Analysis Guide for Bulk Pharmaceutical Excipientsの要求事項又はこの協定で合意し規定された代替様式に一致しなければならない。			
Records required by the agreed upon quality system will be maintained for a period of ____ years from _____ (specify). 合意した品質システムにより要求される記録は _____から_____年間保存する。(規定する)	×		
Storage and Distribution **保管並びに販売**			
Maintain and supply upon request documentation that supports the recommended storage and transportation conditions plus reevaluation or expiry dates. 再評価日又は使用期限を加えた推奨される保管及び輸送条件を支持する文書を保持し、求めに応じ供給する。	×		
Ensure that Excipients are stored and shipped in accordance with manufacturer's recommended storage conditions. 添加剤が製造業者の推奨する保管条件に従い保管及び出荷されることを保証する。	×	×	
Where applicable, agree upon requirements for reusable shipping containers. 必要な場合、再使用可能な運送容器に関する 要件を取り決める。	×	×	
Change Control **変更管理**			
Changes will be evaluated and communicated based upon agreed criteria and timelines. Refer to the IPEC Americas *Significant Change Guide* or specified alternative that is defined in this agreement. 変更は合意された基準及び期限に基づき評価され、やり取りされる。IPEC-Americas Significant Change Guide又はこの協定で規定されたことを参照する。	×		

Responsibilities	Supplier	Customer	NA
Non-Conformance **不適合**			
All non-conformance should be investigated. Where applicable this includes the identification of the root cause, a risk analysis (including the risk to other lots and the impact to other test results) of the actions taken for correction of the problem, prevention of future occurrence and the formal conclusion by Supplier's Quality Assurance. If an investigation reveals that there is an impact to Excipients received by the Customer, Supplier shall inform Customer without unreasonable delay. 全ての不適合は調査されなければならない。 適応可能な場合においては、根本原因の特定、問題の解決の為に取られた対策のリスク分析(他のロットへのリスク、並びに他の試験結果へのインパクトを含む)、将来的な防止策、並びに正式な供給者の品質保証部による結論を含む。 もし調査で顧客の受け取った医薬品添加剤に影響があることが明らかになれば、供給者は遅滞なく顧客に知らせるものとする。	×		
Out of Specification (OOS) **規格外試験結果 (OOS)**			
Out-of-specification (OOS) test results should be investigated and documented according to a documented procedure. 規格外試験結果(OOS)は、調査されそして手順書に従い文書化されるべきである。	×		
Deviations **逸脱**			
If significant deviations from an established process are recorded, there should be evidence of suitable investigations and a review of the quality of the Excipients. もし規定された工程からの著しい逸脱が記録された場合、適切な調査を行った証明、並びに添加剤の品質の確認を行われなければならない。	×		
Complaints **苦情**			
Have a written procedure to investigate and document quality related complaints. A root cause analysis, actions taken for correction of the problem, prevention of future occurrence and the formal conclusion will be provided to the	×		

Customer within a reasonable time after receipt of the complaint. 苦情に関する品質を調査し記録するための手順書を有する。根本原因分析、問題の解決のために行った対応策、将来の予防及び正式な結論を、苦情を受けた後、適切な時間内に顧客に提供する。			
Complaints made shall at least indicate the Supplier's batch number of the Excipients and complaint subject. The complaint shall be communicated to the Supplier within a reasonable time after receipt of the Excipients. Samples will be provided where appropriate and available. 受け付けた苦情は、少なくともその医薬品添加剤の供給者のバッチ番号とクレーム内容を記載する。その苦情は医薬品添加物の受領後、適切な時間内に供給者に伝えるものとする。 必要に応じて可能な場合にはサンプルを提供する。		×	
The parties shall cooperate in the exchange of information required to effectively conduct an investigation. 関係者は効率的に調査を行うのに必要である情報交換に協力するものとする。	×	×	
Recalls 回収			
In the case of a recall of the Excipients, Supplier shall inform Customer without unreasonable delay of the planned recall. 添加剤の回収の場合、供給者は回収計画を遅滞なく顧客に知らせるものとする。	×		
Have a written recall procedure. 書面の回収手順書を有する。	×		

Responsibilities	Supplier	Customer	NA
Customer shall notify Supplier of any finished product recall which has been investigated or is under investigation and has potential to be related to the quality of the Excipients, as soon as possible. 顧客は供給者に対し、添加剤の品質に関連する調査したか、調査中である最終製品の回収を速やかに通知する。		×	
The parties shall cooperate in the exchange of information required to effectively conduct a recall or recall investigation. 関係者は効率的に回収又は回収の調査を行うのに必要な情報交換に協力する。	×	×	
Auditing **査察**			
Have the right to audit Supplier's facilities, systems and documentation, as they relate to the handling of Excipients, at mutually agreed upon times. お互いに合意した日程において、添加剤の取り扱いに関連する、供給者の施設、システム及び文書を監査する権利を有する。		×	
Allow Customer to audit facilities, systems and documentation, as they relate to the manufacture of Excipients, at mutually agreed upon times. お互いに合意された日程において、医薬品添加剤の製造に関連する供給者の施設、システム及び文書を査察することを顧客に許可する。	×		
Agree on requirements for auditing by the Customer the original manufacturer or other third parties. 製造者もしくはサードパーティーに対する顧客による査察に関する要求事項を取り決める。	×	×	
If required, a confidentiality agreement will be executed within a reasonable period of time prior to the audit 要求された場合、適切な期間が設定された秘密保持契約を、査察に先立ち締結する。	×	×	
Customer shall issue a confidential written audit report to the Supplier, which will include audit observations, within X days (mutually agreed upon timeline). 顧客は供給者に対し書面にて指摘事項を含む査察報告書(confidential written audit report)を XX 日以内(相互に合意した期限内)に発行する。		×	
Supplier shall issue responses within X days	×		

(mutually agreed upon timeline) to all observations in writing to Customer Quality Assurance. Where the Supplier commits to a corrective action, a description and timeframe for completion will be included in the written response. 供給者はx日以内(相互に合意した期間)に全ての指摘事項に関し、顧客の品質保証部門に対し書面にて対応書を発行する。 供給者が是正措置をとる場合、完了までの詳細及び期限を対応書に含む。			

GLOSSARY

Active Pharmaceutical Ingredient (API) - Any substance or mixture of substances, intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient of the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure or any function of the body of man or animals.
Agreement – Arrangement undertaken by and legally binding on parties.
Batch (Lot) – A specific quantity of material produced in a process or series of processes so that it can be expected to be homogeneous. In the case of continuous processes, a batch may correspond to a defined fraction of the production. The batch size can be defined either by a fixed quantity or by the amount produced in a fixed time interval.
Batch Number (Lot Number) – A unique combination of numbers, letters and/or symbols that identifies a batch and from which the production and distribution history can be determined.
Certificate of analysis – A document listing the test methods, specification and results of testing a representative sample from the batch to be delivered.
Cefic – The European Chemical Industry Council
Commissioning – The introduction of equipment for use in a controlled manner.
Contract – Business agreement for supply of goods or performance of work at a specified price.
Corrective Action - A change implemented to address a weakness identified in a management system.
Critical – A process step, process condition, test requirement or other relevant parameter or item that must be controlled within predetermined criteria to ensure that the excipient meets its specification.
Customer – The organization receiving the excipient once it has left the control of the excipient manufacturer; includes brokers, agents and users.
Deviation – Departure from an approved instruction or established standard.
Distributor – All parties in the distribution/supply chain starting from the point at which an excipient is transferred outside the control of the original manufacturer's material management system including parties involved in trade and distribution, (re)processors, (re)packagers, transport and warehousing companies, forwarding agents, brokers, traders, and suppliers other than the original manufacturer.
Excipient – Substances other than the API which have been appropriately evaluated for safety and are intentionally included in a drug delivery system.
FECC – European Federation of Chemical Distributors
GDP – Good Distribution Practice. GDP deals with the distribution of products, including requirements for purchase, receiving, storage and export. GDP regulates the movement of products from the premises of the manufacturer to the end user, or to an intermediate point by means of various transport methods.
GMP – Good Manufacturing Practice. Requirements for the quality system under which drug products and their ingredients are manufactured. Current Good Manufacturing Practice (cGMP) is the applicable term in the United States. For the purposes of this guide, the terms GMP and cGMP are equivalent.
IPEC – International Pharmaceutical Excipients Council

IPEC PQG – International Pharmaceutical Excipients Council and the Pharmaceutical Quality Group.
ISO – International Organization for Standardization.
Label – The display of written, printed or graphic matter on the Immediate container of the excipient (inactive ingredient) product.
Labeling – All written, printed or graphic matter accompanying an excipient at any time while it

is in-transit to the customer or being held for sale after shipment or delivery to the customer.
Lot – see Batch
Lot Number – See Batch Number
NACD – National Association of Chemical Distributors
Manufacturer – A party who performs the final processing step.
Original Manufacturer – Person or company manufacturing a material to the stage at which it is designated as a pharmaceutical starting material.
Packaging – The container and its components that hold the excipient for storage and transport to the customer.
Procedure – Written, authorized instruction for performing specified operations.
Quality Agreements - Legally binding agreements that are mutually negotiated between users and suppliers. They are intended to be an agreement between quality departments. A quality agreement is intended to be a formalized, joint agreement on quality responsibilities and activities defining both the users and suppliers respective obligations as they relate to quality. They are intended to address quality commitments between the parties and are based on the quality procedures in place.
Quality Assurance – The sum total of the organized arrangements made with the object of ensuring all excipients are of the quality required for their intended use and that quality systems are maintained.
Recalls – A process for withdrawing or removing a pharmaceutical material from the distribution chain because of defects in the materials or complaints of a serious nature. The recall might be initiated by the manufacturer/importer/distributor or a responsible agency.
Record – Document stating results achieved and/or providing evidence of activities performed. The medium may be paper, magnetic, electronic or optical, photography etc. or a combination thereof.
Retained Sample – Representative sample of a batch/delivery that is sufficient quantity to perform at least 2 full quality control analyses and will be kept for a defined period of time.
Site – A location where the excipient in manufactured. This may be within the facility but in a different operational area or at a remote facility including a contract manufacturer.
Specification – The quality parameters to which the excipient, component or intermediate must conform and that serve as a basis for quality evaluation.
Supply chain – For the purpose of this guideline, supply chain is defined as all steps in the entire chain of distribution starting from the point at which an excipient is transferred outside the control of the original manufacturer's material a management system downstream to the final user of the excipient.
Supplier – Person or company providing pharmaceutical starting materials on request. Suppliers may be distributors, manufacturers, traders, etc.
User – A party who utilizes an excipient in the manufacture of a drug product or another excipient.
USP/NF – United States Pharmacopeia/National Formulary

Validation – A documented program that provides a high degree of assurance that a specific process, method or system will consistently produce a result meeting predetermined acceptance criteria.
WHO – World Health Organization