5.2 The GMP inspectorate should have:

(a) documentation clearly identifying its legal status;

(b) an organizational chart showing clearly the responsibility and reporting structure of the inspectorate and, in particular, the relationship between its inspection and authorization (licensing) functions;

(c) a description of the means by which the inspectorate obtains financial support;

(d) a description of the relationship between the GMP inspectorate and other departments within the drug regulatory authority and other government agencies, where they operate as separate bodies.

5.3 The GMP inspectorate should have and make available a formal statement explaining how the results of inspections are taken into account in granting and maintaining authorizations (licences).

5.4 The senior management of the GMP inspectorate should make a formal commitment to the recommended principles by ensuring that the quality policy of the inspectorate is documented, relevant to the objectives, and implemented.

5.5 The responsibility, authority and reporting structure of the GMP inspectorate should be clearly defined and documented (see above) and should be supported by written job descriptions for each member of staff.

5.6 An appropriately experienced, responsible and qualified person (*2*) should be nominated to carry out the quality assurance function, including implementing and maintaining the quality system. This person should have direct access to senior management. If necessary, this task may be assigned to more than one person.

5.7 The GMP inspectorate should have sufficient resources at all levels to enable it to attain its objectives effectively and efficiently. Senior management should ensure that all personnel are competent to carry out their assigned duties. They should receive appropriate training that should be documented and its effectiveness assessed.

5.8 Periodic management reviews of the quality system should be conducted and documented; records of these reviews should be retained for a specified period of time.

Recommended procedure

The above-mentioned recommendations are intended to ensure a reasonable level of transparency, both nationally and internationally.

The organizational chart, source(s) of finance, legal status of the GMP inspectorate and its relationship with the drug regulatory authority and other government agencies should be documented in the quality manual, together with a description of the quality system.

6. Inspection personnel

6.1 The personnel of the GMP inspectorate should be competent to perform the functions that they undertake.

6.2 The GMP inspectorate should maintain information on the relevant qualifications, training and experience of each inspector. Records of training and experience should be kept up to date.

6.3 Personnel should have clear, documented instructions specifying their duties and responsibilities. These instructions should be kept up to date.

6.4 When work is subcontracted to an external body or use is made of experts, the inspectorate should ensure that the personnel employed meet the relevant requirements of the quality system. The liability of third party inspectors should be clearly defined in the contract or agreement.

6.5 The GMP inspectorate should possess the required personnel, expertise and other resources to perform inspections of manufacturers and wholesale distributors to determine whether they comply with the principles and guidelines of current good practices and with the relevant legislation.

6.6 The staff responsible for inspections should have appropriate qualifications, training, experience and knowledge of the inspection process. They should have the ability to make professional judgements as to the conformity of the inspected party with the requirements of good practices and the relevant legislation and be able to make an appropriate risk assessment. Knowledge of current technology is essential, including computerized systems and information technology.

6.7 The GMP inspectorate should establish a documented system for recruiting and training its personnel. The training received and the training needs of each member of staff should be regularly reviewed, and individual training records should be maintained.

Recommended procedure

The credibility of the GMP inspection process will depend to a large degree on the technical competence and integrity of the inspectors. The quality manual should provide up-to-date details of the names,

qualifications, experience and terms of reference (job description and duties to be performed) of each member of staff engaged in the GMP inspection process (see also section 10).

Formal arrangements should exist for personnel training, and details of these arrangements should be documented. Training undertaken by each member of staff engaged in GMP inspections should be documented (see also "Recommended procedure" in section 10).

A documented procedure for selecting the members of an inspection team and deciding on its size should be available. The inspection team may include a person or persons with specialist knowledge and/or experience of a particular area of technology.

If an inspection is carried out on behalf of the GMP inspectorate by an external body or person, the GMP inspectorate should ensure that the external personnel satisfy the relevant requirements contained in these recommendations.

GMP inspectors working with or advising the GMP inspectorate should:

(a) be academically qualified in a recognized scientific/technological discipline related to pharmaceuticals (normally pharmacy, chemistry or microbiology); direct personal experience of pharmaceutical manufacture or control is not a requirement but would be considered as a valuable asset for an inspector;

(b) have satisfactorily completed a recognized training course on auditing quality management systems;

(c) undergo at least 10 days of training per year (e.g. courses, symposia, conferences, etc.);

(d) have a competent working knowledge of the WHO guidelines on GMP for pharmaceutical products (*2*) and/or the GMP inspection procedures of the relevant national regulatory authority;

(e) have undergone appropriate training in the current procedures and techniques of GMP inspections before conducting an inspection alone;

(f) have the necessary personal qualities of integrity, tact and character to perform the duties of a GMP inspector.

7. Documentation

7.1 The GMP inspectorate should maintain a system for the control of all documentation relating to GMP inspections of manufacturers and recommendations relating to authorization holders, and should ensure that:

(a) the current versions of the appropriate documentation are available at all relevant locations;

(b) all revised documents or amendments to documents are correctly authorized and processed in a manner which ensures that they are introduced without delay;

(c) superseded documents are removed from use throughout the GMP inspectorate and elsewhere in the organization and its agencies, but are retained for a defined period of time.

7.2 The GMP inspectorate should ensure that all of its activities are described in SOPs that clearly describe the responsibilities, policy and actions. These should include, but not be limited to, training (introduction, GMP and task-related), inspections, reporting after inspections, handling of complaints, licensing (issue, suspension, revocation), certification, documentation control, planning and handling of appeals.

7.3 Proper and accessible records should be maintained of the activities carried out, including training, as well as the assessment of inspectors after training, the preparation of inspection reports, the handling of complaints, and the drawing-up of authorized checklists (where in use) and other related documents.

7.4 Reports should be prepared on all inspections performed. They should be prepared in the approved format, and signed and dated by the relevant inspector.

7.5 The documentation system should ensure that any changes to documents are made in a controlled manner and are properly authorized. There should be a means of identifying changes in individual documents.

Recommended procedure

The following information should be included or referred to in the quality manual:

(a) a list of all the documents used;

(b) for each document, the name(s) or position(s) of the person(s) responsible for authorizing its issue and any subsequent amendments or changes;

(c) a description of the system whereby relevant documents and subsequent amendments are made available at the appropriate location from the point of view of the functioning of the inspection process;

(d) the method by which amendments and changes are made, so that documents are speedily updated, changes recorded and superseded documents promptly withdrawn and archived.

8. Records

8.1 The GMP inspectorate should maintain a system of records to suit its particular method of operation and circumstances. It must comply with the relevant obligations under national legislation and demonstrate that the quality system is operating satisfactorily.

8.2 Records should be available which demonstrate that all the relevant procedures have been followed in the performance of each GMP inspection, including the initial inspection, the recommendation for issue of a marketing authorization, routine inspections and corrective action.

8.3 All records should be safely stored for an adequate period, and held under conditions that guarantee their security and confidentiality, unless otherwise required by the national legislation.

Recommended procedure

The quality manual should describe or refer to separate SOPs which describe the system adopted by the GMP inspectorate for maintaining its records. The manual should include blank specimen copies of the various checklists, certificates and reports used during the inspection process and describe the way in which these are processed, stored and archived, and/or disposed of.

The procedures for recommending to the authorization holder the issue, suspension or revocation of marketing authorizations should be described.

Documented staff instructions on security and on the use and handling of inspection reports should be identified and described in accordance with the confidentiality requirements specified in national legislation. Information as to who should have access to confidential information should be given and such access should be controlled.

Records associated with inspection activities should be retained for a minimum period of three full inspection cycles or for 6 years, whichever is the longer.

9. Inspection procedures

9.1 The GMP inspectorate should have the required resources (financial, human, facilities and others) and documented procedures to enable the inspection of manufacturing operations to be carried out

in accordance with the requirements of the WHO guidelines on GMP (*2*) and/or the national GMP guidelines.

9.2 The GMP inspectorate should require the manufacturer to have documented procedures in accordance with a quality management system, and complying with the WHO guidelines on GMP (*2*) and/or the national GMP guidelines.

9.3 The GMP inspectorate should perform regular inspections of the manufacturing premises, procedures and quality systems of authorization holders at least once every 2 years in accordance with a written inspection programme. Written inspection reports should be prepared and sent to the national regulatory authority to keep it informed of the outcome of such inspections.

9.4 The planning of inspections of manufacturers and the assessment of compliance with the planning regarding the performance of the different types of inspections should be documented. The types of inspections should include as a minimum routine inspections, specific inspections, follow-up inspections and concise inspections.

9.5 The activity of the GMP inspectorate should be described, indicating how it relates to the system(s) for granting manufacturers' and product authorizations.

9.6 The activities relating to post-marketing surveillance and product testing should be described. The description should also cover the process of handling non-conforming products (e.g. substandard or counterfeit products).

9.7 The procedure for operations in support of a surveillance sampling programme should be documented.

9.8 The GMP inspectorate should have the documented procedures and resources to enable the inspection of manufacturing and wholesale distribution operations to be carried out in accordance with the official guidelines and national legislation. A formal inspection plan should be followed. All instructions, standards or written procedures, worksheets, checklists and reference data relevant to the work of the GMP inspectorate should be kept up to date and be readily available to staff.

9.9 A chief inspector should be appointed to coordinate inspection activities if more than one inspector is involved in an inspection. The lead inspector, who should be selected by all the participating inspectors, should normally prepare the inspection report.

9.10 Observations and/or data obtained in the course of inspections should be recorded in a timely manner to prevent loss of relevant information.

9.11 Completed inspections should be reviewed to ensure that the requirements have been met.

Recommended procedure

The procedures covering initial inspections of new applicants for marketing authorizations and ongoing inspections of authorization holders should be documented.

Manufacturers should be inspected at least every 1 or 2 years, although new authorization holders should be inspected more frequently until inspectors are confident that the manufacturers are complying with the WHO guidelines on GMP and/or the national GMP guidelines. The frequency of inspection should not normally fall below once every 2 years as lack of continuity may give rise to a reduced awareness of current GMP or allow significant deficiencies to develop.

The time available for undertaking inspections should be adequate to enable sufficient investigations and enquiries to be made to give confidence in the findings of the inspection.

The report to the authorization holders following GMP inspections should include as a minimum:

(a) the name and location of the manufacturing site(s);

(b) the date(s) of the inspection(s);

(c) the reason for the inspection and the product categories and manufacturing areas inspected;

(d) the suitability of key personnel, including the authorized person;

(e) observations, failures to comply with the WHO guidelines on GMP and/or the national GMP guidelines, and the recommended frequency of reinspection;

(f) a recommendation on the issue/continuation, suspension or revocation of the marketing authorization.

The GMP inspectorate should have the power, under the national or regional legislation or other arrangements, to require reinspection of a manufacturer's premises if there are changes in personnel, facilities, internal organization or scope of activity, or if analysis of a complaint or any other information indicates that the manufacturer is failing to comply with the requirements of the WHO guidelines on GMP and/or the national GMP guidelines, or with the conditions imposed by the marketing authorization.

10. Inspection facilities required

10.1 The inspection service should have the required facilities in terms of staff, expertise, equipment and other resources to perform inspections of manufacturers to determine compliance with the requirements of the WHO guidelines on GMP and/or the national GMP guidelines. This does not preclude the use of external resources, when necessary, provided that the requirements as described for "subcontracting" are met (see section 3.3).

10.2 If inspections are carried out on behalf of the GMP inspectorate by an external body or person, the GMP inspectorate should ensure that this body or person satisfies the requirements specified in section 3.3. A properly documented agreement covering these arrangements, including confidentiality aspects and the declaration of any conflict of interests, should be drawn up.

Recommended procedure

A sufficient number of competent personnel should support the GMP inspectorate, whether employed or contracted for the functions that they undertake.

The quality manual should describe the procedures for the management of the GMP inspectors and of the necessary records. A record should be kept for each individual employed to carry out GMP inspections (whether an employee or under contract), which should include the following information:

(a) the name;

(b) the designated area of responsibility within the declared scope of the GMP inspectorate;

(c) the educational qualifications;

(d) the professional qualifications, where relevant to the activities of the GMP inspectorate;

(e) the work experience;

(f) details of the GMP inspector training received, supported by documentary evidence of course attendance and assessment results.

Where an external body or person carries out a GMP inspection, the quality manual should describe the process adopted by the GMP inspectorate to comply with the above-mentioned requirements.

Whenever an external body or person is used to carry out any function on behalf of a GMP inspectorate, the GMP inspectorate should

have documented evidence to demonstrate that the external body or person concerned is competent to do so.

Staff members authorized to carry out audits of external bodies or persons should be identified.

Documented agreements with all external bodies or persons should be available for scrutiny.

A register of all external bodies or persons employed by the GMP inspectorate should be maintained. The register should include:

(a) the name of the external body or person;

(b) the legal status of the external body and details of any relationship with a parent company, group of companies or any other organization of which the external body or person is part, with specific reference to possible conflicts of interest;

(c) the names and qualifications of all personnel engaged in GMP inspection work for the GMP inspectorate.

11. Quality manual

11.1 The GMP inspectorate should define and document its policy and objectives for, and commitment to, quality in a quality manual. It should ensure that this policy is understood, implemented and maintained at all levels in the organization.

11.2 The information contained in the quality manual and procedures should include at least:

(a) a quality policy statement;

(b) a brief description of the legal status of the GMP inspectorate (see section 4.1(a));

(c) a code of ethics and conduct relating to GMP inspection activities;

(d) a description of the organization of the GMP inspectorate, including details of any governing board, its constitution, terms of reference and rules of procedure (see section 5.2(b));

(e) the names, qualifications, experience and terms of reference of the senior staff and other GMP inspection personnel, both internal and external (see sections 6 and 10);

(f) details of training arrangements for inspection personnel (see sections 6 and 10);

(g) an organizational chart showing the responsibility and reporting structure of the inspectorate and the allocation of functions

stemming from the person in charge of the GMP inspectorate (see section 5.2(b));

(h) details of the documented procedures for inspecting manufacturers under the WHO guidelines on GMP and/or the national GMP guidelines (see section 8);

(i) details of the documented procedures for recommendations to the authorization holder for the issue, suspension or revocation of marketing authorizations (see sections 7.2 and 8.1);

(j) a list of any subcontractors used for GMP inspections and details of the documented procedures for assessing and monitoring their competence (see section 6);

(k) details of appeals procedures (see section 14);

(l) a procedure for ensuring that complaints made to the GMP inspectorate are investigated so that any shortcomings of the authorization holders are revealed (see section 16);

(m) a list of those staff members responsible for investigating complaints and those with the authority to take remedial action (see section 16);

(n) details of internal quality audits (see section 15);

(o) details of testing of samples (see sections 9.6–9.8);

(p) the control of non-conforming products (see section 9.6).

Recommended procedure

In order to keep the quality manual brief, reference may be made to other documents and/or procedures contained in other manuals.

12. Confidentiality

12.1 The GMP inspectorate should have adequate arrangements to ensure confidentiality of the information obtained in the course of its inspection activities at all levels of its organization, including committees.

12.2 The exchange of inspection reports between countries should be described. The format and content of reports should be specified.

Recommended procedure

The quality manual should describe how the GMP inspectorate discharges its responsibility for ensuring that all communications between itself and the companies inspected are kept confidential. The following are necessary:

(a) instructions to personnel on confidentiality;

(b) a written undertaking by all personnel not to divulge to third parties any information gained about any business affairs of clients;

(c) the inclusion of provisions in all subcontracts to maintain confidentiality;

(d) provisions to ensure the physical security of all documents and records relating to inspection activities.

13. Publications

13.1 The GMP inspectorate should produce and update, as necessary, a list of authorization holders, together with an outline of the scope of the marketing authorization issued to each manufacturer. The extent to which this list will be distributed should be specified.

13.2 An outline of the inspection and marketing authorization system should be available in published form.

13.3 Other publications, such as GMP guidelines and other guidelines and information brochures, should be available to industry and other interested parties, as appropriate.

Recommended procedure

The quality manual should list the publications issued by the authorization holder and GMP inspectorate. The following information should also be provided:

(a) the name of the person responsible for compiling and updating each publication;

(b) the frequency with which each publication is updated;

(c) how the publications are distributed and to whom;

(d) the procedure for issuing amendments.

14. Appeals

14.1 The GMP inspectorate should have procedures for the consideration of appeals against its decisions.

Recommended procedure

Appeals procedures should be established by the GMP inspectorate and should include:

(a) the method by which an appeal may be lodged;

(b) the method by which an impartial appeals panel, independent of the activity under review, is selected;

(c) the names and positions of the members of the GMP inspectorate to whom appeals are referred, and the procedure for handling them;

(d) a register of all appeals and their outcome.

15. Internal audit and periodic review

15.1 The GMP inspectorate should implement a system of planned and documented internal audits and periodic reviews of its compliance with the criteria of these guidelines.

15.2 There should be procedures for corrective and preventive action whenever faults are detected in the quality system, or in the performance of inspections and the general performance of the inspection service.

15.3 The management of the inspectorate should periodically review the quality system for its continuing suitability and effectiveness.

15.4 Inspectors should be evaluated before being allowed to perform inspections. Periodic reviews should also be undertaken to examine the performance of individual inspectors in order to ensure consistency among them, and in the operations and procedures of the GMP inspectorate.

15.5 A record of all audits and reviews should be kept and should include the findings, conclusions, recommendations and follow-up action. These records should be retained for a specified period of time.

Recommended procedure

Internal periodic review procedures should be documented. The review procedure should include internal audits by staff competent to ensure that all formulated procedures are adhered to. Based on the results of these audits, management must ensure that the GMP inspection system remains effective and that inspections conducted by different inspectors arrive at similar conclusions when the same operation is inspected under the same conditions.

Internal audit procedures should state:

(a) the names or positions of staff members authorized to conduct internal audits;

(b) what is to be examined and how often (a schedule for the examination of the whole organization over a given period should be drawn up);

(c) how the audit will be conducted;

(d) to whom the results will be reported;

(e) who will initiate any corrective action.

Management reviews should take account of the results of internal audits and should include:

(a) consideration of the overall operation of the GMP inspectorate;

(b) uncovering defects or irregularities in the operation of the GMP inspection system;

(c) ensuring that action has been taken to effectively correct defects revealed in previous reviews and audits.

Periodic audit by an experienced person or persons from another national regulatory authority is a useful means of providing an independent review of the GMP inspectorate's operations and procedures.

16. Complaints

16.1 The GMP inspectorate should have documented procedures for dealing with complaints arising from its activities.

16.2 A record should be maintained of all complaints received and the actions taken by the GMP inspectorate. These records should be retained for a specified period of time.

Recommended procedure

The GMP inspectorate should require each authorization holder to keep a record of all complaints received, as well as remedial actions relating to the manufacturing activities and products covered by the marketing authorization.

The GMP inspectorate should have a procedure for recording and investigating complaints received about its inspection activities. The procedure should include a list of those staff members responsible for investigating complaints and those with the authority to take remedial action.

17. Recalls

17.1 The GMP inspectorate should have a documented procedure for dealing with recalls and withdrawals of products from the market.

17.2 Records should be maintained of all recalls and withdrawals registered and dealt with by the inspectorate.

References

1. Provisional guidelines on the inspection of pharmaceutical manufacturers. In: *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-second report.* Geneva, World Health Organization, 1992, Annex 2 (WHO Technical Report Series, No. 823).
2. *Quality assurance of pharmaceuticals. A compendium of guidelines and related materials. Vol. 2. Good manufacturing practices and inspection.* Geneva, World Health Organization, 1999.
3. *Recommendations on quality system requirements for GMP inspectorates of PIC Contracting States.* Geneva, Pharmaceutical Inspection Convention, 1994 (unpublished document PH/7/94; available from EFTA Secretariat, 9–11 rue de Varembé, 1211 Geneva 20, Switzerland).
4. *Quality management and quality assurance standards — guidelines for selection and use. International Standard ISO 9000.* Geneva, International Organization for Standardization, 1990.
5. *Quality systems — model for quality assurance in design/development, production, installation and servicing. International Standard ISO 9001.* Geneva, International Organization for Standardization, 1994.
6. *Quality systems — model for quality assurance in production, installation and servicing. International Standard ISO 9002.* Geneva, International Organization for Standardization, 1994.
7. *Quality systems — model for quality assurance in final inspection and test. International Standard ISO 9003.* Geneva, International Organization for Standardization, 1994.
8. *Quality management and quality system elements — guidelines. International Standard ISO 9004.* Geneva, International Organization for Standardization, 1990.
9. *General criteria for certification bodies operating quality systems certification. European Standard EN 45012.* Brussels, European Committee for Standardization, 1989 (available from CEN Central Secretariat, 36 rue de Stassart, B-1050 Brussels, Belgium).
10. Good manufacturing practices: authorized person — role, functions and training. In: *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-fifth report.* Geneva, World Health Organization, 1999, Annex 4 (WHO Technical Report Series, No. 885).

添付資料5　　WHOの品質システム要求の日本語訳

WHO Technical Report Series, No. 902, 2002

付録8
各国の査察当局における品質システムの要求事項

背景

医薬品製造業者の査察に関する暫定ガイドライン[*1*]に続き、WHO医薬品規格専門家委員会は医薬品の製造管理及び品質管理に関する基準（GMP）[*2*]の履行を促進し、査察当局間の相互承認を強化する為、各当局に向けた追加のガイドラインを作成することが有用であることを認識した。

近年、WHO加盟国では認証機関や試験機関などの非営利組織において、内部業務に品質システムの原則を導入する動きが明らかになってきた。政府の医薬品査察当局や公的医薬品管理試験施設でも同様の原則が適用されつつある。

医薬品製造査察の相互承認に関する協定(PIC)は、PIC/S加盟国の査察当局の業務に、国際標準化機構(ISO)の9000シリーズ及び関連規格[*4-8*]の適用することを目的とする文書 [*3*]を公表している。この文書は欧州規格EN 45012(*品質システム認証登録機関に対する一般的要求事項*) [*9*]に基づいているが、特にこの目的の為に修正が加えられている。

1. 緒言

これらの要求事項は、査察を行う規制当局内での、査察業務の実施に対する品質システムに適用される。各査察機関が自らの品質システムを構築する際の基礎として、これらの要求事項を用いることが意図されている。

品質システムを確立し、実施することは、各国の査察の相互承認における必須要素である。規制当局の査察団が品質システムの原則を取り入れた同一の手順に従っていることがわかれば、その国の査察が大いに受け入れられやすくなる。品質システムには、査察に関連する全ての業務を含める必要がある。

2. 用語集

出荷責任者

市販用の最終製品のバッチの出荷承認の責任を負う者(製造事業所の主要な従業員の一人が行う) [*10*]。

品質点検

特に品質システムの改善を目的として実施される、品質システム全体又は一部に対する点検及び評価。通常、品質点検は外部又は独立の専門家、若しくはこの目的の為に管理者が指名したチームにより実施される。このような点検はサプライヤー及び委託先に対しても実施される[2]。

品質マニュアル

ラボ試験の結果の品質を保証する為のシステムの様々な要素について記述したハンドブック(11項を参照)。

品質システム

製品(又はサービス)が品質に関する所定の要求事項を満たすことに対する十分な信頼度を保証する為に必要とされる適切なインフラストラクチャー、組織体制、手順、プロセス、及び資源[2]。

標準業務手順書（SOP）

特定の製品又は材料に限定したものでなく、より一般的な業務（例：設備の操作、維持及び洗浄；バリデーション；施設の清掃及び環境管理；サンプリング及び検査）を実施する為の指示を記載する承認された手順書。一部のSOPは、特定の製品についてのマスター及びバッチ製造文書を補足する為に使用される[2]。

3. 管理組織

3.1 査察当局の体制、要員及び業務は、公平性が保護されるようなものとする必要がある。

3.2 国の査察機関は、関連国内法令の要求事項が満たされることを保証する責務を負う。

3.3 外部の査察官及び委託職員を含む査察当局の全ての被雇用者又は被使用者は、各自の判断に影響を及ぼす可能性のあるいかなる商業的、金銭的、又はその他の圧力下におかれるべきではない。それらの者は医薬品製造業者の管理下にあってはならず、評価を受け、認定されなければならない。

3.4 手数料収受システムが査察手順に不適切な影響を及ぼすものであってはならない。

推奨手順

品質マニュアルには、査察当局の管理組織、メンバー、業務及び法的地位について記載する必要がある（11項を参照）。

品質マニュアルは、委託職員又は顧問及び助言を行う委員会の委員を含め、査察当局で働く全ての職員が各自の公平性を維持する方法を示す必要がある。査察当局は、それらの職員が以下の要求事項を満たすことを保証する必要がある。

(a) 各自の判断に影響を及ぼす可能性のあるいかなる商業的、金銭的又はその他の圧力下におかれていない。

(b) 評価の対象となる医薬品製造業者又は個人に対する査察の際、不適切な影響を受けない。

(c) コンサルタント業務や商業的取引の形で査察対象設備の計画又は維持に関わっていない。

査察当局の査察業務に従事する職員に対する報酬は、査察業務の結果又は販売承認の可否に左右されるものであってはならない。

例外的な場合に限り、査察当局は助言又はコンサルタント業務の提供を行う。査察当局がこのような業務を行う場合、行動規範を定めるか、又は査察業務と依頼者に対する助言又はコンサルタント業務とを明確に区別するとする一定の規律を作成する必要がある。この業務は業界全体に利益のあるものである必要があり、個々の製造業者のみを利するものであってはならない。

4. 権限

4.1 査察当局の役割を明確に定義し、以下を含める必要がある。

(a) 法的責任

(b) ポリシーの制定

(c) ポリシーの実施の把握

(d) 財務の把握

(e) 必要に応じ、一定の業務を委任する委員会の設置

推奨手順

査察当局の権限、法的責任及び役割、並びにポリシーガイドラインの制定方法は、品質マニュアルとして文書化する必要がある。

査察当局又は調査実施責任者に対して助言を行う為に設置する全ての委員会について、以下の詳細を規定する必要がある。

(a) 役割及び職務

(b) 委員の選任及び指名の手順（委員長、書記及び委員の氏名、各自の現在の役職及び、もしあれば、委員会への利害関係を明確にする必要がある）

(c) 手続規則

5. 組織体制

5.1 査察当局は、その技術的な機能を充分に実施する能力を維持することが可能な組織体制をもつことが求められる。

5.2 査察当局は以下を備える必要がある。

(a) その法的地位を明確に規定する文書

(b) 査察当局の責任及び報告体制、並びに特にその査察と承認（許可）の両職務の関係を明確に示す組織図

(c) 査察当局が財政的支援を得る手段に関する記述

(d) 査察当局と医薬品規制当局内の他の部署との関係、及び他の政府機関が別組織として関係する場合はそれらの機関との関係を示す記述

5.3 査察当局は、査察結果が承認（許可）の付与及び維持に対してどのように考慮されるかを説明する公式見解を作成し、公開する必要がある。

5.4 査察当局の上級管理者は、査察当局の品質ポリシーを目的に即して確実に文書化して実行することにより、推奨された原則に従う姿勢を公式に示す必要がある。

5.5 査察当局の責任、権限及び報告体制は明確に定義して文書化する必要があり（上記を参照）、各職員のる職務記述書により裏付ける必要がある。

5.6 品質システムの実施及び維持を含む品質保証職務の遂行の為、適切な経験、責任及び資格を有する者[2]を1名指名する必要がある。この職員は、上級管理者に直接報告し指示を受けることができる必要がある。必要であれば、この任務は複数の職員に委任することができる。

5.7 査察当局は、その目的の効果的かつ効率的な達成を可能にする為、全てのレベルで十分な資源を保有する必要がある。上級管理者は、全ての職員が与えられた職務の遂行に対して十分な能力を有することを保証する必要がある。これらの職員は適切な訓練を受ける必要があり、訓練の実施は文書化し、効果を評価する必要がある。

5.8 品質システムの定期的なマネジメントレビューを実施して文書化し、レビューの記