Q10
Document History

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PHARMACEUTICAL QUALITY SYSTEM

Draft ICH Consensus Guideline

Released for Consultation on 9 May 2007, at *Step 2* of the ICH Process

TABLE OF CONTENTS

PHARMACEUTICAL QUALITY SYSTEM

1. PHARMACEUTICAL QUALITY SYSTEM

1.1 Introduction

This document establishes a new ICH tripartite guideline describing a model for an effective quality management system for the pharmaceutical industry, referred to as the Pharmaceutical Quality System.

ICH Q10 describes one comprehensive approach to an effective pharmaceutical quality system that is based on ISO concepts, includes applicable Good Manufacturing Practice (GMP) regulations and complements ICH Q8 "Pharmaceutical Development" and ICH Q9 "Quality Risk Management". ICH Q10 is a model for a pharmaceutical quality system that can be implemented throughout the different stages of a product lifecycle. Much of the content of ICH Q10 applicable to manufacturing sites is currently specified by regional GMP requirements. ICH Q10 is not intended to create any new expectations beyond current regulatory requirements. Consequently, the content of ICH Q10 that is additional to current GMP requirements is optional.

Throughout this guideline, the term "pharmaceutical quality system" refers to the ICH Q10 model.

ICH Q10 demonstrates industry and regulatory authorities' support of an effective pharmaceutical quality system to enhance the quality and availability of medicines around the world in the interest of public health. Implementation of ICH Q10 throughout the product lifecycle should facilitate innovation and continual improvement and strengthen the link between pharmaceutical development and manufacturing activities.

1.2 Scope

This guideline applies to pharmaceutical drug substances and drug products, including biotechnology and biological products, throughout the product lifecycle.

The elements of ICH Q10 should be applied in a manner that is appropriate and proportionate to each of the product lifecycle stages, recognizing the differences among, and the different goals of each stage (described later in Section 3).

For the purposes of this guideline, the product lifecycle includes the following technical activities for new and existing products:

- Pharmaceutical Development
    - Drug substance development;
    - Novel excipient development;
    - Formulation development (including container/closure system);
    - Delivery system development (where relevant);
    - Manufacturing process development and scale-up;
    - Analytical method development.
- Technology Transfer
    - New product transfers from Development to Manufacturing;
    - Transfers within or between manufacturing and testing sites for marketed products.

- Manufacturing
  - Procurement of materials;
  - Provision of facilities, utilities and equipment;
  - Production (including packaging and labelling);
  - Quality control and assurance;
  - Release;
  - Storage;
  - Distribution (excluding wholesaler activities).
- Product discontinuation
  - Retention of documentation;
  - Sample retention;
  - Continued product assessment and reporting.

1.3 Relationship of ICH Q10 to Regional GMP Requirements, ISO Standards and ICH Q7

Regional Good Manufacturing Practice requirements, the ICH Q7 Guideline and ISO Quality Management System Guidelines form the foundation for ICH Q10. To meet the objectives described below, ICH Q10 augments GMPs by describing specific quality system elements and management responsibilities. ICH Q10 thereby serves as a bridge between the regional requirements, helping industry and regulators achieve harmonisation of the pharmaceutical quality system throughout the lifecycle of a product.

1.4 Relationship of ICH Q10 to Regulatory Approaches

Regulatory approaches for a specific product or manufacturing facility should be commensurate with the level of product and process understanding, the results of quality risk management, and the effectiveness of the pharmaceutical quality system. When implemented, the effectiveness of the pharmaceutical quality system can normally be confirmed during a regulatory inspection at the manufacturing site. Potential opportunities to enhance science and risk based regulatory approaches are identified in Annex 1. Regulatory processes will be determined by region.

1.5 ICH Q10 Objectives

i) Achieve Product Realisation

To establish, implement and maintain a set of processes that provides a product with the quality attributes appropriate to meet the needs of patients, health care professionals, regulatory authorities (including compliance with marketing authorisations) and internal customers.

ii) Establish and Maintain a State of Control

To develop and use effective monitoring and control systems for process performance and product quality, thereby providing assurance of continued suitability and capability of processes. Quality risk management can be useful in establishing the monitoring and control system.

iii) Facilitate Continual Improvement

To identify and implement appropriate product quality improvements, process improvements, variability reduction, innovations, and pharmaceutical quality system enhancements, thereby increasing the ability to consistently fulfil

quality needs. Quality risk management can be useful to identify and prioritise areas for improvement.

1.6 Enablers

Knowledge management and quality risk management are enablers of ICH Q10 that facilitate a consistent scientific approach to achieve the objectives described in 1.5 above. These enablers should provide the means for science- and risk–based decisions related to product quality.

i) Knowledge management

Knowledge should be managed from development through the commercial life of the product up to and including product discontinuation. Knowledge management is a systematic approach to acquiring, analyzing, storing and disseminating information related to products, processes and components. Sources of knowledge include, but are not limited to, prior knowledge (public domain or internally documented), pharmaceutical development studies, technology transfer activities, process validation studies over the product lifecycle, manufacturing experience, continual improvement and change management activities.

ii) Quality risk management

Quality risk management can provide a proactive approach to identifying and controlling potential risks to quality throughout the product lifecycle. ICH Q9 describes a model for quality risk management approaches within a pharmaceutical context.

1.7 Design and Content Considerations

i) The pharmaceutical quality system should be well structured and clear to facilitate common understanding and consistent application.

ii) The elements of ICH Q10 should be applied in a manner that is appropriate and proportionate to each of the product lifecycle stages, recognizing the differences among, and the different goals of each stage.

iii) The size and complexity of the company's activities should be taken into consideration when developing a new pharmaceutical quality system or modifying an existing one. While some aspects of the pharmaceutical quality system can be company-wide and others site-specific, the effectiveness of the implementation of the pharmaceutical quality system is normally demonstrated at the site level.

iv) Outsourced (contracted) activities should be within the scope of the pharmaceutical quality system.

v) Management responsibilities, as described in Section 2, should be identified within the pharmaceutical quality system.

vi) The pharmaceutical quality system should include the following elements: process performance and product quality monitoring, corrective and preventive action, change management and management review, as described in Section 3.

vii) Key performance indicators should be identified and used to monitor the effectiveness of processes within the pharmaceutical quality system as described in Section 4.

1.8 Quality Manual

A Quality Manual or equivalent documentation approach should be established and should contain the description of the pharmaceutical quality system. The description should include:

i) The quality policy (further described in Section 2).
ii) The scope of the pharmaceutical quality system.
iii) Identification of the processes within the pharmaceutical quality system, as well as their sequences, linkages and interdependencies. Process maps and flow charts can be useful tools to facilitate depicting these in a visual manner.
iv) Management responsibilities within the pharmaceutical quality system, as described in Section 2 of this document.

2. MANAGEMENT RESPONSIBILITY

Leadership is essential to establish and maintain a company-wide commitment to quality and for the performance of the pharmaceutical quality system.

2.1 Management Commitment

i) Senior management has the ultimate responsibility to ensure an effective pharmaceutical quality system is in place, and that responsibilities and authorities are defined, communicated and implemented throughout the company.
ii) Management should:
   (1) Participate in the design, implementation and monitoring of the pharmaceutical quality system;
   (2) Demonstrate strong and visible support for the pharmaceutical quality system and ensure its implementation throughout their organization;
   (3) Ensure a timely and effective communication and escalation process exists to raise quality issues to the appropriate levels of management;
   (4) Define and communicate individual and collective roles, responsibilities and authorities of all organizational units related to the pharmaceutical quality system, and ensure interactions are defined and understood. An independent quality unit/structure with authority to fulfil certain pharmaceutical quality system responsibilities is required by regional regulations;
   (5) Conduct management reviews of process performance and product quality and of the pharmaceutical quality system;
   (6) Advocate continual improvement;
   (7) Commit appropriate resources.

2.2 Quality Policy

i) Senior management should establish a quality policy that describes the overall intentions and direction of the company related to quality.
ii) The quality policy should include an expectation to comply with applicable regulatory requirements and should facilitate continual improvement of the pharmaceutical quality system.

iii) The quality policy should be communicated to and understood by personnel at all levels in the company.

iv) The quality policy should be reviewed periodically for continuing effectiveness.

2.3 Quality Planning

i) As part of quality planning, senior management should ensure the quality objectives needed to implement the quality policy are defined and communicated.

ii) Quality objectives should be supported by all relevant levels of the company.

iii) Quality objectives should align with the company's strategic plans and be consistent with the quality policy.

iv) Management should provide the appropriate resources and training to achieve the quality objectives.

v) Key performance indicators that measure progress against quality objectives should be established, monitored, communicated regularly and acted upon as appropriate.

2.4 Resource Management

i) Management should determine and provide adequate and appropriate resources (human, financial, materials, facilities and equipment) to implement and maintain the pharmaceutical quality system and continually improve its effectiveness.

ii) Management should ensure that resources are appropriately applied to a specific product, process or site.

2.5 Internal Communication

i) Management should ensure appropriate communication processes are established and implemented within the organization.

ii) Communications processes should ensure the flow of appropriate information between all levels of the company.

iii) Communication processes should ensure the escalation of certain product quality and pharmaceutical quality system issues to appropriate levels of management in a timely manner.

2.6 Management Review

Senior management should be responsible for pharmaceutical quality system governance through management review to ensure its continuing suitability and effectiveness. Management should assess the conclusions of periodic reviews of process performance and product quality and of the pharmaceutical quality system, as described in Sections 3 and 4.

2.7 Oversight of Outsourced Activities

A pharmaceutical company can outsource activities at all stages of the product lifecycle. The pharmaceutical quality system, including the management responsibilities described in this section, extends to the oversight and review of outsourced activities. Normally under a contract, the contract giver should be responsible for assessing the suitability and competence of the contract acceptor to

carry out the work required. Responsibilities for quality-related activities of the contract giver and contract acceptor should be specified in a written agreement.

3. CONTINUAL IMPROVEMENT OF PROCESS PERFORMANCE AND PRODUCT QUALITY

Regional GMP requirements and the ICH Q7 guideline form the foundation of ICH Q10. This section describes the four specific pharmaceutical quality system elements that augment this foundation. to achieve the ICH Q10 objectives. It does not restate all regional GMP requirements. The elements described below might be, in part, required under regional GMP regulations; however, the intent is to enhance these elements in order to promote the lifecycle approach to product quality. These four elements are:

- Process performance and product quality monitoring system;
- Corrective action and preventive action (CAPA) system;
- Change management system;
- Management review of process performance and product quality.

These elements should be applied in a manner that is appropriate and proportionate to each of the product lifecycle stages, recognizing the differences among, and the different goals of each stage. Throughout the product lifecycle, companies should evaluate opportunities for innovative approaches to improve product quality.

The goals of each product lifecycle stage are described below, followed by examples of how each pharmaceutical quality system element is applied to that product lifecycle stage.

3.1 Lifecycle Stage Goals

i) Pharmaceutical Development

The goal of pharmaceutical development activities is to design a product and its manufacturing process to consistently deliver the intended performance and meet the needs of patients, healthcare professionals, regulatory authorities and internal customers. Approaches to pharmaceutical development are described in ICH Q8. The results of exploratory and clinical development studies, which are outside the scope of this guidance, are inputs to pharmaceutical development.

ii) Technology Transfer

The goal of technology transfer activities is to transfer product and process knowledge between development and manufacturing, and within or between manufacturing sites to achieve product realisation. This knowledge forms the basis for the manufacturing process, control strategy, process validation approach and ongoing continual improvement.

iii) Manufacturing

The goals of manufacturing activities include achieving product realisation, establishing and maintaining a state of control and facilitating continual improvement. The pharmaceutical quality system should assure that the desired product quality is routinely met, suitable process performance is achieved, the set of controls are appropriate, improvement opportunities are identified, and the body of knowledge is continually expanded.

iv) Product Discontinuation

The goal of product discontinuation activities is to effectively manage the terminal stage of the product lifecycle. For product discontinuation, a pre-defined approach should be used to manage activities such as retention of documentation and samples and continued product assessment (e.g., complaint handling and stability) and reporting in accordance with regulatory requirements.

3.2 Pharmaceutical Quality System Elements

i) Process Performance and Product Quality Monitoring System

Pharmaceutical companies should plan and execute a system for the monitoring of process performance and product quality to ensure a state of control is maintained. An effective monitoring system provides assurance of the continued capability of processes and controls to meet product quality and to identify areas for continual improvement. The process performance and product quality monitoring system should:

(1) Use quality risk management to establish the control strategy that can include parameters and attributes related to drug substance and drug product materials and components, facility and equipment operating conditions, in-process controls, finished product specifications, and the associated methods and frequency of monitoring and control. The control strategy should facilitate timely feedback / feed forward and appropriate corrective action and preventive action;

(2) Provide the tools for measurement and analysis of parameters and attributes identified in the control strategy, e.g., data management and statistical tools;

(3) Analyze parameters and attributes identified in the control strategy to verify continued operation within a state of control;

(4) Identify sources of variation affecting process performance and product quality for potential continual improvement activities to reduce or control variation;

(5) Include feedback on product quality from both internal and external sources, e.g., complaints, product rejections, non-conformances, recalls, deviations, audits and regulatory inspections and findings;

(6) Provide knowledge to enhance process understanding, enrich the design space (where established), and enable innovative approaches to process validation.

Table I: Application of Process Performance and Product Quality Monitoring throughout the Product Lifecycle

Development	Technology Transfer	Manufacturing	Product Discontinuation
Quality risk management and monitoring conducted throughout development can be used to establish a control strategy for manufacturing.	Monitoring of scale-up activities can provide a preliminary indication of process performance and the successful integration into manufacturing. Monitoring of transfer and scale-up activities can be useful in further developing the control strategy.	A well-defined system for process performance and product quality monitoring should be applied to assure performance within a state of control and to identify improvement areas.	Once manufacturing ceases, monitoring such as stability testing should continue to completion of the studies. Appropriate action on marketed product should continue to be executed according to regional regulations.

ii) Corrective Action and Preventive Action System (CAPA)

The pharmaceutical company should have a system for implementing corrective actions and preventive actions resulting from the investigation of complaints, product rejections, non-conformances, recalls, deviations, audits, regulatory inspections and findings, and trends from process performance and product quality monitoring. A structured approach to the investigation process should be used with the objective of determining root cause. The level of effort and formality of the investigation should be commensurate with the level of risk. CAPA methodology should result in product and process improvements and enhanced product and process understanding.

Table II: Application of Corrective Action/Preventive Action throughout the Product Lifecycle

Development	Technology Transfer	Manufacturing	Product Discontinuation
Product or process variability is explored. CAPA methodology can be useful where corrective actions and preventive actions are incorporated into the iterative design and development process.	CAPA can be used as an effective system for feedback, feed forward and continual improvement.	CAPA should be used and the effectiveness of the actions should be evaluated.	CAPA should continue after the product is discontinued. The impact on product remaining on the market should be considered as well as other products which might be impacted.

iii) Change Management System

Innovation, continual improvement, the outputs of process performance and product quality monitoring and CAPA drive change. In order to properly evaluate, approve and implement these changes, a company should have an effective change management system. There is generally a difference in formality of change management processes prior to the initial regulatory submission and after submission, where changes to the regulatory filing might be required under regional requirements.

The change management system ensures continual improvement is undertaken in a timely and effective manner while providing a high degree of assurance there are no unintended consequences of the change.

The change management system should include the following, as appropriate for the stage of the lifecycle:

(1) Quality risk management should be utilised to evaluate proposed changes. The level of effort and formality of the evaluation should be commensurate with the level of risk. There should be an assessment to determine whether a change to the regulatory filing is required under regional requirements;

(2) All changes should be properly evaluated. Proposed changes should be evaluated relative to the marketing authorisation, including design space, where established, and/ or current product and process understanding. As stated in ICH Q8, movement within the design space is not considered a change (from a regulatory filing perspective). However, from a pharmaceutical quality system standpoint, all changes should be evaluated by a company's change management system;

(3) Proposed changes should be evaluated by expert teams contributing the appropriate expertise and knowledge from relevant areas, e.g., Pharmaceutical Development, Manufacturing, Quality, Regulatory

Affairs and Medical, to ensure the change is technically justified. Prospective evaluation criteria for a proposed change should be set;

(4) After implementation, an evaluation of the change should be undertaken to confirm the change objectives were achieved and that there was no deleterious impact on product quality;

(5) Regional regulatory submission/approval requirements should be assessed for a proposed change to a marketed product.

Table III: Application of Change Management System throughout Product Lifecycle

Development	Technology Transfer	Manufacturing	Product Discontinuation
Change is an inherent part of the development process and should be documented; the formality of the change management process should increase as the product moves through development.	The change management system should provide management and documentation of adjustments made to the process during technology transfer activities.	A formal change management system should be in place for commercial manufacturing. Oversight by the quality unit should provide assurance of appropriate science and risk based assessments.	Any changes after product discontinuation should go through an appropriate change management system.

iv) Management Review of Process Performance and Product Quality

Management review should provide assurance that process performance and product quality are managed over the lifecycle. Depending on the size and complexity of the company, management review can be a series of reviews at various levels of management and should include a timely and effective communication and escalation process to raise appropriate quality issues to senior levels of management for review.

(1) The management review system should include:

(a) The results of regulatory inspections and findings, audits and other assessments;

(b) Periodic quality reviews, that can include:

(i) Measures of customer satisfaction such as customer complaints and recalls;

(ii) Conclusions of process performance and product quality monitoring;

(iii) The effectiveness of process and product changes including those arising from corrective action and preventive actions.

(c) Any follow-up actions from previous management reviews;

(2) The management review system should identify appropriate action, such as:

(d) Improvements to manufacturing processes and products;

(e) Provision, training and/or realignment of resources;

(f) Capture and dissemination of knowledge.

Table IV: Application of Management Review of Process Performance and Product Quality throughout the Product Lifecycle

Development	Technology Transfer	Manufacturing	Product Discontinuation
Aspects of management review can be performed to ensure adequacy of the product and process design.	Aspects of management review should be performed to ensure the developed product and process can be manufactured at commercial scale.	Management review should be a structured system, as described above, and should support continual improvement.	Management review should include such items as product stability and product complaints.

4. CONTINUAL IMPROVEMENT OF THE PHARMACEUTICAL QUALITY SYSTEM

This section describes activities that should be conducted to manage and continually improve the pharmaceutical quality system.

4.1 Management Review of the Pharmaceutical Quality System

Management should have a formal process for reviewing the pharmaceutical quality system on a periodic basis. The review should include:

i) Measurement of achievement of pharmaceutical quality system objectives;

ii) Assessment of Key Performance Indicators that can be used to monitor the effectiveness of processes within the pharmaceutical quality system, such as:

(1) Complaint, deviation, CAPA and change management processes;

(2) Self-assessment processes including audits;

(3) External assessments such as regulatory inspections and findings and customer audits.

4.2 Monitoring of Internal and External Factors Impacting the Pharmaceutical Quality System

Factors monitored by management can include:

i) Emerging regulations, guidance and quality issues that can impact the Pharmaceutical Quality System;

ii) Innovations that might enhance the pharmaceutical quality system;

iii) Changes in business strategies and objectives.

4.3 Outcomes of Management Review and Monitoring

The outcome of management review of the pharmaceutical quality system and monitoring of internal and external factors can include:

i) Improvements to the pharmaceutical quality system and related processes;

ii) Allocation or reallocation of resources and/or personnel training;

iii) Revisions to quality policy and quality objectives, as appropriate;

iv) Timely and effective communication of the results of the management review and actions, including escalation of appropriate issues to senior management.

5. GLOSSARY

ICH and ISO definitions are used in ICH Q10 where they exist. For the purpose of ICH Q10, where the words "requirement", "requirements" or "necessary" appear in an ISO definition, they do not necessarily reflect a regulatory requirement. The source of the definition is identified in parenthesis after the definition. Where no ICH or ISO definition was available, an ICH Q10 definition was developed.

Capability of a Process:

Ability of a process to realise a product that will fulfil the requirements of that product. The concept of process capability can also be defined in statistical terms. (ISO 9000-2005)

Change Management:

A systematic approach to proposing, evaluating, approving, implementing and reviewing changes. (ICH Q10 EWG)

Continual Improvement:

Recurring activity to increase the ability to fulfil requirements. (ISO 9000-2005)

Control Strategy:

A planned set of controls, derived from current product and process understanding, that assures process performance and product quality. The controls can include parameters and attributes related to drug substance and drug product materials and components, facility and equipment operating conditions, in-process controls, finished product specifications, and the associated methods and frequency of monitoring and control. (ICH Q10 EWG)

Corrective Action:

Action to eliminate the cause of a detected non-conformity or other undesirable situation. (ISO 9000-2005)

Design Space:

The multidimensional combination and interaction of input variables (e.g., material attributes) and process parameters that have been demonstrated to provide assurance of quality. (ICH Q8)

Enabler:

A tool or process which provides the means to achieve an objective. (ICH Q10 EWG)

Key Performance Indicators:

Metrics used to quantify quality objectives to reflect the performance of an organization, process or system. (ICH Q10 EWG).

Innovation:

The introduction of new technologies or methodologies to pharmaceutical development and manufacturing. (ICH Q10 EWG)

Knowledge Management:

Systematic approach to collecting, analyzing, storing, and disseminating information related to products, processes and components. (ICH Q10 EWG)

Outsourced Activities:

Activities conducted by a contract acceptor under contract with a contract giver. (ICH Q10 EWG)

Pharmaceutical Quality System:

Management system to direct and control a pharmaceutical company with regard to quality. (ICH Q10 EWG based upon ISO 9000-2005)

Preventive Action:

Action to eliminate the cause of a potential non-conformity or other undesirable potential situation. (ISO 9000-2005)

Product Realisation:

Achievement of a product with the quality attributes appropriate to meet the needs of patients, health care professionals, regulatory authorities (including compliance with marketing authorisation) and internal customers. (ICH Q10 EWG)

Quality:

The degree to which a set of inherent properties of a product, system or process fulfills requirements. (ICH Q9)

Quality Manual:

Document specifying the quality management system of an organization. (ISO 9000-2005)

Quality Objectives:

A means to translate the quality policy and strategies into measurable activities. (ICH Q10 EWG)

Quality Planning:

Part of quality management focused on setting quality objectives and specifying necessary operational processes and related resources to fulfill the quality objectives. (ISO 9000-2005)

Quality Policy:

Overall intentions and direction of an organization related to quality as formally expressed by senior management. (ISO 9000-2005)

Quality Risk Management:

A systematic process for the assessment, control, communication and review of risks to the quality of the drug (medicinal) product across the product lifecycle. (ICH Q9)

Senior Management:

Person(s) who direct and control a company or site at the highest levels. (ICH Q10 EWG based on ISO 9000-2005 definition for "Top Management")

State of Control:

A condition in which the set of controls consistently provides assurance of continued process performance and product quality. (ICH Q10 EWG)

Annex 1

Potential Opportunities to Enhance Science and Risk Based Regulatory Approaches *

*Note: This annex reflects potential opportunities to enhance regulatory approaches. The actual regulatory process will be determined by region.

Scenario	Potential Opportunity
1. Comply with GMPs	Compliance – status quo
2. Demonstrate effective pharmaceutical quality system, including effective use of quality risk management principles (e.g., ICH Q9 and ICH Q10).	Opportunity to: • increased use of risk-based approaches for regulatory inspections
3. Demonstrate product and process understanding, including effective use of quality risk management principles (e.g., ICH Q8 and ICH Q9).	Opportunity to: • facilitate science-based pharmaceutical quality assessment; • enable innovative approaches to process validation; • establish real-time release mechanisms.
4. Demonstrate effective pharmaceutical quality system and product and process understanding, including the use of quality risk management principles (ICH Q8, ICH Q9 and ICH Q10).	Opportunity to: • increased use of risk-based approaches for regulatory inspections; • facilitate science-based pharmaceutical quality assessment; • optimize science and risk-based post-approval change processes to maximize benefits from innovation and continual improvement; • enable innovative approaches to process validation; • establish real-time release mechanisms.

添付資料2 Q10 スッテプ2 パブリックコメント通知

「ＩＣＨ Ｑ１０：医薬品品質システム」に関するご意見・情報の募集について

平成１９年 ７月１３日
厚生労働省医薬食品局審査管理課

日米ＥＵ医薬品規制調和国際会議（ＩＣＨ）において、「ＩＣＨ Ｑ１０：医薬品品質システム（案）」が別添のとおりまとまりましたので、広くご意見・情報を募集いたします。

つきましては、本案に関してご意見・情報のある場合には、下記により提出してください。皆様から頂いたご意見・情報については、今後の活動における参考とさせていただきます。

なお、提出していただいたご意見・情報に対する個別の回答はいたしかねますので、その旨ご了承願います。

記

1. 募集期限
平成１９年１０月１日（月）必着

2. 提出方法
提出していただく御意見等には必ず「ＩＣＨ Ｑ１０：医薬品品質システム」と明記の上、以下に掲げるいずれかの方法で提出してください。お電話による御意見・情報の提出はお受けできかねますのでご了承ください。

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3.　ご意見等の提出上の注意

ご意見等は日本語に限ります。また、個人の場合は住所・氏名・年齢・職業を、法人の方は法人名・所在地を記載してください。なお、個人又は法人の属性に関する情報以外は公開することがありますので、あらかじめご了承ください。

1
2 ICH Q10
3 医薬品品質システム
4 Version 12.0
5 ステップ 2 文書
6
7 2007 年 5 月 9 日