ICH Q10 Pharmaceutical Quality System

INTERNATIONAL CONFERENCE ON HARMONISATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE

ICH HARMONISED TRIPARTITE GUIDELINE

제약 품질 시스템

(PHARMACEUTICAL QUALITY SYSTEM)

Q10

Current Step 4 version
dated 4 June 2008

This Guideline has been developed by the appropriate ICH Expert Working Group and has been subject to consultation by the regulatory parties, in accordance with the ICH Process. At Step 4 of the Process the final draft is recommended for adoption to the regulatory bodies of the European Union, Japan and USA.
### Q10

**Document History**

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PHARMACEUTICAL QUALITY SYSTEM
ICH Harmonised Tripartite Guideline

Having reached Step 4 of the ICH Process at the ICH Steering Committee meeting on 4 June 2008, this guideline is recommended for adoption to the three regulatory parties to ICH

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1. 제약 품질 시스템(PHARMACEUTICAL QUALITY SYSTEM)

1.1 서론(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. Throughout this guideline, the term “pharmaceutical quality system” refers to the ICH Q10 model.

ICH Q10 describes one comprehensive model for an effective pharmaceutical quality system that is based on International Standards Organisation (ISO) quality 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 regional GMP requirements is optional.

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...
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*improvement* and strengthen the link between pharmaceutical development and manufacturing activities.

ICH Q10은 공중 보건 향상을 위해 세계 각지의 의약품 품질과 가용성을 높이는 효과적인 제약 품질 시스템을 엽계와 규제 기관 모두가 지지함을 보여준다. 제품 라이프사이클 전체에 걸친 ICH Q10의 구축은 혁신과 지속적 개선을 촉진하고, 의약품 개발과 제조 활동 사이의 연계를 강화시킬 것이다.

1.2 적용 범위(Scope)

This guideline applies to the systems supporting the development and manufacture of pharmaceutical drug substances (i.e., API) and drug products, including biotechnology and biological products, throughout the product lifecycle.

이 가이드라인은 제품 라이프사이클 전체에 걸쳐, 생명공학 제품과 생물학적 제품을 포함하여, 원료의약품(API)과 완제의약품의 개발과 제조를 돕는 시스템에 적용된다.

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

제품 라이프사이클 단계별 서로 다른 목적과 제품 라이프사이클 단계의 차이를 고려하여(섹션 3 참조), 단계별로 적절하고 균형 있게 ICH Q10의 요소를 적용한다.

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

새로운 제품과 기존 제품의 라이프사이클은 다음과 같은 기술적 활동으로 구성된다.

- 의약품 개발(Pharmaceutical Development):
  - 원료의약품 개발(Drug substance development);
  - 조성 개발(용기/마개 시스템 포함)(Formulation development (including container/closure system));
  - 임상 시험 제품 제조(Manufacture of investigational products);
  - 전달 시스템 개발(해당되는 경우)(Delivery system development (where relevant));
  - 제조 공정 개발 및 스케일업(Manufacturing process development and scale-up);
  - 분석 방법 개발(Analytical method development).
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• 기술 이전 (Technology Transfer):
  o 개발 및 제조 단계의 신제품 이전 (New product transfers during Development through Manufacturing);
  o 시판 제품의 제조 시설과 시험 시설 사이 또는 내부의 이전 (Transfers within or between manufacturing and testing sites for marketed products).

• 상업적 제조 (Commercial Manufacturing):
  o 물품 확득 및 관리 (Acquisition and control of materials);
  o 시설, 유털리티, 설비 구비 (Provision of facilities, utilities, and equipment);
  o 생산 (포장 및 라벨링 작업 포함) (Production (including packaging and labelling));
  o 품질 관리 및 품질 보증 (Quality control and assurance);
  o 출하 승인 (Release);
  o 보관 (Storage);
  o 유통 (도매 활동 제외) (Distribution (excluding wholesaler activities)).

• 제품 중단 (Product Discontinuation):
  o 문서 보관 (Retention of documentation);
  o 검체 보관 (Sample retention);
  o 지속적 제품 평가와 보고 (Continued product assessment and reporting).

1.3 지역별 GMP 기준, ISO 표준, ICH Q7과 ICH Q10의 관계 (Relationship of ICH Q10 to Regional GMP Requirements, ISO Standards and ICH Q7)

Regional GMP requirements, the ICH Q7 Guideline, “Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients”, 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 provides a harmonised model for a pharmaceutical quality system throughout the lifecycle of a product and is intended to be used together with regional GMP requirements.

지역별 GMP 기준, ICH Q7 "API GMP 가이드", ISO의 QMS (Quality Management System) 가이드라인이 ICH Q10의 토대를 형성한다. 아래의 목표를 달성하기 위해, ICH Q10은 구체적인 품질 시스템 요소와 경영자 책임을 기술함으로써 GMP를 강화한다. 그에 따라 ICH Q10은 제품 라이프사이클 전체에 걸친 제약 품질 시스템 모델을 제시하며,
The regional GMPs do not explicitly address all stages of the product lifecycle (e.g., Development). The quality system elements and management responsibilities described in this guideline are intended to encourage the use of science and risk based approaches at each lifecycle stage, thereby promoting continual improvement across the entire product lifecycle.

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 evaluated 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.

Implementation of the Q10 model should result in achievement of three main objectives which complement or enhance regional GMP requirements.
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To establish, implement and maintain a system that allows the delivery of products with the quality attributes appropriate to meet the needs of patients, health care professionals, regulatory authorities (including compliance with approved regulatory filings) and other internal and external customers.

1.5.2 관리 상태의 확립/ 유지(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 identifying the monitoring and control systems.

1.5.3 지속적 개선 촉진(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 fulfil quality needs consistently. Quality risk management can be useful for identifying and prioritising areas for continual improvement.

1.6 촉진 요소: 지식 관리와 품질 리스크 관리(Enablers: Knowledge Management and Quality Risk Management)

Use of knowledge management and quality risk management will enable a company to implement ICH Q10 effectively and successfully. These enablers will facilitate achievement of the objectives described in Section 1.5 above by providing the
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means for science and risk based decisions related to product quality.

지식 관리와 품질 리스크 관리는 ICH Q10의 효과적이고 성공적인 구축을 가능하게 한다. 이러한 촉진 요소는 제품 품질과 관련된 과학/리스크 기반 의사 결정 수단을 제공함으로써 상기 1.5에 기술된 목표의 달성을 촉진한다.

1.6.1 지식 관리(Knowledge Management)

Product and process knowledge should be managed from development through the commercial life of the product up to and including product discontinuation. For example, development activities using scientific approaches provide knowledge for product and process understanding. Knowledge management is a systematic approach to acquiring, analysing, storing and disseminating information related to products, manufacturing 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; innovation; continual improvement; and change management activities.

제품 개발부터 상업적 생산을 거쳐 제품 중단에 이르는 전 과정에 걸쳐 제품과 공정 지식을 관리해야 한다. 예를 들어 과학적 방법론의 개발 활동을 통해 제품/공정 이해와 지식을 생산한다. 지식 관리는 제품, 제조 공정, 원료와 관련된 정보를 체계적으로 확보/분석/보관/유포하는 것이다. 지식의 출처로는 선행 지식(공적 영역의 지식 또는 내부적으로 문서화한 지식), 의약품 개발 실험, 기술 이전 활동, 제품 라이프사이클 전체에 걸친 공정 밸리데이션 실험, 제조 경험, 혁신, 지속적 개선, 변경 관리 활동이 있으나 이에 국한되지 않는다.

1.6.2 품질 리스크 관리(Quality Risk Management)

Quality risk management is integral to an effective pharmaceutical quality system. It can provide a proactive approach to identifying, scientifically evaluating and controlling potential risks to quality. It facilitates continual improvement of process performance and product quality throughout the product lifecycle. ICH Q9 provides principles and examples of tools for quality risk management that can be applied to different aspects of pharmaceutical quality.

품질 리스크 관리는 효과적인 제약 품질 시스템의 핵심적인 부분이다. 품질 리스크 관리는 잠재 품질 리스크를 파악하고 과학적으로 평가하고 통제하는 선제적인 방법이다. 제품
1.7 Design and Content Considerations

(a) The design, organisation and documentation of the pharmaceutical quality system should be well structured and clear to facilitate common understanding and consistent application.

(b) The elements of ICH Q10 should be applied in a manner that is appropriate and proportionate to each of the product lifecycle stages, recognising the different goals and knowledge available for each stage.

(c) 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. The design of the pharmaceutical quality system should incorporate appropriate risk management principles. While some aspects of the pharmaceutical quality system can be company-wide and others site-specific, the effectiveness of the pharmaceutical quality system is normally demonstrated at the site level.

(d) The pharmaceutical quality system should include appropriate processes, resources and responsibilities to provide assurance of the quality of outsourced activities and purchased materials as described in Section 2.7.
(e) Management responsibilities, as described in Section 2, should be identified within the pharmaceutical quality system.

(sect. 2에 기술한 경영자 책임을 제약 품질 시스템에 명확히 규정한다.

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

sect. 3에 기술한 공정 성능 및 제품 품질 모니터링, 시정 조치 및 예방 조치, 변경 관리, 경영자 검토 등의 요소를 제약 품질 시스템에 포함시킨다.

(g) Performance indicators, as described in Section 4, should be identified and used to monitor the effectiveness of processes within the pharmaceutical quality system.

sect. 4에 기술한 성능 지표를 파악하고 활용하여, 제약 품질 시스템에 의거한 각종 업무 절차의 효과성을 모니터링한다.

1.8 품질 매뉴얼(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:

품질 매뉴얼 또는 이와 동등한 문서를 확립하며, 제약 품질 시스템을 이 문서에 기술한다. 다음 사항을 포함하여 작성한다.

(a) The quality policy (see Section 2);

품질 방침(sect. 2 참조)

(b) The scope of the pharmaceutical quality system;

제약 품질 시스템의 적용 범위

(c) Identification of the pharmaceutical quality system processes, as well as their sequences, linkages and interdependencies. Process maps and flow charts can be useful tools to facilitate depicting pharmaceutical quality system processes in a visual manner;

제약 품질 시스템의 구성 업무 절차, 이들 업무 절차의 순서, 연계, 상호 의존성. 제약 품질 시스템의 업무 절차를 시각적으로 표현하는데 프로세스 맵과 흐름도가
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유용할 수 있다.

(d) Management responsibilities within the pharmaceutical quality system (see Section 2).

제약 품질 시스템에서 경영자의 책임(섹션 2 참조)

2. 경영자의 책임(MANAGEMENT RESPONSIBILITY)

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

제약 품질 시스템의 운영과 회사 전체 차원의 품질 의지를 확립하고 유지하기 위해서는 리더십이 필수적이다.

2.1 경영자의 의지(Management Commitment)

(a) Senior management has the ultimate responsibility to ensure an effective pharmaceutical quality system is in place to achieve the quality objectives, and that roles, responsibilities, and authorities are defined, communicated and implemented throughout the company.

효과적인 제약 품질 시스템을 갖추어 품질 목표를 달성하고, 역할과 책임, 권한을 규정해 회사 전체에 전파하고 구축할 궁극적인 책임이 고위 경영자에게 있다.

(b) Management should:

경영자가 해야 할 일을 다음과 같다.

(1) Participate in the design, implementation, monitoring and maintenance of an effective pharmaceutical quality system;

효과적인 제약 품질 시스템의 디자인, 구축, 모니터링, 유지 관리에 참여한다.

(2) Demonstrate strong and visible support for the pharmaceutical quality system and ensure its implementation throughout their organisation;

제약 품질 시스템에 대한 강력하고 가시적인 지원을 보여주고, 조직 전체에 걸쳐 구축하도록 한다.

(3) Ensure a timely and effective communication and escalation process exists to raise quality issues to the appropriate levels of management;

품질 문제를 적절한 수준의 경영자에게 효과적으로 적시에 보고하는 커뮤니케이션 및 에스컬레이션 절차를 구축한다.

(4) Define individual and collective roles, responsibilities, authorities and inter-relationships of all organisational units related to the
pharmaceutical quality system. Ensure these interactions are communicated and understood at all levels of the organisation. An independent quality unit/structure with authority to fulfil certain pharmaceutical quality system responsibilities is required by regional regulations;

제약 품질 시스템과 관련된 모든 조직 단위의 개별적/집단적 역할, 책임, 권한, 상호 관계를 규정한다. 이러한 상호 작용을 조직 전체에 전파하고 이해시킨다. 제약 품질 시스템 책임 업무를 수행할 권한을 지닌 독립적인 품질 조직/구조는 지역 규정에서 요구하는 것이다.

(5) Conduct management reviews of process performance and product quality and of the pharmaceutical quality system;

제약 품질 시스템과 공정 성능 및 제품 품질의 경영자 검토를 실시한다.

(6) Advocate continual improvement;

지속적 개선을 지원한다.

(7) Commit appropriate resources.

적절한 자원을 제공한다.

2.2 품질 방침(Quality Policy)

(a) Senior management should establish a quality policy that describes the overall intentions and direction of the company related to quality.

고위 경영자는 품질과 관련하여 회사의 전반적인 의도와 방향을 기술한 품질 방침을 확립해야 한다.

(b) The quality policy should include an expectation to comply with applicable regulatory requirements and should facilitate continual improvement of the pharmaceutical quality system.

품질 방침에 해당 규제 기준의 준수에 관한 사항을 포함시키며, 품질 방침은 제약 품질 시스템의 지속적 개선을 촉진하는 것이어야 한다.

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

품질 방침은 회사의 모든 작업자에게 전파하여 모든 작업자가 이해하게 한다.

(d) The quality policy should be reviewed periodically for continuing effectiveness.
2.3 품질 기획(Quality Planning)

(a) Senior management should ensure the quality objectives needed to implement the quality policy are defined and communicated.
고위 경영자는 품질 방침의 구축에 필요한 품질 목표를 규정하고 전파해야 한다.

(b) Quality objectives should be supported by all relevant levels of the company.
회사의 모든 관련 부문이 품질 목표를 지지해야 한다.

(c) Quality objectives should align with the company’s strategies and be consistent with the quality policy.
품질 목표는 회사의 전략과 연계되어야 하며, 품질 방침에 부합해야 한다.

(d) Management should provide the appropriate resources and training to achieve the quality objectives.
경영자는 품질 목표의 달성을 위해 적절한 자원과 교육훈련을 제공해야 한다.

(e) Performance indicators that measure progress against quality objectives should be established, monitored, communicated regularly and acted upon as appropriate as described in Section 4.1 of this document.
품질 목표에 대비하여 진행 상황을 평가하기 위한 성과 지표를 정해 모니터링하고 주기적으로 전파하며, 이 문서의 섹션 4.1에 기술한 바와 같이, 그에 맞춰 적절하게 조치를 취한다.

2.4 자원 관리(Resource Management)

(a) 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.
경영자는 제약 품질 시스템의 구축과 유지, 그리고 그 효과성의 지속적 개선을 위해 적절한 자원(사람, 돈, 물품, 시설, 설비)을 파악해 제공해야 한다.

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

경영자는 특정 제품, 공정, 사업장에 자원이 적절하게 적용되도록 해야 한다.

2.5 내부 커뮤니케이션 (Internal Communication)

(a) Management should ensure appropriate communication processes are established and implemented within the organisation.

경영자는 적절한 커뮤니케이션 절차를 확립하고 구축하도록 해야 한다.

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

커뮤니케이션 절차는 회사의 모든 부문 사이에 적절한 정보 흐름이 보장되도록 해야 한다.

(c) Communication processes should ensure the appropriate and timely escalation of certain product quality and pharmaceutical quality system issues.

커뮤니케이션 절차는 특정 제품 품질과 제약 품질 시스템 문제가 적시에 적절하게 에스컬레이션되도록 해야 한다.

2.6 경영자 검토 (Management Review)

(a) Senior management should be responsible for pharmaceutical quality system governance through management review to ensure its continuing suitability and effectiveness.

고위 경영자는 제약 품질 시스템의 지속적 적합성과 효과성을 보장하기 위해, 경영자 검토를 통한 제약 품질 시스템의 관리를 책임진다.

(b) 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.

경영자는 섹션 3과 4에 기술된 바에 따라, 공정 성능 및 제품 품질, 그리고 제약 품질 시스템의 주기적 검토 결과와 결론을 평가해야 한다.

2.7 아웃소싱 활동과 구매 물품 관리 (Management of Outsourced Activities and Purchased Materials)
The pharmaceutical quality system, including the management responsibilities described in this section, extends to the control and review of any outsourced activities and quality of purchased materials. The pharmaceutical company is ultimately responsible to ensure processes are in place to assure the control of outsourced activities and quality of purchased materials. These processes should incorporate quality risk management and include:

- Assessing prior to outsourcing operations or selecting material suppliers, the suitability and competence of the other party to carry out the activity or provide the material using a defined supply chain (e.g., audits, material evaluations, qualification);
- Defining the responsibilities and communication processes for quality-related activities of the involved parties. For outsourced activities, this should be included in a written agreement between the contract giver and contract acceptor;
- Monitoring and review of the performance of the contract acceptor or the quality of the material from the provider, and the identification and implementation of any needed improvements;
- Monitoring incoming ingredients and materials to ensure they are from approved sources using the agreed supply chain.

(a) Assessing prior to outsourcing operations or selecting material suppliers, the suitability and competence of the other party to carry out the activity or provide the material using a defined supply chain (e.g., audits, material evaluations, qualification);

(b) Defining the responsibilities and communication processes for quality-related activities of the involved parties. For outsourced activities, this should be included in a written agreement between the contract giver and contract acceptor;

(c) Monitoring and review of the performance of the contract acceptor or the quality of the material from the provider, and the identification and implementation of any needed improvements;

(d) Monitoring incoming ingredients and materials to ensure they are from approved sources using the agreed supply chain.
2.8  제품 소유권 변경 관리 (Management of Change in Product Ownership)

When product ownership changes, (e.g., through acquisitions) management should consider the complexity of this and ensure:

(a) The ongoing responsibilities are defined for each company involved;
(b) The necessary information is transferred.

3. 공정 성능 및 제품 품질의 지속적 개선 (CONTINUAL IMPROVEMENT OF PROCESS PERFORMANCE AND PRODUCT QUALITY)

This section describes the lifecycle stage goals and the four specific pharmaceutical quality system elements that augment regional requirements to achieve the ICH Q10 objectives, as defined in Section 1.5. It does not restate all regional GMP requirements.

3.1  라이프사이클 단계별 목적 (Lifecycle Stage Goals)

The goals of each product lifecycle stage are described below.

3.1.1  의약품 개발 (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 and healthcare professionals, and regulatory authorities and
internal customers’ requirements. Approaches to pharmaceutical development are described in ICH Q8. The results of exploratory and clinical development studies, while outside the scope of this guidance, are inputs to pharmaceutical development.

의약품 개발 활동의 목적은 의도한 바의 성능을 일관되게 제공하며 환자와 건강 관리 전문가의 요구와 규제 기관과 내부 고객의 기준을 충족하는 제품과 제조 공정을 설계하는 것이다. 의약품 개발에 대한 사항은 ICH Q8을 참조한다. 이 가이드라인의 범위를 벗어나는, 탐색 및 임상 개발 시험의 결과는 의약품 개발의 투입 요소이다.

3.1.2 기술 이전 (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.

기술 이전 활동의 목적은 제품 실현을 위해 개발과 제조 사이, 그리고 제조 사업장 내부나 사업장 사이에 제품과 공정 지식을 이전하는 것이다. 이 지식은 제조 공정, 관리 전략, 공정 밸리데이션 방법, 지속적인 개선의 토대가 된다.

3.1.3 상업적 제조 (Commercial 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 evaluated, and the body of knowledge is continually expanded.

제조 활동의 목적은 제품 실험, 관리 상태 확립과 유지, 지속적 개선 촉진이다. 제약 품질 시스템은 바람직한 제품 품질을 항상 충족하고 적합한 공정 성능을 달성하며 관리 체계가 적절하고 개선 기회를 파악하고 평가하며 지식을 지속적으로 확장 시킬 수 있어야 한다.

3.1.4 제품 중단 (Product Discontinuation)

The goal of product discontinuation activities is to manage the terminal stage of the product lifecycle effectively. 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.

제품 중단 활동의 목적으로 제품 라이프사이클의 마지막 단계를 효과적으로 관리하는 것이다. 제품 중단 시에 미리 정한 방법으로 문서와 검체 보관, 그리고 규제 기준에 따른 지속적인 제품 평가(예, 불만 처리 및 안정성)와 보고 등의 활동을 관리한다.

3.2 제약 품질 시스템 요소(Pharmaceutical Quality System Elements)

The elements described below might be, required in part under regional GMP regulations. However, the Q10 model’s intent is to enhance these elements in order to promote the lifecycle approach to product quality. These four elements are:

아래에서 설명하는 구성 요소는 부분적으로 지역 GMP 규정에서 요구하는 것일 수도 있다. 하지만 Q10 모델의 의도는 제품 품질에 대한 라이프사이클 방식을 촉진하기 위해, 이들 요소를 강화하는데 있다. 4개 요소는 다음과 같다.

- Process performance and product quality monitoring system; 공정 성능 및 제품 품질 모니터링 시스템
- Corrective action and preventive action (CAPA) system; CAPA 시스템
- Change management system; 변경 관리 시스템
- Management review of process performance and product quality. 공정 성능 및 제품 품질의 경영자 검토

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

제품 라이프사이클 단계별 차이와 각 단계의 서로 다른 목록을 고려하여, 단계별로 적절하고 균형 있는 방식으로 이들 요소를 적용한다. 제품 라이프사이클 전체에 걸쳐 혁신적인 제품 품질 개선 기회를 평가한다.

Each element is followed by a table of example applications of the element to the stages of the pharmaceutical lifecycle.
3.2.1 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 produce a product of desired quality and to identify areas for continual improvement. The process performance and product quality monitoring system should:

- Use quality risk management to establish the control strategy. This 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 / feedforward and appropriate corrective action and preventive action;

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

- Analyse parameters and attributes identified in the control strategy to verify continued operation within a state of control;
ICH Q10 Pharmaceutical Quality System

(d) Identify sources of variation affecting process performance and product quality for potential continual improvement activities to reduce or control variation; 공정 성능과 제품 품질에 영향을 주는 편차의 출처를 파악하고 지속적 개선 활동을 추진해 편차를 감소시키거나 관리한다.

(e) 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; 내부와 외부에서 제품 품질에 대한 피드백을 확보한다(예, 불만, 제품 부적합, 부적합, 리콜, 일탈, 감사 및 규제 기관 실사 결과).

(f) Provide knowledge to enhance process understanding, enrich the design space (where established), and enable innovative approaches to process validation. 공정 이해를 높이고 디자인 스페이스(확립된 경우)를 강화하며 혁신적인 방식의 공정 벤리데이션을 가능하게 하는 지식을 구비한다.

Table I: 제품 라이프사이클 전반에 걸쳐 공정 성능 및 제품 품질 모니터링 시스템(Application of Process Performance and Product Quality Monitoring System throughout the Product Lifecycle)

<table>
<thead>
<tr>
<th>Pharmaceutical Development (의약품 개발)</th>
<th>Technology Transfer (기술 이전)</th>
<th>Commercial Manufacturing (상업적 제조)</th>
<th>Product Discontinuation (제품 중단)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Process and product knowledge generated and process and product monitoring conducted throughout development can be used to establish a control</td>
<td>Monitoring during scale-up activities can provide a preliminary indication of process performance and the successful integration into manufacturing.</td>
<td>A well-defined system for process performance and product quality monitoring should be applied to assure performance within a state of control and to</td>
<td>Once manufacturing ceases, monitoring such as stability testing should continue to completion of the studies. Appropriate action on marketed</td>
</tr>
</tbody>
</table>
### 3.2.2 CAPA System (Corrective Action and Preventive Action (CAPA) System)

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 the root cause. The level of effort, formality, and documentation of the investigation should be commensurate with the level of risk, in line with ICH Q9. CAPA methodology should result in product and process improvements and enhanced product and process understanding.

<table>
<thead>
<tr>
<th>Knowledge obtained during transfer and scale up activities can be useful in further developing the control strategy.</th>
<th>Identify improvement areas.</th>
<th>Identify improvement areas.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Knowledge obtained during transfer and scale up activities can be useful in further developing the control strategy.</td>
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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 the root cause. The level of effort, formality, and documentation of the investigation should be commensurate with the level of risk, in line with ICH Q9. CAPA methodology should result in product and process improvements and enhanced product and process understanding.

제약 회사는 불만, 제품 부적합, 부적합, 리콜, 일탈, 감사, 규제 기관 실사 결과, 그리고 공정 성능 및 제품 품질 모니터링에서 파악된 경향의 조사에 따른 시정 조치와 예방 조치의 추천 시스템을 구비한다. 체계적으로 조사를 실시해 근본 원인을 파악한다. 조사의 형식과 문서화, 활동 수준은 ICH Q9에 따라 리스크 수준에 맞춰 정한다. CAPA를 통해 제품과
Table II: 제품 라이프사이클에 전개된 CAPA 시스템(Application of Corrective Action and Preventive Action System throughout the Product Lifecycle)

<table>
<thead>
<tr>
<th>Pharmaceutical Development (의약품 개발)</th>
<th>Technology Transfer (기술 이전)</th>
<th>Commercial Manufacturing (상업적 제조)</th>
<th>Product Discontinuation (제품 중단)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product or process variability is explored. CAPA methodology is useful where corrective actions and preventive actions are incorporated into the iterative design and development process. 제품 또는 공정 변동성을 조사한다. 반복적인 디자인 및 개발 절차에 시험 조치와 예방 조치를 통합시키면, CAPA 방법이 유용할 수 있다.</td>
<td>CAPA can be used as an effective system for feedback, feedforward and continual improvement. CAPA는 피드백, 피드포워드, 지속적 개선을 위한 효과적인 시스템으로 활용될 수 있다.</td>
<td>CAPA should be used and the effectiveness of the actions should be evaluated. CAPA를 추진하며, 조치의 효과를 평가한다.</td>
<td>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. 제품 중단 이후에도 CAPA를 계속 한다. 시중에 남아 있는 제품에 대한 영향과, 영향을 받았을 수 있는 다른 제품을 고려한다.</td>
</tr>
</tbody>
</table>

3.2.3 변경 관리 시스템(Change Management System)

Innovation, continual improvement, the outputs of process performance and product quality monitoring and CAPA drive change. In order to evaluate, approve and implement these changes properly, 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. It should provide 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:

(a) 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;

(b) Proposed changes should be evaluated relative to the marketing authorisation, including design space, where established, and/or current product and process understanding. There should be an assessment to determine whether a change to the regulatory filing is required under regional requirements. As stated in ICH Q8, working 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;
스페이스 안에서 직업하는 것은 변경으로 간주되지 않는다(규제 문서 제출 관점에서).
하지만 제약 품질 시스템 관점에서는 모든 변경을 변경 관리 시스템에 의거하여 평가해야 한다.

(c) 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;

(d) 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.

Table III: 제품 라이프사이클 전체에 걸친 변경 관리 (Application of Change Management System throughout the Product Lifecycle)

<table>
<thead>
<tr>
<th>Pharmaceutical Development (의약품 개발)</th>
<th>Technology Transfer (기술 이전)</th>
<th>Commercial Manufacturing (상업적 제조)</th>
<th>Product Discontinuation (제품 중단)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change is an inherent part of the development process and should be documented; the formality of the change management process should be consistent with the stage of</td>
<td>The change management system should provide management and documentation of adjustments made to the process during technology transfer activities. 기술 이전 활동 중의</td>
<td>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</td>
<td>Any changes after product discontinuation should go through an appropriate change management system. 제품 중단 이후의 변경도 적절한 변경 관리 시스템을 통해</td>
</tr>
</tbody>
</table>
### 3.2.4 公 정 성능 및 재생물질의 경영자 검토 (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.

경영자 검토를 통해 공정 성능과 재생물질이 라이프사이클 전체에 걸쳐 관리되도록 보증한다. 회사의 규모와 복잡성에 따라, 여러 관리 수준에서 일련의 경영자 검토를 실시할 수 있으며, 고위 경영자에게 품질 문제를 적시에 효과적으로 보고하여 검토를 받는 커뮤니케이션 및 에스컬레이션 절차를 갖춰야 한다.

(a) The management review system should include:

1. The results of regulatory inspections and findings, audits and other assessments, and commitments made to regulatory authorities;
   - 규제 기관 실사 결과, 감사 결과, 기타 평가 결과, 규제 기관에 약속한 것
2. Periodic quality reviews, that can include:
   - 다음을 포함한 주기적 품질 검토
     (i) Measures of customer satisfaction such as product quality complaints and recalls;
     - 제품 품질 관련 불만 및 리콜 등 고객 만족 지표
     (ii) Conclusions of process performance and product quality
monitoring;

공정 성능 및 제품 품질 모니터링의 결론

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

시정 조치 및 예방 조치에 따른 것을 포함하여, 공정과 제품 변경의 효과

(3) Any follow-up actions from previous management reviews.

이전 경영자 검토에 따른 사후 조치

(b) The management review system should identify appropriate actions, such as:

경영자 검토를 거쳐 다음과 같은 적절한 조치 사항을 결정하여 추진한다.

(1) Improvements to manufacturing processes and products;

제조 공정과 제품 개선

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

자원 제공, 교육훈련, 재배치

(3) Capture and dissemination of knowledge.

지식 포착 및 유포

Table IV: 제품 라이프사이클 전체에 걸친 공정 성능 및 제품 품질의 경영자

경토(Application of Management Review of Process Performance and Product Quality throughout the Product Lifecycle)

<table>
<thead>
<tr>
<th>Pharmaceutical Development (의약품 개발)</th>
<th>Technology Transfer (기술 이전)</th>
<th>Commercial Manufacturing (상업적 제조)</th>
<th>Product Discontinuation (제품 중단)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aspects of management review can be performed to ensure adequacy of the product and process design. 경영자 검토를 실시하여, 제품과 공정 디자인의 적절성을 확인할 수 있다.</td>
<td>Aspects of management review should be performed to ensure the developed product and process can be manufactured at commercial scale. 경영자 검토를 실시하여, 상업적 규모에서 개발</td>
<td>Management review should be a structured system, as described above, and should support continual improvement. 위에서 설명한 바와 같이, 경영자 검토는 체계적인 시스템이어야 하며, 지속적 개선을</td>
<td>Management review should include such items as product stability and product quality complaints. 제품 안정성 및 제품 품질 불만 등을 포함해 경영자 검토를 실시한다.</td>
</tr>
</tbody>
</table>
4. 제약 품질 시스템의 지속적 개선 (CONTINUAL IMPROVEMENT OF THE PHARMACEUTICAL QUALITY SYSTEM)

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

이 섹션에서는 제약 품질 시스템의 관리와 지속적 개선을 위한 활동을 설명한다.

4.1 제약 품질 시스템의 경영자 검토 (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:

경영자는 제약 품질 시스템을 주기적으로 검토하는 공식 절차를 구비해야 한다. 이때 다음 사항을 검토한다.

(a) Measurement of achievement of pharmaceutical quality system objectives;

제약 품질 시스템 목표의 성취도 평가.

(b) Assessment of performance indicators that can be used to monitor the effectiveness of processes within the pharmaceutical quality system, such as:

제약 품질 시스템에 따른 업무 절차의 효과성 모니터링을 위한 다음과 같은 성과 지표 평가.

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

불만, 일탈, CAPA, 변경 관리

(2) Feedback on outsourced activities;

아웃소싱 활동에 관한 피드백

(3) Self-assessment processes including risk assessments, trending, and audits;

리스크 평가, 경향 분석, 감사를 포함한 자체 평가 절차
(4) External assessments such as regulatory inspections and findings and
customer audits.

규제 기관 실사 결과와 고객 감사 등 외부 평가

4.2 제약 품질 시스템에 영향을 주는 내부/외부 요소 모니터링(Monitoring of
Internal and External Factors Impacting the Pharmaceutical Quality
System)

Factors monitored by management can include:

경영자가 모니터링하는 요소는 다음과 같다.

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

제약 품질 시스템에 영향을 줄 수 있는 새로운 규정, 가이드라인, 품질 이슈.

(b) Innovations that might enhance the pharmaceutical quality system;

제약 품질 시스템을 개선시킬 수 있는 혁신.

(c) Changes in business environment and objectives;

비즈니스 환경과 목표의 변화.

(d) Changes in product ownership.

제품 소유권 변화

4.3 경영자 검토 및 모니터링 성과(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:

내부/외부 요소 모니터링과 제약 품질 시스템의 경영자 검토 성과는 다음과 같다.

(e) Improvements to the pharmaceutical quality system and related processes;

제약 품질 시스템 및 관련 업무 절차의 개선

(f) Allocation or reallocation of resources and/or personnel training;
(g) Revisions to quality policy and quality objectives;
품질 방침과 품질 목표의 수정

(h) Documentation and timely and effective communication of the results of the management review and actions, including escalation of appropriate issues to senior management.
고위 경영자에 대한 관련 이슈의 에스컬레이션을 포함하여, 경영자 검토 결과와 조치 사항의 문서화와 효과적인 적시 커뮤니케이션.
5. 용어 정의 (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 parentheses after the definition. Where no appropriate ICH or ISO definition was available, an ICH Q10 definition was developed.

공정 능력 (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)

변경 관리 (Change Management):
A systematic approach to proposing, evaluating, approving, implementing and reviewing changes. (ICH Q10)

지속적 개선 (Continual Improvement):
Recurring activity to increase the ability to fulfil requirements. (ISO 9000:2005)

관리 전략 (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)
ICH Q10 Pharmaceutical Quality System

현재의 제품과 공정 이해를 바탕으로, 공정 성능과 제품 품질을 보장하기 위해 계획하여 설정한 관리 대책. 원료의약품과 원제의약품의 원자재와 관련된 파라미터와 특정 요소, 시설 및 설비 운전 조건, IPC, 최종 제품 규격, 모니터링 및 관리 방법과 주기가 관리 전략에 포함될 수 있다. (ICH Q10)

시정 조치(Corrective Action):
Action to eliminate the cause of a detected non-conformity or other undesirable situation. NOTE: Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence. (ISO 9000:2005)
감지된 부적합 상황 또는 기타 바람직하지 않은 상황의 원인을 제거하기 위한 조치. 주: 시정 조치는 재발을 방지하기 위한 것이며, 예방 조치는 발생을 방지하기 위한 것이다. (ISO 9000:2005)

디자인 스페이스(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)
품질을 보증하는 것으로 증명된 공정 파라미터와 투입 변수(예, 물품 특성)의 다차원적 조합과 상호 작용. (ICH Q8)

촉진 요소(Enabler):
A tool or process which provides the means to achieve an objective. (ICH Q10)
목표 달성 수단을 제공하는 도구 또는 업무 절차. (ICH Q10)

피드백/피드포워드(Feedback / Feedforward):
Feedback: The modification or control of a process or system by its results or effects.
피드백: 업무 절차나 시스템의 결과나 영향에 근거하여, 그 업무 절차나 시스템의 변형 또는 관리.
Feedback/ feedforward can be applied technically in process control strategies and conceptually in quality management. (ICH Q10)
ICH Q10 Pharmaceutical Quality System

피드백/피드포워드를 공정 관리 전략에 기술적으로 적용하고, 품질 관리에 개념적으로 적용할 수 있다. (ICH Q10)

혁신(Innovation):
The introduction of new technologies or methodologies. (ICH Q10)
새로운 기술이나 방법의 도입. (ICH Q10)

지식 관리(Knowledge Management):
Systematic approach to acquiring, analysing, storing, and disseminating information related to products, manufacturing processes and components. (ICH Q10)
제품, 제조 공정, 원자재와 관련된 정보의 체계적인 수집, 분석, 보관, 유포 방법. (ICH Q10)

아웃소싱 활동(Outsourced Activities):
Activities conducted by a contract acceptor under a written agreement with a contract giver. (ICH Q10)
위탁업체와 계약을 체결하여 수탁업체가 수행하는 활동. (ICH Q10)

성과 지표(Performance Indicators):
Measurable values used to quantify quality objectives to reflect the performance of an organisation, process or system, also known as “performance metrics” in some regions. (ICH Q10)
조직, 업무 절차 또는 시스템의 성과를 반영하여 품질 목표를 계량적으로 평가하는데 활용되는 측정 가능한 값. "성과 메트릭"이라고 부르기도 한다. (ICH Q10)

제약 품질 시스템(Pharmaceutical Quality System (PQS)):
Management system to direct and control a pharmaceutical company with regard to quality. (ICH Q10 based upon ISO 9000:2005)
품질과 관련하여 제약 회사의 방향을 제시하고 관리하는 시스템. (ICH Q10, ISO 9000:2005 기반)

예방 조치(Preventive Action):
Action to eliminate the cause of a potential non-conformity or other undesirable potential situation. NOTE: Preventive action is taken to prevent occurrence whereas corrective action is taken to prevent recurrence. (ISO 9000:2005)
잠재적인 부적합 상황 또는 기타 비람직하지 않은 상황의 원인을 제거하는 조치. 주: 예방 조치는 발생을 방지하기 위한 것이며, 시정 조치는 재발을 방지하기 위한 것이다. (ISO 9000:2005)

제품 실현(Product Realisation):
Achievement of a product with the quality attributes appropriate to meet the needs of patients, health care professionals, and regulatory authorities (including compliance with marketing authorisation) and internal customers requirements. (ICH Q10)
환자, 건강 관리 전문가, 규제 기관(판매 허가 기준 준수 포함), 내부 고객의 요구 사항을 충족시키는데 적절한 품질 특성을 갖춘 제품의 확보. (ICH Q10)

품질(Quality):
The degree to which a set of inherent properties of a product, system or process fulfils requirements. (ICH Q9)
제품, 시스템, 업무 절차의 내재적 특성이 요구 기준을 충족시키는 정도. (ICH Q9)

품질 매뉴얼(Quality Manual):
Document specifying the quality management system of an organisation. (ISO 9000:2005)
조직의 품질 경영 시스템을 규정한 문서. (ISO 9000:2005)

품질 목표(Quality Objectives):
A means to translate the quality policy and strategies into measurable activities. (ICH Q10)
품질 방침과 전략을 측정 가능한 활동으로 전환시키는 수단. (ICH Q10)

품질 기획(Quality Planning):
Part of quality management focused on setting quality objectives and specifying necessary operational processes and related resources to fulfil the quality objectives. (ISO 9000:2005)
품질 목표를 설정하고 품질 목표 달성에 필요한 운영 절차와 관련 자원을 규정하는데 중점을 둔 품질 경영 부분. (ISO 9000:2005)

품질 방침(Quality Policy):
Overall intentions and direction of an organisation related to quality as formally
ICH Q10 Pharmaceutical Quality System

expressed by senior management. (ISO 9000:2005)
고위 경영자가 공식적으로 밝힌, 품질과 관련한 조직의 전반적인 의도와 방향. (ISO 9000:2005)

품질 리스크 관리(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)
제품 라이프사이클 전반에 걸쳐 의약품의 품질과 관련된 리스크의 평가, 통제, 커뮤니케이션, 검토를 위한 체계적인 업무 절차. (ICH Q9)

고위 경영자(Senior Management):
Person(s) who direct and control a company or site at the highest levels with the authority and responsibility to mobilise resources within the company or site. (ICH Q10 based in part on ISO 9000:2005)
회사 또는 사업장의 자원을 동원할 수 있는 권한과 책임을 가지며, 최고 수준에서 회사 또는 사업장을 이끌고 관리하는 자. (ICH Q10, ISO 9000:2005 기반)

관리 상태(State of Control):
A condition in which the set of controls consistently provides assurance of continued process performance and product quality. (ICH Q10)
지속적인 공정 성능과 제품 품질을 일관되게 보장하는 관리 조건. (ICH Q10)
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.*

주: 이 부록은 규제 방식을 강화시킬 수 있는 기회를 정리한 것이다. 실제 규제 절차는 지역별로 결정한다.

<table>
<thead>
<tr>
<th>시나리오(Scenario)</th>
<th>기회(Potential Opportunity)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Comply with GMPs GMP 준수</td>
<td>Compliance – status quo 규정 준수 - 현 상태</td>
</tr>
</tbody>
</table>
| 2. Demonstrate effective pharmaceutical quality system, including effective use of quality risk management principles (e.g., ICH Q9 and ICH Q10). 품질 리스크 관리 원칙의 효과적인 활용을 포함해, 효과적인 제약 품질 시스템 증명(예, ICH Q9, ICH Q10). | Opportunity to:  
  • increase use of risk based approaches for regulatory inspections.  
  리스크 기반 규제 실사 방식의 확대 |
| 3. Demonstrate product and process understanding, including effective use of quality risk management principles (e.g., ICH Q8 and ICH Q9). 품질 리스크 관리 원칙의 효과적인 활용을 포함해, 제품 및 공정 이해 증명(예, ICH Q8, ICH Q9). | Opportunity to:  
  • facilitate science based pharmaceutical quality assessment;  
  과학 기반 제약 품질 평가 촉진  
  • enable innovative approaches to process validation;  
  혁신적인 공정 밸리데이션 방식 추진  
  • establish real-time release mechanisms.  
  실시간 출하 승인 메커니즘 확립 |
| 4. Demonstrate effective pharmaceutical quality system and product and process understanding, including the use of quality risk management principles (e.g., ICH Q8, ICH Q9 and ICH Q10). | Opportunity to:  
- increase use of risk based approaches for regulatory inspections;  
- facilitate science based pharmaceutical quality assessment;  
- optimise science and risk based post-approval change processes to maximise benefits from innovation and continual improvement;  
- enable innovative approaches to process validation;  
- establish real-time release mechanisms. |
|---|---|
| 품질 리스크 관리 원칙의 활용을 포함해, 효과적인 제약 품질 시스템과 제품 및 공정 이해 증명(ICH Q8, ICH Q9, ICH Q10). | }
Annex 2
ICH Q10 Pharmaceutical Quality System Model

This diagram illustrates the major features of the ICH Q10 Pharmaceutical Quality System (PQS) model. The PQS covers the entire lifecycle of a product including pharmaceutical development, technology transfer, commercial manufacturing, and product discontinuation as illustrated by the upper portion of the diagram. The PQS augments regional GMPs as illustrated in the diagram. The diagram also illustrates that regional GMPs apply to the manufacture of investigational products.

The next horizontal bar illustrates the importance of management responsibilities explained in Section 2 to all stages of the product lifecycle. The following horizontal bar lists the PQS elements which serve as the major pillars under the PQS model. These elements should be applied appropriately and proportionally to each lifecycle.
stage recognising opportunities to identify areas for continual improvement.
다음에 수평으로 이어진 막대는 섹션 2에서 설명한 경영자 책임을 제품 라이프사이클 전체 단계에 적용하는 것이 중요함을 보여준다. 그 아래의 수평으로 이어진 막대에는 PQS 모델의 주요 구성 요소가 정리되어 있다. 이들 요소를 각 라이프사이클 단계에 적절하고 비례적으로 적용하면서 지속적 개선 대상 영역을 파악한다.

The bottom set of horizontal bars illustrates the enablers: knowledge management and quality risk management, which are applicable throughout the lifecycle stages. These enablers support the PQS goals of achieving product realisation, establishing and maintaining a state of control, and facilitating continual improvement.
가장 아래에 있는 막대는 촉진 요소인 지식 관리와 품질 리스크 관리를 보여주며, 이 두 요소는 라이프사이클 단계 전체에 걸쳐 적용한다. 이들 요소는 제품 실현, 관리 상태 확립 및 유지, 지속적 개선 촉진이라는 PQS 목적을 뒷받침한다.