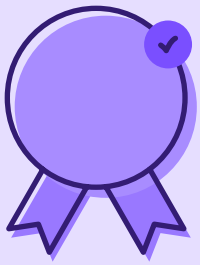
Qualio



# *ICH Q10 compliance checklist*

*ICH Q10 lays out the broad quality requirements for the modern pharmaceutical quality management system. ICH Q10 incorporates many of the core requirements of Good Manufacturing Practice (GMP) seen in ICH Q7 ("Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients"), and is designed to complement both ICH Q8 ("Pharmaceutical Development") and ICH Q9 ("Quality Risk Management"). Use this checklist to embed compliance with all 4 areas of the ICH Q10 standard across your entire product lifecycle, from development and technology transfer to manufacturing and discontinuation.*

## 1. Pharmaceutical quality system

| Item number | Requirement | Complete? |
|---|---|---|
| **1.5** | **ICH Q10 objectives** | |
| **1.5.1** | **Product realization** | |
| | Has a pharmaceutical quality system been established and maintained that allows the delivery of products with the quality attributes appropriate to meet the needs of: | |
| | Patients? | ☐ |
| | Healthcare professionals? | ☐ |
| | Regulatory authorities? | ☐ |
| | Other internal/external customers? | ☐ |
| **1.5.2** | **State of control** | |
| | Are effective monitoring and control systems in place for process performance and product quality, that provide assurance of continued suitability and capability of processes? | ☐ |
| | Are quality risk management principles integrated into these monitoring and control systems? | ☐ |
| **1.5.3** | **Continuous improvement** | |
| | Are effective monitoring and control systems in place for pinpointing and actioning: | |
| | Product quality improvements? | ☐ |
| | Process improvements? | ☐ |
| | Variability reduction? | ☐ |

| | | |
|---|---|---|
| | Innovations? | ☐ |
| | PQS enhancements? | ☐ |
| | Are quality risk management principles integrated into these continuous improvement monitoring and control systems? | ☐ |
| **1.6** | **Enablers: Knowledge management & risk management** | |
| **1.6.1** | **Knowledge management** | |
| | Is product and process knowledge managed from development through the commercial life of the product up to and including product discontinuation?<br><br>*(Knowledge includes information related to products, manufacturing processes and components. Sources of knowledge include pharmaceutical development studies, technology transfer activities, process validation studies over the product lifecycle, manufacturing experience, innovation, continual improvement and change management activities.)* | ☐ |
| **1.6.2** | **Risk management** | |
| | Is a proactive approach in place for identifying, scientifically evaluating and controlling potential risks to quality?<br><br>*(Refer to ICH Q9 for principles and examples of tools for quality risk management that can be applied to different aspects of pharmaceutical quality.)* | ☐ |
| **1.7** | **Design and content considerations** | |
| | Is the design, organization and documentation of the pharmaceutical quality system well structured and clear to facilitate common understanding and consistent application? | ☐ |
| | Are the elements of ICH Q10 applied in an appropriate manner for each of the 4 product lifecycle stages, recognizing the different goals and knowledge available for each stage? | ☐ |
| | Have the size and complexity of the company's activities been taken into consideration when developing the pharmaceutical quality system, bearing in mind that the effectiveness of the pharmaceutical quality system is normally demonstrated at the site level? | ☐ |
| | Does the pharmaceutical quality system include appropriate processes, resources and responsibilities to provide assurance of the quality of outsourced activities and purchased materials? | ☐ |

| | | |
|---|---|---|
| | Are management responsibilities clearly identified within the pharmaceutical quality system? | ☐ |
| | Does the pharmaceutical quality management system include: | |
| | Process performance and product quality monitoring elements? | ☐ |
| | Corrective and preventive action (CAPA) elements? | ☐ |
| | Change management elements? | ☐ |
| | Management review elements? | ☐ |
| **1.8** | **Quality manual** | |
| | Has a quality manual (or equivalent documentation approach) been established, containing the description of the pharmaceutical quality system and: | |
| | The quality policy? | ☐ |
| | The scope of the pharmaceutical quality system? | ☐ |
| | Management responsibilities? | ☐ |
| | Identification of the pharmaceutical quality system processes, as well as their sequences, linkages and interdependencies? | ☐ |

## 2. Management responsibility

| Item number | Requirement | Complete? |
|---|---|---|
| **2.1** | **Management commitment** | |
| | Does senior management have the ultimate responsibility to ensure an effective pharmaceutical quality system is in place to achieve the corporate quality objectives? | ☐ |
| | Are roles, responsibilities and authorities clearly defined, communicated and implemented throughout the company? | ☐ |
| | Does management: | |
| | Participate in the design, implementation, monitoring and maintenance of an effective pharmaceutical quality system? | ☐ |
| | Demonstrate strong and visible support for the pharmaceutical quality system and ensure its implementation throughout their organization? | ☐ |

| | | |
|---|---|---|
| | Ensure a timely and effective communication and escalation process exists to raise quality issues to the appropriate levels of management? | ☐ |
| | Define individual and collective roles, responsibilities, authorities and inter-relationships of all organizational units related to the pharmaceutical quality system, communicated and understood at all organizational levels? | ☐ |
| | Conduct management reviews of process performance and product quality and of the pharmaceutical quality system? | ☐ |
| | Advocate continuous improvement? | ☐ |
| | Commit appropriate resources? | ☐ |
| **2.2** | **Quality policy** | |
| | Has senior management established a quality policy that describes the overall intentions and direction of the company related to quality? | ☐ |
| | Does the quality policy include an expectation to comply with applicable regulatory requirements and facilitate continual improvement of the pharmaceutical quality system? | ☐ |
| | Is the quality policy communicated to and understood by personnel at all levels in the company? | ☐ |
| | Is the quality policy reviewed periodically for continuing effectiveness? | ☐ |
| **2.3** | **Quality planning** | |
| | Does senior management ensure the quality objectives needed to implement the quality policy are defined and communicated? | ☐ |
| | Are the quality objectives supported by all relevant levels of the company? | ☐ |
| | Do the quality objectives align with the company's strategies and with the quality policy? | ☐ |
| | Does management provide the appropriate resources and training to achieve the quality objectives? | ☐ |
| | Are performance indicators that measure progress against quality objectives established, monitored, communicated regularly and acted upon? | ☐ |

| | | |
|---|---|---|
| **2.4** | **Resource management** | |
| | Does management 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? | ☐ |
| | Does management ensure that resources are appropriately applied to a specific product, process or site? | ☐ |
| **2.5** | **Internal communication** | |
| | Does management ensure appropriate communication processes are established and implemented within the organization? | ☐ |
| | Are communications processes devised and maintained to ensure the flow of appropriate information between all levels of the company? | ☐ |
| | Do communication processes ensure the appropriate and timely escalation of certain product quality and pharmaceutical quality system issues? | ☐ |
| **2.6** | **Management review** | |
| | Are senior management actively responsible for pharmaceutical quality system governance through frequent management review to ensure its continuing suitability and effectiveness? | ☐ |
| | Does top management assess the conclusions of periodic reviews of process performance and product quality and of the pharmaceutical quality system? | ☐ |
| **2.7** | **Management of outsourced activities and purchased materials** | |
| | Are processes in place for the control and review of any outsourced activities and quality of purchased materials, including: | |
| | 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? | ☐ |

| | | |
|---|---|---|
| | 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? | ☐ |
| **2.8** | **Management of change in product ownership** | |
| | When product ownership changes, (e.g., through acquisitions) do management ensure: | |
| | The ongoing responsibilities are defined for each company involved? | ☐ |
| | The necessary information is transferred? | ☐ |

## 3. Continual improvement of process performance and product quality

| Item number | Requirement | Complete? |
|---|---|---|
| **3.1** | **Lifecycle stage goals** | |
| | Are processes and policies in place to support all 4 stages of the pharmaceutical lifecycle stage as follows: | |
| | **Pharmaceutical development:** to design a product and its manufacturing process to consistently deliver the intended performance and meet the needs of patients and healthcare professionals, regulatory authorities and internal customers' requirements? | ☐ |
| | **Technology transfer:** to transfer product and process knowledge between development and manufacturing, and within or between manufacturing sites to achieve product realization? | ☐ |
| | **Commercial manufacturing:** to achieve product realization, establish and maintain a state of control, facilitate continual improvement, 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? | ☐ |
| | **Product discontinuation:** to manage the terminal stage of the product lifecycle effectively, including activities such as retention of documentation and samples, continued product assessment (e.g., complaint handling and stability) and reporting in accordance with regulatory requirements? | ☐ |

| | | |
|---|---|---|
| **3.2** | **Pharmaceutical quality elements** | |
| **3.2.1** | **Process performance and product quality monitoring system** | |
| | Is a process performance and product quality monitoring system in place that: | |
| | Uses quality risk management to establish the control strategy and facilitate timely feedback and appropriate corrective and preventive action? | ☐ |
| | Provides the tools for measurement and analysis of parameters and attributes identified in the control strategy (e.g., data management and statistical tools)? | ☐ |
| | Analyzes parameters and attributes identified in the control strategy to verify continued operation within a state of control? | ☐ |
| | Identifies sources of variation affecting process performance and product quality for potential? | ☐ |
| | Includes 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? | ☐ |
| | Provides knowledge to enhance process understanding, enrich the design space (where established), and enable innovative approaches to process validation? | ☐ |
| **3.2.2** | **Corrective and preventive action (CAPA) system** | |
| | Does the organization 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? | ☐ |
| **3.2.3** | **Change management system** | |
| | Does the organization have an effective change management system including: | |
| | Quality risk management for evaluating proposed changes, with the level of effort and formality of the evaluation commensurate with the level of risk? | ☐ |
| | Evaluation of proposed changes relative to the marketing authorization, including design space (where established) and/or current product and process understanding? | ☐ |

| | | |
|---|---|---|
| | Evaluation of proposed changes by expert teams contributing the appropriate expertise and knowledge from relevant areas (e.g., development, manufacturing, quality, regulatory affairs, medical), to ensure the change is technically justified, with set evaluation criteria for a proposed change? | ☐ |
| | After implementation, an evaluation of the change to confirm the change objectives were achieved and there was no negative impact on product quality? | ☐ |

### 3.2.4 Management review of process performance and product quality

| | | |
|---|---|---|
| | Is a management review system in place to provide assurance that process performance and product quality are managed over the lifecycle, including timely and effective communication and escalation process to raise appropriate quality issues to senior levels of management for review? | ☐ |

Does the management review system include:

| | | |
|---|---|---|
| | The results of regulatory inspections and findings, audits and other assessments, and commitments made to regulatory authorities? | ☐ |
| | Periodic quality reviews, that can include: i) Measures of customer satisfaction such as product quality 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? | ☐ |
| | Any follow-up actions from previous management reviews? | ☐ |

Does the management review system identify appropriate actions, such as:

| | | |
|---|---|---|
| | Improvements to manufacturing processes and products? | ☐ |
| | Provision, training and/or realignment of resources? | ☐ |
| | Capture and dissemination of knowledge? | ☐ |

# 4. Continual improvement of the PQS

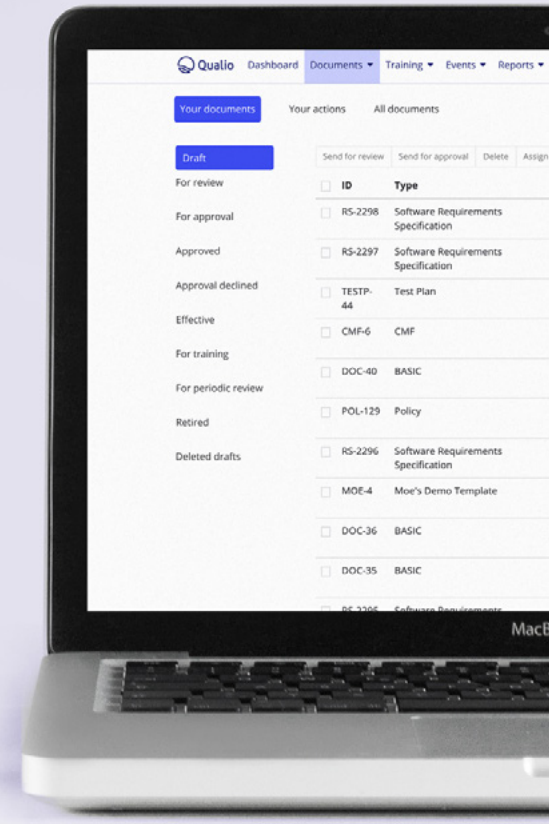
| Item number | Requirement | Complete? |
|---|---|---|
| 4.1 | **Management review of the pharmaceutical quality system** | |
| | Does management have a formal process for reviewing the pharmaceutical quality system on a periodic basis, including: | |
| | Measurement of achievement of pharmaceutical quality system objectives? | ☐ |
| | Assessment of performance indicators that can be used to monitor the effectiveness of processes within the pharmaceutical quality system, such as: i) complaint, deviation, CAPA and change management processes; ii) feedback on outsourced activities; iii) self-assessment processes including risk assessments, trending, and audits; iv) external assessments such as regulatory inspections and findings and customer audits? | ☐ |
| 4.2 | **Monitoring of internal and external factors impacting the pharmaceutical quality system** | |
| | Does management monitor: | |
| | Emerging regulations, guidance and quality issues that can impact the pharmaceutical quality system? | ☐ |
| | Innovations that might enhance the pharmaceutical quality system? | ☐ |
| | Changes in business environment and objectives? | ☐ |
| | Changes in product ownership? | ☐ |
| 4.3 | **Outcomes of management review and monitoring** | |
| | Does the outcome of management review of the pharmaceutical quality system and monitoring of internal and external factors include: | |
| | Improvements to the pharmaceutical quality system and related processes? | ☐ |
| | Allocation or reallocation of resources and/or personnel training? | ☐ |
| | Revisions to quality policy and quality objectives? | ☐ |
| | Documentation and timely and effective communication of the results of the management review and actions, including escalation of appropriate issues to senior management? | ☐ |

Qualio

# *Get your free demo of Qualio QMS*

Qualio is the highest rated eQMS on the market and also the easiest eQMS to use. To learn more about why leading life sciences companies rely on Qualio to improve quality management as they develop medical device products and bring them to market.

**Schedule a demo with us**




**Call us today**

1.855.203.2010 • +353 1 697 1522