Pharmaceutical Quality Management System – Continual Improvement (Part – B)

The checklist applies to the systems supporting the development and manufacture of pharmaceutical drug substances (i.e., active pharmaceutical ingredients (APIs)) and drug products, including biotechnology and biological products, throughout the product lifecycle.

CONTINUAL IMPROVEMENT OF PROCESS PERFORMANCE AND PRODUCT QUALITY

A. Lifecycle Stage objectives

Sl. No	ICH Q10 Reference	Stage	Objective	Result	Evidence or Justification
1.	Section 3.1.1	**Pharmaceutical Development ensures**	The design and manufacturing consistently adheres to its intended purpose and meets the needs of patients, healthcare professionals, internal customers and regulatory authorities.	Complies ☐ Does not comply ☐	
2.	Section 3.1.2	**Technology Transfer**	Manufacturing process validation is carried out to support smooth technology transfer. Product and process knowledge between development and manufacturing site is adequately transferred to ensure product commercialization is error-free.	Complies ☐ Does not comply ☐	
3.	Section 3.1.3	**Commercial Manufacturing includes**	a) Achieving product realization b) Establishing and maintaining the state of control c) Continual improvement d) Product quality is routinely met e) Specified process performance is achieved f) These procedure are appropriate to the manufacturing process g) Improvement opportunities are identified and evaluated within the system	Complies ☐ Does not comply ☐	
4.	Section 3.1.4	**Product Discontinuation ensures**	a) The terminal stage of the product lifecycle is effectively managed b) A predefined plan is used to discontinue a product c) Sample retention and the necessary documentation are maintained for discontinued products d) Regulatory Authorities are informed about such changes in the product portfolio	Complies ☐ Does not comply ☐	

B. Pharmaceutical Quality System Elements

Sl. No	ICH Q10 Reference	Stage	Objective	Result	Evidence or Justification
1.	Section 3.2.1	**Process performance and product quality monitoring system**	a) A procedure to plan and execute process performance and product quality monitoring system is defined b) Quality risk management to establish the control strategy is utilized c) Data management and statistical tools for measurement and analysis of parameters are provided d) For potential improvement, sources of variation affecting process performance and product quality are identified e) Procedure to reduce variation is implemented f) Feedback on product quality include both internal and external sources (eg. complaints, process rejections, non-conformances, product recalls, deviations, audit & regulatory inspections, and findings) g) Innovative approaches to process validation are defined and enabled	Complies ☐ Does not comply ☐	
2.	Section 3.2.2	**Corrective action and preventive action (CAPA) system**	a) Well established procedure on CAPA should be available and implemented b) CAPA is carried out for all complaints, process rejections, non-conformances, product recalls, deviations, audit and regulatory inspections and findings c) CAPA is a structured approach with root cause analysis and documentation of findings d) CAPA is applied throughout the product lifecycle i.e. *Pharmaceutical Development, Technology Transfer, Manufacturing, Product discontinuation*	Complies ☐ Does not comply ☐	
3.	Section 3.2.3	**Change management system**	a) A written procedure for change management exists b) It ensures continual improvement in a timely and effective manner c) It provides an assurance that there are no unintended consequences of changes	Complies ☐ Does not comply ☐	

			d) Quality risk management is utilized to evaluate proposed changes e) Proposed changes are evaluated relative to the marketing authorization f) All proposed changes are evaluated by expert teams from relevant areas g) An evaluation post-implementation is done to assure conformity with the objective without having a deleterious effect on product quality h) Change Management System is visible throughout the product lifecycle i.e. *Pharmaceutical Development, Technology Transfer, Manufacturing, Product discontinuation*		
4.	Section 3.2.4	**Management review of process performance and product quality**	a) A well-defined procedure for a management review system is made available b) Management review meetings are carried out within a set periodic interval c) Appropriate quality issues are discussed and addressed d) Results of regulatory inspections and findings, audits and other assessments, and commitments made to regulatory authorities are included in reviews e) Periodic reviews include--measurement of customer satisfaction, complaints, recalls, quality monitoring, CAPA actions, previous review findings, f) Management review is integrated throughout the product lifecycle i.e. *Pharmaceutical Development, Technology Transfer, Manufacturing, Product discontinuation*	Complies ☐ Does not comply ☐	

CONTINUAL IMPROVEMENT OF THE PHARMACEUTICAL QUALITY SYSTEM

Sl. No	ICH Q10 Reference	Stage	Objective	Result	Evidence or Justification
1.	Section 4.1	**Management Review of the Pharmaceutical Quality System**	a) Management periodically reviews the pharmaceutical quality management system b) Achieved quality objectives are measured	Complies ☐ Does not comply ☐	

			c) Performance indicators (complaints, deviations, CAPA, change management, risk management, internal & external audit findings, regulatory inspections) are assessed to ensure the effectiveness of processes		
2.	Section 4.2	**Monitoring of internal & external factors includes**	a) Emerging regulations, guidance, standards, quality issues monitored b) Innovations to enhance the pharmaceutical system c) Changes in the business environment d) New opportunities and markets e) Changes in product ownership	Complies ☐ Does not comply ☐	
3.	Section 4.3	**Outcomes of management review and Monitoring**	a) Improvements to the quality system and process observed b) Resources or training are provided c) Quality policy and objectives are revised d) Review meetings are communicated at all levels e) Quality issues may be escalated to the next level whenever required	Complies ☐ Does not comply ☐	

Reference:
Guidance for Industry - Q10 Pharmaceutical Quality System, April 2009 ICH; U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER).

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