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STANDARDS & GUIDANCE REPORT · INTERNATIONAL · ICH GUIDELINE

ICH Q10

Pharmaceutical Quality System

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What It Covers

A model for an effective quality system across the product life cycle — development, technology transfer, commercial manufacturing, and discontinuation — built on GMP and ISO quality concepts.

Who It Applies To

Manufacturers of drug substances and drug products, including biotechnology and biological products.

Key Requirements

- Management responsibility: commitment, policy, planning, resources, communication, and review.
- Four system elements: process performance and product quality monitoring, CAPA, change management, and management review.
- Two enablers: knowledge management and quality risk management (ICH Q9(R1)).
- Oversight of outsourced activities and purchased materials.

Structure at a Glance

PART	TOPIC	WHAT IT ASKS FOR
1	Pharmaceutical quality system	Scope, relationship to GMP, ISO and regulatory approaches, objectives, enablers, design and content, quality manual.
2	Management responsibility	Commitment, quality policy, planning, resource management, communication, review, oversight of outsourced activities.
3	Continual improvement of process performance and product quality	Life cycle stage goals and the four system elements.
4	Continual improvement of the quality system	Management review of the system and monitoring of internal and external factors.
Annexes	Opportunities and diagram	Where regulatory approaches can be enhanced, and the model diagram.

What an Auditor Asks to See

- Management review records showing decisions on process performance and product quality.

- Change management records with risk assessment and effectiveness review.
- Monitoring data that triggered CAPA, and evidence the CAPA worked.

Requirements Checklist

Work down the list with the evidence in hand; write where each item is evidenced in the right-hand column.

#	REQUIREMENT	EVIDENCE ON FILE
1	Quality manual describing the system, its scope, and its processes.	
2	Quality policy and objectives deployed to the levels that act on them.	
3	Process performance and product quality monitoring system across the life cycle.	
4	CAPA system covering complaints, rejections, nonconformances, recalls, deviations, audits, inspections, and trends.	
5	Change management system with risk assessment, expert evaluation, and post-implementation review.	
6	Management review of process performance, product quality, and the system itself.	
7	Knowledge management capturing development and manufacturing knowledge.	
8	Quality risk management applied per ICH Q9(R1).	
9	Oversight of outsourced activities through written agreements and monitoring.	
10	Monitoring of internal and external factors affecting the system.	
11	Life cycle stage goals defined for development, transfer, manufacturing, and discontinuation.	
12	Evidence of continual improvement, not only of compliance.	

Implementation Roadmap

1. Describe	Write the quality manual around the four elements and two enablers.
2. Monitor	Define the process and product indicators and how they are reviewed.
3. Connect	Link monitoring to CAPA, and CAPA and change to effectiveness review.
4. Govern	Run management review as the place where these decisions are made and recorded.

How It Fits With Other Requirements

Q10 sits on top of regional GMP (21 CFR 210/211, EU GMP) rather than replacing it, uses ICH Q9(R1) as its risk method, and maps closely onto ISO 9001 concepts. For APIs it complements ICH Q7.

Findings We See Most Often

- Management review as a slide presentation with no recorded decisions.
- Change control without post-implementation effectiveness review.
- Monitoring data collected and never trended.
- Outsourced activities without a quality agreement or monitoring.

Where Systems Fall Short

- Management review that receives data and makes no decisions.
- Change control that checks paperwork but never reviews effectiveness.
- CAPA effectiveness checks that re-use the evidence that opened the CAPA.

How QES helps. A management review that decides things, and CAPA and change control built to prove their own effectiveness. See the gap assessment: qesisbest.com/services.html#gap-assessment · +1 (401) 246-3204 · mweeden@qesisbest.com

Sources, checked October 24, 2026. ICH — Quality guidelines — www.ich.org/page/quality-guidelines; ICH — Q10 guideline (PDF) — database.ich.org/sites/default/files/Q10%20Guideline.pdf; European Commission — EudraLex Volume 4, EU GMP guidelines — health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en.

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