KOENIG SOLUTIONS · COURSE OUTLINE

Process Validation for Medical Devices

2 Days	8	46	46-11-22-0064
DURATION	MODULES	TOPICS	COURSE CODE

COURSE OVERVIEW

Medical device manufacturers are expected to demonstrate that manufacturing processes consistently produce products that meet predetermined specifications and regulatory requirements. For many manufacturing technologies, product quality cannot be fully verified through final inspection alone, making process validation an essential component of an effective quality management system. This comprehensive two-day training provides participants with the practical knowledge required to design, implement, document, and maintain compliant process validation programs for medical devices. The course explains the regulatory foundations of process validation and equipment qualification, including key requirements from ISO 13485:2016, FDA 21 CFR 820 (QMSR), MDSAP expectations, and internationally recognized guidance documents. Participants will gain a clear understanding of Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ), including qualification of computerized systems and automated manufacturing equipment. The training also explores Validation Master Plans (VMPs), validation protocols, documentation requirements, and the role of risk management throughout validation activities. Special emphasis is placed on risk-based validation strategies, including determining validation scope, developing statistically justified sampling plans, applying confidence and reliability concepts, and using AQL and RQL principles to support decision making. Participants will learn how process risk analyses can be used to define validation requirements and optimize resource utilization while maintaining compliance. Practical workshops and industry examples allow participants to apply the concepts learned to realistic manufacturing scenarios. The course concludes with guidance on change control, revalidation, ongoing monitoring of validated processes, statistical process control (SPC), and documentation practices to ensure long-term process effectiveness and regulatory readiness.

WHO THIS COURSE IS FOR

- This course is designed for professionals involved in medical device manufacturing, quality systems, and validation activities, including:
- Quality Assurance Specialists
- Quality Engineers
- Validation Engineers

- Manufacturing Engineers
- Process Engineers
- Process Technicians
- Production Managers
- Product Development Engineers
- Regulatory Affairs Professionals
- Compliance Specialists
- Supplier Quality Professionals
- Project Managers
- Auditors and Consultants
- Contract Manufacturers and Suppliers supporting medical device production

PREREQUISITES

- No formal prerequisites are required.
- However, a basic understanding of medical device manufacturing, quality systems, ISO 13485, or quality assurance processes will help participants maximize the value of the training.

LEARNING OBJECTIVES

What You Will Learn

- Explain the regulatory and quality system requirements governing process validation.
- Distinguish between qualification, verification, and validation activities.
- Apply the principles of Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ).
- Assess qualification requirements for equipment, utilities, tooling, and computerized systems.
- Develop validation plans and Validation Master Plans (VMPs).
- Establish process acceptance criteria and validation strategies.
- Design risk-based statistical sampling plans using AQL and RQL concepts.
- Apply risk management principles to validation decision making.
- Implement effective change-control and revalidation processes.
- Monitor and maintain validated processes using suitable controls and performance indicators.
- Apply good documentation practices throughout the validation lifecycle.
- Create compliant validation documentation for audits and inspections.
- Understand international regulatory expectations for process validation in medical device manufacturing.
- Apply process validation requirements from ISO 13485:2016 and FDA QMSR.
- Implement risk-based approaches to equipment qualification and process validation.
- Plan and execute IQ, OQ, and PQ activities effectively.
- Develop validation plans, protocols, and reports.
- Establish statistically justified sampling strategies.
- Integrate process validation activities with risk management principles.
- Evaluate the impact of manufacturing changes and determine revalidation needs.
- Maintain validated processes using monitoring, trending, and SPC methods.
- Improve audit readiness and regulatory compliance across manufacturing operations and supply chains.
- Gain practical experience through workshop exercises and real-world examples.

COURSE SYLLABUS

8 Modules, 46 Topics

MODULE 1

01

Regulatory Foundations and Terminology

TOPICS

- Process validation fundamentals
- Qualification, verification, and validation terminology
- Regulatory requirements
- ISO 13485:2016
- FDA 21 CFR 820 (QMSR)
- MDSAP expectations
- Relevant guidance documents and standards

MODULE 2

02

Installation Qualification (IQ)

TOPICS

- Equipment qualification principles
- Qualification scope determination
- Utilities and infrastructure
- Calibration requirements
- Environmental controls
- Maintenance and cleaning considerations
- Computerized systems and software validation concepts

MODULE 3

03

Operational Qualification (OQ) and Performance Qualification (PQ)

TOPICS

- Defining process operating windows
- Worst-case conditions
- OQ test planning and execution
- PQ strategies
- Process capability considerations
- Acceptance criteria

MODULE 4

04

Validation Planning

TOPICS

- Validation lifecycle
- Validation plans and protocols
- Validation Master Plans (VMP)
- Deliverables and documentation requirements
- Validation reporting

MODULE 5

05

Risk-Based Sampling Strategies

TOPICS

- Principles of statistical sampling
- Variable versus attribute data
- AQL and RQL concepts
- Confidence and reliability approaches
- Risk-based sampling plans
- Validation sample-size justification

MODULE 6

06

Change Control and Process Monitoring

TOPICS

- Managing validated-state processes
- Revalidation triggers
- Change assessment methodologies
- Ongoing process monitoring
- Statistical Process Control (SPC)
- Continuous validation effectiveness

MODULE 7

07

Practical Workshop

TOPICS

- Validation planning exercise
- OQ development exercise
- Medical device manufacturing case studies
- Group problem solving

MODULE 8

08

Good Documentation Practices

TOPICS

- Validation protocol development
- Test planning
- Managing deviations and failures
- Documentation review and approval
- Inspection-ready records

DELIVERY NOTE

How It Is Delivered

- Expert-led presentations
- Regulatory interpretation and guidance
- Real-life medical device case studies
- Interactive discussions
- Group exercises
- Validation planning workshops
- Practical examples
- Knowledge checks and quizzes
- Q&A sessions with subject matter experts

WHAT IS INCLUDED

Everything You Need to Succeed

- Koenig course material for every module
- Delivery by certified instructors and subject matter experts
- Hands-on exercises throughout the course
- Course completion certificate from Koenig

ABOUT KOENIG

Who We Are

Established in 1993, Koenig Solutions is a globally recognised training provider with 35+ technology partnerships, 5,000+ training programmes and a network of certified instructors and subject matter experts, supporting individuals and enterprise teams worldwide.

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