Quality by Design (QbD) in Manufacturing Training Course

Professional Development Training Course Outline

Category	Quality Assurance and ISO standards	**Duration**	10 Days
Base Fee	$3,000 USD	**Delivery Mode**	Online / On-site Hybrid

Course Introduction

Quality by Design (QbD) in Manufacturing has become one of the most transformative approaches in modern industrial processes, empowering organizations to create robust, efficient, and compliant manufacturing systems. Quality by Design (QbD) in Manufacturing Training Course emphasizes data-driven strategies, regulatory compliance, process optimization, and risk-based methodologies that align with global quality standards. Participants will gain practical skills in applying QbD principles to design high-quality products, reduce variability, and achieve sustainable operational excellence.

The program blends theoretical concepts with hands-on applications to ensure participants can implement QbD frameworks across pharmaceutical, biotech, and advanced manufacturing industries. Through interactive modules, case studies, and practical exercises, this training provides in-depth knowledge of critical quality attributes (CQAs), design of experiments (DoE), risk assessment, regulatory expectations, and lifecycle management. By the end of the course, participants will be equipped to lead innovation, enhance compliance, and support continuous improvement within their organizations.

Programme Curriculum

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Course Objectives

1. Understand the principles and framework of Quality by Design in manufacturing.
2. Identify and define critical quality attributes (CQAs) and critical process parameters (CPPs).
3. Apply risk assessment methodologies to enhance product quality and process consistency.
4. Utilize design of experiments (DoE) for process optimization.
5. Implement real-time monitoring and process analytical technology (PAT).
6. Align QbD practices with global regulatory requirements (FDA, EMA, ICH).
7. Integrate quality risk management with product lifecycle management.
8. Reduce manufacturing variability and ensure robust process design.
9. Apply data-driven decision-making to enhance quality outcomes.
10. Develop effective control strategies to achieve continuous compliance.
11. Build organizational capacity for innovation and operational excellence.
12. Analyze real-world case studies to strengthen problem-solving skills.
13. Foster a culture of proactive quality within manufacturing environments.

Organizational Benefits

- Enhanced compliance with global regulatory frameworks.
- Reduced product recalls and deviations.
- Improved efficiency through optimized process design.
- Increased profitability with reduced waste and variability.
- Strengthened competitive advantage in manufacturing markets.
- Streamlined product development timelines.
- Empowered workforce with advanced quality skills.
- Enhanced customer satisfaction through consistent product quality.
- Sustainable operational excellence across manufacturing units.
- Proactive risk management and reduced quality-related costs.

Target Audiences

- Quality assurance professionals
- Regulatory affairs specialists
- Manufacturing engineers
- Process development scientists
- Research and development teams
- Production managers
- Continuous improvement specialists
- Compliance and validation officers

Course Duration: 10 days

Course Modules

Module 1: Introduction to Quality by Design (QbD)

- Fundamentals of QbD in manufacturing
- Historical evolution and regulatory drivers
- Key terminologies and principles of QbD
- Role of QbD in pharmaceutical and biotech industries
- Advantages of QbD adoption in manufacturing
- Case study: Evolution of QbD in a global pharma company

Module 2: Critical Quality Attributes (CQAs)

- Definition and identification of CQAs
- Importance of CQAs in product quality
- Tools for establishing CQAs in product design
- Linking CQAs to customer expectations
- Regulatory perspectives on CQAs
- Case study: CQA identification in biologics manufacturing

Module 3: Critical Process Parameters (CPPs)

- Understanding process parameters
- Determining criticality in CPPs
- Statistical tools for CPP analysis
- Relationship between CQAs and CPPs
- Monitoring and controlling CPPs
- Case study: CPP determination in sterile manufacturing

Module 4: Design of Experiments (DoE)

- Principles of experimental design
- Full factorial and fractional factorial designs
- Response surface methodology
- Applications of DoE in process optimization
- Software tools for DoE implementation
- Case study: DoE in optimizing tablet formulation

Module 5: Risk Assessment and Management

- Introduction to quality risk management (QRM)
- Tools: FMEA, HACCP, Ishikawa diagrams
- Risk ranking and prioritization
- Integrating QRM into manufacturing systems
- Benefits of proactive risk assessment
- Case study: Risk management in vaccine production

Module 6: Process Analytical Technology (PAT)

- Definition and scope of PAT
- Real-time monitoring tools and sensors
- Data integration for PAT systems

- Regulatory expectations for PAT adoption
- Challenges and opportunities in PAT
- Case study: PAT in continuous manufacturing

Module 7: Regulatory Requirements in QbD

- ICH guidelines: Q8, Q9, Q10, Q11
- FDA and EMA expectations
- Linking QbD to regulatory submissions
- Common regulatory challenges
- Best practices for compliance readiness
- Case study: Regulatory approval based on QbD

Module 8: Control Strategies in Manufacturing

- Concept of control strategy
- Designing robust control measures
- Real-time release testing (RTRT)
- Linking controls with risk assessments
- Continuous improvement in control strategies
- Case study: Control strategy in parenteral manufacturing

Module 9: Lifecycle Management

- QbD across the product lifecycle
- Post-approval changes and flexibility
- Continuous process verification
- Knowledge management systems
- Benefits of lifecycle approach
- Case study: Lifecycle management in biosimilars

Module 10: Data-Driven Decision-Making

- Role of big data in QbD
- Data collection and integration
- Statistical process control (SPC) tools
- Predictive analytics in manufacturing
- Artificial intelligence applications
- Case study: AI-enabled QbD decision making

Module 11: Variability Reduction

- Sources of variability in manufacturing
- Tools for measuring and analyzing variability
- Strategies for minimizing variability
- Impact on product quality and cost reduction
- Variability in raw materials and supply chain
- Case study: Variability reduction in tablet coating

Module 12: Knowledge Management in QbD

- Importance of structured knowledge capture

- Systems for managing manufacturing knowledge
- Knowledge transfer and retention strategies
- Integration of digital platforms
- Benefits of centralized knowledge bases
- Case study: Knowledge management in a biotech firm

Module 13: Innovation and Continuous Improvement

- Role of QbD in fostering innovation
- Continuous improvement models (Kaizen, Lean, Six Sigma)
- Linking innovation with regulatory compliance
- Tools for driving manufacturing excellence
- Empowering teams for innovation
- Case study: QbD and continuous improvement in medical devices

Module 14: Implementation Challenges in QbD

- Common barriers to QbD adoption
- Organizational resistance and cultural factors
- Resource and cost considerations
- Overcoming technical challenges
- Strategies for successful implementation
- Case study: Overcoming resistance in QbD deployment

Module 15: Future Trends in QbD and Manufacturing

- Digital transformation and Industry 4.0
- QbD in personalized medicine
- Advances in analytical technologies
- Regulatory evolution in QbD frameworks
- Global harmonization of QbD practices
- Case study: QbD in future-oriented smart factories

Training Methodology

- Interactive lectures with real-life examples
- Group discussions and brainstorming sessions
- Hands-on workshops and practical demonstrations
- Case study analysis and problem-solving exercises
- Role plays and scenario-based learning
- Assessments and feedback sessions for continuous improvement

Register as a group from 3 participants for a Discount

Send us an email: info@fineskilltrainingcenter.org or call *+254769199797*

Certification

Upon successful completion of this training, participants will be issued with a globally- recognized certificate.

Tailor-Made Course

We also offer tailor-made courses based on your needs.

Key Notes

a. The participant must be conversant with English.

b. Upon completion of training the participant will be issued with an Authorized Training Certificate

c. Course duration is flexible and the contents can be modified to fit any number of days.

d. The course fee includes facilitation training materials, 2 coffee breaks, buffet lunch and A Certificate upon successful completion of Training.

e. One-year post-training support Consultation and Coaching provided after the course.

f. Payment should be done at least a week before commence of the training, to Fineskill Training Center account, as indicated in the invoice so as to enable us prepare better for you.

Upcoming Scheduled Sessions

Start Date	End Date	Location	Price
23 Nov 2026	04 Dec 2026	Online	$2,000
23 Nov 2026	04 Dec 2026	Physical	$3,000
23 Nov 2026	04 Dec 2026	Physical	$6,000
23 Nov 2026	04 Dec 2026	Physical	$6,000
23 Nov 2026	04 Dec 2026	Physical	$12,000
23 Nov 2026	04 Dec 2026	Physical	$9,000
23 Nov 2026	04 Dec 2026	Physical	$12,000
23 Nov 2026	04 Dec 2026	Physical	$12,000

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