Quality by Design (QbD) for Pharmaceutical Products Training Course

Professional Development Training Course Outline

Category	Biotechnology and Pharmaceutical Development	**Duration**	10 Days
Base Fee	$4,000 USD	**Delivery Mode**	Online / On-site Hybrid

Course Introduction

In the rapidly evolving pharmaceutical industry, Quality by Design (QbD) has become a key approach to ensure the development of safe, effective, and cost-efficient products. Quality by Design (QbD) for Pharmaceutical Products Training Course is designed to provide professionals in the pharmaceutical sector with the skills and knowledge required to implement QbD principles in the development and manufacturing of pharmaceutical products. Leveraging state-of-the-art tools and methodologies, QbD ensures that quality is integrated into every stage of drug development, from formulation to production. As regulatory agencies around the world push for more efficient and risk-based manufacturing approaches, mastering QbD is essential for anyone involved in pharmaceutical product design and development.

This course delves into the core concepts of QbD, emphasizing critical factors like risk management, process understanding, design space, and control strategies. Through real-world case studies and hands-on applications, participants will understand how to identify critical quality attributes (CQAs) and critical process parameters (CPPs), as well as how to optimize manufacturing processes to achieve consistent product quality. The training covers the implementation of QbD in both small molecule and biologic product development, providing participants with a comprehensive understanding of how to integrate quality into the pharmaceutical development lifecycle.

Programme Curriculum

Quality by Design (QbD) for Pharmaceutical Products Training Course

Introduction

The pharmaceutical industry is undergoing a paradigm shift from traditional, reactive quality control to a proactive, science- and risk-based framework. Quality by Design (QbD) is at the forefront of this transformation, ensuring product quality and process understanding are built in from the earliest stages of development. This course provides a comprehensive and practical guide to implementing QbD principles, aligning your organization with global regulatory expectations and fostering a culture of continuous improvement. By mastering QbD, professionals can streamline drug development, enhance product robustness, and gain a competitive advantage in a complex and evolving market.

Quality by Design (QbD) for Pharmaceutical Products Training Course is designed to empower participants with the knowledge and skills to navigate the complexities of QbD, from defining the Quality Target Product Profile (QTPP) to establishing a robust control strategy. We delve into key concepts such as Critical Quality Attributes (CQAs), Critical Process Parameters (CPPs), and Design Space, using real-world case studies to illustrate their practical application. Our expert-led modules will guide you through the latest ICH guidelines (Q8, Q9, Q10, Q11), enabling you to not only achieve regulatory compliance but also drive operational excellence and innovation in pharmaceutical manufacturing.

Course Duration

10 days

Course Objectives

1. Define and apply Quality by Design (QbD) principles for modern drug development and lifecycle management.
2. Translate the Quality Target Product Profile (QTPP) into tangible and measurable Critical Quality Attributes (CQAs) and Critical Material Attributes (CMAs).
3. Conduct comprehensive Quality Risk Management (QRM) using trending methodologies like FMEA and Ishikawa diagrams.
4. Utilize Design of Experiments (DoE) and multivariate data analysis for process understanding and optimization.
5. Establish a scientifically sound Design Space and a robust Control Strategy aligned with ICH Q8 guidelines.
6. Implement Process Analytical Technology (PAT) for real-time monitoring and control of critical processes.
7. Integrate QbD into a Pharmaceutical Quality System (PQS) in accordance with ICH Q10.
8. Leverage digital twins and predictive analytics for enhanced process modeling and performance.
9. Streamline technology transfer and scale-up using a QbD-enabled knowledge management system.
10. Align QbD submissions with regulatory expectations from the FDA, EMA, and other global agencies.
11. Drive continuous improvement and post-approval change management with QbD principles.
12. Explore the application of Analytical Quality by Design (AQbD) for method development and validation.
13. Apply QbD to both small molecule and biologics development for enhanced product quality and safety.

Target Audience

1. Pharmaceutical R&D Scientists.
2. Quality Assurance (QA) and Quality Control (QC) Professionals.
3. Manufacturing and Process Engineers.
4. Regulatory Affairs Specialists.
5. Senior Management and Team Leaders.
6. Technology Transfer and Validation Specialists.

7. API and Excipient Suppliers.
8. Academics and Researchers.

Course Modules

Module 1: Introduction to QbD and Regulatory Landscape

- A paradigm shifts from quality by testing to quality by design.
- Understanding ICH Q8, Q9, and Q10 and their global adoption (FDA, EMA).
- Defining the foundation of the QbD framework.
- Reduced development time, enhanced product quality, and regulatory flexibility.
- **Case Study:** The story of a generic drug manufacturer's transition from a traditional approach to a QbD model, resulting in a streamlined submission and faster market approval.

Module 2: Quality Target Product Profile (QTPP)

- A prospective summary of the desired quality characteristics of a drug product.
- Linking the QTPP to attributes that impact patient safety and product performance.
- Utilizing prior knowledge, clinical data, and target market analysis.
- A step-by-step exercise in defining a QTPP for a hypothetical new oral tablet.
- **Case Study**: A case study on developing a QTPP for a new formulation of an existing drug to improve its dissolution profile and bioavailability.

Module 3: Critical Quality Attributes (CQAs)

- Using risk assessment to identify the attributes that must be controlled.
- Differentiating between product and process-related CQAs.
- Ensuring the right tools are used to measure critical attributes.
- Setting limits that guarantee product quality and efficacy.
- **Case Study**: An analysis of how a biopharmaceutical company identified and controlled CQAs like glycosylation and aggregation to ensure the safety and efficacy of a new monoclonal antibody.

Module 4: Quality Risk Management (QRM) in QbD

- A systematic approach to risk assessment, control, communication, and review.
- Applying FMEA, FMECA, and Hazard Analysis to identify potential risks.
- Developing plans to reduce or eliminate identified risks.
- : Ensuring QRM is a living process throughout the product lifecycle.
- **Case Study**: A multinational pharma company's use of QRM during a manufacturing scale-up to prevent batch failures and ensure process robustness.

Module 5: Critical Process Parameters (CPPs)

- Identifying process parameters that significantly impact a CQA.
- Establishing Operating Ranges: Setting acceptable limits for each CPP to maintain product quality.
- Using statistical methods to demonstrate the relationship between CPPs and CQAs.
- Understanding Critical Material Attributes (CMAs) and their influence on CPPs.
- **Case Study**: A case study on optimizing the drying step in tablet manufacturing, where moisture content was identified as a CPP affecting tablet hardness (a CQA).

Module 6: Design of Experiments (DoE) for Process Understanding

- Introduction to DoE
- Understanding fractional factorial, full factorial, and response surface designs.
- Using statistical software to analyze results and build predictive models.
- Discovering how multiple variables affect a CQA.
- **Case Study:** A pharmaceutical firm's use of a fractional factorial design to identify which variables significantly impact the content uniformity of a tablet formulation.

Module 7: Defining the Design Space

- Concept of Design Space
- Using DoE results and prior knowledge to define the boundaries of the process.
- Regulatory Flexibility
- Verification and Maintenance
- **Case Study:** A company's success story in gaining regulatory flexibility for minor process changes after establishing and validating a robust design space for a new injectable drug product.

Module 8: Process Analytical Technology (PAT)

- Introduction to PAT.
- PAT Tools and Sensors.
- Applications of PAT.
- Addressing technical and cultural barriers to PAT adoption.
- **Case Study:** The use of PAT sensors in a continuous manufacturing line to monitor and control tablet granulation, ensuring every product is within specification in real-time.

Module 9: Developing a Robust Control Strategy

- Elements of a Control Strategy.
- Setting up controls to monitor the process during manufacturing.
- The role of final product testing in a QbD framework.
- the control strategy to identify opportunities for process enhancement.
- **Case Study:** How a company developed an integrated control strategy for a lyophilized product, combining IPCs and real-time release testing to reduce batch-to-batch variability.

Module 10: QbD and Pharmaceutical Quality Systems (PQS)

- Integrating QbD into the pharmaceutical quality system.
- The importance of documenting and sharing process knowledge.
- Applying QbD from development to commercialization and beyond.
- The role of leadership in fostering a quality culture.
- **Case Study:** A case study on an organization that restructured its quality system to align with ICH Q10, resulting in improved cross-functional collaboration and a more efficient change control process.

Module 11: QbD for Technology Transfer and Scale-Up

- Communicating the design space and control strategy to the receiving site.
- Using QbD principles to anticipate and mitigate challenges during scale-up.
- Verifying that the process is stable across different manufacturing scales.
- Presenting a QbD-enabled technology transfer package for regulatory review.
- **Case Study:** A contract manufacturing organization's successful technology transfer of a complex oral solid dosage form by using a QbD-based knowledge package, which minimized process deviations and

accelerated the launch timeline.

Module 12: Analytical Quality by Design (AQbD)

- Applying QbD principles to analytical method development.
- Defining the performance requirements for an analytical method.
- Method Operable Design Region (MODR)
- **Case Study**: A case study on developing a new HPLC method for an impurity, demonstrating how AQbD reduced variability and improved the method's robustness.

Module 13: QbD for Biologics and Advanced Therapies

- The unique challenges and opportunities of applying QbD to large molecules.
- Identifying CQAs and CPPs in complex biological systems.
- Purification and Downstream Processing
- Designing a robust formulation for long-term stability.
- **Case Study**: A biopharma company's use of QbD to optimize a cell culture process, resulting in higher product yield and consistent quality attributes.

Module 14: Practical Implementation and Tools

- Overview of statistical software (JMP, Minitab) and digital platforms.
- Building a QbD Team.
- Developing a Project Plan.
- Addressing common barriers like budget, culture, and expertise.
- **Case Study:** A fictional company's project plan for its first QbD-enabled product, highlighting key milestones and resource allocation.

Module 15: Post-Approval Changes and Continuous Improvement

- Leveraging QbD to support regulatory submissions for changes.
- The continuous improvement loop in a QbD framework.
- Using process performance data to inform decisions.
- The role of AI, machine learning, and data analytics in the future of QbD.
- **Case Study**: An example of a company making a post-approval change to a supplier without a new regulatory filing, thanks to its established design space and robust control strategy.

Training Methodology

This program uses an interactive, blended learning methodology to ensure maximum engagement and knowledge retention.

- Expert-Led Lectures.
- Practical Workshops.
- Interactive Case Studies.
- Group Discussions and Q&A: Fostering a collaborative learning environment.
- Online Resources: Access to course materials, templates, and reference guides.
- Simulations: Virtual lab simulations for a risk-free learning environment.
- Assessments: Quizzes and a final project to evaluate mastery of the concepts.

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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