Advanced Quality Metrics and CMMI in Pharma 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

The pharmaceutical industry is undergoing a paradigm shift, moving beyond mere regulatory compliance to adopt a philosophy of Quality Management Maturity (QMM). In this data-intensive environment, traditional Quality Assurance (QA) practices are insufficient. Organizations must leverage Advanced Quality Metrics (AQM), mandated by global regulators like the FDA?ÇÖs Quality Metrics Initiative, to gain predictive insights, manage supply chain risk, and ensure sustainable compliance. Advanced Quality Metrics and CMMI in Pharma Training Course is meticulously designed to bridge the gap between reactive quality control and proactive operational excellence. It focuses on developing a robust, data-driven framework that elevates quality from a cost center to a competitive advantage.

This intensive training delves into the synergy between next-generation Pharmaceutical Quality Systems (PQS) and the principles of CMMI. Attendees will learn to implement CMMI's structured, process-improvement framework to achieve higher maturity levels, specifically focusing on process areas critical to pharmaceutical operations such as Process Performance, Measurement and Analysis, and Quantitative Project Management. By mastering both the collection of leading and lagging indicators and the application of maturity models, participants will gain the expertise required to drive a culture of Right First Time (RFT), significantly mitigate the risk of drug shortages, and ultimately enhance patient safety and product efficacy in an increasingly complex and globalized regulatory landscape.

Programme Curriculum

Advanced Quality Metrics and CMMI in Pharma Training Course

Introduction

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Course Duration

10 days

Course Objectives

Upon completion of this course, participants will be able to:

1. Strategically design a modern Pharmaceutical Quality System (PQS) aligned with ICH Q10 and the FDA's Quality Management Maturity framework.
2. Define and implement a core set of Advanced Quality Metrics (AQM), differentiating between leading and lagging indicators.
3. Apply CMMI Level 4 principles to establish statistical process control and predictive quality monitoring.
4. Conduct rigorous data governance and ensure ALCOA+ principles are upheld across all quality data systems.
5. Calculate and utilize key metrics like Right First Time (RFT), Batch Acceptance Rate, and Invalidated OOS Rate for process stabilization.
6. Implement effective CAPA systems and measure CAPA Effectiveness Ratios as critical PQS performance indicators.
7. Structure and execute a CMMI-based SCAMPI Appraisal readiness assessment for quality process areas.
8. Leverage big data and process mining techniques to identify hidden bottlenecks and cost of poor quality (CoPQ) contributors.
9. Develop a risk-based inspection strategy using quality metrics to enhance regulator trust and achieve Audit Efficiency.
10. Align supplier quality metrics with internal QMS standards to ensure Supply Chain Resilience and mitigate material risk.
11. Drive organizational change to foster a Quality Culture as measured by behavioral and process maturity metrics.
12. Master Quantitative Project Management (QPM) techniques for predictable execution of complex manufacturing and process improvements.

13. Benchmark organizational performance against industry leaders to attain Operational Excellence and CMMI Optimizing practices.

Target Audience

1. Quality Assurance (QA) & Quality Control (QC) Professionals.
2. Manufacturing & Operations Managers.
3. Process Improvement Specialists.
4. C-Suite & Senior Leadership.
5. IT & Data Scientists in Pharma.
6. Regulatory Affairs & Compliance Officers
7. R&D and Technical Transfer Teams.
8. Supplier Quality Management (SQM) Personnel.

Course Modules

Module 1: The Quality Management Maturity (QMM) Imperative

- Evolution of Pharma Quality.
- The ICH Q10 Model and its integration with PQS.
- The FDA's Quality Metrics Initiative.
- Defining Quality Culture and its measurable characteristics.
- Case Study: Analyzing the financial impact of a QMM program on reduced warning letters.

Module 2: Fundamentals of Advanced Quality Metrics (AQM)

- Differentiating between Lagging and Leading Metrics.
- Categorizing metrics.
- Establishing Metric Ownership and Accountability.
- Introduction to Metric Hierarchies and Dashboards.
- Case Study: Developing a dashboard for Lot Acceptance Rate and its leading indicators.

Module 3: Metrics for Manufacturing Process Performance

- Calculating and interpreting Right First Time and Right in Batch.
- Measuring Yield, Throughput, and Cycle Time efficiency metrics.
- Understanding and mitigating Batch Failure Rate root causes.
- Using process metrics for capacity planning and scheduling adherence.
- Case Study: A generics manufacturer uses RFT data to justify an investment in automated equipment.

Module 4: Metrics for Laboratory & Quality System Effectiveness

- Tracking the Invalidated Out-of-Specification Rate and its investigation cycle time.
- Measuring QC Lab On-Time Completion Rate and resource utilization.
- Evaluating the effectiveness of Change Control and its associated risk.
- Metrics for Training Compliance and competency assessment.
- Case Study: Reducing Invalidated OOS results through CMMI-guided instrument calibration process improvement.

Module 5: Metrics for Post-Market Surveillance & Patient Safety

- The critical role of the Product Quality Complaint Rate.

- Metrics for Complaint Resolution Cycle Time and effectiveness.
- Analyzing Recall Frequency and their classification impact.
- Tracking Adverse Event (AE) reporting timeliness and data quality.
- Case Study: Linking a rise in customer complaints to a change in packaging vendor via metrics analysis.

Module 6: Introduction to CMMI for Process Improvement

- CMMI V2.0 Overview.
- The Staged vs. Continuous Representation of CMMI.
- The CMMI Maturity Levels and their meaning for a PQS.
- Key CMMI Process Areas for Quality and R&D.
- Case Study: Mapping a company?ÇÖs existing QMS to CMMI Level 2

Module 7: CMMI Level 3: Defining the Standard Process

- Organizational Process Definition.
- Standardizing skill and competency development.
- Integrated Project Management.
- Importance of a central Organizational Process Asset Library.
- Case Study: Developing a standardized, integrated CAPA process (GG3) across all manufacturing sites.

Module 8: CMMI Level 4: Quantitative Management

- Introduction to Quantitative Project Management (QPM).
- Defining Process Performance Objectives (PPOs) and baselines.
- Statistical Process Control (SPC) and Control Charting for process stability.
- Process Capability Measurement and Indices
- Case Study: Using SPC charts on critical process parameters (CPPs) to achieve Level 4 predictability.

Module 9: CMMI Level 5: Optimization and Innovation

- Organizational Performance Management.
- Causal Analysis and Resolution.
- Fostering a culture of Continuous Improvement and process innovation.
- Implementing incremental and revolutionary process improvements.
- Case Study: A biologics company uses CAR to eliminate a recurring microbial contamination source.

Module 10: Data Governance and Data Integrity (ALCOA+)

- The ALCOA+ Principles
- Establishing a Data Governance Framework for quality metrics.
- Auditing data sources for reliability and completeness.
- Validation of computerized systems (CSV) used for data collection and analysis.
- Case Study: An inspection finding due to poor audit trail review is resolved by implementing a new data integrity policy.

Module 11: Quantitative Management of CAPA and Deviation Systems

- Applying QPM to the entire CAPA Life Cycle
- Measuring and improving the CAPA Closure Cycle Time.
- Advanced techniques for determining and verifying CAPA Effectiveness.
- Using statistical data to prioritize high-risk deviations for immediate Causal Analysis.

- Case Study: Implementing a statistical model to predict the probability of CAPA recurrence based on initial investigation quality.

Module 12: Supply Chain Quality Metrics and Vendor Oversight

- Developing metrics for Supplier Quality Management
- Auditing and monitoring Contract Manufacturing Organizations with CMMI principles.
- Risk-ranking vendors based on their quality metrics and regulatory history.
- Ensuring Material Traceability and its impact on final product metrics.
- Case Study: Using a "Supplier Scorecard" to transition a high-risk material supplier to a more mature status.

Module 13: Audit Strategy and Regulatory Engagement

- Preparing for the SCAMPI Appraisal
- Using quality metrics data to proactively inform regulatory bodies
- Aligning quality metrics with international regulatory requirements
- Developing a Risk-Based Inspection playbook informed by QMM status.
- Case Study: Presenting a metrics package to the FDA that results in a reduced-scope surveillance inspection.

Module 14: Tools and Technology for AQM and CMMI

- Overview of QMS Software and integrated platforms
- Introduction to Process Mining and its application in PQS process discovery.
- Leveraging AI/Machine Learning for anomaly detection and predictive maintenance.
- Implementing digital quality platforms for real-time data visualization.
- Case Study: Implementing a digital control tower to visualize RFT in real-time across multiple global sites.

Module 15: Driving Continuous Improvement & Future Trends

- The concept of Continuous Compliance through automated monitoring.
- Integrating Lean Six Sigma methodologies with the CMMI optimization level.
- Personalized Medicine and decentralized manufacturing quality.
- Creating an Organizational Improvement Infrastructure
- Case Study: Designing a strategy to move from CMMI Level 4 to Level 5 maturity within three years.

Training Methodology

The course employs an immersive, practical, and blended learning approach to maximize knowledge transfer and skill application:

- Interactive Lectures & Discussions.
- Hands-on Workshops.
- Real-World Case Studies.
- CMMI Appraisal Simulation.
- Tools & Templates.

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
21 Sep 2026	02 Oct 2026	Online	$2,000
21 Sep 2026	02 Oct 2026	Physical	$3,000
21 Sep 2026	02 Oct 2026	Physical	$0
21 Sep 2026	02 Oct 2026	Physical	$0
21 Sep 2026	02 Oct 2026	Physical	$0
21 Sep 2026	02 Oct 2026	Physical	$0
21 Sep 2026	02 Oct 2026	Physical	$0
21 Sep 2026	02 Oct 2026	Physical	$0

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