Advanced Quality Culture and Human Factors in GMP 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

Advanced Quality Culture and Human Factors are the next frontier in Good Manufacturing Practice (GMP) compliance, moving organizations beyond mere rule-following to a state of proactive quality excellence. The industry recognizes that over 80% of deviations and regulatory non-compliance stem from human error, a problem that traditional SOP-driven training fails to adequately address. Advanced Quality Culture and Human Factors in GMP Training Course provides an essential, in-depth exploration of the psychological, systemic, and environmental determinants of human performance in highly regulated environments. It introduces behavioral science principles and organizational change management strategies to transition a reactive, blame-centric environment into a just and learning culture where quality is an intrinsic organizational value rather than an external mandate.

This program goes beyond basic GMP refreshers, focusing on sustainable compliance and risk reduction through the application of Human Organizational Performance (HOP) and Quality by Design (QbD) principles. Participants will gain advanced skills to investigate deviations using a systems-thinking approach, implement effective Corrective and Preventive Actions (CAPA), and act as Quality Champions to drive a measurable and enduring cultural shift. By mastering the intersection of human behavior and robust quality systems, organizations can achieve a tangible reduction in errors, enhance data integrity, improve audit readiness, and ultimately safeguard patient safety the core mission of the pharmaceutical and biotech sectors.

Programme Curriculum

Advanced Quality Culture and Human Factors in GMP Training Course

Introduction

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10 days

Course Objectives

1. Systematically Identify and Mitigate Human Error in critical GMP processes.
2. Differentiate between Human Factors (HF) and Human Error for effective root cause analysis (RCA).
3. Analyze the Organizational and Systemic Factors that influence employee behavior and compliance.
4. Implement a Just Culture framework to encourage open reporting and non-punitive learning.
5. Apply Behavioral Science models to design error-proof procedures and training.
6. Develop and Measure Quality Culture metrics
7. Drive Continuous Improvement (CI) by integrating Human Factors into CAPA and Change Management systems.
8. Master Advanced Deviation Investigation techniques focusing on System-Level Root Causes.
9. Design Effective GMP Training using Adult Learning Principles and Instructional Design best practices.
10. Evaluate the impact of Leadership Behavior on Quality Mindset and Accountability.
11. Apply Human Factors principles to Facility/Equipment Design and SOP Simplification.
12. Integrate Data Integrity and ALCOA+ principles with a human-centric approach.
13. Benchmark internal Quality Culture against Industry Best Practices and Regulatory Expectations

Target Audience

1. Quality Assurance (QA) & Quality Control (QC) Professionals
2. Manufacturing & Operations Managers/Supervisors
3. Training & Organizational Development Specialists
4. GMP Auditors and Compliance/Regulatory Affairs Personnel
5. Deviation, CAPA, and Investigation Specialists
6. Senior Leadership/Executives
7. Engineers involved in process, equipment, and facility design
8. Document/System Control Personnel and SOP Authors

Course Modules

Module 1: The Modern Regulatory Imperative for Quality Culture (QC)

- The evolution of GMP.
- FDA's Case for Quality initiative and EMA/PIC/S emphasis on organizational maturity.
- Defining and assessing Quality Culture Maturity within a pharmaceutical context.
- Linking QC directly to Patient Safety and product quality risk management.
- Case Study: Regulatory Warning Letters analysis revealing systemic QC failures leading to compliance action.

Module 2: Fundamentals of Human Factors (HF) in GMP

- Distinguishing Human Factors from the simplistic label of "human error."
- Introduction to the Swiss Cheese Model and defenses-in-depth for error prevention.
- Categorizing human error.
- The role of Cognitive Load and attention in critical manufacturing tasks.
- Case Study: Analysis of a high-profile medication mix-up traced back to poor label design

Module 3: Implementing a Just Culture

- Principles of Just Culture.
- Establishing Psychological Safety to enable open reporting of errors and deviations.
- Designing an effective, non-punitive Error Reporting System and investigation triage.
- Training investigators and management on the Blame-Free Interview technique.
- Case Study: Transforming a punitive QA environment to a Learning Organization using a Just Culture roadmap.

Module 4: Advanced Deviation and Human Error Root Cause Analysis (RCA)

- Moving beyond "lack of training" to find System-Level Root Causes.
- Utilizing Fishbone and 5-Why with a Human Factors lens.
- Applying the System Engineering Initiative for Patient Safety Model to investigations.
- Identifying latent failures in process, environment, and organizational structure.
- Case Study: Deep dive into a batch contamination event where the RCA exposed flaws in shift handover and communication protocols.

Module 5: Human Factors in Procedure Design (SOPs)

- Principles of Procedural Compliance.
- Applying Instructional Design to create visual, task-supportive SOPs.
- Techniques for reducing Cognitive Load and eliminating ambiguity in instructions.
- Integrating Human Performance Tools (HPTs) into procedures
- Case Study: Before-and-after analysis of a complex weigh-and-dispense SOP showing error reduction after HF-based redesign.

Module 6: Behavioral Science for Quality Improvement

- Introduction to behavioral models for sustained change.
- Using Behavioral Nudges to guide employees toward the desired quality behavior.
- The power of Feedback Loops and real-time data visualization to influence actions.
- Designing Intrinsic Motivation into quality tasks instead of relying solely on extrinsic rewards.

- Case Study: Implementing a digital documentation system that "nudges" operators to complete checks accurately and on time.

Module 7: Leadership's Role in Shaping Quality Culture

- Defining and demonstrating Quality Leadership Behaviors
- Techniques for Go-to-Gemba and Management Walk-arounds with a Quality focus.
- Aligning executive strategy, metrics, and resource allocation to support quality.
- The critical role of middle management as the cultural translators of executive vision.
- Case Study: Transformation led by a new CEO/VP of Quality to visibly champion the quality culture change initiative.

Module 8: Human Factors in Equipment and Facility Design

- Applying HF principles to the User Interface (UI) and User Experience (UX) of manufacturing equipment.
- Designing physical workspaces to minimize fatigue and maximize visibility.
- Minimizing opportunities for cross-contamination and material mix-ups through layout and flow.
- Ergonomic considerations to reduce physical strain and procedural variance.
- Case Study: Re-designing a vial filling line workspace after an investigation revealed frequent posture-related procedural deviations.

Module 9: Advanced Training Program Design & Effectiveness

- Moving from "Check-the-Box" compliance training to Competency-Based Training.
- Applying Adult Learning Principles to GMP topics.
- Developing and validating On-the-Job Training (OJT) to ensure real-world skill transfer.
- Measuring Training Effectiveness beyond the test score
- Case Study: Designing a simulated cleanroom scenario training to test operator response to an unplanned deviation.

Module 10: Human Factors in Data Integrity (DI)

- The human-centric challenges of achieving and sustaining Data Integrity in paper and electronic systems.
- Applying Human Factors to ensure ALCOA+ principles are easy to follow
- Designing systems and procedures to prevent unintended data omission and retrospective documentation.
- Strategies for training employees on the why behind Audit Trails and electronic signatures.
- Case Study: Investigation of data omission in a QC lab, tracing the root cause back to an overly complex logbook design and time pressure.

Module 11: Human Factors in CAPA and Change Management

- Designing Corrective Actions that address Human Factor Root Causes and are sustainable.
- Applying the Hierarchy of Controls to CAPAs
- Integrating Human Factors principles into the Change Management process to predict and mitigate user resistance.
- Assessing CAPA Effectiveness with a focus on post-implementation behavioral sustainment.
- Case Study: Review of an ineffective CAPA for a repeated cleaning error that failed because it only addressed procedure and not the equipment interface.

Module 12: Measuring and Benchmarking Quality Culture

- Developing meaningful, Leading Quality Indicators for culture assessment
- Conducting Quality Culture Surveys and focus groups to gather quantitative and qualitative data.
- Benchmarking internal performance against industry standards and peer groups.
- Using data visualization and storytelling to communicate cultural insights to all levels.
- Case Study: Utilizing a Cultural Maturity Model to track a company's year-over-year progress in its quality journey.

Module 13: The Psychology of Compliance and Risk Perception

- Understanding the cognitive biases that lead to non-compliance
- The impact of organizational pressure on employee decision-making and risk-taking.
- Strategies for fostering a culture where risk communication is transparent and effective.
- Techniques for challenging Normalization of Deviance and promoting vigilance.
- Case Study: Analyzing a deviation that resulted from a long-standing, uncorrected workaround driven by production targets.

Module 14: Integrating Human Factors into Supplier and Contract Manufacturing Oversight

- Assessing the Quality Culture and Human Factors program maturity of Contract Manufacturing Organizations and suppliers.
- Developing Quality Agreements that specifically address Human Factors and Training requirements.
- Techniques for auditing a partner's Deviation Investigation and RCA capabilities.
- Harmonizing SOPs and Communication Protocols to minimize human error at the interface.
- Case Study: Investigating a raw material quality issue that traced back to the supplier's poor warehouse documentation and a lack of Just Culture.

Module 15: Developing a Sustainable Quality Culture Action Plan

- Conducting a GAP Analysis of the organization's current quality culture maturity.
- Developing a 3-Year Cultural Transformation Roadmap with milestones and ownership.
- Creating a Communication Strategy for sustained cultural change and employee buy-in.
- Establishing a Quality Culture Governance Team and Quality Champions Network.
- Case Study: Participants developing their own company's 90-day Quality Culture Implementation Plan based on course learnings.

Training Methodology

The course employs an Advanced, Interactive, and Applied Learning methodology:

- Case Study Driven.
- Interactive Workshops.
- Simulations & Role-Playing.
- Tools & Templates.
- Expert-Led Discussions.
- Action Planning.

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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