Advanced Risk Assessment in Biopharma Auditing 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 global biopharmaceutical landscape is experiencing unprecedented complexity, driven by the rise of Advanced Therapy Medicinal Products, decentralized clinical trials, and the ubiquitous presence of digital transformation. Traditional, checklist-based auditing methodologies are no longer sufficient to manage the inherent, escalating risks associated with global supply chains, intricate manufacturing processes, and critical Data Integrity (DI) vulnerabilities. This advanced course shifts the focus from reactive compliance to proactive, science- and risk-based quality management as mandated by global guidelines like ICH Q9 (R1). Attendees will master sophisticated analytical tools like Failure Mode and Effects Analysis (FMEA) and Hazard and Operability Study (HAZOP), translating theoretical risk models into actionable, resilient GxP systems that safeguard product quality and patient safety.

Advanced Risk Assessment in Biopharma Auditing Training Course is specifically designed for seasoned quality and audit professionals seeking to elevate their strategic influence by aligning the audit function with the Enterprise Risk Management (ERM) framework. The curriculum integrates the latest FDA 483 and EMA inspection trends, focusing on areas such as Computer System Validation (CSV), the Pharmaceutical Quality System (PQS), and auditing the culture of quality. By adopting an advanced, data-driven approach, participants will be able to develop multi-year, risk-prioritized audit plans, significantly reduce the likelihood of critical regulatory non-conformance, and demonstrate a measurable contribution to operational excellence and patient-centric outcomes.

Programme Curriculum

Advanced Risk Assessment in Biopharma Auditing Training Course

Introduction

The global biopharmaceutical landscape is experiencing unprecedented complexity, driven by the rise of Advanced Therapy Medicinal Products, decentralized clinical trials, and the ubiquitous presence of digital transformation. Traditional, checklist-based auditing methodologies are no longer sufficient to manage the inherent, escalating risks associated with global supply chains, intricate manufacturing processes, and critical Data Integrity (DI) vulnerabilities. This advanced course shifts the focus from reactive compliance to proactive, science- and risk-based quality management as mandated by global guidelines like ICH Q9 (R1). Attendees will master sophisticated analytical tools like Failure Mode and Effects Analysis (FMEA) and Hazard and Operability Study (HAZOP), translating theoretical risk models into actionable, resilient GxP systems that safeguard product quality and patient safety.

Advanced Risk Assessment in Biopharma Auditing Training Course is specifically designed for seasoned quality and audit professionals seeking to elevate their strategic influence by aligning the audit function with the Enterprise Risk Management (ERM) framework. The curriculum integrates the latest FDA 483 and EMA inspection trends, focusing on areas such as Computer System Validation (CSV), the Pharmaceutical Quality System (PQS), and auditing the culture of quality. By adopting an advanced, data-driven approach, participants will be able to develop multi-year, risk-prioritized audit plans, significantly reduce the likelihood of critical regulatory non-conformance, and demonstrate a measurable contribution to operational excellence and patient-centric outcomes.

Course Duration

10 days

Course Objectives

1. Master the application of the updated ICH Q9 (R1) Quality Risk Management principles across the entire product lifecycle.
2. Design and implement a comprehensive Risk-Based Audit Plan that aligns with the organization's Enterprise Risk Management (ERM) strategy.
3. Evaluate and apply Quantitative and Qualitative Risk Scoring Models for effective audit prioritization and resource allocation.
4. Execute advanced Failure Mode and Effects Analysis specifically tailored for complex bioprocesses and manufacturing systems.
5. Conduct Hazard and Operability Studies (HAZOP) for high-risk areas like utility systems, aseptic processing, and cleanroom environments.
6. Audit for compliance with the latest FDA Data Integrity (DI) guidance and ALCOA+ principles in computerized GxP systems
7. Identify and assess unique process and compliance risks within Advanced Therapy Medicinal Products (ATMPs) and biologics manufacturing.
8. Develop robust auditing protocols for Supply Chain Resilience and third-party vendor risk management.
9. Translate current Regulatory Intelligence (FDA/EMA) into actionable audit focus areas and inspection readiness strategies.
10. Assess and audit the Culture of Quality and Human Factors risks driving non-compliance and recurring deviations.
11. Formulate comprehensive, risk-driven Corrective and Preventive Action (CAPA) plans with verifiable effectiveness checks.
12. Leverage Audit Data Analytics and Key Risk Indicators (KRIs) for continuous monitoring and proactive risk signal detection.

13. Apply the Phased and Lifecycle Approach to risk assessment in Computer System Validation (CSV) and GxP IT infrastructure.

Target Audience

1. Senior GxP Auditors and Lead Auditors
2. Quality Assurance (QA) Managers and Directors.
3. Regulatory Affairs Professionals
4. Quality Risk Management (QRM) Specialists and Process Excellence Leaders.
5. Validation and IT Compliance Managers.
6. Heads of Manufacturing and Technical Operations.
7. Clinical Quality Assurance (CQA) and Pharmacovigilance (PV) Auditors.
8. Enterprise Risk Management (ERM) and Internal Audit Directors in biopharma companies.

Course Modules

Module 1: The Strategic Shift

- Differentiating Advanced Risk Assessment from basic QRM application.
- Integrating the ICH Q9 (R1) Principles into the audit philosophy.
- Aligning the Audit Universe with the Enterprise Risk Management (ERM) framework.
- Developing a Multi-Year Risk-Based Audit Plan using a comprehensive risk-ranking matrix.
- Case Study: Prioritizing a global audit schedule for a top-tier biopharma firm based on recent EMA/FDA non-conformance data and internal KRI trends.

Module 2: Auditable Universe Segmentation and Quantitative Risk Scoring

- Techniques for defining and segmenting the complex biopharma Auditable Universe
- Applying Quantitative Risk Scoring Models for audit frequency determination.
- Mapping Critical Quality Attributes and Key Quality Indicators (KQIs) to audit focus areas.
- The role of audit history, regulatory status, and product criticality in risk weighting.
- Case Study: Creating a weighted risk score for a single-site manufacturer with both legacy small molecule and new cell therapy production lines.

Module 3: Deep Dive into Advanced Risk Assessment Tool: FMEA/FMECA

- Mastering the application of Failure Mode and Effects Analysis for biopharmaceutical processes.
- Calculating the Risk Priority Number and justifying when to use FMECA
- Best practices for cross-functional team formation and accurate estimation of Occurrence and Detection scores.
- Techniques for auditing the rigor and completeness of the sponsor's FMEA documentation.
- Case Study: Performing an FMEA on a Cell Culture Bioreactor System to mitigate the risk of microbial contamination and identify critical control points.

Module 4: Process Hazard Analysis: Hazard and Operability Study (HAZOP)

- Understanding the structured, systematic approach of HAZOP for process design and complex GxP systems.
- Application of Guide Words to deviations in utility and cleanroom systems.
- Auditing the implementation and effectiveness of controls identified through a HAZOP.
- Integrating HAZOP findings into the design and qualification phases

- Case Study: A HAZOP study on a Cleanroom HVAC System to assess the risk of non-viable particle ingress and cross-contamination in an aseptic fill-finish area.

Module 5: Auditing Data Integrity (DI) in GxP Computerized Systems

- Regulatory expectations for DI.
- Developing DI Audit Checklists focused on ALCOA+ principles in QC labs and Manufacturing Execution Systems (MES).
- Techniques for forensic-style auditing to uncover potential data manipulation and security breaches.
- Auditing the lifecycle of Computer System Validation (CSV) and the management of audit trails.
- Case Study: Auditing a Chromatography Data System (CDS) in a Quality Control lab to identify and assess risks related to unreviewed audit trails and system access controls.

Module 6: Risk in Biologics and ATMPs Auditing

- Unique process risks in Biologics and Advanced Therapy Medicinal Products.
- Auditing Aseptic Processing, Sterility Assurance, and the use of isolator/RABS technology
- Risk assessment for Cold Chain Management and product stability during storage and distribution.
- Phase-appropriate auditing for clinical versus commercial manufacturing and supply.
- Case Study: Assessing the risk of contamination and mislabeling during the scale-up and transfer of a Cell Therapy Product from a clinical lab to a commercial manufacturing suite.

Module 7: Supply Chain Resilience and Third-Party Vendor Audits

- Risk-based vendor qualification.
- Developing protocols for remote and focused Contract Manufacturing Organization (CMO) and Contract Research Organization (CRO) audits.
- Auditing the effectiveness of vendor oversight programs and quality agreements.
- Assessing the vulnerability of the global supply chain
- Case Study: Auditing a critical raw material supplier in a high-risk region following a natural disaster to assess their business continuity plan (BCP) and supply resilience.

Module 8: Auditing Regulatory Inspection Readiness and Response

- Using risk assessment to conduct Mock Inspections and identify critical inspection gaps
- Auditing the effectiveness of the Inspection Management Process
- Techniques for assessing the quality and speed of the Regulatory Submission process
- Risk scoring potential inspectional findings and developing rapid, comprehensive Remediation Plans.
- Case Study: Developing a detailed, risk-prioritized CAPA and response strategy following a critical FDA 483 observation related to inadequate OOS (Out-of-Specification) Investigations.

Module 9: Advanced Audit Interviewing and Behavioral Auditing

- Techniques for advanced interviewing to identify intentional and systemic deficiencies, not just errors.
- Behavioral Auditing: Auditing the impact of Organizational Culture on quality and compliance.
- Identifying and auditing Human Factors risks in high-stress manufacturing and laboratory environments.
- Auditing the effectiveness of the training, competency, and "Speak-Up" Culture.
- Case Study: Investigating a series of seemingly unrelated Human Error deviations to identify a systemic Culture Risk driven by unmanaged production pressure.

Module 10: Corrective and Preventive Action (CAPA) System Audits

- Advanced techniques for auditing Root Cause Analysis (RCA) methodologies to ensure depth.
- Auditing the rigor and effectiveness of CAPA Effectiveness Checks (EUCs) a frequent regulatory focus.
- Distinguishing between reactive Correction and true, systemic Preventive Action.
- Auditing the overall CAPA backlog and prioritization based on risk to product quality.
- Case Study: Auditing the CAPA system following a Repeat Deviation to determine if the true root cause was ever identified and eliminated, or if the CAPA was a "false closure."

Module 11: Auditing the Pharmaceutical Quality System (PQS) Maturity

- Frameworks for assessing PQS Maturity
- Auditing the effectiveness of Management Review and the commitment of senior leadership to quality.
- Assessing the control over quality documentation, change control, and deviation management processes.
- Techniques for auditing Quality Metrics and their use in risk-based decision-making.
- Case Study: Conducting a comprehensive PQS audit for a company moving from a startup/clinical phase to commercial production, focusing on scale-up risks.

Module 12: Advanced Auditing of Pharmacovigilance (PV) and GCP Systems

- Applying QRM to Good Clinical Practice) and GVP (Good Pharmacovigilance Practice) auditing.
- Auditing the accuracy of Safety Signal Detection and the completeness of Risk Management Plans
- Focusing on source data verification and the auditing of Electronic Health Records (EHRs) in decentralized trials.
- Assessing the vendor oversight of Contract Research Organizations (CROs) for data handling and reporting.
- Case Study: Auditing a CRO for non-compliance with GCP/GVP that resulted in questionable source data and delayed serious adverse event (SAE) reporting.

Module 13: Continuous Monitoring and Audit Data Analytics

- Implementing and utilizing Key Risk Indicators (KRIs) and Key Performance Indicators (KPIs) for continuous assurance.
- Introduction to Audit Data Analytics (ADA) for identifying anomalies and emerging trends in GxP data.
- Leveraging technology in the audit process to shift from periodic to continuous auditing.
- Techniques for effective visualization and reporting of audit results and risk posture to the Board/Executive Management.
- Case Study: Analyzing 24 months of deviation and CAPA data using basic analytics to predict the next three high-risk areas for a follow-up, focused audit.

Module 14: Auditing IT Governance and Cybersecurity Risk

- Auditing the IT Governance framework and its alignment with GxP requirements.
- Assessing Cybersecurity Risks related to loss of GxP data integrity and system availability.
- Auditing cloud-based GxP systems and the management of SaaS vendor quality agreements.
- Focusing on disaster recovery, business continuity, and data backup/archiving controls.
- Case Study: Auditing the disaster recovery plan for an Electronic Batch Record (EBR) system after a simulated ransomware attack to test data restoration integrity.

Module 15: Future Trends

- Auditing the use of Artificial Intelligence (AI) and Machine Learning (ML) in drug discovery, clinical trials, and manufacturing quality control.
- Assessing the risks of Real-World Evidence (RWE) integration and its impact on post-market surveillance.
- Techniques for proactive regulatory engagement and the benefits of continuous manufacturing auditing.
- The auditor's role in driving the adoption of new technologies while maintaining compliance.
- Case Study: Evaluating the risk management plan for a new automated inspection system using AI for visual defect detection.

Training Methodology

The course employs an Advanced Blended Learning approach, focused heavily on practical application and decision-making for senior professionals:

1. Risk Simulation & Scenario-Based Learning.
2. Interactive Workshops.
3. Expert-Led Discussions
4. Practical Toolkits.
5. Competency Assessment.

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

Ready to enroll or request a customized program? Book online or contact us:

Register Online Now

Email: info@fineskilltrainingcenter.com | Website: www.fineskilltrainingcenter.com