Advanced Quality Assurance in the Blood and Tissue Industry 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 blood and tissue industry operates under an unprecedented scrutiny and faces rapidly evolving regulatory landscapes, making expert-level Quality Assurance (QA) leadership non-negotiable for patient safety and product efficacy. This advanced training course moves beyond foundational GxP compliance, focusing instead on cutting-edge strategies for Quality Management Systems (QMS), Data Integrity, and Biovigilance. Professionals will master the implementation of a Risk-Based Quality Management (RBQM) framework and navigate complex international regulations such as FDA 21 CFR Part 1271, EU Tissues and Cells Directives, and AABB Standards. Participants will learn to leverage modern Quality by Design (QbD) principles and advanced root cause analysis (RCA) techniques to drive operational excellence and ensure a state of continuous inspection readiness in this rapidly digitizing sector.

Advanced Quality Assurance in the Blood and Tissue Industry Training Course is engineered for QA and Regulatory Affairs leaders seeking to solidify their expertise in the unique challenges of Human Cell, Tissue, and Cellular and Tissue-Based Product (HCT/P) and blood product manufacturing. We delve into advanced topics such as aseptic processing validation, supply chain risk mitigation, and the strategic use of digital quality tools and AI-driven automation. A core emphasis is placed on proactive non-conformance management, developing robust audit strategies, and fostering a sustainable Quality Culture enterprise-wide. Graduates will be prepared to lead their organizations to the forefront of quality and compliance, ensuring an uncompromised blood and tissue supply chain safety in a world where regenerative medicine and Advanced Therapy Medicinal Products (ATMPs) are setting new industry benchmarks.

Programme Curriculum

Advanced Quality Assurance in the Blood and Tissue Industry Training Course

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10 days

Course Objectives

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

1. Interpret and apply FDA (21 CFR Part 1271), EU Tissues and Cells Directives, AABB, and AATB Standards for advanced QA.
2. Design, implement, and optimize a Risk-Based Quality Management System across the entire product lifecycle
3. Develop and maintain a robust Data Governance framework compliant with ALCOA+ principles for electronic records and laboratory systems.
4. Establish and manage effective Hemovigilance and Tissue Vigilance systems, including mandatory Serious Adverse Event/Reaction reporting.
5. Plan and execute Risk-Informed Audits focusing on high-risk processes like sterile aseptic processing and cryopreservation.
6. Utilize advanced Root Cause Analysis (RCA) methodologies to implement Corrective and Preventive Actions (CAPA) with demonstrably effective closures.
7. Manage complex validation protocols for critical equipment, automated systems, and specialized processes like pathogen reduction and cryopreservation.
8. Assess and manage Global Supply Chain risks, particularly for novel materials, transportation logistics, and third-party contract services.
9. Integrate quality requirements for Advanced Therapy Medicinal Products (ATMPs), including Cell and Gene Therapy starting materials, into the existing QMS.
10. Oversee the QA review and final disposition of Complex Donor Eligibility Determination records, minimizing risk of Transfusion/Transplantation-Transmitted Infection (TTI).

11. Develop and execute strategies to foster a proactive, human-factors-aware Quality Culture throughout the organization.
12. Design an efficient, electronic Document Management System (DMS) that supports rapid search, revision control, and inspection readiness.
13. Strategically manage complex deviations, recalls, and quarantines to ensure regulatory notification and minimize patient impact.

Target Audience

1. Quality Assurance/Control Managers.
2. Regulatory Affairs Specialists.
3. Laboratory Directors & Technical Supervisors
4. R&D and Process Development Scientists.
5. Biovigilance & Haemovigilance Officers.
6. Internal & Supplier Auditors.
7. Compliance and Inspection Readiness Teams
8. Hospital Transfusion Service Managers.

Course Modules

Module 1: Advanced Regulatory Frameworks and Harmonization

- Deep dive into 21 CFR Part 1271 and EU Tissues and Cells Directives
- Integrating AABB, AATB, and FACT accreditation standards into the QMS.
- Understanding the QA implications of Good Distribution Practice for blood and tissue products.
- Strategy for navigating conflicts between domestic and international regulations
- Case Study: Analyzing a recent cross-border product recall due to a discrepancy between FDA and EMA QA standards.

Module 2: Risk-Based Quality Management (RBQM) Implementation

- Applying ICH Q9 Quality Risk Management principles to blood and tissue banking.
- Using tools like Failure Mode and Effects Analysis to identify high-risk processes
- Developing a Risk-Prioritized Audit Schedule and resource allocation strategy.
- Establishing Acceptable Risk Thresholds for TTI and product contamination.
- Case Study: Implementing an FMEA for a new automated TTI testing platform to mitigate critical risks before go-live.

Module 3: Advanced Quality Systems and Quality Metrics

- Structuring the QMS to meet both compliance and operational efficiency goals
- Developing, tracking, and trending meaningful Quality Metrics beyond basic counts
- The role of Management Review in driving QMS improvements and resource allocation.
- Managing Change Control for critical systems, processes, and validated equipment.
- Case Study: Using a dashboard of key quality metrics to demonstrate an 18-month trend of increasing CAPA effectiveness to senior management.

Module 4: Data Integrity and Governance

- Implementing ALCOA+ principles for all paper and electronic records
- Validating Computerized Systems and managing access control/audit trails in accordance with 21 CFR Part 11.

- Strategies for preventing and detecting data manipulation or falsification.
- Ensuring archival, retrieval, and retention of long-term product and donor records.
- Case Study: Addressing an FDA 483 on insufficient audit trail review for a critical component tracking software.

Module 5: Donor Eligibility and Complex Determination QA

- QA oversight of Donor Screening Protocols for high-risk infectious disease markers.
- Review and final disposition QA for complex donor eligibility scenarios
- Managing look-back procedures and counselling donors with positive TTI results.
- Developing SOPs for autologous and directed donations with specialized QA requirements.
- Case Study: Managing the QA response and required regulatory reporting following a confirmed transfusion-transmitted infection event.

Module 6: Aseptic Processing and Environmental Monitoring QA

- QA requirements for Cleanroom Classification and operation
- Designing and reviewing the Environmental Monitoring Program
- QA oversight of Aseptic Technique validation and staff qualification/re-qualification.
- Investigating Aseptic Processing Deviations and implementing root cause corrections.
- Case Study: Developing an EM program and associated alert/action limits for a new cord blood processing facility.

Module 7: Validation Master Plan and Critical Process Validation

- Developing a Validation Master Plan that includes all critical equipment and processes.
- Advanced QA review of IQ/OQ/PQ protocols.
- Validation of specialized processes
- Managing Revalidation schedules and the impact of changes via Change Control.
- Case Study: Drafting a PQ protocol to demonstrate the consistent quality of a new closed-system cryopreservation device.

Module 8: Corrective and Preventive Action (CAPA) Program Leadership

- Distinguishing between Root Cause Analysis and simple fix/band-aid.
- Advanced RCA techniques.
- Implementing Effectiveness Checks and metrics to prove the CAPA resolution is sustainable.
- The link between CAPA, Audit Findings, and the Change Control system.
- Case Study: Performing an RCA on a recurring labeling error, determining the true root cause was human factors/SOP design, not just operator training.

Module 9: Deviation and Non-Conformance Management

- Categorizing and classifying deviations based on patient/product risk.
- Establishing robust Quarantine, Investigation, and Disposition procedures for non-conforming product.
- QA oversight and final release determination for product impacted by a deviation.
- Timely and accurate Regulatory Notification for critical deviations.
- Case Study: Navigating a critical temperature excursion for a shipment of frozen HCT/Ps, including client notification and final product disposition.

Module 10: Bio vigilance

- Establishing and managing an effective post-market surveillance program.
- Detailed requirements for SAE/SAR reporting to regulatory authorities.
- Utilizing Trend Analysis of adverse events to inform preventative actions in the QMS.
- Implementing the QA role in Look-Back and Withdrawal procedures
- Case Study: Analyzing a cluster of non-fatal transfusion reactions to identify a potential process or material issue upstream in the QMS.

Module 11: Audits, Inspections, and Supplier Qualification

- Planning and executing Risk-Informed Internal Audits of the entire QMS.
- The QA role in Mock Inspections and preparing staff for regulatory interaction.
- Designing an effective Supplier Qualification Program for critical materials and services
- Managing Audit Observations and tracking commitments to closure.
- Case Study: Conducting a qualification audit of a new third-party testing laboratory, identifying critical gaps in their data integrity controls.

Module 12: Quality in Advanced Therapy Medicinal Products

- Applying GxP principles to the manufacture of Cell and Gene Therapy starting materials.
- Specific QA challenges for Autologous and Allogeneic cellular therapies.
- Vector Manufacturing and its quality implications for blood/tissue collection.
- Documentation and traceability for the vein-to-vein and donor-to-recipient chain of custody.
- Case Study: Reviewing the QMS impact of adding a novel, minimally-manipulated cellular product line to an existing blood bank.

Module 13: QA in Product Labelling, Storage, and Distribution

- Compliance with ISBT 128 international standard for blood and tissue labeling.
- QA oversight of Controlled Temperature Storage, including temperature monitoring and alarm systems.
- Validation of the Cold Chain Logistics and packaging for temperature-sensitive products.
- Managing the final Product Release and Distribution process with all required QA checks.
- Case Study: Investigating a series of shipping-related temperature deviations and designing a corrective action plan for the cold chain transport SOP.

Module 14: Quality Culture and Human Factors in QA

- Understanding the role of Human Factors in non-conformance and deviation.
- Strategies for building a Proactive Quality Culture that encourages error reporting.
- Implementing Just Culture principles to promote psychological safety and learning.
- The QA manager's role as a Quality Leader and Coach.
- Case Study: Using a Behavioral Quality Assessment to identify and address underlying cultural factors contributing to procedural drift in the lab.

Module 15: Digital Quality and Future Trends

- Leveraging Laboratory Information Management Systems and Electronic Quality Management Systems for QA efficiency.
- The potential of AI and Machine Learning for predictive quality control and risk modeling.
- Preparing the QMS for the adoption of Bioprinting and Robotics in tissue processing.
- Cybersecurity risks and QA requirements for a highly digitized environment.

- Case Study: Evaluating a new eQMS module for automated CAPA tracking and calculating its impact on overall compliance time.

Training Methodology

This course utilizes an intensive, interactive, and practical methodology to ensure immediate applicability of advanced QA concepts.

- Interactive Workshops.
- Advanced Case Studies.
- Simulations.
- Expert-Led Lectures.
- QMS Tool Development.

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

Start Date	End Date	Location	Price
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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