Advanced Preparation for PAI (Pre-Approval Inspection) 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 successful commercialization of a new drug, biologic, or medical device hinges critically on a positive Pre-Approval Inspection (PAI) by regulatory bodies like the FDA. This high-stakes audit, guided by the FDA ?ÇÖs Compliance Program, scrutinizes a manufacturing facility's cGMP compliance, its readiness for commercial scale, and the data integrity supporting the application. Advanced Preparation for PAI (Pre-Approval Inspection) Training Course moves beyond basic compliance, providing an intensive, cross-functional curriculum focused on strategic leadership and tactical execution to achieve a state of continuous inspection readiness. Participants will master the three core PAI objectives Readiness for Commercial Manufacturing, Conformance to Application, and Data Integrity Audit by analyzing current FDA enforcement trends and utilizing mock audit scenarios to anticipate and remediate potential deficiencies proactively.

This program is specifically designed to transform an organization's inspection preparation from a reactive scramble into a proactive, systemic quality defense. We equip senior professionals and Subject Matter Experts (SMEs) with the skills to effectively manage the entire inspection lifecycle, from a robust gap analysis and CAPA implementation to expert inspection conduct and effective communication with regulatory investigators. The ultimate goal is to safeguard the product's market entry timeline, prevent critical observations like Form 483s or Warning Letters, and demonstrate an exemplary Quality Culture that instills confidence in the integrity and reliability of the manufacturing process and the submitted Chemistry, Manufacturing, and Controls (CMC) data.

Programme Curriculum

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Course Objectives

1. Strategize and implement a Proactive Inspection Readiness program, embedding PAI preparation into daily Quality Management System (QMS) operations.
2. Mastering Commercial Manufacturing Readiness, Conformance to Application, and Data Integrity Audit.
3. Execute Mock FDA Audits with high fidelity, focusing on realistic SME interview simulations and document retrieval drills.
4. Conduct a comprehensive PAI Gap Analysis against the latest FDA Compliance Program 7346.832 and recent enforcement actions.
5. Develop robust CAPA plans with demonstrable Effectiveness Checks for pre-inspection findings.
6. Ensure ALCOA+ principles are uniformly applied and auditable across all electronic and paper-based GxP Documentation.
7. Verify Critical Data Traceability and the complete link between submitted CMC data and source manufacturing/laboratory records.
8. Validate the Scale-Up Process and Process Performance Qualification (PPQ) data to confirm commercial consistency and reliability.
9. Train and empower Front Room/Back Room/War Room teams for seamless Inspection Management and logistics.
10. Defend Laboratory Control Systems, including OOS investigations, Method Validation, and audit trails.
11. Strengthen Change Control and Deviation Management systems to withstand regulatory scrutiny of product lifecycle changes.
12. Anticipate and mitigate high-risk PAI triggers, including First-Time Facility and High-Risk API product types.
13. Foster a measurable Culture of Quality and transparency that builds trust with the regulatory inspectors.

Target Audience

1. Quality Assurance (QA) & Quality Control (QC) Leadership
2. Regulatory Affairs (RA) Professionals responsible for application submissions

3. Manufacturing/Operations Management (Site Heads, Production Managers)
4. Process Development and Validation Scientists
5. Subject Matter Experts (SMEs) who will be interviewed by inspectors
6. Senior Management/Executive Sponsors of the PAI process
7. Document and Training Managers involved in inspection logistics
8. Internal Audit Team Leaders

Course Modules

Module 1: The PAI Mandate and Strategic Planning

- Deep-dive into FDA CPG 7346.832
- Establishing the cross-functional PAI Project Team and governance structure.
- Developing a risk-based PAI readiness timeline
- Case Study: Analysis of a delayed product launch due to missed PAI triggers.
- Defining the scope based on the NDA/BLA/ANDA and facility history.

Module 2: Readiness for Commercial Manufacturing

- Evaluating facility suitability, capacity, and equipment qualification
- Demonstrating control over critical utilities
- Presenting the Process Performance Qualification (PPQ) protocol and final report.
- Case Study: A Form 483 on insufficient cleaning validation for multi-product facilities.
- Supplier Qualification and Material Control integrity.

Module 3: Conformance to Application

- Verifying alignment between the submission's CMC section and site documents
- Auditing Technology Transfer and its impact on commercial process changes.
- Handling post-submission changes and effective Change Control documentation.
- Case Study: Inspection findings relating to unapproved changes between biobatch and commercial process.
- Review of analytical method transfer and site-specific validation.

Module 4: Data Integrity Audit & ALCOA+

- Implementing and auditing ALCOA+ principles across all data streams
- Reviewing computer system validation and Audit Trail security.
- Scrutiny of raw data for pivotal stability and biobatch testing.
- Case Study: Examination of a high-profile Warning Letter citing manipulated chromatography data.
- Policies on data review, archival, and restricted access.

Module 5: Comprehensive Mock Inspection Execution

- Designing the mock PAI scope, agenda, and internal "inspector" profile.
- Conducting high-pressure SME Interview Simulations and coaching.
- Managing the Document Request Log and tracking immediate responses.
- Case Study: Lessons learned from a mock PAI failure.
- Executive debriefing and prioritization of critical findings.

Module 6: Root Cause Analysis and Robust CAPA

- Applying advanced Root Cause Analysis techniques to PAI findings.
- Developing systemic, preventative, and timely Corrective and Preventive Actions
- Establishing meaningful and measurable CAPA Effectiveness Checks.
- Case Study: Review of ineffective CAPAs that led to repeat 483 observations in subsequent inspections.
- Integrating CAPA follow-up into management review and quality metrics.

Module 7: Inspection Management Logistics: The War Room

- Establishing the Front Room, Back Room, and War Room roles and protocols.
- Mastering the document flow, review-before-release, and security controls.
- Developing rapid response protocols for unexpected or complex data requests.
- Case Study: Simulation of a facility tour gone wrong due to unprepared escorts and poor communication.
- Daily briefing/debriefing procedures and managing the inspector's expectations.

Module 8: Subject Matter Expert (SME) Interview Training

- Coaching SMEs on professional demeanor, clarity, and conciseness.
- Strategies for answering based on facts and referencing approved SOPs.
- Techniques for handling difficult, open-ended, or challenging questions.
- Case Study: Analysis of SME interviews that resulted in expansion of inspection scope.
- The "Don't Guess" rule and how to appropriately escalate questions.

Module 9: Laboratory Controls and Analytical Data Defense

- Defending the analytical methods
- Reviewing Out-of-Specification (OOS) and Out-of-Trend (OOT) investigation files.
- Ensuring integrity of computerized laboratory systems.
- Case Study: The regulatory impact of poor OOS investigation closure and scientific justification.
- Controlling and presenting stability study data and trending.

Module 10: Manufacturing Operations and Control

- Auditing Batch Production Records for completeness and contemporaneous recording.
- Reviewing environmental monitoring and Aseptic Process Simulation data.
- Controlling Deviations and process variances and their investigation rigor.
- Case Study: PAI finding related to incomplete or illegible entry in critical batch records.
- Demonstrating maintenance, calibration, and equipment logbook compliance.

Module 11: Utilities and Critical Systems Validation

- Reviewing documentation for HVAC, Compressed Air, and Purified Water systems.
- Demonstrating ongoing monitoring, maintenance, and alarm handling.
- Assessing the system's impact on product quality and manufacturing environment.
- Case Study: A PAI-driven failure due to a breakdown in the pharmaceutical water system validation.
- Managing and presenting the validation master plan (VMP) summary.

Module 12: Preparing the Regulatory Response (483/CRL)

- The anatomy of a Form 483 and the strategy for the 15-day response.
- Structuring the response with immediate containment, systemic CAPA, and evidence.
- Maintaining a cooperative and transparent tone with the regulatory agency.
- Case Study: Deconstructing a successful 483 responses that prevented a Warning Letter.

- Preparing for follow-up questions and potential re-inspection.

Module 13: Quality Culture and Management Oversight

- Demonstrating management's active role and commitment to the QMS.
- Reviewing Quality Metrics and trending for system health assessment.
- Linking employee training and competency to PAI readiness.
- Case Study: Analysis of how lack of management oversight was cited as a systemic quality failure.
- Sustaining Continuous Inspection Readiness post-approval.

Module 14: Special Topic: High-Risk PAI Scenarios

- Preparation for a facility named for the first time in an application.
- Focus areas for High-Risk API or Narrow Therapeutic Index (NTI) products.
- Inspection considerations for Contract Manufacturing Organizations (CMOs).
- Case Study: Navigating a PAI following an acquisition or facility merger.
- Specific focus on stability protocol, storage, and handling of new products.

Module 15: Post-Inspection Activities and Approval

- Finalizing all documentation, Back Room files, and inspection notes.
- Tracking Commitments made to the inspector during the visit.
- Post-PAI internal debriefing and implementing "lessons learned."
- Case Study: The final approval process and the role of the PAI recommendation
- Integrating new insights to update the QMS for the next cycle.

Training Methodology

This course utilizes an Adult Learning Methodology focused on application, not just theory.

- Interactive Lectures.
- Case Studies.
- Mock Audit Workshop.
- Group Exercises.
- Expert Q&A.

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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