Advanced Good Distribution Practice (GDP) for ATMPs 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 revolutionary transformation driven by Advanced Therapy Medicinal Products (ATMPs), including gene therapies, cell therapies, and tissue-engineered products. These innovative, often personalized, medicines represent the future of healthcare, offering curative potential for previously untreatable diseases. However, the distribution of ATMPs presents unique and formidable challenges that extend far beyond traditional Good Distribution Practice (GDP). The critical nature of these life-saving therapies, characterized by extreme temperature-sensitive logistics, ultra-short shelf-lives, and complex vein-to-vein traceability, necessitates a highly specialized and robust supply chain. Adherence to an advanced and harmonized GDP framework is non-negotiable to maintain product quality, efficacy, and patient safety throughout the entire supply chain integrity.

Advanced Good Distribution Practice (GDP) for ATMPs Training Course is specifically designed to bridge the current expertise gap, focusing on the heightened regulatory scrutiny and the unique operational complexities of distributing these cutting-edge therapies. It goes beyond basic GDP, delving into critical areas like cryogenic storage and transport, Contamination Control Strategy (CCS) in logistics, Quality Risk Management (QRM) tailored for high-risk, high-value products, and seamless integration with Good Manufacturing Practice (GMP). Mastery of these advanced principles is essential for Responsible Persons (RPs) and distribution professionals to ensure regulatory compliance with global standards, including the evolving EMA guidelines and specific FDA requirements. By equipping professionals with the knowledge to establish a resilient, compliant, and patient-centric supply chain, this course secures the therapeutic promise of ATMPs for patients worldwide.

Programme Curriculum

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Introduction

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Course Duration

10 days

Course Objectives

1. Master the latest EU and FDA regulatory frameworks for the distribution of ATMPs
2. Implement a robust Quality Management System (QMS) specifically adapted for the complexity and high-risk nature of Advanced Therapy logistics.
3. Develop and execute a complete Contamination Control Strategy (CCS) throughout the distribution chain, focusing on cross-contamination risk mitigation.
4. Establish and manage end-to-end Vein-to-Vein and Traceability systems for personalized autologous and allogeneic therapies.
5. Design and validate highly specialized Cold Chain Logistics and Cryogenic Supply Chain processes, including the use of dry ice and liquid nitrogen.
6. Apply advanced Quality Risk Management (QRM) methodologies to identify and mitigate critical supply chain failure points.
7. Ensure robust Data Integrity (DI) across all electronic and paper-based distribution records, including monitoring and tracking systems.
8. Conduct comprehensive Temperature Mapping and qualification of shipping containers, vehicles, and temporary storage facilities for extreme conditions.
9. Implement effective procedures for handling Deviations, Temperature Excursions, and managing time-critical Product Recalls for ATMPs.
10. Define and audit Contract Giver/Acceptor relationships and quality agreements for third-party logistics providers specialized in ultra-cold transport.

11. Interpret the GDP intersection with GMP and GCP guidelines, particularly concerning final packaging, labelling, and dispensing.
12. Optimize inventory management strategies to account for ultra-short shelf-life and time-sensitive administration, minimizing waste of high-value product.
13. Prepare for and effectively respond to Health Authority Inspections and internal/external audits focused on ATMP distribution compliance.

Target Audience

1. Responsible Persons (RPs) and Deputy RPs.
2. Quality Assurance (QA) and Quality Control (QC) professionals.
3. Logistics and Supply Chain Managers.
4. Manufacturing and Operations Personnel.
5. Regulatory Affairs Professionals.
6. Qualified Persons (QPs).
7. Audit and Inspection Teams
8. Third-Party Logistics (3PL) Providers and specialized courier services handling ATMPs.

Course Modules

Module 1: Introduction to ATMPs and the Advanced GDP Landscape

- Definition and Classification of ATMPs
- The Unique GDP Challenges.
- Regulatory Evolution
- Hand-off from manufacturing to distribution.
- Case Study: Analyzing a failed clinical trial shipment due to a breakdown in the initial GMP-to-GDP transfer process.

Module 2: Quality Management System (QMS) for ATMP Distribution

- Scaling and tailoring the QMS for ATMP risk and complexity.
- Management Responsibility and RP Role.
- Risk-Based Approach.
- Handling modifications and deviations in the ultra-cold chain.
- Case Study: Developing a Change Control protocol for introducing a new type of cryoshipper.

Module 3: Personnel and Training Specialization

- Role of the Responsible Person (RP).
- Specialized Training Programs.
- Competency Assessment.
- Minimizing error in high-stress, time-sensitive logistics.
- Case Study: A training gap analysis following a critical deviation caused by operator error during LN2 replenishment.

Module 4: Premises and Storage for ATMPs

- Design and Qualification of Storage Areas
- Cryogenic Storage Systems.
- Temperature Monitoring Systems (TMS).
- Quarantine, Rejected, and Returned Products.

- Case Study: A mock-audit of a central ATMP depot, focusing on the qualification file for a new ultra-low freezer bank.

Module 5: Equipment and Transportation Qualification

- Qualification/Validation of Active and Passive Shippers.
- Detailed procedures for charging, monitoring, and maintaining liquid nitrogen dry shippers.
- Specialized equipment needs for local and long-haul Cold Chain Logistics.
- Calibration and Maintenance.
- Case Study: Reviewing the Shipping Validation report for a new lane involving extreme temperature swings.

Module 6: End-to-End Vein-to-Vein Traceability

- Maintaining the link between the patient and the product
- Documenting every hand-off and transfer of the ATMP container.
- Tracking and Monitoring Systems.
- Data Integrity (DI).
- Case Study: Tracing an autologous cell product from collection site to manufacturing to final administration, identifying potential CoI/CoC breaks.

Module 7: Advanced Quality Risk Management (QRM) in Logistics

- QRM Principles (ICH Q9).
- Risk Assessment Tools.
- Identifying and controlling high-risk stages like customs clearance or transshipment.
- Developing contingency plans for power failure, transport delay, and political instability.
- Case Study: Conducting a Lane Risk Analysis for an international shipment, resulting in the selection of a preferred carrier and route.

Module 8: Procurement and Supplier Qualification (3PL)

- Due Diligence and Supplier Qualification.
- Technical and Quality Agreements.
- Audit Requirements.
- Contract Giver/Acceptor Responsibilities.
- Case Study: Evaluating two competing 3PL providers based on their GDP for ATMPs audit reports and cryoshipper management protocols.

Module 9: Documentation and Data Integrity

- GDP Documentation Hierarchy.
- Good Documentation Practice (GDocP) for ATMPs.
- Electronic Records and Signatures.
- Data Integrity (DI) in Automated Systems.
- Case Study: Reviewing a set of shipping records that were flagged for Data Integrity concerns due to incomplete time stamps.

Module 10: Handling and Segregation of Advanced Therapies

- Receipt and Dispatch Protocols.
- Preventing Cross-Contamination.

- Specific Handling for Allogeneic vs. Autologous.
- Final Destination/Hospital Interface.
- Case Study: Developing a strict segregation protocol for an area handling both cryopreserved final product and return samples.

Module 11: Deviations, Complaints, and Recalls

- Deviation Investigation (OOS/OOT).
- Determining the potential effect of a deviation on the ATMP's critical quality attributes.
- Rapid Recall Procedures
- Communication with Health Authorities.
- Case Study: A simulated Product Recall scenario involving an unrecoverable temperature excursion of a gene therapy batch during transit.

Module 12: Advanced Temperature Management and Monitoring

- Temperature Mapping.
- Selection criteria and operational management for each type of shipper.
- Validation of Shipping Routes.
- Cryogenic Handling Safety.
- Case Study: A workshop on interpreting complex temperature logger data to determine if a temperature excursion invalidated the product.

Module 13: Self-Inspection and External Audits

- Preparing for Inspections.
- Conducting Self-Inspections
- Audit Response and CAPA.
- Practicing the flow of an inspection interview, focusing on the RP's role.
- Case Study: Analyzing a recent regulatory warning letter issued to a logistics company regarding a Vein-to-Vein failure.

Module 14: Final Mile and Hospital Interface

- Specific challenges of local, time-critical delivery to treatment centers.
- Hospital and Pharmacy GDP.
- Dispensing and Administration Interface.
- Returns, Waste, and Destruction.
- Case Study: Collaborating with a hospital pharmacy team to define a compliant "last-mile" delivery and storage protocol.

Module 15: Future Trends and Harmonization in ATMP GDP

- Decentralized Manufacturing.
- Digitalization and Blockchain.
- Global Harmonization Efforts.
- Sustainability in Cold Chain.
- Case Study: Discussing the regulatory challenges and QRM requirements for a hypothetical future launch of a point-of-care cell therapy.

Training Methodology

This course employs a participatory and hands-on approach to ensure practical learning, including:

- Interactive lectures and presentations.
- Group discussions and brainstorming sessions.
- Hands-on exercises using real-world datasets.
- Role-playing and scenario-based simulations.
- Analysis of case studies to bridge theory and practice.
- Peer-to-peer learning and networking.
- Expert-led Q&A sessions.
- Continuous feedback and personalized guidance.

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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