Biologics Manufacturing Supply Chain andCold Chain Management 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 advent of Biologics, including next-generation Cell and Gene Therapy (CGT) and mRNA vaccines, has fundamentally transformed the pharmaceutical landscape. These innovative, life-saving products are inherently complex and temperature-sensitive, demanding a new paradigm for their handling and distribution. A critical success factor in this new era is a robust, resilient End-to-End Supply Chain specifically engineered to ensure Product Integrity from drug substance manufacturing to patient administration. Managing the delicate molecules in transit, especially those requiring Ultra-Cold or cryogenic conditions, represents the most significant challenge, making specialized cold chain expertise non-negotiable for Good Distribution Practice (GDP) compliance and patient safety.

The Biologics supply chain requires a strategic shift from traditional logistics to a technology-enabled, data-driven approach. Digital Transformation is key, leveraging tools like Real-Time Monitoring (RTM), IoT sensors, and Blockchain for immutable traceability and transparency. Biologics Manufacturing Supply Chain andCold Chain Management Training Course is essential for proactive Risk Mitigation against temperature excursions, customs delays, and quality deviations. Investing in highly skilled personnel trained in modern Cold Chain Logistics and rigorous Regulatory Compliance is paramount. This course provides the Logistics Optimization strategies and operational expertise needed to build a secure, efficient, and cost-effective cold chain, thereby securing a competitive edge in the global biopharma market.

Programme Curriculum

Biologics Manufacturing Supply Chain andCold Chain Management Training Course

Introduction

The advent of Biologics, including next-generation Cell and Gene Therapy (CGT) and mRNA vaccines, has fundamentally transformed the pharmaceutical landscape. These innovative, life-saving products are inherently complex and temperature-sensitive, demanding a new paradigm for their handling and distribution. A critical success factor in this new era is a robust, resilient End-to-End Supply Chain specifically engineered to ensure Product Integrity from drug substance manufacturing to patient administration. Managing the delicate molecules in transit, especially those requiring Ultra-Cold or cryogenic conditions, represents the most significant challenge, making specialized cold chain expertise non-negotiable for Good Distribution Practice (GDP) compliance and patient safety.

The Biologics supply chain requires a strategic shift from traditional logistics to a technology-enabled, data-driven approach. Digital Transformation is key, leveraging tools like Real-Time Monitoring (RTM), IoT sensors, and Blockchain for immutable traceability and transparency. Biologics Manufacturing Supply Chain andCold Chain Management Training Course is essential for proactive Risk Mitigation against temperature excursions, customs delays, and quality deviations. Investing in highly skilled personnel trained in modern Cold Chain Logistics and rigorous Regulatory Compliance is paramount. This course provides the Logistics Optimization strategies and operational expertise needed to build a secure, efficient, and cost-effective cold chain, thereby securing a competitive edge in the global biopharma market.

Course Duration

10 days

Course Objectives

1. Master End-to-End Biologics Supply Chain planning and strategy.
2. Implement current Good Distribution Practices (GDP) and GxP principles for temperature-sensitive products.
3. Design and validate Thermal Packaging Solutions including Phase Change Materials and dry ice systems.
4. Apply Real-Time Temperature Monitoring (RTM) and IoT for enhanced supply chain Visibility and control.
5. Develop robust Risk Mitigation Strategies for excursion management and supply chain resilience.
6. Understand and manage Ultra-Cold and Cryogenic Storage and transportation requirements
7. Analyze and optimize Logistics Performance Indicators (KPIs) for cold chain efficiency.
8. Navigate complex Global Trade and Customs regulations for cross-border biologics shipment.
9. Leverage Digital Twin and Predictive Analytics to forecast demand and anticipate supply chain bottlenecks.
10. Integrate Blockchain Technology for Immutable Traceability and anti-counterfeiting measures.
11. Execute proper Reverse Logistics and destruction procedures for non-conforming or expired biologics.
12. Establish effective Supplier Qualification and management programs for 3PLs and specialty couriers.
13. Drive Continuous Improvement using Quality Management System (QMS) principles within the cold chain.

Target Audience

1. Supply Chain and Logistics Managers in Biopharma and Pharmaceutical companies.
2. Quality Assurance (QA) and Quality Control (QC) Professionals.
3. Regulatory Affairs Specialists.
4. Manufacturing Operations Leaders.
5. Warehouse and Inventory Managers.

6. 3PL/4PL Provider Personnel.
7. Procurement and Sourcing Professionals.
8. Project Managers and Engineers.

Course Modules

Module 1: Fundamentals of Biologics and the GxP Environment

- Biologics and Small Molecules.
- Overview of the Biologics product lifecycle
- GMP/GDP/GWP Interplay.
- FDA, EMA, WHO, and regional requirements for biologics.
- Quality Risk Management (QRM) essentials.
- Case Study: A major Monoclonal Antibody recall due to non-compliant storage conditions.

Module 2: Cold Chain Fundamentals and Thermal Science

- Defining the Cold Chain: 2?êÿC to 8?êÿC, controlled deep freeze, ultra-low, and cryogenic ranges.
- Temperature effects on biological product stability
- Principles of heat transfer and insulation in passive and active systems.
- Understanding and utilizing Phase Change Materials (PCMs) and dry ice.
- Standard operating procedures (SOPs) for product handling and staging.
- Case Study: Failure analysis of a vaccine shipment due to incorrect dry ice replenishment protocol.

Module 3: Thermal Packaging Design and Validation

- Operational Qualification (OQ) and Performance Qualification (PQ).
- Active and Passive packaging systems.
- Shipping lane validation and mapping.
- Package documentation: Labeling, internal temperature sensors, and shock indicators.
- Sustainable cold chain packaging solutions and environmental impact.
- Case Study: Design and qualification of a reusable shipper for gene therapy product distribution.

Module 4: Temperature Monitoring and Visibility

- Selection of Data Loggers and sensor placement.
- Implementing Real-Time Monitoring via GPS and cellular/satellite technologies
- Alert and escalation protocols for temperature excursions and geo-fence breaches.
- Data integrity, data review, and storage for regulatory audit trails.
- Establishing a Cold Chain Control Tower for 24/7 global oversight.
- Case Study: Using an RTM system to intervene and save a high-value shipment at a transit hub.

Module 5: Ultra-Cold and Cryogenic Management

- Specialized requirements for Cell and Gene Therapies (CGT) and mRNA products.
- Design and maintenance of Ultra-Low Temperature (ULT) Freezers
- Handling and safety protocols for liquid nitrogen LN2?Çï and Cryogenic Storage
- Validation of cryogenic storage tanks and continuous monitoring systems.
- Logistics for small-volume, high-value, patient-specific products.
- Case Study: Setting up a compliant chain of custody for an autologous cell therapy product.

Module 6: Warehouse and Inventory Management (GWP)

- Temperature Mapping of cold rooms, freezers, and ambient storage areas.
- Inventory control principles.
- Design, layout, and maintenance of Cold Storage Infrastructure.
- Security and access control for high-value biologics.
- Warehouse Management Systems (WMS) integration with cold chain monitoring.
- Case Study: Optimizing a regional distribution center layout based on a new temperature mapping study.

Module 7: Global Cold Chain Logistics and Distribution

- Air freight, sea freight, and ground logistics.
- Route risk assessment and contingency planning for major transit lanes.
- Carrier selection and 3PL Qualification and service level agreements
- Managing customs clearance, border checks, and international paperwork
- Last-Mile Delivery challenges and solutions for clinical sites and patients.
- Case Study: Navigating complex customs in an emerging market for a biologic shipment.

Module 8: Serialization and Traceability Technologies

- Global requirements for Serialization and unique product identifiers.
- The role of Blockchain Technology in creating an immutable audit trail.
- Implementation of Track and Trace systems from manufacturer to dispenser.
- Combating Counterfeiting and diversion in the biologics supply chain.
- Data standardization and exchange protocols
- Case Study: Implementing a blockchain solution to enhance transparency and fight counterfeit biologics in a high-risk region.

Module 9: Supply Chain Risk Management and Business Continuity

- Comprehensive risk identification.
- Developing and testing robust Contingency and Business Continuity Plans
- Strategies for ensuring Redundancy in cold chain infrastructure and suppliers.
- Root Cause Analysis and Corrective and Preventive Actions for excursions.
- Cybersecurity risks and protection of sensitive supply chain data.
- Case Study: Review of a BCP following a major hurricane that disrupted air freight lanes.

Module 10: Regulatory Compliance and Audit Readiness

- Detailed review of ICH Q10 and Q12 for pharmaceutical quality systems.
- Preparing for and successfully navigating Regulatory Audits
- Good Documentation Practice for all cold chain records.
- Handling Deviations, Out-of-Specification, and product disposition.
- Documentation required for release, transit, and receipt of biologics.
- Case Study: Responding to a 483 observation related to cold storage monitoring and alarm procedures.

Module 11: Procurement and Supplier Management

- Criteria for selecting and qualifying specialist cold chain 3PLs and vendors.
- Negotiation and structuring of Quality Agreements and Service Level Agreements
- Supplier performance monitoring and key performance indicators
- Auditing third-party cold storage facilities and transportation partners.
- Cost-Benefit Analysis of in-house logistics vs. outsourcing.

- Case Study: Developing a supplier scorecard to evaluate and consolidate cold chain logistics partners.

Module 12: Digital Transformation and Predictive Analytics

- Introduction to AI and Machine Learning for demand forecasting and inventory optimization.
- The concept and utility of Digital Twins for supply chain simulation.
- Advanced data analytics to identify risk factors
- Automated temperature monitoring and Predictive Maintenance for cold chain equipment.
- Leveraging data for strategic decision-making and continuous improvement.
- Case Study: Using predictive analytics to adjust a shipping route based on extreme heat forecasts.

Module 13: Biologics Manufacturing Handoff and Interface

- The critical interface between GMP Manufacturing and GDP Distribution.
- Final packaging, labeling, and inspection before release to the cold chain.
- Managing specialized requirements for clinical trial material (CTM) distribution.
- Roles and responsibilities for product release, transfer, and receipt.
- In-plant cold room management and buffer storage protocols.
- Case Study: Streamlining the final packaging and release process to minimize the product's out-of-spec time.

Module 14: Sustainability and Green Cold Chain

- Minimizing the Carbon Footprint of cold chain operations.
- Strategies for optimizing refrigerated space and energy efficiency.
- Design and implementation of Reusable Packaging Systems.
- Regulations and best practices for the disposal of cold chain packaging
- Integrating sustainability KPIs into logistics performance metrics.
- Case Study: A pharmaceutical company's transition to a reusable packaging fleet and its environmental impact analysis.

Module 15: Reverse Logistics and Product Disposition

- Planning and execution of Reverse Logistics for returns
- Product Disposition protocols.
- Regulatory requirements for the destruction of controlled and high-value biologics.
- Documentation and record-keeping for all reverse flow activities.
- Managing the logistics of unused patient-specific CGT products.
- Case Study: Establishing a secure and compliant process for recalling and destroying a batch of temperature-abused biologics.

Training Methodology

The course employs an Active Learning approach to ensure practical mastery and application of technical knowledge:

- Instructor-Led Didactic Sessions.
- Interactive Workshops.
- Real-World Case Studies.
- Practical Tools and Templates.
- Q&A and Peer-to-Peer Learning.

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