

Upskill. Reskill. New Skill.  
E-Learning & On-site Hands-on  
GMP Biomanufacturing Training Programs

**TRAINING CATALOG**

Course/Module List	Part of the Learning Path: Advanced Therapies GMP Onboarding
<b>GMP Foundations</b>	
Introduction To Good Manufacturing Practices	X
Foundational Knowledge and Biocontainment	X
Historical Development of GMP: Finished Dose Manufacturing	X
Basic Microbiology	X
Executive Responsibility in Pharmaceutical Manufacturing	
Laboratory GMP	
<b>Aseptic Cleanroom Systems and Workflow</b>	
Concepts and Controls	X
Cleanrooms and Control Technologies	X
Gowning (for ISO 5/6, 7 & 8)	X
Contamination Control	X
Decontamination and Sterilization Technologies	X
Hand Hygiene	X
<b>Quality</b>	
<b>Quality Management Systems</b>	
Foundations of Quality Management Systems	X
<b>Documentation</b>	
Good Documentation Practices – SOPs and Batch Records	X

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<b>Quality by Design</b>	
GLP – An Introduction	
Planning a Validation Strategy – Intro to Quality by Design	X
Process Validation – Process Design	X
Process Validation – Process Qualification and Control	X
Laboratory Equipment Qualification	
Method Validation Parameters	
Data Integrity for GxP Regulated Industries	X
GxP Computerized Systems Validation	
Roles and Responsibilities Under ICH Good Clinical Practice (GCP)	
<b>Risk management</b>	
Understanding Risk Management	X
The Quality Risk Management Lifecycle	X
Corrective Actions Preventive Actions	X
CAPA for Non-Conformities	X
<b>Regulatory</b>	
Planning to Meet GMP Requirements Globally	X
An Orientation to Canadian Regulations & Regulators	
Planning for Cell Therapy Clinical Trial Applications	
Adopting a Life-Cycle Approach to Cell & Gene Therapy Manufacturing	
GMP Inspection Readiness – Interacting with the Inspector	
Introduction to 21 CFR Part 11	
<b>Manufacturing</b>	
Quality Control	X

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Critical Elements for Product Release	X
Isolators	
Bioreactors in Bioprocessing	
Cell Biology and Recombinant DNA Technology	
Cell Culture in Biopharmaceutical Manufacturing	
Clean in Place	
Downstream Processing: Centrifugation	
Downstream Processing: Protein Purification - Chromatography	
Downstream Processing: Ultrafiltration and Diafiltration	
Fill and Finish Operations - Four Level Serialization Structure	
Fill and Finish Operations - Serialization and Product Tracking	
Fill and Finish Operations - Serialization and the Supply Chain	
Out of Specification & Atypical Results	
Overview of Biopharmaceutical Manufacturing	
Process Flow Diagrams (PFDs)	
HPLC Troubleshooting	
Introduction to HPLC	
Solution Preparation	
Sterile Filtration	
Valves	
Weighing	
Wet Chemistry	