

2024 Catalog of Training Courses & Certification Programs

Training programs are listed by category. We have over 300 courses available. All programs are current, include professional voiceovers, a final assessment, certificate of completion, and engaging activities.

Key Benefits of Biopharma Institute Training Certifications:

Immediate access to training- Instructions, username, password, and receipt of payment are emailed instantly upon online enrollment.

Expertise- All courses have been developed by subject matter experts (SMEs) in material being taught. **Current and validated-** All courses are current with respect to regulations and procedures and are 3rd party validated and/or internationally accredited.

Optimized for learning- Courses include voiceovers, easy navigation, case studies, progress checks, and high-quality animations to increase retention of subject matter.

Secure and safe access- Website and LMS provide an encrypted connection with firewall protection and daily scans for malware to deliver optimal level of security and performance.

Categories of Training:

- Change Control
- Clinical Trials Management and Monitoring
- CSV & SVA: Computer / Software Validation
- Contamination Control
- Data Integrity
- Drug Safety & Pharmacovigilance
- Electronic Records & Signatures
- GDP: Good Distribution Practices
- GDocP: Good Documentation Practices
- GLP: Good Laboratory Practices
- GMP: Food Manufacturing
- GMP: Pharmaceutical Manufacturing
- Medical Devices (GMP, MDSAP, & EU MDR)
- OSHA and EEO
- Pharmaceutical Microbiology
- Regulatory Affairs: Pharmaceuticals
- Pharmaceutical Sales and Marketing
- QA: Quality Assurance
- Validation (Process & Equipment)



Biopharma Institute

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Clinical Trials Management and Monitoring

Professional Certification Program:

Clinical Trials Management (US & EU) Professional Certification Program

Program ID: GCP00A1 (Learning Time: See Programs Webpage) | Post-nominal Letters: CTPro Price: \$1295.00 USD (URL: https://www.biopharmainstitute.com/course/GCP00A1)

Professional Certification Program:

Clinical Research Associate (CRA) Professional Certification Program

Program ID: GCP00A (Learning Time: See Programs Webpage) | Post-nominal Letters: CMPro Price: \$845.00 USD (URL: https://www.biopharmainstitute.com/course/GCP00A)

Professional Certification Program:

Clinical Research Coordinator (CRC) Professional Certification Program

Program ID: CRCPRO (Learning Time: See Programs Webpage) | Post-nominal Letters: CRCPro Price: \$995.00 USD (URL: https://www.biopharmainstitute.com/course/CRCPRO)

Training Program for Professionals:

Obtaining Approval for Clinical Trials in US & EU for Regulatory Professionals

Program ID: GCP00A2 (Learning Time: See Programs Webpage)

Price: \$895.00 USD (URL: https://www.biopharmainstitute.com/course/GCP00A2)

Individual Course w/Certificate of Completion:

GCP: ICH-GCP Good Clinical Practice

Program ID: GCP001 (Learning Time: 180 minutes) | Credit Hours (CPD): 3 Price: \$195.00 USD (URL: https://www.biopharmainstitute.com/course/GCP001)

Individual Course w/Certificate of Completion:

GCP: ICH, Harmonization, and Principles (Fundamentals)

Program ID: CT03A (Learning Time: 30 minutes)

Price: \$95.00 USD (URL: https://www.biopharmainstitute.com/course/CT03A)

Individual Course w/Certificate of Completion:

GCP: Clinical Research Teamwork (Fundamentals)

Program ID: CT03B (Learning Time: 30 minutes)

Price: \$95.00 USD (URL: https://www.biopharmainstitute.com/course/CT03B)

Individual Course w/Certificate of Completion:

GCP: Clinical Trial Documentation (Fundamentals)

Program ID: CT03C (Learning Time: 30 minutes)



Price: \$95.00 USD (URL: https://www.biopharmainstitute.com/course/CT03C)

Individual Course w/Certificate of Completion:

GCP: Clinical Trial Sponsors GCP Responsibilities (Fundamentals)

Program ID: CT03D (Learning Time: 30 minutes)

Price: \$95.00 USD (URL: https://www.biopharmainstitute.com/course/CT03D)

Individual Course w/Certificate of Completion:

GCP: Clinical Trial Investigators GCP Responsibilities (Fundamentals)

Program ID: CT03E (Learning Time: 30 minutes)

Price: \$95.00 USD (URL: https://www.biopharmainstitute.com/course/CT03E)

Individual Course w/Certificate of Completion:

GCP: Informed Consent in Clinical Trials (Fundamentals)

Program ID: CT03F (Learning Time: 30 minutes)

Price: \$95.00 USD (URL: https://www.biopharmainstitute.com/course/CT03F)

Individual Course w/Certificate of Completion:

GCP: Clinical Trial Monitors GCP Responsibilities (Fundamentals)

Program ID: CT03G (Learning Time: 30 minutes)

Price: \$95.00 USD (URL: https://www.biopharmainstitute.com/course/CT03G)

Individual Course w/Certificate of Completion:

Clinical Trials: Preparation and Design

Program ID: GCP002 (Learning Time: 240 minutes) | Credit Hours (CPD): 4 Price: \$225.00 USD (URL: https://www.biopharmainstitute.com/course/GCP002)

Individual Course w/Certificate of Completion:

Clinical Trials and Drug Development

Program ID: GCP003 (Learning Time: 90 minutes) | Credit Hours (CPD): 1.5 Price: \$175.00 USD (URL: https://www.biopharmainstitute.com/course/GCP003)

Individual Course w/Certificate of Completion:

Clinical Trials in Drug Development (Fundamentals)

Program ID: CT04A (Learning Time: 30 minutes)

Price: \$95.00 USD (URL: https://www.biopharmainstitute.com/course/CT04A)

Individual Course w/Certificate of Completion:

Clinical Trials: Protocol Design (Fundamentals)

Program ID: CT04B (Learning Time: 30 minutes)

Price: \$95.00 USD (URL: https://www.biopharmainstitute.com/course/CT04B)



Individual Course w/Certificate of Completion:

Clinical Trials: Preparation (Fundamentals)

Program ID: CT04C (Learning Time: 30 minutes)

Price: \$95.00 USD (URL: https://www.biopharmainstitute.com/course/CT04C)

Individual Course w/Certificate of Completion:

Clinical Trials: Endpoints (Fundamentals)

Program ID: CT04D (Learning Time: 30 minutes)

Price: \$95.00 USD (URL: https://www.biopharmainstitute.com/course/CT04D)

Individual Course w/Certificate of Completion:

Clinical Trials: Statistical Elements (Fundamentals)

Program ID: CT04E (Learning Time: 30 minutes)

Price: \$95.00 USD (URL: https://www.biopharmainstitute.com/course/CT04E)

Individual Course w/Certificate of Completion:

Clinical Trials: Study Design (Fundamentalse)

Program ID: CT04F (Learning Time: 30 minutes)

Price: \$95.00 USD (URL: https://www.biopharmainstitute.com/course/CT04F)

Individual Course w/Certificate of Completion:

Clinical Trials: Data Capture (Fundamentals)

Program ID: CT04G (Learning Time: 30 minutes)

Price: \$95.00 USD (URL: https://www.biopharmainstitute.com/course/CT04G)

Individual Course w/Certificate of Completion:

Clinical Trial Monitoring: Site Evaluation and Set-up

Program ID: GCP004 (Learning Time: 90 minutes) | Credit Hours (CPD): 1.5 Price: \$175.00 USD (URL: https://www.biopharmainstitute.com/course/GCP004)

Individual Course w/Certificate of Completion:

Clinical Trial Monitoring: Documentation and Closure

Program ID: GCP005 (Learning Time: 180 minutes) | Credit Hours (CPD): 2 Price: \$195.00 USD (URL: https://www.biopharmainstitute.com/course/GCP005)

Individual Course w/Certificate of Completion:

Clinical Trials: Preparing for an Audit or Inspection

Program ID: GCP006 (Learning Time: 150 minutes) | Credit Hours (CPD): 2.5 Price: \$225.00 USD (URL: https://www.biopharmainstitute.com/course/GCP006)

Individual Course w/Certificate of Completion:



Clinical Trials: The Investigational New Drug Application (IND) to Conduct FDA-regulated Clinical Trials

Program ID: GCP007 (Learning Time: 180 minutes) | Credit Hours (CPD): 3 Price: \$225.00 USD (URL: https://www.biopharmainstitute.com/course/GCP007)

Individual Course w/Certificate of Completion:

Clinical Trials: How to Obtain Approval to Conduct Clinical Trials in the EU

Program ID: GCP020 (Learning Time: 180 minutes) | Credit Hours (CPD): 3 Price: \$175.00 USD (URL: https://www.biopharmainstitute.com/course/GCP020)

Individual Course w/Certificate of Completion:

Clinical Trials: How to Gain Authorization for Clinical Research Under the EU Clinical Trials Regulation

Program ID: CT11 (Learning Time: 120 minutes) | Credit Hours (CPD): 2 Price: \$225.00 USD (URL: https://www.biopharmainstitute.com/course/CT11)

Individual Course w/Certificate of Completion:

Clinical Trials: How to Conduct Clinical Research Under the EU Clinical Trials Regulation

Program ID: CT12 (Learning Time: 60 minutes) | Credit Hours (CPD): 1 Price: \$175.00 USD (URL: https://www.biopharmainstitute.com/course/CT12)

Individual Course w/Certificate of Completion:

DIGR-ACT Solution: Critical Thinking Skills - Including Root Cause Analysis & CAPA

Program ID: CP001a (Learning Time: 60 minutes)

Price: \$399.00 USD (URL: https://www.biopharmainstitute.com/course/CP001a)

Individual Course w/Certificate of Completion:

GCP Training: ICH E6(R2) - (Refresher Training for Novice)

Program ID: CP002a (Learning Time: 75 minutes)

Price: \$199.00 USD (URL: https://www.biopharmainstitute.com/course/CP002a)

Individual Course w/Certificate of Completion:

GCP Refresher Training for the Experienced Professional

Program ID: CP003a (Learning Time: 35 minutes)

Price: \$199.00 USD (URL: https://www.biopharmainstitute.com/course/CP003a)

Individual Course w/Certificate of Completion:

ICH E6(R2) GCP Training for Investigator Site Personnel

Program ID: CP004a (Learning Time: 60 minutes)

Price: \$199.00 USD (URL: https://www.biopharmainstitute.com/course/CP004a)



Individual Course w/Certificate of Completion:

Overview of ICH E8(R1): General Considerations for Clinical Studies Guideline

Program ID: CP019a (Learning Time: 45 minutes)

Price: \$199.00 USD (URL: https://www.biopharmainstitute.com/course/CP019a)

Individual Course w/Certificate of Completion:

Good Documentation Practices and ALCOA-C

Program ID: CP005a (Learning Time: 60 minutes)

Price: \$199.00 USD (URL: https://www.biopharmainstitute.com/course/CP005a)

Individual Course w/Certificate of Completion:

Corrective and Preventive Action (CAPA) Process Planning for Clinical Research Professionals

Program ID: CP006a (Learning Time: 60 minutes)

Price: \$199.00 USD (URL: https://www.biopharmainstitute.com/course/CP006a)

Individual Course w/Certificate of Completion:

CRO Oversight

Program ID: CP007a (Learning Time: 45 minutes)

Price: \$199.00 USD (URL: https://www.biopharmainstitute.com/course/CP007a)

Individual Course w/Certificate of Completion:

ISO 14155:2020 Medical Device Standard

Program ID: CP008a (Learning Time: 45 minutes)

Price: \$199.00 USD (URL: https://www.biopharmainstitute.com/course/CP008a)

Individual Course w/Certificate of Completion:

Medical Device vs. Drug: Comparing and Contrasting

Program ID: CP010a (Learning Time: 60 minutes)

Price: \$199.00 USD (URL: https://www.biopharmainstitute.com/course/CP010a)

Individual Course w/Certificate of Completion:

Investigator Initiated Clinical Trials

Program ID: CP011a (Learning Time: 30 minutes)

Price: \$199.00 USD (URL: https://www.biopharmainstitute.com/course/CP011a)

Individual Course w/Certificate of Completion:

Clinical Safety Data Management: Definitions and Standards for Expedited Reporting (ICH E2A)

Program ID: CP012a (Learning Time: 45 minutes)

Price: \$199.00 USD (URL: https://www.biopharmainstitute.com/course/CP012a)



Individual Course w/Certificate of Completion:

Structure and Content of Clinical Study Reports (ICH E3)

Program ID: CP013a (Learning Time: 45 minutes)

Price: \$199.00 USD (URL: https://www.biopharmainstitute.com/course/CP013a)

Individual Course w/Certificate of Completion:

Overview of 21 CFR Part 50 Human Subject Protection (HSP) and 21 CFR Part 56 IRB/IEC

Program ID: CP014a (Learning Time: 45 minutes)

Price: \$199.00 USD (URL: https://www.biopharmainstitute.com/course/CP014a)

Individual Course w/Certificate of Completion:

Overview of 21 CFR Part 312 Investigational New Drug Application (IND) and 21 CFR 314 Application for FDA Approval to Market a New Drug (NDA)

Program ID: CP015a (Learning Time: 60 minutes)

Price: \$199.00 USD (URL: https://www.biopharmainstitute.com/course/CP015a)

Individual Course w/Certificate of Completion:

Overview of 21 CFR Part 54 Financial Disclosure & Part 11 Electronic Data Signatures

Program ID: CP016a (Learning Time: 45 minutes)

Price: \$199.00 USD (URL: https://www.biopharmainstitute.com/course/CP016a)

Individual Course w/Certificate of Completion:

Regulatory Requirements for Clinical Trials in Europe (Directive to Regulation)

Program ID: CP018a (Learning Time: 45 minutes)

Price: \$199.00 USD (URL: https://www.biopharmainstitute.com/course/CP018a)

Individual Course w/Certificate of Completion:

HIPAA Training for Clinical Trial Professionals

Program ID: CP017a (Learning Time: 60 minutes)

Price: \$199.00 USD (URL: https://www.biopharmainstitute.com/course/CP017a)

Individual Course w/Certificate of Completion:

Clinical Trial eSystems Inspection Readiness

Program ID: CP021a (Learning Time: 45 minutes)

Price: \$199.00 USD (URL: https://www.biopharmainstitute.com/course/CP021a)

Individual Course w/Certificate of Completion:

The General Data Protection Regulation (GDPR) and Clinical Trials

Program ID: CP009a (Learning Time: 45 minutes)

Price: \$199.00 USD (URL: https://www.biopharmainstitute.com/course/CP009a)



CSV & SVA: Computer / Software Validation

Training Program for Professionals:

Computer System Validation for Professionals

Program ID: VAL00S2 (Learning Time: See Programs Webpage) | Post-nominal Letters: CSVPro

Price: \$695.00 USD (URL: https://www.biopharmainstitute.com/course/VAL00S2)

Individual Course w/Certificate of Completion:

Validation: Computer System Validation (Part 1 of 2) (Planning)

Program ID: VAL09 (Learning Time: 60 minutes) | Credit Hours (CPD): 1

Price: \$195.00 USD (URL: https://www.biopharmainstitute.com/course/VAL09)

Individual Course w/Certificate of Completion:

Validation: Computer System Validation (Part 2 of 2) (Implementation)

Program ID: VAL10 (Learning Time: 60 minutes) | Credit Hours (CPD): 1

Price: \$195.00 USD (URL: https://www.biopharmainstitute.com/course/VAL10)



Drug Safety & Pharmacovigilance

Professional Certification Program:

Drug Safety and Pharmacovigilance Professional Certification Program

Program ID: AV01 (Learning Time: See Programs Webpage) | Post-nominal Letters: DSPro Price: \$995.00 USD (URL: https://www.biopharmainstitute.com/course/AV01)

Professional Certification Program:

Good Pharmacoepidemiology Practice Professional Certification Program

Program ID: AV01B (Learning Time: See Programs Webpage) | Post-nominal Letters: GPPro Price: \$1195.00 USD (URL: https://www.biopharmainstitute.com/course/AV01B)

Training Program for Professionals:

Pharmacokinetics and Pharmacodynamics for Professionals

Program ID: AV01A (Learning Time: See Programs Webpage) | Post-nominal Letters: PKDPro Price: \$359.00 USD (URL: https://www.biopharmainstitute.com/course/AV01A)

Individual Course w/Certificate of Completion:

Introduction to Drug Safety and Pharmacovigilance

Program ID: AV02 (Learning Time: 180 minutes) | Credit Hours (CPD): 2 Price: \$225.00 USD (URL: https://www.biopharmainstitute.com/course/AV02)

Individual Course w/Certificate of Completion:

Drug Safety: Signal Detection and Management in Pharmacovigilance

Program ID: PV04 (Learning Time: 90 minutes) | Credit Hours (CPD): 1.5 Price: \$195.00 USD (URL: https://www.biopharmainstitute.com/course/PV04)

Individual Course w/Certificate of Completion:

Drug Safety: Risk Management Planning for Medicinal Products

Program ID: PV05 (Learning Time: 90 minutes) | Credit Hours (CPD): 1.25 Price: \$195.00 USD (URL: https://www.biopharmainstitute.com/course/PV05)

Individual Course w/Certificate of Completion:

Drug Safety: Urgent Safety Restrictions

Program ID: PV06 (Learning Time: 45 minutes) | Credit Hours (CPD): 0.75 Price: \$195.00 USD (URL: https://www.biopharmainstitute.com/course/PV06)

Individual Course w/Certificate of Completion:

Drug Safety: Good Pharmacoepidemiology Practice

Program ID: PV07 (Learning Time: 60 minutes) | Credit Hours (CPD): 1



Price: \$195.00 USD (URL: https://www.biopharmainstitute.com/course/PV07)

Individual Course w/Certificate of Completion:

Safety Reporting in Clinical Trials (Adverse Event Reporting)

Program ID: CT13 (Learning Time: 120 minutes) | Credit Hours (CPD): 2 Price: \$225.00 USD (URL: https://www.biopharmainstitute.com/course/CT13)

Individual Course w/Certificate of Completion:

Clinical Trial Safety Reporting Requirements in the EU and USA

Program ID: CT14 (Learning Time: 120 minutes) | Credit Hours (CPD): 2 Price: \$225.00 USD (URL: https://www.biopharmainstitute.com/course/CT14)

Individual Course w/Certificate of Completion:

Introduction to Pharmacokinetics and Pharmacodynamics in Drug Development and Registration

Program ID: PKPD01 (Learning Time: 90 minutes) | Credit Hours (CPD): 1.5 Price: \$189.00 USD (URL: https://www.biopharmainstitute.com/course/PKPD01)

Individual Course w/Certificate of Completion:

Conducting Pharmacokinetic and Pharmacodynamic Studies

Program ID: PKPD02 (Learning Time: 90 minutes) | Credit Hours (CPD): 1.5 Price: \$189.00 USD (URL: https://www.biopharmainstitute.com/course/PKPD02)



Electronic Records & Signatures

Individual Course w/Certificate of Completion:
Compliance with Regulation 21 CFR Part 11 (Electronic Records and Electronic Signatures)

Program ID: ESR01A (Learning Time: 90 minutes) | Credit Hours (CPD): 1.5 Price: \$225.00 USD (URL: https://www.biopharmainstitute.com/course/ESR01A)



GMP for Dietary Supplement Manufacturing

Individual Course w/Certificate of Completion: cGMPs for Dietary Supplements (21 CFR Part 111)

Program ID: GMPDS (Learning Time: 60 minutes)

Price: \$95.00 USD (URL: https://www.biopharmainstitute.com/course/GMPDS)



GMP for Food Manufacturing

Training Program for Professionals:

GMP: Food Manufacturing for Professionals (21 CFR Part 117)

Program ID: GMPF (Learning Time: See Programs Webpage)

Price: \$159.00 USD (URL: https://www.biopharmainstitute.com/course/GMPF)

Individual Course w/Certificate of Completion:

GMP Awareness: Food Manufacturing

Program ID: GMPF01 (Learning Time: 20 minutes)

Price: \$59.00 USD (URL: https://www.biopharmainstitute.com/course/GMPF01)

Individual Course w/Certificate of Completion:

GMP: Food Manufacturing Warning Letters and Case Studies

Program ID: GMPF02 (Learning Time: 20 minutes)

Price: \$59.00 USD (URL: https://www.biopharmainstitute.com/course/GMPF02)

Individual Course w/Certificate of Completion:

GMP for Food Manufacturing: The Nine (9) Principles of 21 CFR Part 117

Program ID: GMPF03 (Learning Time: 35 minutes)

Price: \$95.00 USD (URL: https://www.biopharmainstitute.com/course/GMPF03)



GLP: Good Laboratory Practices

Individual Course w/Certificate of Completion: Introduction to Good Laboratory Practice (GLP)

Program ID: GLP-101 (Learning Time: 60 minutes)

Price: \$145.00 USD (URL: https://www.biopharmainstitute.com/course/GLP-101)



GMP: Good Manufacturing Practices

Professional Certification Program:

Current Good Manufacturing Practice (cGMP) Professional Certification Program

Program ID: GMP001S1 (Learning Time: See Programs Webpage) | Post-nominal Letters: GMPro

Price: \$1795.00 USD (URL: https://www.biopharmainstitute.com/course/GMP001S1)

Training Program for Professionals:

GMP Refresher Program for Professionals

Program ID: GMPREF (Learning Time: See Programs Webpage)

Price: \$995.00 USD (URL: https://www.biopharmainstitute.com/course/GMPREF)

Individual Course w/Certificate of Completion:

cGMP: Introduction to Good Manufacturing Practice (GMP)

Program ID: GMP01 (Learning Time: 60 minutes)

Price: \$199.00 USD (URL: https://www.biopharmainstitute.com/course/GMP01)

Individual Course w/Certificate of Completion:

cGMP: Warehouse for Pharmaceuticals

Program ID: GMP02 (Learning Time: 60 minutes)

Price: \$199.00 USD (URL: https://www.biopharmainstitute.com/course/GMP02)

Individual Course w/Certificate of Completion:

cGMP: Microbiology in the Workplace

Program ID: GMP03 (Learning Time: 60 minutes)

Price: \$199.00 USD (URL: https://www.biopharmainstitute.com/course/GMP03)

Individual Course w/Certificate of Completion:

cGMP: Cleaning and Sanitation

Program ID: GMP04 (Learning Time: 60 minutes)

Price: \$199.00 USD (URL: https://www.biopharmainstitute.com/course/GMP04)

Individual Course w/Certificate of Completion:

cGMP: Documentation and Record Keeping

Program ID: GMP05 (Learning Time: 60 minutes)

Price: \$199.00 USD (URL: https://www.biopharmainstitute.com/course/GMP05)

Individual Course w/Certificate of Completion:

cGMP: Contamination Control

Program ID: GMP06 (Learning Time: 60 minutes)



Price: \$199.00 USD (URL: https://www.biopharmainstitute.com/course/GMP06)

Individual Course w/Certificate of Completion:

cGMP: Production Controls

Program ID: GMP07 (Learning Time: 60 minutes)

Price: \$199.00 USD (URL: https://www.biopharmainstitute.com/course/GMP07)

Individual Course w/Certificate of Completion:

cGMP: Packaging Controls

Program ID: GMP08 (Learning Time: 60 minutes)

Price: \$199.00 USD (URL: https://www.biopharmainstitute.com/course/GMP08)

Individual Course w/Certificate of Completion:

cGMP: Quality Assurance and Quality Control (QA/QC)

Program ID: GMP09 (Learning Time: 60 minutes)

Price: \$199.00 USD (URL: https://www.biopharmainstitute.com/course/GMP09)

Individual Course w/Certificate of Completion:

cGMP: Pharmaceutical Corrective and Preventive Action (CAPA) - Including Root Cause Analysis

Program ID: GMP10 (Learning Time: 60 minutes)

Price: \$199.00 USD (URL: https://www.biopharmainstitute.com/course/GMP10)

Individual Course w/Certificate of Completion:

cGMP: Data Integrity

Program ID: GMP11 (Learning Time: 60 minutes)

Price: \$199.00 USD (URL: https://www.biopharmainstitute.com/course/GMP11)

Individual Course w/Certificate of Completion:

GxP: Good Practices (GxP) in Drug Development and Manufacturing

Program ID: GXP01 (Learning Time: 30 minutes) | Credit Hours (CPD): 1 Price: \$95.00 USD (URL: https://www.biopharmainstitute.com/course/GXP01)

Individual Course w/Certificate of Completion:

cGMP: Introduction to Good Manufacturing Practice for Medicinal Products

Program ID: CGMP01 (Learning Time: 90 minutes) | Credit Hours (CPD): 1.5 Price: \$195.00 USD (URL: https://www.biopharmainstitute.com/course/CGMP01)

Individual Course w/Certificate of Completion:

cGMP: What is GMP and Why is it Important (Fundamentals)

Program ID: CGMP01a (Learning Time: 30 minutes)



Price: \$95.00 USD (URL: https://www.biopharmainstitute.com/course/CGMP01a)

Individual Course w/Certificate of Completion:

cGMP: The Principles of GMP (Fundamentals)

Program ID: CGMP01b (Learning Time: 30 minutes)

Price: \$95.00 USD (URL: https://www.biopharmainstitute.com/course/CGMP01b)

Individual Course w/Certificate of Completion:

cGMP: Hygiene, Cleaning, and Sanitation (Fundamentals)

Program ID: CGMP01c (Learning Time: 30 minutes)

Price: \$95.00 USD (URL: https://www.biopharmainstitute.com/course/CGMP01c)

Individual Course w/Certificate of Completion:

cGMP: Documentation and Record Keeping (Fundamentals)

Program ID: CGMP01d (Learning Time: 30 minutes)

Price: \$95.00 USD (URL: https://www.biopharmainstitute.com/course/CGMP01d)

Individual Course w/Certificate of Completion:

cGMP: Good Documentation Practice (GDocP)

Program ID: CGMP02 (Learning Time: 60 minutes) | Credit Hours (CPD): 1 Price: \$195.00 USD (URL: https://www.biopharmainstitute.com/course/CGMP02)

Individual Course w/Certificate of Completion:

cGMP: Good Manufacturing Practice in Cleaning and Sanitation

Program ID: CGMP03 (Learning Time: 60 minutes) | Credit Hours (CPD): 1

Price: \$195.00 USD (URL: https://www.biopharmainstitute.com/course/CGMP03)

Individual Course w/Certificate of Completion:

cGMP: Good Manufacturing Practice for the Warehouse

Program ID: CGMP04 (Learning Time: 90 minutes) | Credit Hours (CPD): 1.5 Price: \$195.00 USD (URL: https://www.biopharmainstitute.com/course/CGMP04)

Individual Course w/Certificate of Completion:

cGMP: Good Manufacturing Practice in Processing Medicinal Products

Program ID: CGMP05 (Learning Time: 60 minutes) | Credit Hours (CPD): 1

Price: \$195.00 USD (URL: https://www.biopharmainstitute.com/course/CGMP05)

Individual Course w/Certificate of Completion:

cGMP: Good Manufacturing Practice in Packaging Medicinal Products

Program ID: CGMP06 (Learning Time: 60 minutes) | Credit Hours (CPD): 1

Price: \$195.00 USD (URL: https://www.biopharmainstitute.com/course/CGMP06)



Individual Course w/Certificate of Completion: cGMP: Corrective and Preventive Action (CAPA) in Medicinal Product Manufacturing -Including Root Cause Analysis

Program ID: CGMP07 (Learning Time: 60 minutes) | Credit Hours (CPD): 1 Price: \$195.00 USD (URL: https://www.biopharmainstitute.com/course/CGMP07)



Medical Devices (MDSAP & EU MDR)

Individual Course w/Certificate of Completion:
Introduction to the Regulation of Medical Devices

Program ID: MDA0 (Learning Time: 60 minutes) | Credit Hours (CPD): 1 Price: \$195.00 USD (URL: https://www.biopharmainstitute.com/course/MDA0)



OSHA and EEO

Training Program for Professionals:

OSHA for Healthcare Professionals

Program ID: OSHAPRO (Learning Time: See Programs Webpage) | Post-nominal Letters: OSHAPro

Price: \$995.00 USD (URL: https://www.biopharmainstitute.com/course/OSHAPRO)

Individual Course w/Certificate of Completion:

OSHA: Bloodborne Pathogens for Healthcare Workers

Program ID: OSHA-01 (Learning Time: 30 minutes)

Price: \$95.00 USD (URL: https://www.biopharmainstitute.com/course/OSHA-01)

Individual Course w/Certificate of Completion:

OSHA: Chemical Safety

Program ID: OSHA-02 (Learning Time: 20 minutes)

Price: \$95.00 USD (URL: https://www.biopharmainstitute.com/course/OSHA-02)

Individual Course w/Certificate of Completion:

OSHA: Compressed Gas Safety

Program ID: OSHA-03 (Learning Time: 22 minutes)

Price: \$95.00 USD (URL: https://www.biopharmainstitute.com/course/OSHA-03)

Individual Course w/Certificate of Completion:

OSHA: Electrical Safety for Healthcare

Program ID: OSHA-04 (Learning Time: 20 minutes)

Price: \$95.00 USD (URL: https://www.biopharmainstitute.com/course/OSHA-04)

Individual Course w/Certificate of Completion:

OSHA: Emergency Response Plan

Program ID: OSHA-05 (Learning Time: 15 minutes)

Price: \$95.00 USD (URL: https://www.biopharmainstitute.com/course/OSHA-05)

Individual Course w/Certificate of Completion:

OSHA: Environmental Cleaning-Exam Rooms

Program ID: OSHA-06 (Learning Time: 20 minutes)

Price: \$95.00 USD (URL: https://www.biopharmainstitute.com/course/OSHA-06)

Individual Course w/Certificate of Completion:

OSHA: Fire Safety and Emergency Evacuation

Program ID: OSHA-07 (Learning Time: 25 minutes)



Price: \$95.00 USD (URL: https://www.biopharmainstitute.com/course/OSHA-07)

Individual Course w/Certificate of Completion:

OSHA: Flammable Liquid Safety

Program ID: OSHA-08 (Learning Time: 20 minutes)

Price: \$95.00 USD (URL: https://www.biopharmainstitute.com/course/OSHA-08)

Individual Course w/Certificate of Completion:

OSHA: Formaldehyde Safety

Program ID: OSHA-09 (Learning Time: 20 minutes)

Price: \$95.00 USD (URL: https://www.biopharmainstitute.com/course/OSHA-09)

Individual Course w/Certificate of Completion:

OSHA: Hand Hygiene

Program ID: OSHA-10 (Learning Time: 25 minutes)

Price: \$95.00 USD (URL: https://www.biopharmainstitute.com/course/OSHA-10)

Individual Course w/Certificate of Completion:

OSHA: Hazard Communications for Healthcare

Program ID: OSHA-11 (Learning Time: 28 minutes)

Price: \$95.00 USD (URL: https://www.biopharmainstitute.com/course/OSHA-11)

Individual Course w/Certificate of Completion:

OSHA: Incident Reporting in Healthcare

Program ID: OSHA-12 (Learning Time: 15 minutes)

Price: \$95.00 USD (URL: https://www.biopharmainstitute.com/course/OSHA-12)

Individual Course w/Certificate of Completion:

OSHA: Infection Control for Healthcare Professionals

Program ID: OSHA-13 (Learning Time: 20 minutes)

Price: \$95.00 USD (URL: https://www.biopharmainstitute.com/course/OSHA-13)

Individual Course w/Certificate of Completion:

OSHA: Laser Safety

Program ID: OSHA-14 (Learning Time: 20 minutes)

Price: \$95.00 USD (URL: https://www.biopharmainstitute.com/course/OSHA-14)

Individual Course w/Certificate of Completion:

OSHA: Latex Allergy

Program ID: OSHA-15 (Learning Time: 15 minutes)

Price: \$95.00 USD (URL: https://www.biopharmainstitute.com/course/OSHA-15)



Individual Course w/Certificate of Completion:

OSHA: Lockout/Tagout Control of Hazardous Energy

Program ID: OSHA-16 (Learning Time: 18 minutes)

Price: \$95.00 USD (URL: https://www.biopharmainstitute.com/course/OSHA-16)

Individual Course w/Certificate of Completion:

OSHA: Patient Abuse & Neglect

Program ID: OSHA-17 (Learning Time: 20 minutes)

Price: \$95.00 USD (URL: https://www.biopharmainstitute.com/course/OSHA-17)

Individual Course w/Certificate of Completion:

OSHA: Patient Rights

Program ID: OSHA-18 (Learning Time: 15 minutes)

Price: \$95.00 USD (URL: https://www.biopharmainstitute.com/course/OSHA-18)

Individual Course w/Certificate of Completion:

OSHA: Personal Protective Equipment for Healthcare Workers

Program ID: OSHA-19 (Learning Time: 20 minutes)

Price: \$95.00 USD (URL: https://www.biopharmainstitute.com/course/OSHA-19)

Individual Course w/Certificate of Completion:

OSHA: Preventing Needlestick Injuries

Program ID: OSHA-20 (Learning Time: 15 minutes)

Price: \$95.00 USD (URL: https://www.biopharmainstitute.com/course/OSHA-20)

Individual Course w/Certificate of Completion:

OSHA: Preventing Workplace Violence in Healthcare Settings

Program ID: OSHA-21 (Learning Time: 25 minutes)

Price: \$95.00 USD (URL: https://www.biopharmainstitute.com/course/OSHA-21)

Individual Course w/Certificate of Completion:

OSHA: Radiation Safety

Program ID: OSHA-22 (Learning Time: 15 minutes)

Price: \$95.00 USD (URL: https://www.biopharmainstitute.com/course/OSHA-22)

Individual Course w/Certificate of Completion:

OSHA: Safe Patient Handling

Program ID: OSHA-23 (Learning Time: 20 minutes)

Price: \$95.00 USD (URL: https://www.biopharmainstitute.com/course/OSHA-23)

Individual Course w/Certificate of Completion:



OSHA: TB Protection for Healthcare Workers

Program ID: OSHA-24 (Learning Time: 25 minutes)

Price: \$95.00 USD (URL: https://www.biopharmainstitute.com/course/OSHA-24)

Individual Course w/Certificate of Completion:

OSHA: Active Shooter Response

Program ID: OSHA-25 (Learning Time: 20 minutes)

Price: \$95.00 USD (URL: https://www.biopharmainstitute.com/course/OSHA-25)

Individual Course w/Certificate of Completion:

OSHA: Back Care/Ergonomics

Program ID: OSHA-26 (Learning Time: 25 minutes)

Price: \$95.00 USD (URL: https://www.biopharmainstitute.com/course/OSHA-26)

Individual Course w/Certificate of Completion:

OSHA: Laboratory Safety

Program ID: OSHA-27 (Learning Time: 35 minutes)

Price: \$95.00 USD (URL: https://www.biopharmainstitute.com/course/OSHA-27)

Individual Course w/Certificate of Completion:

OSHA: Slips, Trips & Falls

Program ID: OSHA-28 (Learning Time: 15 minutes)

Price: \$95.00 USD (URL: https://www.biopharmainstitute.com/course/OSHA-28)

Individual Course w/Certificate of Completion:

OSHA: Violence in the Workplace

Program ID: OSHA-29 (Learning Time: 25 minutes)

Price: \$95.00 USD (URL: https://www.biopharmainstitute.com/course/OSHA-29)

Individual Course w/Certificate of Completion:

HR/EEO: Preventing Harassment and Discrimination for Employees

Program ID: HR-01 (Learning Time: 25 minutes)

Price: \$95.00 USD (URL: https://www.biopharmainstitute.com/course/HR-01)

Individual Course w/Certificate of Completion:

HR/EEO: Preventing Harassment and Discrimination for Managers

Program ID: HR-02 (Learning Time: 40 minutes)

Price: \$95.00 USD (URL: https://www.biopharmainstitute.com/course/HR-02)

Individual Course w/Certificate of Completion:

HR/EEO: Preventing Sexual Harassment for Employees



Program ID: HR-03 (Learning Time: 20 minutes)

Price: \$95.00 USD (URL: https://www.biopharmainstitute.com/course/HR-03)

Individual Course w/Certificate of Completion:

HR/EEO: Preventing Sexual Harassment for Managers

Program ID: HR-04 (Learning Time: 35 minutes)

Price: \$95.00 USD (URL: https://www.biopharmainstitute.com/course/HR-04)



Regulatory Affairs: Pharmaceuticals

Professional Certification Program:

Global Pharmaceutical Regulatory Affairs Professional Certification Program

Program ID: PRA00A1 (Learning Time: See Programs Webpage) | Post-nominal Letters: RAPro

Price: \$1795.00 USD (URL: https://www.biopharmainstitute.com/course/PRA00A1)

Professional Certification Program:

US Pharmaceutical Regulatory Affairs Professional Certification Program

Program ID: PRA00B1 (Learning Time: See Programs Webpage) | Post-nominal Letters: RAPro Price: \$1295.00 USD (URL: https://www.biopharmainstitute.com/course/PRA00B1)

Individual Course w/Certificate of Completion:

Regulatory Affairs: Essentials for Human Medicinal Products - EU and US

Program ID: PRA01 (Learning Time: 180 minutes) | Credit Hours (CPD): 3 Price: \$225.00 USD (URL: https://www.biopharmainstitute.com/course/PRA01)

Individual Course w/Certificate of Completion:

Regulatory Affairs: Orphan Drug Application - EU and US

Program ID: PRA02 (Learning Time: 90 minutes) | Credit Hours (CPD): 1.5 Price: \$145.00 USD (URL: https://www.biopharmainstitute.com/course/PRA02)

Individual Course w/Certificate of Completion:

Regulatory Affairs: Preparing Submissions in the Common Technical Document (CTD) Format

Program ID: PRA03 (Learning Time: 90 minutes) | Credit Hours (CPD): 1.5 Price: \$145.00 USD (URL: https://www.biopharmainstitute.com/course/PRA03)

Individual Course w/Certificate of Completion:

Regulatory Affairs: Electronic Common Technical Document (eCTD)

Program ID: PRA04 (Learning Time: 150 minutes) | Credit Hours (CPD): 2.5 Price: \$225.00 USD (URL: https://www.biopharmainstitute.com/course/PRA04)

Individual Course w/Certificate of Completion:

Regulatory Affairs: Registration of Drugs Based on Monoclonal Antibodies

Program ID: PRA05 (Learning Time: 180 minutes) | Credit Hours (CPD): 3 Price: \$225.00 USD (URL: https://www.biopharmainstitute.com/course/PRA05)

Individual Course w/Certificate of Completion:

Regulatory Affairs: How to Gain Approval to Market Generic Drugs in the US



Program ID: PRA06 (Learning Time: 180 minutes) | Credit Hours (CPD): 3 Price: \$225.00 USD (URL: https://www.biopharmainstitute.com/course/PRA06)

Individual Course w/Certificate of Completion:

Regulatory Affairs: Submitting a New Drug Application (NDA) to Obtain Approval to Market in the US

Program ID: PRA07 (Learning Time: 210 minutes) | Credit Hours (CPD): 3.5 Price: \$225.00 USD (URL: https://www.biopharmainstitute.com/course/PRA07)

Individual Course w/Certificate of Completion:

Regulatory Affairs: The Regulatory Pathway to Licensing Follow-on Biologics (Biosimilars) in the USA

Program ID: PRA08 (Learning Time: 30 minutes) | Credit Hours (CPD): 0.5 Price: \$115.00 USD (URL: https://www.biopharmainstitute.com/course/PRA08)

Individual Course w/Certificate of Completion:

Regulatory Affairs: The European Centralized Procedure (CP)

Program ID: PRA20 (Learning Time: 90 minutes) | Credit Hours (CPD): 1.5 Price: \$145.00 USD (URL: https://www.biopharmainstitute.com/course/PRA20)

Individual Course w/Certificate of Completion:

Regulatory Affairs: The Mutual Recognition Procedure (MRP)

Program ID: PRA21 (Learning Time: 120 minutes) | Credit Hours (CPD): 2 Price: \$195.00 USD (URL: https://www.biopharmainstitute.com/course/PRA21)

Individual Course w/Certificate of Completion:

Regulatory Affairs: Variations to Marketing Authorizations in Europe

Program ID: PRA22 (Learning Time: 210 minutes) | Credit Hours (CPD): 3.5 Price: \$225.00 USD (URL: https://www.biopharmainstitute.com/course/PRA22)

Individual Course w/Certificate of Completion:

Regulatory Affairs: The Decentralized Procedure (DCP)

Program ID: PRA23 (Learning Time: 120 minutes) | Credit Hours (CPD): 2 Price: \$195.00 USD (URL: https://www.biopharmainstitute.com/course/PRA23)

Individual Course w/Certificate of Completion:

Regulatory Affairs: Essentials of Monoclonal Antibodies

Program ID: PRA24 (Learning Time: 60 minutes) | Credit Hours (CPD): 1 Price: \$145.00 USD (URL: https://www.biopharmainstitute.com/course/PRA24)

Individual Course w/Certificate of Completion:



The Biologics License Application (BLA) for Marketing Approval in the USA

Program ID: SUB15 (Learning Time: 210 minutes) | Credit Hours (CPD): 3.5 Price: \$225.00 USD (URL: https://www.biopharmainstitute.com/course/SUB15)

Individual Course w/Certificate of Completion:

The 505(b)(2) Application for Marketing Approval in the USA

Program ID: SUB16 (Learning Time: 30 minutes) | Credit Hours (CPD): 0.5 Price: \$145.00 USD (URL: https://www.biopharmainstitute.com/course/SUB16)



Pharmaceutical Sales and Marketing

Professional Certification Program:

Pharmaceutical Sales & Marketing Compliance Professional Certification

Program ID: SAMPRO (Learning Time: See Programs Webpage) | Post-nominal Letters: SMPro

Price: \$645.00 USD (URL: https://www.biopharmainstitute.com/course/SAMPRO)

Individual Course w/Certificate of Completion:

Pharmaceutical Sales & Marketing: Legal and Regulatory Framework for Advertising and Promotion of Prescription Drugs in the USA

Program ID: SAM01 (Learning Time: 60 minutes) | Credit Hours (CPD): 1 Price: \$185.00 USD (URL: https://www.biopharmainstitute.com/course/SAM01)

Individual Course w/Certificate of Completion:

Pharmaceutical Sales & Marketing: Regulatory Requirements and Guidance on Advertising and Promotion of Prescription Drugs in the USA

Program ID: SAM02 (Learning Time: 90 minutes) | Credit Hours (CPD): 1.5 Price: \$185.00 USD (URL: https://www.biopharmainstitute.com/course/SAM02)

Individual Course w/Certificate of Completion:

Pharmaceutical Sales & Marketing: Consumer-directed Advertising and Online Promotion of Prescription Drugs in the USA

Program ID: SAM03 (Learning Time: 60 minutes) | Credit Hours (CPD): 1 Price: \$185.00 USD (URL: https://www.biopharmainstitute.com/course/SAM03)

Individual Course w/Certificate of Completion:

Pharmaceutical Sales & Marketing: Marketing of Prescription Drugs in the USA-Interactions with Healthcare Professionals

Program ID: SAM04 (Learning Time: 60 minutes) | Credit Hours (CPD): 1 Price: \$185.00 USD (URL: https://www.biopharmainstitute.com/course/SAM04)



Validation (Process & Equipment)

Professional Certification Program:

Pharmaceutical Validation Management Professional Certification Program

Program ID: VAL00S1 (Learning Time: See Programs Webpage) | Post-nominal Letters: VALPro

Price: \$1299.00 USD (URL: https://www.biopharmainstitute.com/course/VAL00S1)

Individual Course w/Certificate of Completion:

Validation: Introduction to Validation

Program ID: VAL01 (Learning Time: 90 minutes) | Credit Hours (CPD): 1.5 Price: \$195.00 USD (URL: https://www.biopharmainstitute.com/course/VAL01)

Individual Course w/Certificate of Completion:

Validation: Plans and Documentation

Program ID: VAL02 (Learning Time: 90 minutes) | Credit Hours (CPD): 1.5 Price: \$195.00 USD (URL: https://www.biopharmainstitute.com/course/VAL02)

Individual Course w/Certificate of Completion:

Validation: Commissioning and Installation Qualification (IQ)

Program ID: VAL03 (Learning Time: 90 minutes) | Credit Hours (CPD): 1.5
Price: \$195.00 USD (URL: https://www.biopharmainstitute.com/course/VAL03)

Individual Course w/Certificate of Completion:

Validation: Operational and Performance Qualification (OQ/PQ)

Program ID: VAL04 (Learning Time: 60 minutes) | Credit Hours (CPD): 1 Price: \$195.00 USD (URL: https://www.biopharmainstitute.com/course/VAL04)

Individual Course w/Certificate of Completion:

Validation: Equipment Cleaning Validation

Program ID: VAL08 (Learning Time: 90 minutes) | Credit Hours (CPD): 1.5 Price: \$195.00 USD (URL: https://www.biopharmainstitute.com/course/VAL08)



Additional Information:

Certification Requirements:

Students must view the entire course and successfully pass an online, multiple-choice final assessment within a 12-month period. A certificate of completion is immediately accessible in PDF format after satisfying the requirements.

Biopharma Institute's online training courses include immediate access after enrollment. Username, password, and instructions are emailed to the student directly following online enrollment into the program. Course takers may attempt the final assessment any number of times, as needed, to achieve a passing score. The certificate of completion is promptly launched and made available to the student upon course completion. Certificates are issued in an encrypted PDF format, and include a watermark, unique validation code, and QR verification barcode.

Once all training requirements have been satisfied the achievement can be verified from our website using the unique certificate ID or QR barcode located on the certificate. For professional certification programs, a digital badge is additionally issued to verify training and document the achievement. Digital badges can be displayed on social networking sites, such as LinkedIn, Facebook, Twitter, and Badgr.

Biopharma Institute certificates and digital badges include the date of completion, but do not have an expiration date. However, compliance training is typically considered valid for a period of 3 years. Many organizations suggest that compliance training should be refreshed at least every three years to stay up to date with regulations, standards, guidelines, and to reinforce the importance of maintaining compliance. The validity or recertification period for employee compliance training would be determined by those responsible for managing quality within the company.

Benefits of Being Certified from Biopharma Institute:

Throughout our training students will be engaging in active learning using interactive eLearning modules validated by 3rd party organizations for relevancy, compliance, and regulatory content. Courses are developed by subject matter experts (SMEs) and instructional design professionals with the goal to promote the students' retaining of key knowledge. The programs further offer access to regulatory references, real-life case studies, and introduce other important information necessary to assist with learning.

Since 2003, Biopharma Institute has been aiding both professionals and their corporate employers with fulfilling training requirements. Biopharma Institute's certifications are recognized by a wide spectrum of industries, regulators, and companies around the world. Furthermore, our training solutions are customizable to any organization's training needs. Today, Biopharma Institute offers over 300 courses



training on clinical research, drug manufacturing (cGMP), regulatory affairs, validation systems, pharmacovigilance, good laboratory practice (GLP), and data integrity. We supply our training to clinical research, pharmaceutical, and medical device industries.

Employee / Corporate Training:

For corporations seeking a method to train employees, economically, without having to set aside time for travel, webinars, or live, in-person training; Biopharma Institute is the training partner you can rely on. Our training provides an effective, engaging, self-paced learning experience which fits conveniently into the day-to-day activities of most types of learners. Our eLearning modules are SCORM-compliant and can be delivered from most corporate learning management systems (LMS). We catering to both small-scale and large-scale training requests, with the same goal in mind: To make this a good experience for everyone involved, from the students to those managing the group training.

Benefits of Training with Biopharma Institute:

Immediate access to courses: Username, password, instructions, and receipt of payment are immediately emailed upon online enrollment.

Self-paced, asynchronous eLearning: 24/7 access to all course materials and assessments for 12 months.

Open enrollment: No prior course prerequisites or work experience required.

Expertise: Courses developed by subject matter experts (SMEs) in the area being taught.

Current and validated: Training is current with respect to regulations, procedures, and 3rd party validated and/or accredited.

Optimized for learning: Courses include voiceovers, easy navigation, reading materials, case studies, progress checks, and high-quality animations to increase retention of subject matter.

Secure and safe access: Encrypted website and LMS connections, firewall, and daily malware scans deliver optimal security and performance.

Flexible final assessments: Multiple-choice questions can be taken repeatedly until a passing score is achieved.

Direct access to certificates: Certificate of completion is issued in an encrypted PDF format immediately after satisfying the requirements. Certificates include a watermark, unique validation code, and QR verification barcode.



Verification of training: Certificates are verifiable online using QR barcode or the unique ID code. Digital badges are additionally issued for all professional certification programs.

Training manager access: A proprietary portal offers access to download enrollment reports, training records, account balance, and more.

SCORM-compliant courses: Courses can be delivered directly to most corporate Learning Management Systems (LMS).

Purchase orders (POs): POs are accepted from all companies. Request an invoice when starting the procurement process.

Reimbursement: Some employers may reimburse their employees for training expenses. Check your company's policy.

Financial assistance: Payment plans are available to those who qualify. Alternatively, purchasing individual courses one at a time is also an option.

Career advancement: Professional certifications help demonstrate interest and dedication to career and job performance. They may be helpful for those seeking to grow their career or transitioning to a different position within an organization. Professional certifications are a great addition to a resume, offer talking points for the interview, and practical knowledge for performing duties.

Have Questions? Contact Us:

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Email: support@biopharmainstitute.com