

Professional Training Catalog

Biotechnology and Pharmaceutical Sciences

2011



**BIOPHARMA
INSTITUTE**

Excellence in
Education

The BioPharma Institute is world-class training facility with a mission: To provide the tools necessary for companies and professionals to achieve a competitive edge in the marketplace. The institute prides itself on its catalog of comprehensive training, online certifications, and professional designation programs targeted in the life sciences, biotechnology and pharmaceutical industries.

BIOPHARMA INSTITUTE

Wyckoff, New Jersey, USA
(888) 4-BIO-LRN – Toll free
(201) 800-4430 – Phone

CATALOG

Clinical Trials, Audits, and Monitoring Courses
Good Laboratory Practice Courses
Good Manufacturing Practices Courses
BioPharma IT/IS Courses
Medical Devices Courses
Pharmaceutical Regulatory Affairs Courses
Pharmaceutical Validation Courses
Pharmacovigilance (Drug Safety) Courses
Medical Device and GMP Training for Employees
Electronic Records and Signatures (21 CFR Part 11)
Biotechnology Applications
Genetic Identity and Inheritance

Complete List of Online Certification Courses and Professional Designation Training Programs

BIOTECHNOLOGY and PHARMACEUTICAL ONLINE TRAINING COURSES:

Clinical Trials, Audits, and Monitoring Courses



Comprehensive Training Program

Professional Designation in Clinical Trials Monitoring - GCP00S

PRICE: \$359 |



Comprehensive Training Program

Professional Designation in Clinical Trials Management - GCP00S1

PRICE: \$1289 |



Comprehensive Training Program

Professional Designation in Good Clinical Practice - GCP00S2

PRICE: \$1090 |



GCP: An Introduction to ICH Good Clinical Practice (ICH-GCP) - GCP01

PRICE: \$199 |



GCP: An Introduction to Clinical Trial Preparation and Design - GCP02

PRICE: \$199 |



GCP: Introduction to Clinical Trials and Drug Development - GCP03

PRICE: \$199 |



GCP: Clinical Trial Monitoring: Site Evaluation and Set-up - GCP04

PRICE: \$199 |



**GCP: Clinical Trial Monitoring: Study Monitoring, Documentation and Closure-
GCP05**

PRICE: \$199 |



GCP: Preparing for an Audit or Inspection - GCP06

PRICE: \$199 |



GCP: The IND, How to Gain Approval for Clinical Trials in the USA - GCP07

PRICE: \$199 |



GCP: How to Obtain Approval to Conduct Clinical Trials in the EU - GCP20

PRICE: \$199 |



GCP: An Introduction to Clinical Trials in India - GCP21
PRICE: \$199 |

Good Laboratory Practice Courses



Comprehensive Training Program
Professional Designation in Good Laboratory Practices - GLP00S1
PRICE: \$1799 |



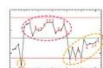
Comprehensive Training Program
Professional Designation in Quality Control in the Laboratory (GLPs) - GLP00S2
PRICE: \$599 |



Comprehensive Training Program
Professional Designation in Microbiology Lab Techniques and Quality Control (GLP) - GLP00S3
PRICE: \$599 |



GLP: QC in a Regulated Laboratory - GLP02
PRICE: \$219 |



GLP: Basic Statistics for QC Laboratories- GLP03
PRICE: \$219 |



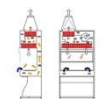
GLP: Sampling Plans - GLP04
PRICE: \$219 |



GLP: Stability Programs - GLP05
PRICE: \$219 |



GLP: Microbiology and QC - GLP06
PRICE: \$219 |



GLP: Microbiology Laboratory Techniques - GLP07
PRICE: \$219 |



GLP Quality Control: Analytical Method Validation - GLPQ01
PRICE: \$219 |



GLP Quality Control: IQ/OQ and Calibration of Lab Equipment - GLPQ02
PRICE: \$219 |

Good Manufacturing Practices Courses



Comprehensive Training Program

Professional Designation in Good Manufacturing Practices (GMP) - GMP001S1

PRICE: \$1795 |



Comprehensive Training Program

Professional Designation in Microbiology and Good Manufacturing Practices (GMP) - GMP001S2

PRICE: \$359 |



GMP: An Introduction to Good Manufacturing Practices - GMP01

PRICE: \$199 |



GMP: Warehouse - GMP02

PRICE: \$199 |



GMP: Microbiology in the Workplace - GMP03

PRICE: \$199 |



GMP: Cleaning and Sanitation - GMP04

PRICE: \$199 |



GMP: Documentation and Record Keeping - GMP05

PRICE: \$199 |



GMP: Contamination Control - GMP06

PRICE: \$199 |



GMP: Production Controls - GMP07

PRICE: \$199 |



GMP: Packaging Controls - GMP08

PRICE: \$199 |



GMP: Quality Assurance and Quality Control - GMP09

PRICE: \$199 |



GMP: Pharmaceutical CAPAs - GMP10

PRICE: \$199 |



GMP: Surviving and FDA Inspection - GMPSP04

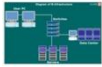
PRICE: \$139 |



GMP: Understanding Validation - GMPSP05

PRICE: \$139 |

BioPharma IT/IS Courses



Comprehensive Training Program

Professional Designation in BioPharma IT/IS Compliance and Qualifications - ISIT0S1

PRICE: \$395 |



BioPharma IS/IT: Introduction to Compliance - ISIT1

PRICE: \$229 |



BioPharma IS/IT: Infrastructure Qualification - ISIT2

PRICE: \$229 |

Medical Devices Courses



Comprehensive Training Program

Professional Designation in Global Medical Device Regulatory Affairs - MD00S1

PRICE: \$395 |



Comprehensive Training Program

Professional Designation in US Medical Device Regulatory Affairs - MD00S2

PRICE: \$395 |



Comprehensive Training Program

Professional Designation in Medical Device Quality Management - MD00S3

PRICE: \$539 |



Medical Device Regulatory Affairs: Australian Overview - MDA1

PRICE: \$169 |



Medical Device Regulatory Affairs: Australian Requirements for Registration- MDA2

PRICE: \$169 |



Medical Device Regulatory Affairs: Global - MDG1

PRICE: \$149 |



Medical Device Regulatory Affairs: Global Quality Management Systems, the Requirements - MDG2

PRICE: \$149 |



Medical Device Regulatory Affairs: Global Risk Management - MDG3

PRICE: \$149 |



Medical Device Quality Management: Managing a QMS - MDQ1
PRICE: \$199 |



Medical Device Quality Management: Documentation and Records - MDQ2
PRICE: \$199 |



Medical Device Quality Management: CAPA Systems - MDQ3
PRICE: \$199 |



Medical Device Regulatory Affairs: US Overview - MDU1
PRICE: \$169 |



Medical Device Regulatory Affairs: US Quality Systems Requirements, 21 CFR 820 - MDU2
PRICE: \$169 |



Medical Device Regulatory Affairs: US 510(k) Premarket Notification Scheme - MDU3
PRICE: \$169 |

Pharmaceutical Regulatory Affairs Courses



Comprehensive Training Program
Professional Designation in US Pharmaceutical Regulatory Affairs - PRA000S1
PRICE: \$1295 |



Pharmaceutical Regulatory Affairs: Essentials for Human Medicinal Products - EU and US - PRA001
PRICE: \$199 |



Pharmaceutical Regulatory Affairs: Orphan Drug Application - EU and US - PRA002
PRICE: \$199 |



Pharmaceutical Regulatory Affairs: Preparing Submissions in the Common Technical Document (CTD) Form - PRA003
PRICE: \$199 |



Pharmaceutical Regulatory Affairs: Electronic Common Technical Document (eCTD) - PRA004
PRICE: \$199 |



Pharmaceutical Regulatory Affairs: Registration of Monoclonal Antibodies - PRA005
PRICE: \$199 |



Pharmaceutical Regulatory Affairs: The ANDA, Requirements for Obtaining FDA Approval for Generic Pro - PRA006

PRICE: \$199 |



Pharmaceutical Regulatory Affairs: The NDA Process, Requirements for Obtaining Approval for a New Dr - PRA007

PRICE: \$199 |



Pharmaceutical Regulatory Affairs: The European Centralised Procedure (CP) - PRA020

PRICE: \$199 |



Pharmaceutical Regulatory Affairs: The Mutual Recognition Procedure (MRP) - PRA021

PRICE: \$199 |



Pharmaceutical Regulatory Affairs: EU Variations Procedure - PRA022

PRICE: \$199 |



Pharmaceutical Regulatory Affairs: The Decentralised Procedure (DCP) - PRA023

PRICE: \$199 |

Pharmaceutical Validation Courses



Comprehensive Training Program

Professional Designation in Pharmaceutical Validation Management- VAL00S1

PRICE: \$1490 |



Comprehensive Training Program

Professional Designation in Computer System Validation for BioPharma Companies - VAL00S2

PRICE: \$629 |



Validation: Principles/International Regulations - VAL01

PRICE: \$229 |



Validation: Master Plans and Documentation - VAL02

PRICE: \$229 |



Validation: Commissioning and Installation Qualification - VAL03

PRICE: \$229 |



Validation: Operational/Performance Qualification Protocols - VAL04
PRICE: \$229 |



Validation: Equipment Cleaning Validation - VAL08
PRICE: \$229 |



Validation: Computer Systems - Part I - VAL09
PRICE: \$229 |



Validation: Computer Systems - Part II - VAL10
PRICE: \$229 |



GLP: Introduction to QC - GLP01
PRICE: \$219 |

Pharmacovigilance (Drug Safety)



Drug Safety: Pharmacovigilance, Monitoring Drug Safety - DS01
PRICE: \$199 |

Medical Device and GMP Training for Employees



Comprehensive Training Program
Employee Certification in Understanding Pharmaceutical cGMPs - E1GMP
PRICE: \$589 |



Comprehensive Training Program
Employee Certification in Understanding Medical Device cGMPs - E1GMPMD
PRICE: \$489 |



21 CFR Part 211: cGMP Regulations and Controls - ECFRP211
PRICE: \$79 |



21 CFR Part 211 Subpart B: Organization and Personnel - ECFRP211B
PRICE: \$79 |



21 CFR Part 211 Subpart C: Buildings and Facilities - ECFRP211C
PRICE: \$139 |



21 CFR Part 211 Subpart D: Equipment - ECFRP211D
PRICE: \$139 |



21 CFR Part 211 Subpart E: Materials - ECFRP211E
PRICE: \$139 |



21 CFR Part 211 Subpart F: Production and Process Controls - ECFRP211F
PRICE: \$79 |



GMP: Contamination Control for Employees - EGMPSP01
PRICE: \$139 |



GMP: Proper Documentation Practices - EGMPSP02
PRICE: \$139 |



GMP: Root Cause Analysis - EGMPSP03
PRICE: \$139 |



21 CFR Part 820: cGMP System Regulation - EMDUSP01
PRICE: \$139 |

Electronic Records and Signatures (21 CFR Part 11)



Comprehensive Training Program

Professional Designation in Electronic Signatures & Records (21 CFR Part 11) - ESR001S

PRICE: \$1795 |



Electronic Signatures & Records - 21 CFR Part 11 - ESR01

PRICE: \$275 |



Excel Spreadsheet and FDA Device Regulations - ESR02

PRICE: \$399 |



FDA 21 CFR Part 11 for Technical Employees - ESR03

PRICE: \$299 |



21 CFR Part 11: Ins and Outs of Audit Trails - ESR04

PRICE: \$249 |



21 CFR Part 11: How to Successfully Prepare for and Host an FDA Inspection - ESR05

PRICE: \$349 |



21 CFR Part 11: Auditing for Part 11 Compliance - ESR06

PRICE: \$249 |



21 CFR Part 11: Compliance for Electronic Medical Records - ESR07

PRICE: \$249 |

Biotechnology Applications



Circulating Tumor Cells as Biomarkers in Clinical Development - CTC01

PRICE: \$95 |

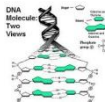
Genetic Identity & Inheritance



Comprehensive Training Program

Professional Designation in Genetic Inheritance and Identification - GENE05S

PRICE: \$99.00 |



Genetics: Introduction to DNA - The Building Blocks of Life - GENE001

PRICE: \$19.50 |



Genetic Inheritance: Dominant vs. Recessive - GENE002

PRICE: \$19.50 |



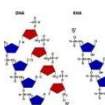
Genetic Inheritance: Incomplete Dominance and Co-dominance - GENE003

PRICE: \$19.50 |



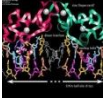
Genetic Inheritance: Understanding Punnet Squares - GENE004

PRICE: \$19.50 |



Genetic Inheritance: Sex Determination and Linkage - GENE005

PRICE: \$19.50 |



Genetic Inheritance: Crossing Over during Meiosis - GENE006

PRICE: \$19.50 |



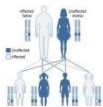
Genetic Inheritance: Natural Selection - GENE007

PRICE: \$19.50 |



Genetic Inheritance: Understanding Hardy-Weinberg Equilibrium - GENE008

PRICE: \$19.50 |



Genetic Counseling: The Role of a Genetic Counselor - GENE009

PRICE: \$19.50 |



Genetic Identity: DNA Fingerprinting to Solve Crimes - GENE010

PRICE: \$19.50 |

Online Professional Training Programs include:

1. 24/7 access to the courses for a 90 day (3 month) period OR 270 days (6 months) for Professional Designation Programs,
2. A printable PDF file including the course notes (not available with all courses),
3. An online, multiple-choice final assessment used to measure the level of understanding for the material provided within the course, and

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www.BioPharmaInstitute.com/FREECOURSES

A Certificate of Completion, which is immediately available once the course requirements have been satisfied.
