

BIOPHARMA **INSTITUTE**

EXCELLENCE IN TRAINING FOR BIOPHARMA PROFESSIONALS

About the BioPharma Institute

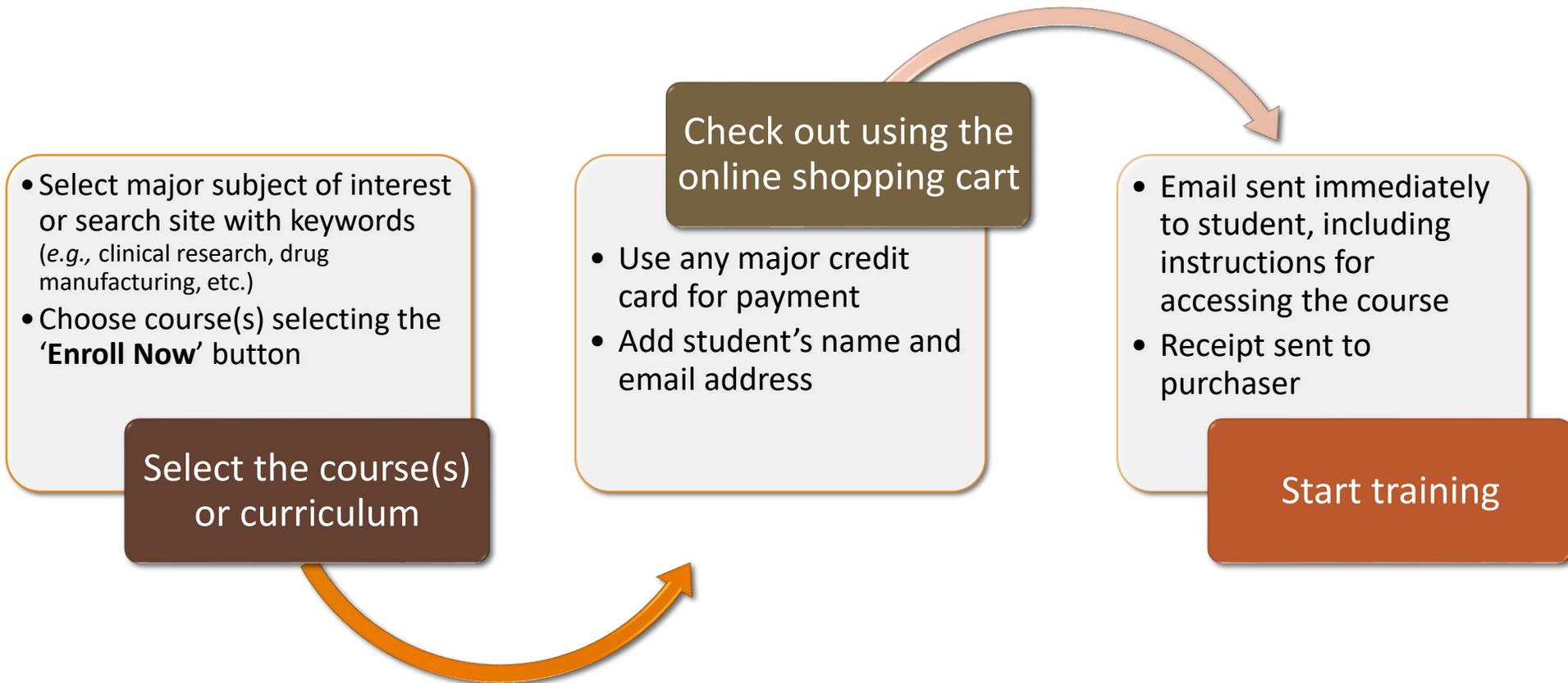
- ✓ A Division of GeneTree, Inc., founded in 1997
 - ✓ GeneTree has multiple divisions providing customer-oriented service to professionals in the pharmaceutical and healthcare industries
- ✓ The BioPharma Institute launched in 2003 for training individuals in the highly-regulated biopharmaceutical industry



About our training programs:

- ✓ Online training offers high-quality voiceovers, illustrations and progress checks throughout the modules
- ✓ Individual courses provide certificates of completion
- ✓ Comprehensive training curricula may lead to Professional Certification
- ✓ Certificates immediately available upon course completion
- ✓ Training records maintained indefinitely

Easy enrollment offering immediate access...



Step #1: Select from our diverse collection of courses



GOOD CLINICAL PRACTICES (GCP)



GOOD MANUFACTURING PRACTICES (GMP)



GOOD LABORATORY PRACTICES (GLP)



VALIDATION SYSTEMS



PHARMACOVIGILANCE



REGULATORY AFFAIRS



IT / IS FOR BIOPHARMA



ELECTRONIC RECORDS



MEDICAL DEVICES

Select the course category of interest:

- Good Manufacturing Practice
- GMP Employee Training
- Good Laboratory Practice
- Validation for BioPharma
- Good Clinical Practice
- Pharmacovigilance
- Regulatory Affairs
- Medical Devices
- IT/IS for BioPharma
- 21 CFR Part 11
- 21 CFR Part 211
- 21 CFR Part 820

Step #2:

Select course(s)

Choose your course from the list and click 'Add to Cart'



Professional Certification Program
Clinical Trials Management Professional Certification Program
Course ID: GCP00A1
PRICE: \$1299
Learn More...

[Enroll Here](#)



Professional Certification Program
Good Clinical Practice Professional Certification Program
Course ID: GCP00A2
PRICE: \$1120
Learn More...

[Enroll Here](#)



GCP. ICH Good Clinical Practice (ICH-GCP), An Abridged Course
Course ID: GCP00
PRICE: \$0
Learn More...

[Enroll Here](#)



GCP. ICH Good Clinical Practice (ICH-GCP)
Course ID: GCP001
PRICE: \$195
Learn More...

[Enroll Here](#)



GCP. Clinical Trial Preparation and Design
Course ID: GCP002
PRICE: \$195
Learn More...

[Enroll Here](#)

Comprehensive Training Programs include a curriculum of several courses leading to a Professional Designation certification

Individual courses lead to a certificate of completion

Step #3: Access training course(s) *Login at BioPharmaInstitute.com homepage*

STUDENT INFORMATION:

John Balestrini

Username: JBalestrini@xmail.com

Password: Pr3Wbqj

A username (student's email address) and password with instructions are immediately emailed to student after ordering.



Login at BioPharmaInstitute.com homepage

Step #4: Welcome to the Learning Management System (LMS)

Once logged in, you can access all your courses

The screenshot displays the BioPharma Institute LMS homepage. At the top, the logo and name 'BIOPHARMA INSTITUTE' are visible. Below the header, there is a navigation menu on the left with categories like 'Site Administration', 'Main Menu', and 'FDA Alerts'. The main content area features a table of 'Available Courses' with columns for course title, administrator, and description. A red oval highlights the course list, and a red callout box points to it with the text: 'A list of your enrolled courses are accessible from the LMS homepage after you login.' The course list includes:

Course Title	Administrator	Description
GMP0: Documentation and Record Keeping (an Abridged Course)	BioPharma Institute	The role of documentation in providing a history of manufacturing from supplier to customer. Documentation and Record Keeping. course.
GMP01: Good Manufacturing Practices, Overview	BioPharma Institute	Good Manufacturing Practices: Overview.
GMP02: GMP for the Warehouse	BioPharma Institute	GMP: An introduction to control and management of manufacturing and quality control testing of pharmaceutical products from the perspective of the warehouse.
GMP03: Microbiology in the Workplace	BioPharma Institute	GMP: An introduction to control and management of manufacturing and quality control testing of pharmaceutical products Microbiology in the Workplace
GMP04: Cleaning and Sanitation	BioPharma Institute	Participants are given a thorough understanding of the importance of cleaning and sanitizing procedures and their responsibilities, and why these are important parts of their (and not cleaners') jobs.
GMP05: Documentation and Record Keeping	BioPharma Institute	The role of documentation in providing a history of manufacturing from supplier to customer. The requirements of Standard Operating Procedures (SOPs), Batch Processing Records, Quality Control Records and Logs are discussed and developed.
GMP06: Contamination Control	BioPharma Institute	Addresses the GMP requirements for contamination control. Participants are encouraged to examine their own work practices to identify potential physical and chemical sources of contamination. Methods for preventing contamination are developed.
GMP07: Production Controls	BioPharma Institute	Builds on the Contamination Control module. Controls for starting materials, dispensing and processing, and what actions to take when confronted with non-conforming materials, products and processes.
GMP08: Packaging Controls	BioPharma Institute	The GMP requirements for the control of packaging materials and operations. Participants explore why labelling problems are still one of the most common causes of product recall.
GMP09: Quality Assurance and Quality Control	BioPharma Institute	An introduction to control and management of manufacturing and quality control testing of pharmaceutical products.

Step #5: Navigate the course page

Access to training, assessment and certificate of completion

BIOPHARMA INSTITUTE

HOME > GMP04

Administration

- Turn editing on
- Settings
- Assign roles
- Grades
- Groups
- Backup
- Restore
- Import
- Reset
- Reports
- Questions
- Files
- Profile

Clinical Trial Alerts

Add/Edit Feeds

- Sugarcane extract may relieve stress-induced insomnia
- Reducing inflammation without lowering cholesterol cuts risk of cardiovascular events
- Multiple sclerosis: Are we close to a cure?
- Osteoporosis: Potential new drug target uncovered
- Peanut allergy could be cured with probiotics

Topic outline

- GMP: Cleaning and Sanitation
- GMP: Cleaning and Sanitation (GMP04)
- 1 Final Assessment: GMP: Cleaning and Sanitation
- 2 Certificate of Completion

Access to course

Access to final assessment

Access to certificate of completion

Step #6:

Navigate the course

Courses include voiceovers and easy navigation

BIOPHARMA INSTITUTE Introduction to Documentation and Records Keeping, an Abridged Course

Introduction

Need for documentation

What do you think?
GMP solution

- Need for documentation
- GMP compliant documents

Documentation & records

Document control
GMP rules for control
Introducing a standard procedure
Review
Contact us

Glossary/Resources

GMP compliant documents

A compliant documentation system should:

- have written procedures that are well-defined, understood and deployed
- prevent misinterpretation and error
- be unambiguous
- have accurate records that provide evidence of performance
- allow calculations to be checked
- allow tracing of a batch history, in some situations, over months or years

Batch records must be stored safely, and must be able to be retrieved when necessary.

GMP Codes

- International
- FDA
- Guidance

Contents My Notes

Volume

Time 0:32 / 0:32

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Easy menu bar navigation

Volume control for voiceovers

Scroll to rewind and /or forward through course module.

Step #7: Navigate to final assessment

Includes multiple choice and true/false questions

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HOME > GMP04 > Quizzes > Final Assessment: GMP: Cleaning and Sanitation > Attempt 1

Info Results Preview

Preview Final Assessment: GMP: Cleaning and Sanitation

Start again

Page: 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26

1 Which one of the following provides the best indication of potential microbial contamination of product?

Marks: 1

Choose one answer.

- a. equipment cleaning logs and status cards
- b. microbiological test records
- c. air conditioning pressure records
- d. QC analytical test records

Save without submitting Submit all

Page: 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26

Moodle Docs for this page

You are logged in as BioPharma Institute (Logout)

GMP04

Navigate through all questions

Final assessment includes both multiple choice and true/false questions. One question is presented on a single page.

Options to save without submitting, or saving and submit. The final assessment can be taken as many times as necessary to pass during the access period (usually 90 days)

Step #8: Certificate of Completion



Includes student's name.

Name of course completed with date of completion.

Number of credit hours achieved including unique validation code



Corporate Account Training Manager Portal

Real-time access to training records

	A	B	C	D	E	F	G			
1	lastname	firstname	username	fullname	lastip	grade	name			
2	DOELAST	JOHN	user@bioph.com	PRA001: Essentials for Hu	208.93.249.82	87.5	Final Assessment: Essentials fo			17:28
3	DOELAST	JOHN	user@bioph.com	PRA002: Orphan Drug Ap	208.93.249.82	100	Final Assessment: Orphan Drug			17:28
4	DOELAST	JOHN	user@bioph.com	ESR01: Electronic Signatu	160.62.4.10	92.59	Final Assessment: Electronic Si			4 5:31
5	DOELAST	JOHN	user@bioph.com	EGMPSP02: Proper Docur	160.62.4.10	90.48	Final Assessment: Proper Docu			14 5:31
6	DOELAST	JOHN	user@bioph.com	VAL01: Validation - Princi	160.62.4.10	96.67	Final Assessment: Validation: Principle	3/5/2014 10:03	8/5/2014 2:49	8/4/2014 5:31
7	DOELAST	JOHN	user@bioph.com	VAL09: Validation: Comp	160.62.4.10	86.21	Final Assessment: VAL09 - Validatio	2/6/2014 10:22	8/5/2014 2:49	8/4/2014 5:31
8	DOELAST	JOHN	user@bioph.com	VAL10: Validation: Comp	160.62.4.10	84.62	Final Assessment: VAL10 - Valid			4 5:31
9	DOELAST	JOHN	user@bioph.com	GMP01: Good Manufactu	69.123.204.14	89.66	Final Assessment, Good Manufa			2 9:50
10	DOELAST	JOHN	user@bioph.com	GLP01: Introduction to QC	69.123.204.14	89.29	Final Assessment: GLP: Introduction to	9/27/2012 13:48	4/16/2013 18:52	9/27/2012 9:50
11	DOELAST	JOHN	user@bioph.com	GMP07: Production Contr	97.112.11.245	82.93	GMP07: Production Controls - Final Ass	8/6/2013 21:31	11/21/2014 11:08	8/6/2013 18:14
12	DOELAST	JOHN	user@bioph.com	GMP08: Packaging Contr	97.112.11.245	80.56	GMP08: Packaging Controls - Final Ass	11/21/2014 11:07	11/21/2014 11:08	8/6/2013 18:14
13	DOELAST	JOHN	user@bioph.com	GMP01: Good Manufactu	173.56.119.34	96.55	Final Assessment, Good Manufacturing	3/16/2015 14:23	3/16/2015 14:27	3/16/2015 8:13
14	DOELAST	JOHN	user@bioph.com	ESR01: Electronic Signatu	64.30.86.145	85.19	Final Assessment: Electronic Signature	3/6/2012 9:54	9/20/2012 10:52	3/6/2012 9:55
15	DOELAST	JOHN	user@bioph.com	ESR01: Electronic Signatu	24.218.189.46	81.48	Final Assessment: Electronic Signature	11/26/2012 19:02	8/12/2013 9:32	11/26/2012 16:07
16	DOELAST	JOHN	user@bioph.com	GMP04: Cleaning and San	97.112.13.126	90	Final Assessment: GMP: Cleaning and S	8/5/2010 13:21	12/10/2014 11:34	12/9/2014 15:32
17	DOELAST	JOHN	user@bioph.com	GMP05: Documentation a	97.112.13.126	100	Final Assessment: GMP: Documentatio	8/31/2011 15:20	12/10/2014 11:34	12/9/2014 15:32
18	DOELAST	JOHN	user@bioph.com	GMP06: Contamination C	97.112.13.126	93.33	GMP06: Contamination Control - Final	9/13/2012 13:56	12/10/2014	4 15:32
19	DOELAST	JOHN	user@bioph.com	GMP07: Production Contr	97.112.13.126	97.56	GMP07: Production Controls - Final Ass	7/18/2013 15:46	12/10/2014	4 15:32
20	DOELAST	JOHN	user@bioph.com	GMP08: Packaging Contr	97.112.13.126	80.56	GMP08: Packaging Controls - Final Ass	11/21/2014 11:07	11/21/2014	4 15:32

Student's name and email address

Course names and scores on final assessments and sections viewed

Date of first access and completion





Thank you!

VISIT [BIOPHARMAINSTITUTE.COM](https://www.biopharmainstitute.com) FOR MORE INFORMATION AND TO DEMO OUR ONLINE TRAINING PROGRAMS

