

BIOPHARMA INSTITUTE

EXCELLENCE IN TRAINING FOR BIOTECH AND PHARMA PROFESSIONALS



About the BIOPHARMA INSTITUTE

- A d/b/a of GeneTree Incorporated, founded in 1997.
- The company has been providing quality services to professionals in pharmaceutical and healthcare capacities as well as direct to consumer products and services.
- Christina Carmichael, Managing Director of the Institute, has over 20 years experience in clinical research and training.



About the courses:

- Courses delivered offer high-quality voiceovers and illustrations, including progress reports throughout the module.
- Individual courses yield a certificate of completion.
- Comprehensive training curriculums lead to a Professional Designation Certification.
- Certificates are immediately accessible in PDF format upon completion of course requirements.
- Training records are maintained indefinitely.



Easy enrollment offering immediate access...



Step #1:

Select from our diverse compilation of courses



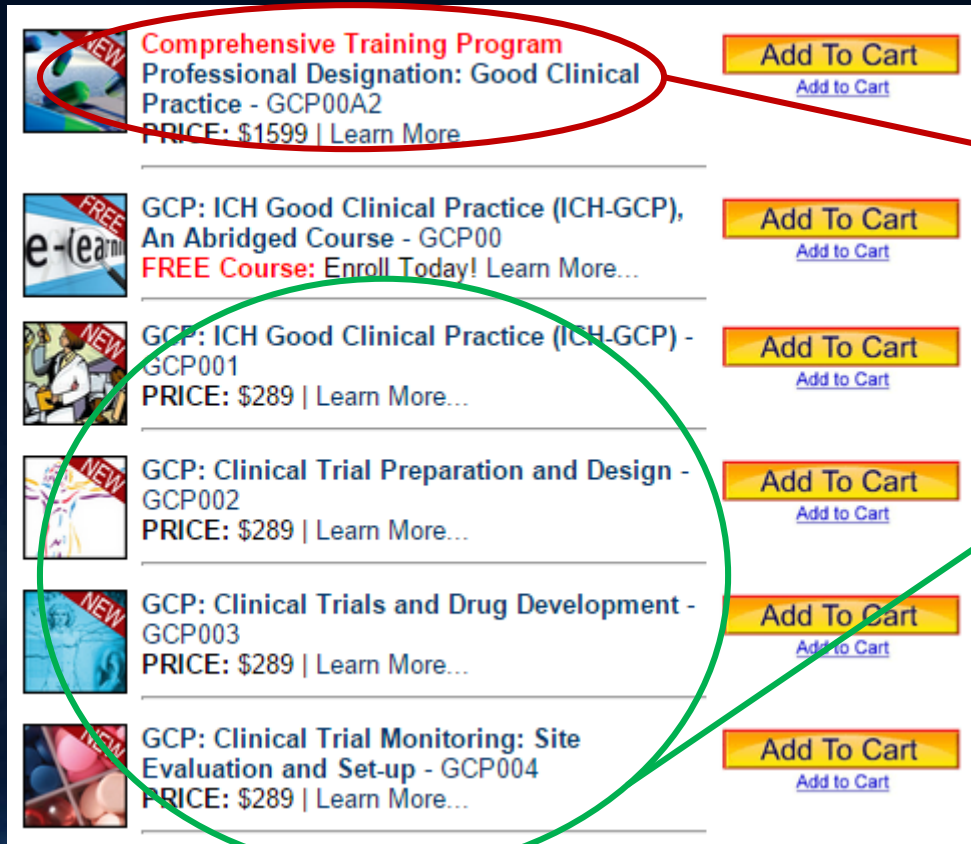
Select the course category you are most interested in:

- Clinical Research
- Drug Manufacturing
- Regulatory Affairs
- Validation Systems
- Pharmacovigilance
- Good Laboratory Practices
- IT/IS for BioPharma
- Biotechnology
- Medical Devices



Step #2: Selecting the course(s)

Choose your course from the list by clicking 'Add to Cart'



The screenshot displays a list of six courses from the Biopharma Institute. A red oval highlights the first course, 'Comprehensive Training Program Professional Designation: Good Clinical Practice - GCP00A2', with a red line pointing to a red callout box. A green oval highlights the remaining five individual courses, with a green line pointing to a green callout box. Each course entry includes a thumbnail image, the course title, a price, and an 'Add To Cart' button with a smaller 'Add to Cart' link below it.

Course Title	Price	Action
Comprehensive Training Program Professional Designation: Good Clinical Practice - GCP00A2	PRICE: \$1599 Learn More	Add To Cart Add to Cart
FREE GCP: ICH Good Clinical Practice (ICH-GCP), An Abridged Course - GCP00	FREE Course: Enroll Today! Learn More...	Add To Cart Add to Cart
NEW GCP: ICH Good Clinical Practice (ICH-GCP) - GCP001	PRICE: \$289 Learn More...	Add To Cart Add to Cart
NEW GCP: Clinical Trial Preparation and Design - GCP002	PRICE: \$289 Learn More...	Add To Cart Add to Cart
NEW GCP: Clinical Trials and Drug Development - GCP003	PRICE: \$289 Learn More...	Add To Cart Add to Cart
NEW GCP: Clinical Trial Monitoring: Site Evaluation and Set-up - GCP004	PRICE: \$289 Learn More...	Add To Cart Add to Cart

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: Accessing the training course(s)

Login at the BioPharmaInstitute.com homepage

STUDENT INFORMATION:

John Balestrini

Username: JBalestrini@xmail.com

Password: Pr3Wbqj

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

Login at the BioPharmaInstitute.com homepage

The screenshot shows the BioPharmaInstitute.com homepage. At the top is a banner with the logo and tagline "Excellence in training for biotech & pharmaceutical professionals". Below the banner is a navigation bar with links: Books and Reports, Online Training, Corporate Training, About BioPharma Institute, and View Cart. The date "Monday, March 16, 2015" is displayed. The main heading is "Pharmaceutical & Biotech Training & Certification Programs". A featured section on the left promotes a "FREE course" with a "CLICK HERE" button. To the right of this is a "Student Login" box with fields for Username (pre-filled with "Biopharma") and Password (masked with dots), and a "Login" button. Below the login box is a "Training Manager Login" link. At the bottom, there are three columns of job listings under the heading "BioPharma Job Search", each with a "2014" badge. The columns are labeled "CLINICAL RESEARCH", "DRUG MANUFACTURING & WAREHOUSING", and "REGULATORY AFFAIRS".



Step #4: Welcome to the LMS

Once logged in, you can access all your courses

BIOPHARMA INSTITUTE
Training for Pharma and Biotech Professionals

You are logged in as BioPharma Institute (Logout) English (en)

Welcome to BioPharma Institute's Learning Management System (LMS), your access to online training courses and seminars for biotechnology and pharmaceutical professionals.

NOTE: Your web browser's 'pop-up blocker' settings may prohibit the launch of some courses and/or access to your certificate of completion. Turn 'OFF' popup blocker or depress the 'control key' when launching these activities to avoid this issue. Most courses require a 80% or greater score on the final assessment before the certificate of completion can be accessed. If you have any questions please email support@biopharmainstitute.com.

Available Courses

Course ID	Course Title	Description
GMP0: Documentation and Record Keeping (an Abridged Course)	Administrator: BioPharma Institute	The role of documentation in providing a history of manufacturing from supplier to customer. This is an abridged, GMP05 Documentation and Record Keeping, course.
GMP01: Good Manufacturing Practices, Overview	Administrator: BioPharma Institute	Good Manufacturing Practices: Overview.
GMP02: GMP for the Warehouse	Administrator: BioPharma Institute	GMP: An introduction to control and management of manufacturing and quality control testing of pharmaceutical products from the prospective of the warehouse.
GMP03: Microbiology in the Workplace	Administrator: BioPharma Institute	GMP: An introduction to control and management of manufacturing and quality control testing of pharmaceutical products Microbiology in the Workplace

Site Administration

- Notifications
- Users
- Courses
- Grades
- Location
- Language
- Modules
- Security
- Appearance
- Front Page
- Server
- Networking
- Reports
- Miscellaneous

Main Menu

- Site news
- BioPharma Website
- Course Catalog
- Clinical Glossary
- Book Catalog

A list of the courses you are enrolled into is accessible from the LMS homepage after you login.

March 2015

Sun	Mon	Tue	Wed	Thu	Fri	Sat
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	27	28
29	30	31				

Clinical Trial Alerts

Add/Edit Feeds

New cholesterol-lowering drug 'could halve risk of heart attack, stroke'

Stalled drug trials provide information that needs to be shared

Telemedicine allows UTHealth to enroll patients remotely into acute stroke trial

Moffitt Cancer Center seeks smokers looking to quit



Step #5: Navigating the course page

The course page provides access to training, assessment, and the certificate of completion

The screenshot shows the Biopharma Institute website interface. At the top, the logo and name 'BIOPHARMA INSTITUTE' are displayed, along with the tagline 'Training for Pharma and Biotech Professionals'. A user is logged in as 'BioPharma Institute'. The main navigation bar includes 'HOME' and 'GMP0'. On the left, there is an 'Administration' sidebar with options like 'Turn editing on', 'Settings', 'Assign roles', 'Grades', 'Groups', 'Backup', 'Restore', 'Import', 'Reset', 'Reports', 'Questions', 'Files', and 'Profile'. Below this is an 'FDA Alerts' section. The main content area is titled 'Topic outline' and lists three items: 'GMP: Documentation and Record Keeping (an Abridged Course)', 'Final Assessment: Documentation and Record Keeping, An Abridged Course', and 'Certificate of Completion'. Each item is circled with a colored line (red, green, and brown respectively) that points to a corresponding callout box on the right. The right side also features a 'Switch role to...' dropdown, a 'Turn editing on' button, and a 'Clinical Trial Alerts' section at the bottom.

BIOPHARMA INSTITUTE
Training for Pharma and Biotech Professionals

You are logged in as BioPharma Institute (Logout)

HOME ► GMP0

Administration

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

FDA Alerts

Add/Edit Feeds

FDA Trial Data Standards Plan Has NDA, BLA Implications

SI Units May Become Standard for U.S. Marketing Applications

Third Time's the Charm? Not For Alimera's Eye Treatment

Topic outline

- GMP: Documentation and Record Keeping (an Abridged Course)
- Final Assessment: Documentation and Record Keeping, An Abridged Course
- Certificate of Completion

Switch role to... Turn editing on

Group User

Clinical Trial Alerts

Add/Edit Feeds

New cholesterol-lowering drug 'could halve risk of heart attack, stroke'

Stalled drug trials provide information that needs to be shared

Telemedicine allows UHealth to enroll patients remotely into acute

Access to the course

Access to the final assessment

Access to the certificate of completion

Step #6: Navigating the course

The course includes voiceovers and easy navigation

SeerPharma®
CONFIDENCE IN COMPLIANCE

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

Easy navigation with menu bar

Volume control for voiceovers

Scrolling to rewind and forward through the course module.

Step #7: Navigating the final assessment

Includes multiple choice and true and false questions

BIOPHARMA INSTITUTE
Training for Pharma and Biotech Professionals

HOME ► GMP0 ► Quizzes ► Final Assessment: Documentation and Record Keeping, An Abridged Course ► Attempt 1

Info Results Preview Edit

Preview Final Assessment: Documentation and Record Keeping, An Abridged Course

Start again

Page: (Previous) 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 (Next)

8 Marks: 1

Specifications for finished products should include (or reference):

Choose one answer.

- ☐ a. sampling instructions
- ☐ b. the product strength, potency, or assay
- ☐ c. the raw material lot number
- ☐ d. physical appearance
- ☐ e. A, B, and D

Save without submitting Submit all and finish

Page: (Previous) 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 (Next)

Moodle Does for this page

You are logged in as BioPharma Institute (Logout)

GMP0

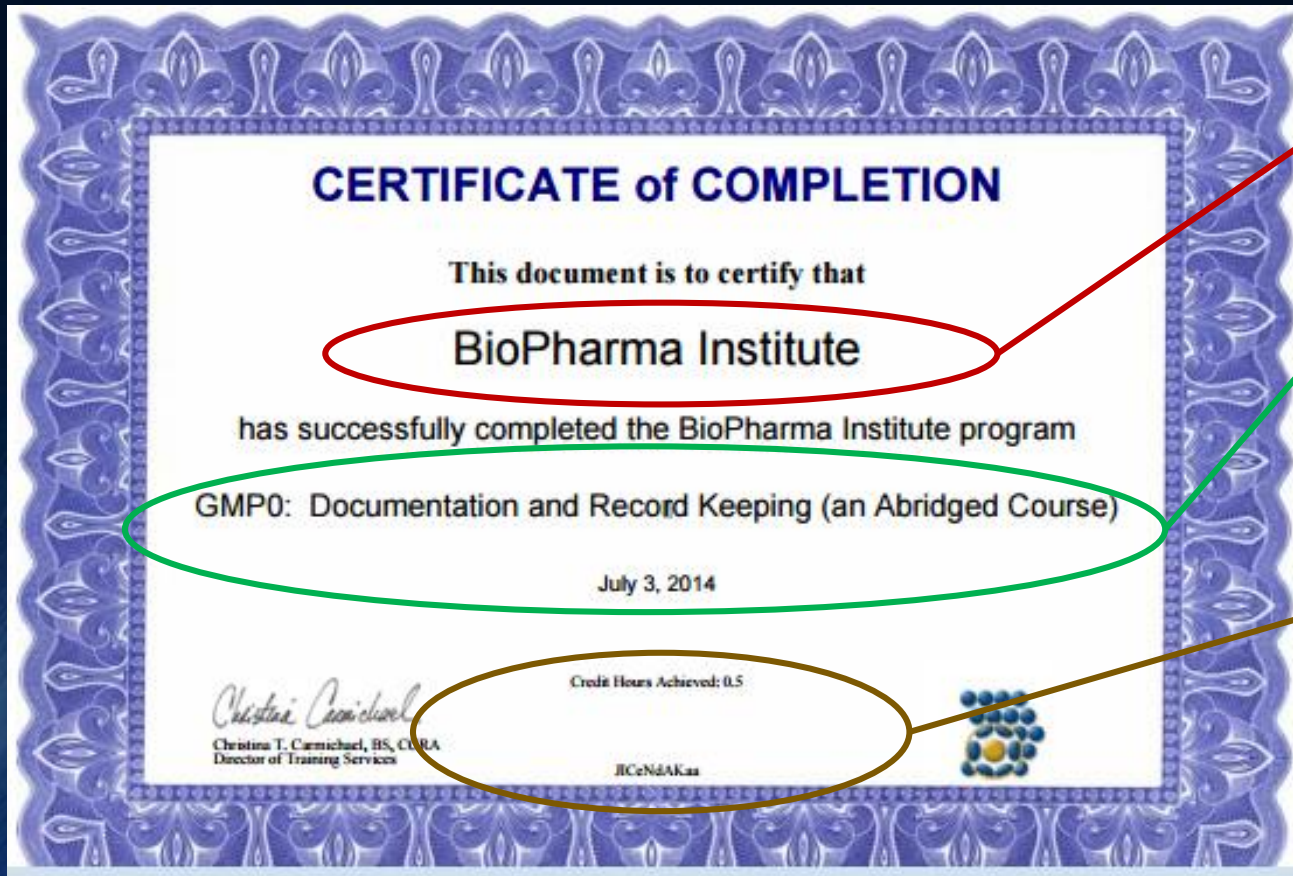
Navigate through all the questions

The final assessment includes both multiple choice and true and 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 necessary to pass during the access period (usually 90 days)

Step #8: The Certificate of Completion

Includes date of issuance and unique validation code



Includes the students name.

Name of the course completed with the date of completion.

Number of credit hours achieved and a unique validation code is issued on the certificate.



Corporate Training Managers

Real-time access to training records and scores

	A	B	C	D	E	F	G	
1	lastname	firstname	username	fullname	lastip	grade	name	FROM
2	DOELAST	JOHName	user@bioph.com	PRA001: Essentials for Hu	208.93.249.82	87.5	Final Assessment: Essentials for Human	11/6/2012 10:23
3	DOELAST	JOHName	user@bioph.com	PRA002: Orphan Drug App	208.93.249.82	100	Final Assessment: Orphan Drug Applica	1/2/2013 10:23
4	DOELAST	JOHName	user@bioph.com	ESR01: Electronic Signatu	160.62.4.10	92.59	Final Assessment: Electronic Signature	3/6/2012 9:54
5	DOELAST	JOHName	user@bioph.com	EGMPSP02: Proper Docum	160.62.4.10	90.48	Final Assessment: Proper Documentati	3/6/2012 9:54
6	DOELAST	JOHName	user@bioph.com	VAL01: Validation - Princi	160.62.4.10	96.67	Final Assessment: Validation: Principle	3/6/2012 9:54
7	DOELAST	JOHName	user@bioph.com	VAL09: Validation: Comp	160.62.4.10	86.21	Final Assessment: VAL09 - Validation: C	3/6/2012 9:54
8	DOELAST	JOHName	user@bioph.com	VAL10: Validation: Comp	160.62.4.10	84.62	Final Assessment: VAL10 - Validation: C	3/6/2012 9:54
9	DOELAST	JOHName	user@bioph.com	GMP01: Good Manufactur	69.123.204.14	89.66	Final Assessment, Good Manufacturing	9/27/2012 13:48
10	DOELAST	JOHName	user@bioph.com	GLP01: Introduction to Q	69.123.204.14	89.29	Final Assessment: GLP: Introduction to	4/16/2013 18:52
11	DOELAST	JOHName	user@bioph.com	GMP07: Production Contr	97.112.11.245	82.93	GMP07: Production Controls - Final Ass	9/27/2012 9:50
12	DOELAST	JOHName	user@bioph.com	GMP08: Packaging Contr	97.112.11.245	80.56	GMP08: Packaging Controls - Final Ass	8/6/2013 21:31
13	DOELAST	JOHName	user@bioph.com	GMP01: Good Manufactur	173.56.119.34	96.55	Final Assessment, Good Manufacturing	11/21/2014 11:07
14	DOELAST	JOHName	user@bioph.com	ESR01: Electronic Signatu	64.30.86.145	85.19	Final Assessment: Electronic Signature	11/21/2014 11:08
15	DOELAST	JOHName	user@bioph.com	ESR01: Electronic Signatu	24.218.189.46	81.48	Final Assessment: Electronic Signature	8/6/2013 18:14
16	DOELAST	JOHName	user@bioph.com	GMP04: Cleaning and San	97.112.13.126	90	Final Assessment: GMP: Cleaning and S	3/16/2015 14:23
17	DOELAST	JOHName	user@bioph.com	GMP05: Documentation a	97.112.13.126	100	Final Assessment: GMP: Documentatio	3/16/2015 14:27
18	DOELAST	JOHName	user@bioph.com	GMP06: Contamination C	97.112.13.126	93.33	GMP06: Contamination Control - Final	3/16/2015 8:13
19	DOELAST	JOHName	user@bioph.com	GMP07: Production Contr	97.112.13.126	97.56	GMP07: Production Controls - Final Ass	3/6/2012 9:15
20	DOELAST	JOHName	user@bioph.com	GMP08: Packaging Contr	97.112.13.126	81.44	GMP08: Packaging Controls - Final Ass	11/26/2012 19:02
								8/12/2013 9:32
								11/26/2012 16:07
								8/5/2010 13:21
								12/10/2014 11:34
								12/9/2014 15:32
								8/31/2011 15:20
								12/10/2014 11:34
								12/9/2014 15:32
								9/13/2012 13:56
								12/10/2014 11:34
								12/9/2014 15:32
								7/18/2013 15:46
								12/10/2014 11:34

Student's names and email address

Course names and scores on the final assessments and sections viewed

Date of first access and completion

Thank you!

VISIT WWW.BIOPHARMAINSTITUTE.COM FOR MORE
INFORMATION AND TO DEMO A TRAINING COURSE.

