COBBLESTONE

COURSE ID 3107

cGMPs for Biologics

DIRECTED BY

Laura Jeannel, Senior Quality Consultant, Farbridge Pharma Consulting

8 Hours

ACCREDITED COURSE

- Fundamentals of cGMPs for Biologics
- Regulatory Requirements (FDA & EU Current Practices)
- CMC/Manufacturing
- Working with CDMOs
- Facilities, Contamination Controls and Environmental Monitoring
- Key Advancements

about the course

This intensive 8-hour accredited training will provide an oversight into cGMPs for Biologics, and large molecule manufacturing from development to engineering batches to Process Performance Qualification (PPQ) lots including analytical method validation. A review of vital and current Biopharmaceutical/Biologics processes will be reviewed for current Quality/Regulatory expectations. Key insights are presented for both FDA and EU regulatory requirements with crucial differences highlighted.

This course will cover in-depth reviews of CMC/Manufacturing for in-house and CDMO oversight. Additionally, this course will offer a perspective on Quality Assurance / Quality Control operations including external manufacturing (CDMOs/Contract Testing Labs) and an end-to-end view of Drug Substances, Drug Products, Packaging & Labeling, and Logistics. This will include a review of Facilities/Clean Rooms, Environmental Monitoring impact, and Contamination Controls. Several key case studies and a review of 483s / warning letters will be incorporated to emphasize lessons learned and examine the recent history of biologics to where we are now from a Technical, Quality, Compliance, and Regulatory perspective.

Experience top-notch training LIVE from an industry expert that goes beyond traditional lectures. You will engage in an interactive and stimulating learning experience that will help develop the skills needed to excel in the field.

Those attending the LIVE training event must have a webcam on their computer equipped with a microphone and speakers/headset to fully participate.

who should attend

This online training is designed for professionals in the Pharmaceutical, Medical Device and other life science industries. It will be especially valuable to the personnel and management, including senior management, in these areas:

- Quality Assurance
- Manufacturing
- Supply Chain
- Contract Testing Labs
- Quality Control
- Facilities
- CDMOs
- Regulatory Affairs

learning objectives

Upon completion of this course, you will be able to:

- Explain key principles of Biologics/Biopharmaceuticals
- Demonstrate knowledge of FDA/EU and current practices for Quality/Regulatory expectations
- Evaluate the history of biologics, advancements and where industry is now and future state for biologics
- Determine key focus points for CMC/Manufacturing, Quality Assurance, Quality Control Supply Chain, Facilities, Regulatory submissions for Phase-based approach and novel technologies
- Take part in key discussion forums in defined Q&A sessions answering customized questions for large molecule development, Biologics/Biopharmaceuticals manufacturing

course outline

Review of Learning Objectives
Module 1

- cGMPs and Biologics
- Biologics Manufacturing, key history, and where the industry is now
- Upstream/Downstream Processes
- EU Approach and key advancements
- FDA Approach and key advancements

Module 2:

- Overview of EU/FDA regulatory requirements and updates
- Review of recent 483s/Warning Letters
- Key Differences and Market Challenges – FDA and EU
- PPQ Lots, scale-up, and Tech Transfer topics

Case Examples

Q&A Opportunity & Review

Module 3:

- Working with CDMOs and Contract Labs for Biologics Manufacturing
- Key Aspects for CMC – Manufacturing
- Key Aspects for Quality Assurance
- Key Aspects for Quality Control

Module 4:

- Key Aspects for Supply Chain (End-to-End Processes)
- Key Aspects for Facilities
- Contamination Control and Environmental Monitoring
- Lessons Learned and Where Are We Now

Case Examples

Question and Answer Session

Assessment Opportunity

course instructor

Laura Jeannel, Senior Quality Consultant for Farbridge Pharma Consulting, is an experienced Quality Assurance professional leading as a former Quality Director and key consultant for >20 years. During her career, she has led major pharmaceutical companies in establishing, executing, and continuous improvement for sustainable Quality Management Systems. Ms. Jeannel has been responsible for the launch of multiple complex projects in pharmaceuticals, biologics, cell and gene therapy, and medical devices.
She is a recognized trainer for key Quality Systems and pragmatic solutions for building positive partnerships for continuous improvement.

Accreditations

International Accreditors for Continuing Education and Training (IACET)
Cobblestone has been approved as a CEU Accreditor by IACET and awards CEUs for participation in qualified courses. Cobblestone has demonstrated that it complies with the ANSI/IACET Standards and is authorized to offer IACET CEUs for its programs. CEUs will be awarded for participation in Cobblestone's courses at the rate of .1 CEU per contact hour upon successful completion of the entire course and 70% accuracy in the required Learners' Assessment. A minimum score of 80% is required for all courses within a Cobblestone Certification Program. This course offers a total of 8 contact hours or .8 CEUs. For further information, visit www.iacet.org

Regulatory Affairs Professional Society (RAPS)
Cobblestone is committed to enhancing the ongoing professional development of regulatory affairs professionals and other stakeholders through appropriate regulatory affairs learning activities and programs. Cobblestone has agreed to follow RAPS-established operational and educational criteria. This course may be eligible for up to 12 credits towards a participant's RAC recertification upon full completion. The requirements and standards for recertification are developed and administered by the Regulatory Affairs Certification Board (RACB), which manages all areas of the RAC program. Additional information about RAC is available on the RAPS website at RAPS.org/rac.

The American Society for Quality (ASQ)
The American Society for Quality (ASQ)-Recertification Opportunities
Cobblestone is committed to enhancing the ongoing professional development of Quality professionals and other stakeholders through appropriate learning activities and programs. Many Cobblestone courses offer training that may help obtain required ASQ recertification education units.
For more information, visit: www.asq.org