

cGMPs for BioPharmaceuticals

A FASTRAIN REGIONAL TRAINING COURSE

THIS FASTRAIN COURSE:

OFFERED IN THE
FOLLOWING
LOCATIONS

Seattle, WA June 11-13

San Diego, CA July 14-16

San Francisco, CA August 27-29

FasTrain

- High Quality
- Up-to-Date
- No Hidden Agendas!
- Practical

4 Ways to Sign Up:

Phone:
916-729-0109

Fax in the Form:
916-729-2602

Web:
www.bioquality.biz

Email:
bq_editor@surewest.net

Putting the Current into cGMPs

All companies developing and marketing human biopharmaceuticals and biologics must, by law, comply with the Current Good Manufacturing Practices (CGMPs) of the region to which they wish to market. You could and should read these regulations, but how are you going to interpret them? The CGMPs are full of general language such as adequate, appropriate, suitable and meaningful. This course will give you the tools you need to apply the CGMPs successfully to your particular product, process, and stage of development.

This regularly updated three-day course is designed for all persons who work in a Current Good Manufacturing Practices (CGMP) regulated environment within a Biopharmaceutical or Biologics company.

About Your Instructor



Dr. Thomas Pritchett PhD
Leading Biopharmaceutical
Technical and Regulatory
Expert in

Thomas J. Pritchett, Ph.D. : has over 18 years experience working with pharmaceutical, biopharmaceutical, and biologics CGMPs. He currently specializes in technical and regulatory issues surrounding QA and QC of biopharmaceuticals and biologics. Tom has been teaching since 1994, and has directed courses for many organizations in addition to FasTrain, including the Center for Professional Advancement (CfPA), the PDA, and the Center for Professional Innovation and Education (CfPIE). Tom has taught training courses for regulatory authorities including the FDA.

What You Will Learn at This Course

- Fundamental principles underlying the CGMPs
- How to talk "compliance speak"
- The CGMP regulations of both the USA and Europe
- Why the "C" is the most important part of CGMP
- Recent changes to the CGMP regulations
- How to interpret all the general language in the regulations (for example: adequate, appropriate, meaningful)
- Key Guidance Documents and how to use them to your advantage
- Compliance during clinical development and why it is different than marketed product compliance
- How to assess your current level of compliance and improve it
- How to use inspectional results such as 483s and Warning Letters to stay out of regulatory trouble
- Current regulatory hot topics and trends—and how to predict them
- An internet-based "desktop" regulatory intelligence (RI) system to assure you keep up with regulatory changes—and it won't cost you a penny!

Course Description:

Interactive

Problem-solving

Informative

Entertaining

Up-to-Date

Course Objective and Outline

This course opens with a brief history of drug, biologic, and biopharmaceutical regulation. Then continues to demystify the jargon of cGMP and introduces the two fundamental Acts underpinning the U.S. CGMPs. Includes analysis of the "21st Century program":

Next there is a comprehensive review and explanation of the U.S. CGMPs: including Part 210 and 211 with an emphasis on subparts A through K from a biopharmaceutical perspective. The coverage will include hints and stories about how to comply.

Next the European (EU) cGMPs are reviewed. A comprehensive

review and explanation of the E.U. GMPs, include a session comparing and contrasting the U.S. and E.U. GMPs

Additionally special topics covered such as:

- ?? Top CGMP problems FDA sees at companies
- ?? Top CGMP problems for U.S. companies exporting to Europe
- ?? Effective handling of Deviations, Out Of Specification Results: and CAPAs
- ?? Essential Documentation
- ?? Effective Lab, Failure, and

- Complaint investigations
- ?? Compliance during clinical development: How much and when.
- ?? Quality Systems approach to CGMP compliance
- ?? Regulatory Update: Current Hot Topics and CGMP Trends
- ?? A basic risk analysis primer and why this is crucial
- ?? Important FDA Notices of Deficiency (483s) and Warning Letters
- And so much more!

COMPLETE COURSE AGENDA AVAILABLE AT WWW.BIOQUALITY.BIZ

RESERVE YOUR PLACE TODAY!

Preferred Course:

- Seattle GMP Course
- San Francisco GMP Course
- San Diego GMP Course

Bring a Colleague and get a Group Discount!

- One attendee 1 x 1390.00 = _____
- Two attendees 2 x 1290.00 = _____
- Three or More _____ x 1190.00 = _____

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"I gained more from this 2-day course than any other conference or course I have ever attended."
Previous Course Attendee

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