



Date: 03/16/2010-03/17/2010

Time: 8:30am-4:30pm

Newark Center Campus
Room 1100

GOOD MANUFACTURING PRACTICES FOR BIOPHARMACEUTICAL DRUGS

Biotechnology Training Workshops

THE WORKSHOP

Designed for biopharmaceutical personnel, this two-day introduction to cGMP is suitable for professionals responsible for compliance, regulatory affairs, project planning, QC/QA, R&D, and manufacturing. Through lectures, case study discussions, and group exercises, participants will learn about:

- Current approaches to quality
- SOPs
- Documentation & records basics
- Quality requirements & exceptions
- Inspections & audits (including FDA & European approaches)

This workshop covers 21 CFR 210, 211, and there will be a brief overview of Eudralex.

THE INSTRUCTOR

Paula Shadle, Ph.D., has over 20 years of hands-on and executive experience in biopharmaceutical and pharmaceutical process development and quality, 40+ publications and 4 biotechnology process patents. She received her B.S. in zoology and Ph.D. in biochemistry at the University of California and her postdoctoral training at the Max-Planck Institute in Germany. She worked in both scientific and managerial positions of increasing responsibility at Chiron (Novartis) Corporation, Scios Inc., GlaxoSmithKline plc, and Bayer Corporation, in the areas of protein chemistry, process and analytical methods development, quality assurance, and quality control.



For registration information, visit:

<http://www.ohlone.edu/org/entrepreneurial/biotechworkshops.html>

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Questions?
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Ohlone College's Professional Development Biotechnology Workshops are sponsored by the California Applied Biotechnology Center for Silicon, Central, & San Joaquin Valleys.

