



Date: 03/01/2010

Time: 8:30am-4:30pm

Newark Center Campus
Room 2309



Biotechnology Workshops

THE WORKSHOP

Failure to follow one's own procedures continues to be the single most-cited violation of the GMP regulations. Meanwhile, despite numerous re-write attempts and multiple reviewers, many SOPs are not well-written or easy to follow. During this one full day of lecture and discussion, examples of effective and problematic technical writing will be used to illustrate common pitfalls and highlight best practices. Participants will then, with the instructor's guidance, have the opportunity to write a draft procedure and critique writing. By the end of the workshop, participants will have learned how to identify, define, and write better standard operating procedures.

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.

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WRITING SOPs

For Pharmaceutical & Biopharmaceutical GMP Environments