The application of Process Validation is becoming an increasingly important activity for pharmaceutical and biotech organizations given the critical role validated processes have in ensuring product conformance. To assist industry, several guidances have been developed by regulatory agencies in the last few years that define the requirements and best practices for the effective implementation of Process Validation.

Organizations that fail to develop an effective process validation system will face significant regulatory consequences including For Cause audits by regulators, recalls or plant closure. However, the application of process validation is not limited to the manufacturer; it also extends to include suppliers. Regulations have been established which direct organizations to assess the adequacy of process validation activities at their suppliers. For example, regulators expect organizations to begin process validation activities before new equipment is installed.

This course, entirely updated to reflect the current requirements and guidances published by the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme, the European Medicines Agency, FDA and International Conference on Harmonization, will provide participants with a thorough understanding of the requirements of process validation for both small molecule (pharmaceuticals) and Biologic products. They will learn how to establish an effective process validation system and integrate it with other systems such as Risk Management, Corrective and Preventive Action and Supplier Management.

Participants will learn how to develop rigorous protocols and reports, as well as create monitoring programs to ensure that defined critical parameters remain in control. The course will also review validation requirements for systems that generate electronic signatures and records as most new processes have this capability.

Attendees are encouraged to bring examples of Process Validation issues/concerns that they would like to reviewed and discussed during the course.
INSTRUCTOR CREDENTIALS

Steven A. Ostrove, Ph.D., has been involved in the Bio-Pharmaceutical business for over 35 years and is an invited course leader, lecturer and guest speaker for both national and international conferences.

In 1999, he opened Ostrove Associates, Inc. (OAI) – a validation, compliance and regulatory-affairs consulting company – to provide consulting services to both major pharmaceutical/biotechnology companies and small, start-up companies.

Previously, Dr. Ostrove worked as Senior Technical Specialist in the Technical Service Department of Pharmacia Biotechnology. He also served as Senior Director of Validation and Regulatory Affairs with a number of major design/build engineering companies.

In addition, Dr. Ostrove has also served as an adjunct professor of Pharmaceutical Engineering for Validation and Regulatory Affairs for the New Jersey Institute of Technology and as an adjunct professor of Biology for Kean College. He recently served as industry representative on an FDA advisory panel and as Acting Manager of Validation for a contract pharmaceutical/OTC manufacturer.

LEARNING OBJECTIVES

By the end of the two-day course you will:

- Understand the new FDA perspective of a "Process Validation Life-Cycle" that starts at the Process Design phase (Process/Product Development) and continues through Process Qualification (Confirmation) and Continued Process Verification (Monitoring and Assessment of the process effectiveness) as stated by the FDA's new Guideline on Process Validation and its impact on how process validation activities are carried out
- Understand the perspective of the EMEA, ICH, WHO and PIC/S on process validation and how they can be incorporated into a single process validation system
- Be able to set up process validation programs and corresponding documentation including protocols and reports that meet current FDA, WHO, PIC/S and EU regulations
- Prepare and defend your own process validation approach/program and avoid costly delays and rejections by regulatory agencies

FIRST DAY

Regulatory Perspective – Biologics vs. Pharma
- Defining Validation
- Recognize the role process validation plays in understanding process and product variability – Making the Validation Fit Your Product
- Process Validation- What it means to your product
- Types of Process Validation – Retrospective – Concurrent-Prospective
- Understand the perspectives of the FDA, international regulators and the GHTF

II. Implementing a Process Validation System
- Establishing the Infrastructure
  - The process validation procedure
  - Roles and responsibilities
  - Equipment and facilities
  - Purchasing
- Process Validation Requirements
  - Requirements of Title 21
  - Review of the FDA Guidance on Process Validation
- Differences between Regulatory Agencies Requirements
  - ICH
  - EMEA
  - PIC/S

Group Exercise: “Challenges and experiences with existing process validation system”

Individual Assignment: Participants will develop a checklist of the requirements of the elements of process validation

SECOND DAY

Other Related Components of Validation
- Facility Validations
- Cleaning Validations
- Processing Equipment Validations
- Viral Clearance Validation
- Sterilization Validation
- Packaging Validations
- Computer System Validation

Basics of Statistical Tools
- Use of statistical tools in validation
- Acceptance Sampling tables (Use of AQL)
- Use of separate samples testing vs. combined samples
- Cpk or process capability
- Control charting to monitor performance
- Data handling and data analysis

Individual Exercise: Participants will develop a Validation Protocol

IV. Supplier Process Validations
Requirements of Suppliers
- Validation based on supplier criticality
- Role of Quality Agreement in Process Validation
- Communication of process changes
- Inspection vs Validation of supplied components

V. The Validation Life Cycle
Re-validation
- When, why and what
- Handling problems during re-validation
- Product and process implications

Product complaints and process failures
- Evaluating process parameters as a cause of product failures
- Incidental design changes
- Process change history
- Amending the existing MVP

Implementing the System
- Assessing the status of existing systems
- Identifying the systems to be validated
- Assigning the priority and importance
- Determining when revalidation is required
- Defining and controlling the Master Validation Plan (MVP)
- An audit perspective of the MVP

VI. Process Validation Compliance
Avenues for Assessing Compliance
- Internal audits
- Complaints and corrective action
- Process changes
- Process FMEA
- Review of recent Warning Letters and Consent Decrees

HOTEL INFORMATION

The Hilton LAX, Los Angeles, CA (CPIE room rate of $167/night if booked 3 weeks in advance of the course date)
The Desmond Hotel & Conference Center, Malvern, PA (CPIE room rate of $141/night if booked 3 weeks in advance)
Club Quarters Hotels, Boston, MA (CPIE room rate of $255/night if booked 4 weeks in advance)
DoubleTree by Hilton London - Victoria (CPIE room rate of £199.00/night if booked 4 weeks in advance)