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Masterclass 01

CASE STUDY

CERTIFIED

LIVE

# Statistical Methods for Process Validation

Tara Scherder

26th - 28th February 2025

9.00am – 1.00pm EDT (UTC- 5)

## Overview

No matter the industry, manufacturers that leverage fit-for-use statistical methods have a competitive advantage over those that don't. The pharmaceutical industry is no different. The powerful combination of statistical methods and scientific knowledge can result in accelerated development timelines, improved process understanding, optimal processes, lower lifetime COGS, and reduced business and patient risk. Additionally, since the adoption of the lifecycle approach to process validation based on regulatory guidance, there has been an increase in expectation for rigorous evidence of product quality and process control. In this course, participants will learn the basics of the key statistical tools to ensure compliance plus reap the benefits of effective and efficient design of optimal processes, process robustness, and ongoing process control.

## Trainer

**Tara Scherder** has over 20 years of experience in the pharmaceutical industry as a statistician, process engineer, educator, and master black belt. As principal at SynoloStats, she passionately shares the opportunity for patient and business benefit through the powerful combination of statistics and science. She combines statistical expertise with extensive knowledge of manufacturing platforms/analytical sciences and CMC requirements to increase knowledge, optimize manufacturing, analytical and business processes, and manage risk. She frequently speaks at industry forums and publishes on the practical incorporation of statistical methods for Lifecycle Process Validation.
Tara earned a BS degree in Chemical Engineering from the University of Pittsburgh and a MS degree in Statistics from Carnegie Mellon University.

## Who should attend?

- Process Development teams
- Manufacturing Science and Technology teams
- Qualified and Responsible Persons (QPs, RPs)
- Validation and Qualification teams
- Contract Manufacturing organizations (CMOs) and Contract Development and Manufacturing organizations (CDMOs)

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# Agenda Day 1

**09:00 am** — **Welcome and Introductions**

- Session 1: Lifecycle process validation and process design

**09:20 am** — **The lifecycle approach and the use of statistical methods to manage risk**

**09:40 am** — **Tea / Coffee Break**

**10:25 am** — **DOE (cont'd)**

- Session 2: Modelling populations to assure quality

**10:50 am** — **Sampling uncertainty and common statistical intervals**

**11:50 am** — **Tea / Coffee Break**

**12:00 pm** — **Understanding the use of process performance data to establish specification limits**

**12:30 pm** — **Designing sampling plans for Process Performance Qualification (PPQ) batches**

**01:00 pm** — **End of day summary / Q&A**

# Agenda Day 2

| | | |
|---|---|---|
| 09:00 am | | **Review and Questions**<br>• Session 1: Evaluating PPQ data for demonstrated assurance of ongoing quality |
| 09:15 am | | **Connecting the PPQ sampling plan to PPQ results and conclusions** |
| 10:15 am | | **Tea / Coffee Break** |
| 10:25 am | | **Understanding variability using variance components**<br>• Session 2: Comparability & Stability Testing |
| 11:00 am | | **Evaluating comparability –equivalence vs difference testing** |
| 11:15 am | | **Tea / Coffee Break** |
| 12:00 pm | | **Statistical fundamentals for stability monitoring and shelf life** |
| 01:00 pm | | **End of day summary / Q&A** |

# Agenda Day 3

| | | |
|---|---|---|
| 09:00 am |  | **Review and Questions**<br>• Session 1: Statistical Methods for the commercial manufacturing stage |
| 09:15 am | | **Designing an effective Continued Process Verification (CPV) program** |
| 10:15 am |  | **Tea / Coffee Break** |
| 10:25 am | | **Fundamentals and Nuances of Statistical Process Control (SPC) for CPV** |
| 11:40 am |  | **Tea / Coffee Break** |
| 10:25 am | | • Session 2: Leveraging statistics for investigations and common pitfalls |
| 11:50 am | | **Speed root cause analysis with data visualization** |
| 12:30 am | | **Best practices and common mistakes in data analysis** |
| 12:45 pm | | **Review and Questions** |
| 01:00 pm | | **End of day summary / Q&A** |

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Masterclass 02

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# Advanced Process Validation for Biotechnological Products

3rd - 6th March 2025

9.00am – 1.00pm EDT (UTC- 5)

Mylène Talabardon, PhD

Hervé Broly, PhD

## Overview

Manufacturing processes should be validated before initiating commercial manufacturing. Regulatory bodies expect the manufacturer to understand the process so that the quality, safety, and efficacy of the product are designed or built into the product through the appropriate control of each manufacturing process step. Today, process validation comprises three main steps: (1) Stage 1 – Process Design (FDA) or Process Evaluation (EMA); (2) Stage 2 – Process Qualification (FDA) or Process Verification (EMA); and (3) Continued Process Verification (FDA) or Ongoing Process Verification (EMA). The training aims to provide a deeper understanding of how process validation for biotechnological processes, which is the collection and evaluation of data from the process design stage through commercial production, would be appropriately designed and executed to establish scientific evidence that a manufacturing process is capable of consistently delivering quality products.

## Trainer Mylène Talabardon, PhD

With over 20 years in the pharmaceutical industry, Mylène brings strong expertise in process development, technology transfer, and validation. She earned a PhD in biotechnology from The Ohio State University and an environmental engineering degree from EPFL. In 2001, she joined BiogenIdec in cell culture, focusing on scaling antibody production. In 2004, she became head of the cell culture department at Merck Serono, working on QbD validation for biotech products. After two years as CMC lead for a biosimilar, she was appointed Process Validation Expert, where she developed the company's Global Process Validation strategy in line with European and FDA regulations, supporting CMC teams for both new and legacy biologics.

## Trainer Hervé Broly, PhD

After earning an engineering degree in agriculture and a PhD in plant physiology, I joined the Blood Transfusion Center in Lille, France (1982), establishing a unit for developing monoclonal antibodies against blood groups, proteins, and viral antigens. In 1991, I became Head of Process Development and Manufacturing at Sorebio, a CMO specializing in monoclonal antibodies. I led Sorebio after Serono acquired it in 1994, then moved to Serono in 2003 as Global Product Team Leader, advancing a recombinant Ig-fusion protein to Phase III. Since 2006, as VP at Merck-Serono, I've overseen biotech process development, implementing ICH Q8(R2)/Q11 guidelines and introducing advanced manufacturing processes.

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# Agenda Day 1

Introduction to Process Validation

**09:00 AM** — ***Introduction***

- Overview of Process Validation by EMA and FDA's guidelines as well as ICH Q8(R2) and ICH Q11

**09:30 AM** — **Validation Master Plan (VMP)**

**10:15 AM** — **Tea / Coffee Break**

**10:30 AM** — **TPP and QTPP**

**11:15 AM** — **Stage 1 - Process Design (DS & DP)**

- Assessment of criticality of quality attributes (cQAs)
- Structure-function relationship studies

**12:00 PM** — **Assessment of criticality of material attributes (CMAs) and assessment of criticality of process parameters (CPPs)**

**12:45 PM** — **Qualification of scale-down model (SDM)**

**01:00 PM** — **End of Day 1**

# Agenda Day 2

Process Characterization and Control Strategy

**09:00 AM** | **Process characterization studies**

- Design space and Monte Carlo simulations

**09:45 AM** | **Worst case and excursion studies**

- Clearance of impurities

**10:30 AM**  **Tea / Coffee Break**

**10:45 AM** | **Deliverables – Process Control Strategy**

**11:30 AM** | **ICH Q12 - Established Conditions (ECs)**

**12:15 PM** | **Stage 2 - DS & DP Process Performance Qualification (PPQ)**

- Facility Qualification and Process Performance Qualification

**01:00 PM** | **End of Day 2**

# Agenda Day 3

Process Performance Qualification and Continued Verification

**09:00 AM** | **Number of PPQ batches**

- Assessment of PPQ campaign

**09:45 AM** | **Stability of Process Solutions and Samples**

- Process Intermediates Hold Times

**10:30 AM**  **Tea / Coffee Break**

**10:45 AM** | **Stage 3 - Continued Process Verification (CPV)**

- State of Control
- Process Control and Process Capability

**11:30 AM** | **Run charts and Statistics**

**12:15 PM** | **Process Validation specificities for Continuous BioManufacturing**

- Principles
- Start-up/Shutdown and In-Process Disturbances
- Residence Time Distribution (RTD)

**01:00 PM** | **End of Day 3**

# Agenda Day 4

Ancillary Studies and Conclusion

**09:00 AM**

## Ancillary Process Validation Studies (DS and DP when appropriate)

- Cell bank system qualification (evaluation of clonality, ICH Q5(D), Cell bank establishment and testing, EoPCB and LIVCA)

**09:45 AM**

## Viral Safety Evaluation (regulatory guidelines, cell bank safety testing, biological raw material testing, unprocessed bulk testing, viral clearance studies)

**10:30 AM**

Tea / Coffee Break

**10:45 AM**

## Resin/Membrane Lifetime Studies

- Microbiological Control in Bioprocessing
- Toxicological assessment of residual raw materials
- Nitrosamines impurities
- Extractables & Leachables
- Elemental impurities
- Mixing studies

**11:30 PM**

## Ancillary Process Validation Studies (continued)

- Homogeneity & uniformity studies
- Freeze-thaw studies
- Sterility
- Aseptic Process Simulation (Media Fill)
- Sterile Filtration
- Container Closure Integrity
- Qualification of Visual Inspection
- Forced Degradation studies
- Stability studies
- Photostability studies
- Reprocessing and Reworking
- Shipment studies

**11:30 PM**

## Definition of process validation terms

- Questions & answers

**01:00 PM**

## End of Day 4

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