US

Online Masterclass

METAMORPH

LIVE

CERTIFIED

CASE STUDY

Advanced Process Validation for Biotechnological Products

03rd - 06th March 2025

9.00am – 1.00pm EDT (UTC- 5)

Mylène Talabardon, PhD

Hervé Broly, PhD

Course outline

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.

COMPANIES REPRESENTED BY OUR PARTICIPANTS

astellas | AHEAD Therapeutics | ThermoFisher SCIENTIFIC | GILEAD | immatics | melinta therapeutics | ACELYRIN | TriLink BIOTECHNOLOGIES | revance | XGen Pharmaceuticals DJB

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Learning Objectives:

- Understand how to qualify scale-down models, to assess the criticality of quality attributes (CQAs), material attributes (CMAs), and process parameters (CPPs).
- Propose methods to build up process characterization studies looking at interactions between CQAs/CMAs and CPPs and determining the acceptable ranges of process parameters to deliver quality products.
- Learn how to perform clearance of impurities, worst-case studies, and excursion studies.
- Understand how to set up a control strategy.
- Learn about the qualifications of cell banks.
- Understand how to assess microbiological risks (including viruses) during manufacturing, toxicological risks related to raw materials, extractables/leachables from consumables, and elemental impurities.
- Learn how to perform viral clearance studies, mixing studies, resin and membrane lifetime studies, homogeneity and uniformity studies, freeze-thaw studies, shipment qualification studies, reprocessing studies, container closure integrity testing, and validation of sterile filtration.
- Guide the performance of stability studies related to process performance qualification.
- Understand how to determine the number of process performance qualification (PPQ) runs, how to perform PPQ, and how to assess PPQ-derived data.
- Guide the purpose and design of continued process verification.

Target audience

- Process development scientists and managers
- CMC development program managers
- Pharmaceutical development scientists and managers
- Manufacturing managers
- QC and stability control managers
- Heads of Quality Assurance
- Drug Regulatory Affairs managers

Trainer

Mylène Talabardon, PhD

With over 20 years of experience in the pharmaceutical industry, Mylène has a strong experience in process development, technology transfer and process validation. She obtained her PhD in biotechnology from The Ohio State University and her environmental engineering degree from the Swiss Federal Institute of Technology (EPFL). In 2001, she joined BiogenIdec in cell culture process department, focusing on antibody production from lab scale to manufacturing scale. In 2004, she has been appointed head of cell culture department at Merck Serono and started working in validation according to QbD for biotechnological products. After 2 years as CMC lead for a biosimilar product, she was nominated Process Validation Expert, and in this position, she developed the Global Process Validation strategy for the company according to European and FDA regulations for pharmaceuticals, and supported CMC teams in developing Process Validation plans for new biologics as well as for legacy products.

Trainer

Hervé Broly, PhD

Starting with an engineering degree in agriculture, followed by a PhD in plant physiology, I joined the Blood Transfusion Center (Lille, France) in 1982 where I implemented a unit for the development and manufacture of monoclonal antibodies against blood groups, blood proteins and viral antigens. In 1991, I took the position of Head of Process Development and Manufacturing at Sorebio (Martillac, France), a contract manufacturing organization specialized in the development and manufacture of monoclonal antibodies for clinical development. I took the lead of that company in 1998 after it was bought by Serono, a Swiss biotech company (Geneva, Switzerland) in 1994.

In 2003, I moved to Serono in Geneva as Global Product Team Leader in charge of managing the development of a recombinant Ig-fusion protein for the treatment of autoimmune diseases, moving that product from Phase I to Phase III.

As of November 2006, I've been appointed Vice-President, Head of Biotech Process Sciences at Merck-Serono, based in Vevey, Switzerland, in charge of developing and validating the manufacturing processes for biotechnological products. In that context, whereas Serono was mainly using perfusion processes for recombinant hormones and cytokines, we moved the company to large-scale manufacture of monoclonal antibodies using proprietary chemically-defined cell culture media and feeds. After our participation to the FDA's pilot program on Quality by Design, the concepts described in ICH Q8(R2) and ICH Q11 were implemented in our approach to gain process understanding. It was concluded by issuing a modernized approach for process validation at Merck (Darmstadt, Germany). More recently, we have introduced advanced processes such as intensified fed-batch and continuous downstream processing.

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

Advanced Process Validation for Biotechnological Products

Registration Form

Please complete this form and send it back to: E-mail: booking@metamorphedu.com | Phone: +1 657 452 8174

Registration Details

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