Process Validation for Biotechnological Products
MasterClass

Mylene Talabardon *Hervé Broly*

Time Zone: Eastern Standard Time (EST) - UTC–05:00

TRAINING OVERVIEW

Manufacturing processes should be validated prior to initiate commercial manufacturing. Regulatory bodies expect that the manufacturer understand the process so that quality, safety and efficacy of the product are designed or built into the product through the appropriate control of each manufacturing process steps. 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 On-going Process Verification (EMA). The training aims to provide deeper understanding on 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 product.

LEARNING OUTCOMES

- 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 product.
- Learn how to perform clearance of impurities, worst-case studies and excursion studies
- Understand how to set-up a control strategy.
- Learn on the qualification 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.
- Provide guidance on 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.
- Provide guidance on the purpose and design of continued process verification.

WHO SHOULD ATTEND?

- 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

Meet the Trainer:
Hervé Broly

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.

Meet the Trainer:
Myléne Talabardon

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 biotech 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.

All dates and times are expressed in Eastern Standard Time (EST) on the Agenda - UTC−05:00

DAY1

09:20 Connecting to the Online MasterClass

09:30 *Introduction*

- Overview of Process Validation in accordance with EMA and FDA's guidelines as well as ICH Q8(R2) and ICH Q11
- Risk Management for accelerated pathways
- Validation Master Plan
- QTPP
- Structure-function relationships

10:30 *Stage 1 – Process Design (DS & DP)*

- Qualification of scale-down models
  - *Analytical methods*
  - *Study designs and statistical demonstration of equivalence*
- Prior knowledge
- Assessment of criticality of quality attributes
- Selection of stability-indicating CQAs
- Assessment of criticality of material attributes

11:30 Break

12:00 *Stage 1 – Process Design (continued)*

- Assessment of criticality of process parameters
- NORs and Planned Characterization Ranges
- Selection of pCPPs for the characterization studies
- Process characterization studies
  - *Selection of pCPPs*
  - *Analytical methods*
  - *Establishment of the Maximum Permitted Range of Variation of CQAs*
  - *Experimental designs*
  - *Determination of the Proven Acceptable Ranges*
- Worst case and excursion studies
- Clearance of impurities
- Deliverables – Process Control Strategy

14:30 End of Day 1

DAY2

09:20 Connecting to the Online MasterClass

09:30 *Stage 2 – Process Qualification (DS & DP)*

- Facility Qualification and Process Performance Qualification
- Process Performance Qualification
  - *Setting acceptance criteria and action limits*
  - *Process inputs and Process outputs*
  - *Established conditions*
  - *Determination of the number of PPQ runs*
  - *Assessment of success or failure of PPQ*
  - *Stability studies related to PPQ*
  - *Hold time and cumulative hold time studies*

11:30 Break

12:00 *Stage 3 – Continued Process Verification (DS & DP)*

- Understanding Continuous vs Continued Process Verification
- Purpose of CPV
- Protocol content
- Data analysis

14:30 End of Day 2

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DAY3

09:20 **Connecting to the online MasterClass**

09:30 *Ancillary Process Validation Studies (DS & DP where appropriate)*

- Cell bank system qualification
- Viral clearance studies
- Assessment of manufacturing microbiological and viral agents
- Toxicological assessment of residual raw materials
- Extractables and leachables
- Elemental impurities
- Mixing studies
- Resin & membrane lifetime studies

11:30 **Break**

12:00 *Ancillary Process Validation Studies (continued)*

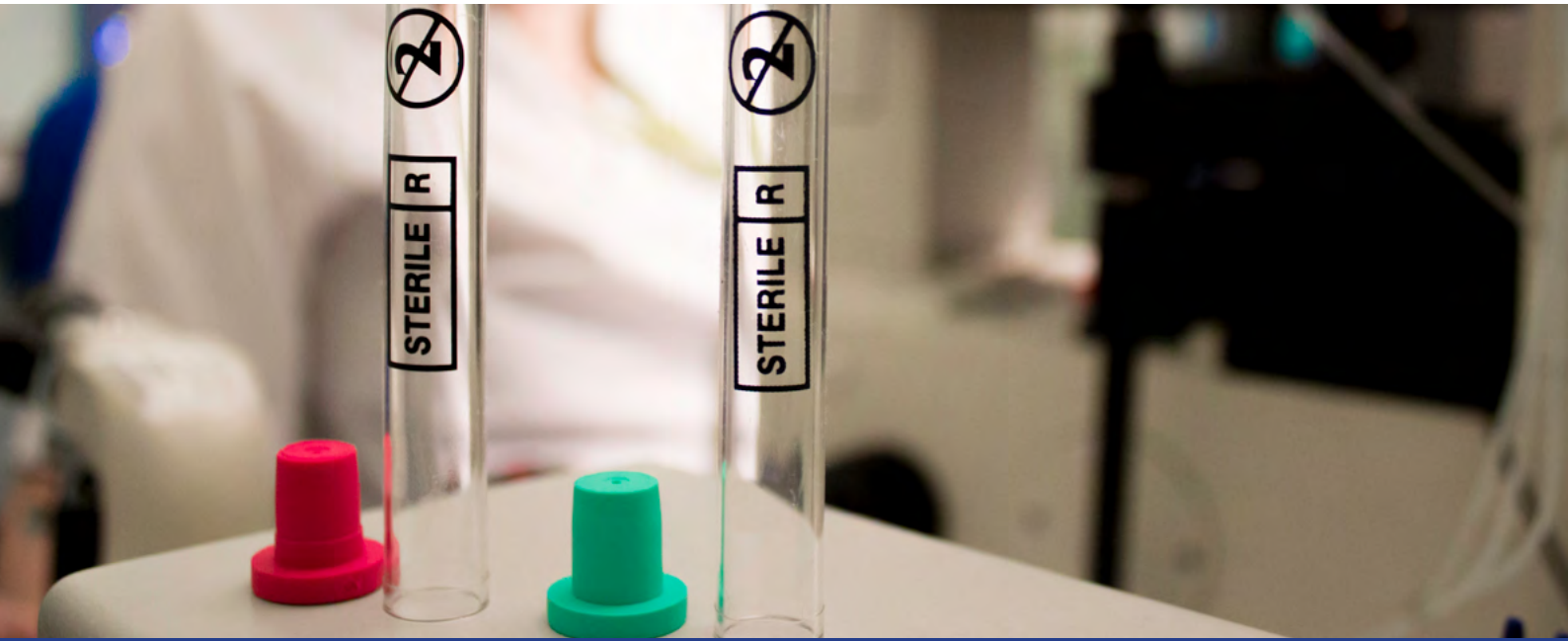
- Homogeneity & uniformity studies
- Freeze-thaw studies
- Shipment qualification
- Resin & membrane lifetime studies
- Reprocessing & reworking
- Container closure integrity
- Sterile filtration

Definition of process validation terms

14:00 *Questions & answers*

14:20 *Feedback/Evaluation session*

14:30 **End of Day 3**



Upcoming Events

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- Fraud Prevention, Detection and Investigation MasterClass — September, 2021
- Effective Remote Internal Auditing MasterClass — September, 2021
- Facing Risks in Business MasterClass — September, 2021
- Fixed Income Portfolio Management MasterClass — October, 2021
- The Future of Internal Audit MasterClass — October, 2021
- Advanced Enterprise Risk Management MasterClass — November, 2021

PHARMACEUTICAL EVENTS

- Analysing and Drafting Commercial Contracts in Life Sciences MasterClass — August, 2021
- VBA & Innovative Contracting in Pharma MasterClass — August, 2021
- Pharma Contract Drafting MasterClass — August, 2021
- A Stakeholder Engagement Approach to Clinical Trials MasterClass — September, 2021
- Pharma Mergers and Acquisitions MasterClass — September, 2021
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- Advanced CMC MasterClass for the US Market — October, 2021
- Advanced CMC MasterClass + How to Submit Variations in Europe MasterClass — November 2021

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- Manage the Annual Salary Review MasterClass — September, 2021

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- H&S Legal Compliance and Leadership MasterClass — September, 2021

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