Critical Quality Attributes of Recombinant Proteins for Therapeutic Use

MasterClass

Mylene Talabardon *Hervé Broly*

KEY TAKEAWAYS

- Purpose of understanding the product quality variations
- Understanding the heterogeneity of recombinant proteins
- Assessing the criticality of quality attributes
- Selecting critical quality attributes to be considered in process characterization studies and biosimilarity/comparability studies
- Understanding, through published examples, the risks for the patients of variations in quality attributes

TRAINING OVERVIEW

The introduction of the Quality by Design concept in the early 2000's has changed the paradigm of product and process development for recombinant biotherapeutics, switching from the process makes the product to the product makes the process.

The Quality by Design approach starts by the understanding of the impact of changes in quality attributes on product clinical efficacy and safety. Without understanding it, it is difficult to develop a manufacturing process that would have to consistently deliver a product of the desired quality. Therefore, it is important to understand the quality attributes possibly generated by the manufacturing process (process-related impurities), the intrinsic heterogeneity of recombinant proteins, the post-translational physical and chemical modifications, and their risks for the patients.

The Master Class on critical quality attributes of recombinant proteins for therapeutic use will address the understanding of quality attributes, the purpose of assessing their criticality and how to select critical quality attributes. The Master Class will be illustrated by a review of physico-chemical variants, process- and product-related impurities and their impact on the product efficacy and safety.

WHO SHOULD ATTEND?

- Product and process development scientists and managers
- CMC development program managers
- Manufacturing and QC managers
- Quality Assurance specialists and managers
- Drug Regulatory Affairs specialists and 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.

DAY1

08:50 Connecting to the online MasterClass

09:00 *Welcome and introduction*

09:15 *Context*

- Definition of CQAs
- Purpose of Quality by Design
- Purpose of critical quality attributes selection
- Selection of CQAs to be considered for process characterization
- Selection of CQAs for biosimilarity and comparability
- Classes of critical quality attributes

10:30 Break

11:00 *Source of information*

- Mandatory CQAs
- Product characterization
- Literature
- Structure-function relationship studies
- How to translate to clinical efficacy and safety

12:30 End of Day 1

DAY2

08:50 Connecting to the online MasterClass

09:00 *Process-related impurities*

- Host Cell Proteins
- Residual host cell DNA
- Residual Protein A
- Remains of raw material and excipients
- Elemental impurities
- Other examples of impurities

10:30 Break

11:00 *Product-related impurities and variants*

- Deamidation, succinimide and isomerization
- Oxidation
- Cysteine-related modifications
- Glycosylation
- Glycation
- N- and C-term heterogeneity
- Aggregation
- Fragmentation
- Charge variants

12:20 *Feedback/Evaluation session*

12:30 End of Day 2

All dates and times are expressed in UTC/GMT+2 on the Agenda (CET Time Zone).

Upcoming Events

FINANCIAL EVENTS

- 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
- Advanced Precision Medicine MasterClass — September, 2021
- Pharmacovigilance on the Internet and Social Media MasterClass — September, 2021
- Advanced CMC MasterClass — September, 2021
- How to Submit Variations in Europe MasterClass — September, 2021
- Advanced Pharma Root Cause Analysis MasterClass — September, 2021
- Blockchain in Pharmaceuticals Masterclass — September, 2021
- Unlocking the Potential of Cell and Gene Therapies MasterClass — September, 2021
- Critical Quality Attributes of Recombinant Proteins for Therapeutic Use MasterClass — September, 2021
- Building Digital Health Solutions MasterClass — September, 2021
- Meeting the In Vitro Medical Devices Regulation MasterClass — September, 2021
- Advanced Nanotechnology in Medicine MasterClass — October, 2021
- Advanced Genome Editing MasterClass — October, 2021
- US Healthcare & Smart Pharma Packaging – Regulations & Technical MasterClass — October, 2021
- Synthetic biology & Biopharma – a unique platform for growth and sustainable future MasterClass — October, 2021
- Risk Based Monitoring - During & Beyond Covid MasterClass — October, 2021
- Advanced CMC MasterClass for the US Market — October, 2021
- Advanced CMC MasterClass + How to Submit Variations in Europe MasterClass — November 2021

HUMAN RESOURCES EVENTS

- Digitalization Compensation & Benefit Processes MasterClass — August, 2021
- Manage the Annual Salary Review MasterClass — September, 2021

CROSS INDUSTRY EVENTS

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

About GLC

Global Leading Conferences (GLC) is an industry leader in the field of business intelligence. We provide interactive & impactful business platforms and networking opportunities for senior level executives by bringing them together for B2B Conferences, Global Summits, Training & Workshops. Being customer focused and having our client's priorities at the forefront, are amongst our core values and is of high importance to the way we operate our business.

Our passion for customer satisfaction and results, drive us to work with industry experts closely - who fully understand their peers interests and day-to-day challenges - in order to deliver the most impactful events. We are specialized in industries such as; Pharmaceutical, Banking & Finance, Energy, Oil & Gas, IT & Communication, Sales & Marketing, Law and Human Resources.

Our commitment is to deliver the latest information to our clients, while maintaining highest quality and standards. By attending GLC events your company will be able to apply advanced strategies to your operations, gain the latest know-how's and benchmark yourself higher against the competition while enjoying a 5 star environment.

GLC'S CUSTOM IN-HOUSE TRAININGS

What is it?

- No travel or logistic expenses for the team (we deliver it at your facilities)
- Maximize ROI with a depth tailored content accordingly to your corporate needs
- 360 degrees GLC Learning experience – Individual pre-questionnaire for each participant, several case studies and post training diagnose with participants
- Maturity assessment for the team during the preparation of the course

Contact us for more information and tailored details:
booking@glceurope.com

Media Partners