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# TRAINING PROGRAM FOR CMC LEADERS

## 7 modules: 14 September 2026 - 09 April 2027

## Training Features

- Interactive discussions and Q&A sessions
- Discussion & consultancy with the trainers
- Comprehensive course documentation
- Case studies from the trainer's experience
- Certificate of completion issued by the trainers


**The trainers' books for free, as valuable source of written guidance and references**

## Learning Outcomes

Rich with practical insights and real-world applications, this comprehensive "CMC Training Program" is an invaluable resource for CMC leaders in biotech seeking support for their product/process development and validation activities, by acquiring the comprehensive knowledge of the latest regulatory standards and industry best practices. Whether you are an experienced CMC project leader or junior to the field, this program will empower you to achieve excellence in leading your projects to success.

**Upon completion of the 7-month training program, attendees will:**

- **Integrate all the sciences and guidelines** needed to navigate in the complex landscape of QbD and regulatory standards for product development to achieve successfull CMC dossier submissions.
- Become confident to **establish and efficiently lead CMC programs** at all stages, with ease (from phases I, II, III up to product launch).

## The Trainers

### Hervé BROLY, PhD

Hervé is an internationally recognized bioprocess expert with over 42 years of experience in the development, manufacture and validation of biotech processes. He is credited with 21 patents and has authored 69 scientific papers. Over his 35-year career at Merck-Serono, he served as Vice-President of the Process Development Department. Hervé's expertise spans all CMC aspects of biotechnological products for IND/CTA and BLA/MAA applications, leading to the approval of several BLA/MAA submissions. He has extensive experience in creating high-quality, compliant CMC regulatory documents and developing strategies for complex CMC challenges. Hervé has also played a crucial role in health authority interactions and inspections at company sites.

### Mylène TALABARDON, PhD

Mylène brings 25 years of extensive experience in the biotechnology industry, having worked with BiogenIdec, Sanofi, and Merck-Serono. She has demonstrated exceptional leadership in CMC, contributing directly to multiple clinical and commercial drug substance and drug product manufacturing facilities in both technical and management roles. Prior to transitioning to consultancy, Mylène led a multi-disciplinary CMC team to successfully achieve commercial approval for a biosimilar. Her expertise encompasses process development and validation, innovative technologies, process technology transfer and scale-up, manufacturing operations and investigations, CRO/CMO management, continuous improvement, regulatory requirements, and product launches.

**Contact: mylene.talabardon@biotechnologyconsultant.com**
**www.biotechnologyconsultant.com**

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**MODULE 1**

**14-15-16-17 September 2026 (2pm to 5:30pm CET)**

# Quality Content (ICH M4Q) of the Common Technical Document (CTD) for New Biotechnological Entities

## Workshop (2pm to 5:30pm CET, September 18th)

### About ICH

- History of ICH (Mission, Purpose and Formal ICH procedure)
- Awareness of ICH guidelines (ICHQ1 to ICHQ14, Pharmacopeias, National Guidelines)

### Overview of ICH M4(CTD)

- ICH M4 and M4Q
- Structure of the CTD
- Format of the CTD
- Module 2 - CTD summaries
- Module 2.3 - Quality
- Comprehensive Quality Overall Summary
- Modules 2.4/2.6/3 - Non-clinical Studies
- Modules 2.5/2.7/5 - Clinical Studies
- Modules 3 - Quality

### Preclinical and clinical modules

- Summary of preclinical and clinical development
- ICH M4S - Non clinical overview
  - Preclinical development
  - Preclinical manufacturing
  - The CAACB review and analysis
- ICH M4E - Clinical overview
  - Clinical development
  - Phase 1 clinical studies
  - Phase 2 clinical studies
  - Phase 3 clinical studies

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**www.biotechnologyconsultant.com**

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**Content of CTD Modules 2/3 Quality (ICH M4Q) - Drug Substance (DS)**

- Understanding of Modules 2/3 contents
- Module 3 - Quality - Drug Substance (DS)
  - 3.2.S.1 General Information
  - 3.2.S.2 Manufacturing
  - 3.2.S.3 Characterization
  - 3.2.S.4 Control of Drug Substance
  - 3.2.S.5 Reference Standards or Materials
  - 3.2.S.6 Container Closure System
  - 3.2.S.7 Stability

**Content of CTD Modules 2/3 Quality (ICH M4Q) - Drug Product (DP)**

- Understanding of Modules 2/3 contents
- Module 3 - Quality - Drug Substance (DP)
  - 3.2.P.1 General Description and Composition
  - 3.2.P.2 Pharmaceutical Developoment
  - 3.2.P.3 Manufacture
  - 3.2.P.4 Control of Excipients
  - 3.2.P.5 Control of Drug Product
  - 3.2.P.6 Reference Standards or Materials
  - 3.2.P.7 Container Closure System
  - 3.2.P.8 Stability
- Module 3 - Quality - Appendices
  - Appendix A.1 Facilities and Equipment
  - Appendix A.2 Adventitious Agents Safety Evaluation

**Differences in Modules 2/3 content for IMPD/IND vs MAA/BLA**

- Clinical phase-appropriate level of CMC information
  - Process description and process controls
  - Control of Materials
  - Non-clonal cells
  - Critical steps
  - Process characterization and Process Validation
  - Control of the active substance
  - Control of excipients
  - Control of drug product
- Revision of ICHM4Q

**Speed-up from gene to First-in-Human**

**Contact: mylene.talabardon@biotechnologyconsultant.com**
**www.biotechnologyconsultant.com**

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**MODULE 2**

**05-06-07-08 October 2026 (2pm to 5:30pm CET)**

# Product Development Plan,

# Manufacturing Process Validation for Biotech Products

## Workshop (2pm to 5:30pm CET, October 09th)

### Product Development Plan (Gantt chart template)

- Review of all activities: pre-clinical studies, phases I, II, III and product launch

### Introduction to Process Validation

- Overview of Process Validation in accordance with EMA and FDA's guidelines as well as ICH Q8(R2) and ICH Q11
- Validation Master Plan (VMP)
- Target Product Profile (TPP) and QTPP (Quality Target Product Profile)
- Glossary

### Stage 1 – Process Design (DS & DP)

- Assessment of criticality of quality attributes (cQAs)
- Structure-function relationship studies
- Assessment of criticality of material attributes (CMAs)
- Assessment of criticality of process parameters (CPPs)
- Qualification of scale-down models (SDM)
- Process characterization studies
- Design space and Monte-Carlo simulations
- Clearance of impurities
- Deliverables – Process Control Strategy (PCS)
- How to set-up specifications at release and at shelf-life
- ICHQ12 – Established Conditions (ECs)

### Stage 2 – DS & DP Process Performance Qualification (PPQ)

- Prospective, Concurrent Validation and Continuous Process Verification
- Facility Qualification and Process Performance Qualification
- Number of PPQ batches
- Stability of Process Solutions and Samples
- Process Intermediates Hold Times
- Cumulated Hold Times
- Assessment of PPQ campaign

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**www.biotechnologyconsultant.com**

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**Stage 3 – Continued Process Verification (CPV)**

- State of Control
- Process Control and Process Capability
- Run charts and statistics

**Ancillary Process Validation Studies**

- Cleaning validation
- Resin/Membrane Lifetime Studies
- Toxicological assessment of residual raw materials
- Nitrosamines impurities
- Extractables & Leachables
- Elemental Impurities
- Residual solvents
- Mixing studies
- Homogeneity & Uniformity studies
- Freeze-thaw studies
- Forced degradation studies
- Reprocessing and Reworking
- Shipment studies

**Stability studies**

- Regulatory landscape
- Identification of stability indicating cQAs
- Stability evaluation
- Shelf-life determination
- Photostability studies

**Drug Product Sterility**

- Sterility
- Aseptic Process simulation (Media Fill)
- Sterile filtration
- Container Closure Integrity
- Qualification of Visual inspection

**Lessons Learnt**

**Real Life case studies: what could go wrong?**

**How to drive a product to market approval?**

**Prior Knowledge**

**Effective Project Management**

- Project initiation
- Project kick-off and planning
- Risk management
- Project leadership
- How to manage CRO/CDMO

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**MODULE 3**

## 02-03-04-05 November 2026 (2pm to 5:30pm CET)

# Cell Line Development,

# Manufacturing Cell Bank Establishment and Testing,

# Design and Development of Cell-based assays

## Workshop (2pm to 5:30pm CET, November 06th)

**Overview of the regulatory requirements for cell line development and manufacturing cell bank establishment and testing**

- Examine the US FDA and EMA requirements
- Understand the genetic plasticity of the parental cell line
- Cell line development
- Examine the specific requirements of the Research Cell Bank (RCB)
- Cell bank system components
  - Master Cell Bank (MCB)
  - Working Cell Bank (WCB)
  - End-of-Production Cell Bank (EoPCB)
- End-of-Production Cell Bank (EoPCB) and limit of in vitro cell age (LIVCA)
- Cell bank establishment and testing for commercial vs clinical production

**Best practices for cell bank system qualification**

- Identity testing
- Phenotypic characterization
- Genotypic characterization
- Discuss what safety testing is required
- Discuss strategies to prevent virus contamination
- Alternative methods to cell-based methods and in vivo methods for virus testing

**Review best practices for cell freezing and thawing**

- Understand the design area for cell banking
- Maintaining homogeneity and distribution
- Review cell freezing techniques (static/dynamic)
- Understand the effect of cell phase at freezing
- The critical steps of freezing cells in bags
- A review on Anti-icing agents
- Conditioned media
- The cell thawing procedure
- Options for the seed train: traditional vs continuous

**Contact: mylene.talabardon@biotechnologyconsultant.com**
**www.biotechnologyconsultant.com**

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**Examine cell banking for cell and gene therapy products (ATMPs)**

- Examine the main differences with cell and gene therapy products from biologics
- What regulatory requirements and testing are applicable?

**Cell-based potency assays**

- Bioassays terminology
- Regulatory guidelines and bibliography related to Bioassays
- What bioassays are and their purpose
- Common bioassay formats and regulatory expectations for reflecting the mechanism of
- action of a biotherapeutic
- Examine particularities of cell banking for bioassays
- Design and development of bioassays, including assay parameters
- Statistical considerations
- Suitability testing
- Data analysis
- Case study – replacement of an *in vivo* potency assay with an *in vitro* cell-based assay

**Contact: mylene.talabardon@biotechnologyconsultant.com**
**www.biotechnologyconsultant.com**

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**MODULE 4**

**07-08-09-10 December 2026 (2pm to 5:30pm CET)**

# Critical Quality Attributes of Biotherapeutics, Development and Validation of Analytical Methods

## Workshop (2pm to 5:30pm CET, December 11th)

### Context

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

### Source of information

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

### 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

### Product-related impurities and variants

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

**Contact: mylene.talabardon@biotechnologyconsultant.com**
**www.biotechnologyconsultant.com**

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## Development and Validation of Analytical Methods

- Relevant guidelines
- Methods description (content of 3.2.S.4 section)
- What to test?
- What is In or Out of CoA?
- ICHQ14 and Established conditions
- Analytical validation, including validation of Bioassays
- Life Cycle Management

**Contact: mylene.talabardon@biotechnologyconsultant.com**
**www.biotechnologyconsultant.com**

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**MODULE 5**

**25-26-27-28 January 2027 (2pm to 5:30pm CET)**

# Prevention and Detection of Viral and Bacterial Contamination, Viral Clearance Strategies

## Workshop (2pm to 5:30pm CET, January 29th)

**Microbiological control of bioprocesses**

- Regulatory expectations
- Hazard Analysis and Critical Control Points (HACCP) risk assessment
- The 7 principles
- Critical Control Points (CCP) identification, limits and monitoring procedures
- Case by Case Assessment of Bioburden (CCAB) assessment

**Risk, impact, detection and prevention of mycoplasma contamination**

**Risk, impact, detection and prevention of viral contamination in biopharmaceutical manufacturing**

- Understand the risk of viral contamination and why it is critical to remove potential viruses
- Examine the biology of viruses
- Reported events
- Sources of contamination
- Impacts of viral contamination
- Review case studies of viral contamination (discuss the lessons learnt)
- Product Quality Impact Assessment (PQIA)

**Regulatory landscape**

- Review the regulatory requirements surrounding viral contamination and clearance
- Source documentation
- Analyse ICH Q5A(R2) Guideline on viral safety evaluation of biotechnology products

**Examine the requirements of specific products including**

- Recombinant proteins
- Gene therapies
- Cell therapies

**Contact: mylene.talabardon@biotechnologyconsultant.com**
**www.biotechnologyconsultant.com**

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**Risk prevention**

- Examine methods, processes and strategies to reduce viral contamination.
- Source of raw materials, prevention and testing
- Learn what cell bank testing is required
- Testing of process intermediates
- Discuss critical environmental controls
- Personnel control
- Segregation of manufacturing activities
- Closed processes
- Impact of the COVID pandemic

**Viral clearance studies**

- What studies are required throughout CMC development?
- When are the studies required throughout CMC development?
- Examine how to develop a viral clearance strategy
- Discuss virus inactivation and removal
  - Techniques of virus inactivation
  - Techniques of virus removal
- Viral clearance using orthogonal process steps
- Review scale-down models
- Model viruses
- Pre-requisites to spiking studies
- Spiking studies
- Testing methods
- New and aged chromatography resins
- Virus-Like Particles (VLP) quantification
- Overall process capability to remove / inactivate viruses
- Learn how to manage viral clearance within a continuous manufacturing process

**Contact: mylene.talabardon@biotechnologyconsultant.com**
**www.biotechnologyconsultant.com**

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**MODULE 6**

**01-02-03-04 March 2027 (2pm to 5:30pm CET)**

# CMC Readiness Challenge in Case of Expedited Programs, Process Changes, Comparability Studies and Biosimilars

## Workshop (2pm to 5:30pm CET, March 05th)

### Overview of expedited programs

- FDA - Fast-Track, Breakthrough Therapy Designation, Accelerated Approval, Priority Review
- EU - Prime, Conditional Approval, Accelerated Assessment, Exceptional Circumstances
- Other countries

### Impact of expedited programs on CMC readiness

- Regulatory expectations: timing, quality, flexibility
- Interactions with Regulatory Agencies
- The Manufacturing Readiness Plan

### Strategies and tactics to accelerate CMC development

- Early Development Activities
- Process & Formulation Development Considerations
- Manufacturing & Launch Site Considerations
- Process Validation Considerations
- Analytical Development Considerations
- Control Strategy Considerations
- Stability Data Considerations
- Pharmaceutical Quality System Alignment

### Process changes and comparability studies

- Regulatory landscape on process changes and comparability studies
- Classification of process changes
- Content of comparability studies
- Product characterization
- Statistics

### Evolution of biosimilar development

- FDA current approach and Pilot Program
- EMA’s tailored clinical approach to biosimilar development
- Impacts on CMC development

**Contact: mylene.talabardon@biotechnologyconsultant.com**
**www.biotechnologyconsultant.com**

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**MODULE 7**

**05-06-07-08 April 2027 (2pm to 5:30pm CET)**

# Continuous Manufacturing Processes,

# Tech Transfer and Scale-up for Manufacturing

## Workshop (2pm to 5:30pm CET, April 09th)

### Overview of continuous biomanufacturing

- History of continuous manufacturing
- Reviewing and understanding the pros and cons of a continuous approach in biotech
- Latest technologies for large-scale production of recombinant proteins
- The necessity for flexible manufacturing processes
- The challenge of managing manufacturing costs
- The implementation of single-use systems

### Upstream perfusion technologies

- Principles of various cell culture modes: batch, fed-batch, intensified fed-batch, and perfusion
- Examine cell metabolism in fed-batch vs perfusion
- How to move from batch to perfusion system:
  - Cell retention technologies
  - Continuous media feed
  - Bleed

### Downstream technologies

- Fundamentals of continuous chromatography
- Available technologies based on chromatography resins
- Continuous viral inactivation

### Regulatory & quality considerations for continuous biomanufacturing

- Understand the current regulatory landscape
- ICH, EU and US FDA Guidelines
- Review of ICH Q13
- Steady state vs State-of-Control
- Understand the diversion points
- Review the limitations for biopharmaceutical processes
- Expectations for Process Analytical Technologies (PAT)

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### Validation for continuous processes

- General principles of process validation
- Understand the key differences to classical batch processing
- Continuous process performance qualification and batch definition
- Setting-up the control trategy
- Residence time distribution
- Continuous viral clearance
- Continuous filtration
- Bioburden control

### The future of continuous processing

- What are the latest purification technologies?
- Review the business case for continuous manufacturing
- Further development of Process Analytical Technologies
- Real-time of drug substance release (RTR)

### Regulatory and quality aspects of Tech Transfer

- Introduction to technology transfer in the biopharmaceutical industry
- Regulatory considerations:
    - Overview of regulatory guidelines
    - Documentation requirements for submissions
    - Managing regulatory interactions
- Audits: facilities and equipment considerations
    - Assessing facility suitability for new processes
    - Equipment qualification and validation
    - Mitigating risks from facility and equipment changes
- Product comparability
    - Impact of differences in CQAs
    - Mitigation strategies

### Managing Technology Transfer

- Fostering collaboration and communication between source and receiving sites
    - Importance of cross-functional collaboration
    - Effective communication strategies across stakeholders
    - Overcoming challenges in interdisciplinary projects
- Driving efficiency and quality in project management
    - Best practices for technology transfer project management
    - Tools for transferring process information and knowledge
    - Optimizing timelines and ressources allocation
- Implementing quality systems to ensure compliance and data integrity
- Risk management and change control

**Contact: mylene.talabardon@biotechnologyconsultant.com**
**www.biotechnologyconsultant.com**

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**Managing process Scale-up and process validation in Tech Transfer projects**

- Scaling-up principles
  - USP
  - DSP
- Process validation
  - Overview of validation requirements
  - Risk-based approaches to validation
- Strategies for re-risking technology transfer

**Dealing with Complexity**

- Understanding complexity in technology transfer
- Key criteria for selecting a receiving site
- Analytical method transfer and QC assays
  - Strategies for transferring analytical methods between sites
  - Maintaining assay robustness and consistency across sites
  - Addressing challenges in analytical method validation and verification
- Technology transfer strategies during the product lifecycle

**Best practices and Future trends**

- Emerging technologies and trends shaping technology transfer
- Strategies to remain competitive in a rapidly evolving landscape
- Driving excellence though continuous learning and improvement

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