GLC

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MASTERING THE COMMON TECHNICAL DOCUMENT (CTD) FOR BIOLOGICS MASTERCLASS

From guidelines to submissions

EU EVENT

ONLINE MASTERCLASS | 12-16 JANUARY, 2026

AT GLANCE

EVENT INTRODUCTION

The Master Class focuses on ICH M4Q, providing guidance on the format and content of a registration application for drug substances and their corresponding drug products, as defined in the scope of the ICH Guidelines Q6B for biotechnological products. The Master Class also includes links to other existing ICH guidelines and their contents.

WHO SHOULD ATTEND?

- Regulatory professionals (CMC) responsible for creating a dossier
- Heads of CMC functions (e.g., Cell Line Development, Drug Substance Process Development, Analytical Development, Formulation and Drug Product Development)
- CMC Project Leaders
- Quality Assurance professionals
- Any other professionals responsible for generating data to be shared with regulatory authorities

YOU WILL LEARN ABOUT

- A comprehensive review of Chemistry, Manufacturing, and Control (CMC) data to be included in an Investigational New Drug application (IND)/ Investigational Medicinal Product Dossier (IMPD) and Biological License Application (BLA)/ Marketing License Application (MAA) for new biotechnological products
- The format, structure, and content of information to be shared with Regulatory Authorities when submitting an application for a clinical trial or a license/marketing authorization application
- Going through each section of Module 2 and Module 3 of the CTD, listing and describing the CMC data to be provided in each Quality section
- The objectives of ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) and an overview of applicable CMC guidelines, highlighting differences in data content when applying for a clinical trial or a license/marketing authorization application
- What needs to be provided in an application dossier
- How to build the CMC package and create a successful IND/IMPD or BLA/ MAA

MEET THE TRAINERS

Mylène Talabardon, Phd

Mylène brings 25 years of extensive experience in the biotechnology Mylène brings 25 years of extensive experience in the biotechnology industry, having worked with renowned companies such as Biogenldec, 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.

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-years 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.

DAY 1

13:55	JOINING THE COURSE
14:00	**ABOUT ICH**

	• History of ICH
	  • Mission of ICH
	  • Purpose of ICH
	  • Formal ICH procedure
	• Awareness of ICH technical guidelines
	  • ICHQ1- Stability
	  • ICHQ2 and Q12 – Analytics
	  • ICH Q3 – Impurities
	  • ICH Q4 – Pharmacopeias
	  • ICH Q4B – Annexes
	  • ICH Q5 – Quality of Biotech Products
	  • ICH Q6 – Specifications
	  • ICH Q7 – GMPs
	  • ICH Q8/Q9/Q10/Q11/Q12/Q13/Q14 – Quality by Design
	  • Pharmacopeias
	  • National Guidelines

15:30	COFFEE BREAK
16:00	**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

17:30	END OF DAY 1

DAY 2

13:55	JOINING THE COURSE
14:00	**CONTENT OF CTD MODULES 2/3 QUALITY (ICH M4Q) – DRUG SUBSTANCE**

	• Understanding 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

15:30	COFFEE BREAK
16:00	**CONTENT OF CTD MODULES 2/3 QUALITY (ICH M4Q) – DRUG SUBSTANCE (CONTINUED)**

	• Understanding 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

17:30	END OF DAY 2

ALL DATES AND TIMES ARE EXPRESSED IN UTC/GMT+1 ON THE AGENDA (CET TIME ZONE)
STARTING TIME – GMT 13:00 P.M.

WE RESERVE THE RIGHT TO MAKE SLIGHT ADJUSTMENT IN THE TRAINING PROGRAM

DAY 3

13:55	JOINING THE COURSE
14:00	**CONTENT OF CTD MODULES 2/3 QUALITY (ICH M4Q) – DRUG PRODUCT**

	• Module 3 – Quality – Drug Product (DP)
	  • 3.2.P.1 General Description and Composition
	  • 3.2.P.2 Pharmaceutical Development
	  • 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

15:30	COFFEE BREAK
16:00	**CONTENT OF CTD MODULES 2/3 QUALITY (ICH M4Q) – DRUG PRODUCT (CONTINUED)**

	• Module 3 – Quality – Drug Product (DP)
	  • 3.2.P.1 General Description and Composition
	  • 3.2.P.2 Pharmaceutical Development
	  • 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

17:30	END OF DAY 3

DAY 4

13:55	JOINING THE COURSE
14:00	**DIFFERENCES IN MODULES 2/3 CONTENT FOR IMPD/IND VS**

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

15:30	COFFEE BREAK
16:00	**SPEED-UP FROM GENE TO FIRST-IN-HUMAN**
17:30	FEEDBACK/EVALUATION SESSION
17:40	END OF DAY 4

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DAY 5

13:55	JOINING THE COURSE
14:00	**WORKSHOP**
	Breakout Sessions • Participants will engage in interactive group work focused on diverse case studies. **Issue-Based Discussions** • Open forum to address pre-submitted issues and concerns, encouraging collaborative problem-solving. **Networking Opportunities** • Connect with industry professionals and peers throughout the session. **Practical Takeaways** • Actionable insights and tools to apply directly in your professional context. **Session Overview** • A comprehensive summary to wrap up key learnings and outcomes.
17:30	END OF DAY 5

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BUSINESS COMMUNICATION MASTERCLASS

04-05 November, 2025 | 2 pm to 6 pm

INFO

GLCEUROPE.COM | MARKETING@GLCEUROPE.COM | +36 1 848 05 96

EVENT INTRODUCTION

The training will focus on key components of communication. We will explore key topics including Emotional Intelligence, Asking, Listening, Feedback, Verbal and Non-verbal Communication, Teamwork, and will touch on Conflict Resolution. By definition, these are all substantial topics in and of themselves, so , of necessity we'll focus on the practical understanding and application in real-life scenarios. Content will include a combination of slides, images and video clips. The event will be interactive, with plenty of opportunity for questions.

COMPETENCY GOALS

• Enhanced communication skills • Facial recognition skills • Body language awareness • Advanced listening skills • Increased ability to cultivate trust • Understanding of the dynamics of feedback • Utilising the power of silence • Advanced observational skills • The art of asking questions • Application of Emotional Intelligence

JOSEPH MCGUIRE

FACIAL PROFILER

CLEARSIGHT COMMUNICATIONS

UPCOMING EVENTS

EU MASTERCLASSES AND CONFERENCES		US MASTERCLASSES AND CONFERENCES	
Impurities Training Program	16.09.2025 – 26.11.2025	Training program for CMC leaders	29.09.2025 – 24.04.2026
Risk based Quality management in Clinical Trials MasterClass	14-15 October	Risk based Quality management in Clinical Trials MasterClass	14–15 October
Business Communication MasterClass	04-05 November	HSE360° Summit	23–24 October
ICHQ7 Compliance challenges in modern API manufacturing MasterClass	04-06 November	AI for Pharma, Bio, and Life-Sciences Lawyers MasterClass	27–28 October
Fundamentals of Pharmacokinetics MasterClass	05-06 November	ICHQ7 Compliance challenges in modern API manufacturing MasterClass	04–06 November
Key Aspects of Analytical Development MasterClass	10-11 November	Fundamentals of Pharmacokinetics MasterClass	05–06 November
Process Validation for Biotechnological Products MasterClass	10-13 November	Process Validation for Biotechnological Products MasterClass	10–13 November
Interest Rate Risk in the Banking Book (IRRBB) MasterClass	10-13 November	Advanced Pharma Technology Transfer MasterClass	12–14 November
Advanced Pharma Technology Transfer MasterClass	12–14 November	Pharma Contract Drafting MasterClass	17–20 November
Pharma Contract Drafting MasterClass	17-20 November	Patient engagement in gene therapy MasterClass	18–19 November
Patient engagement in gene therapy MasterClass	18–19 November	PKPD in Drug Discovery and Development MasterClass	19–20 November
PKPD in Drug Discovery and Development MasterClass	19–20 November	Nitrosamine impurities MasterClass	20–21 November
Advanced Pharmacovigilance MasterClass	24–26 November	Risk Based Monitoring and the impact of ICH-GCP E6 R3 MasterClass	25–26 November
Risk Based Monitoring and the impact of ICH-GCP E6 R3 MasterClass	25–26 November	Fundamentals of Toxicology MasterClass	08–11 December
Fundamentals of Toxicology MasterClas	08–11 December		
7th Annual Credit Risk Management Forum	10–11 February 2026		
Training program for CMC leaders	29.09.2025 – 24.04.2026		

ABOUT GLC

THE COMPANY

Global Leading Conferences (GLC) is an industry leader 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 knowhow's and benchmark yourself higher against the competition while enjoying a 5 star environment.

CONTACT US FOR MORE INFORMATION AND TAILORED DETAILS:

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14+	600+	4000+	25,000 +
Years of experience	Events organized	Speakers	Attendees

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

MEDIA PARTNERS

Mastering the Common Technical Document (CTD) for Biologics Masterclass | 12-16 January, 2026

REGISTRATION FORM

PLEASE COMPLETE THIS FORM AND SEND BACK TO marketing@glceurope.com
You are able to type the required details by clicking on the text fields.

YOUR GLC CONTACT PERSON: DS74

danodya@glceurope.com

DATE:

REGISTRATION DETAILS DELEGATE 1

Firstname:

Lastname:

Job Title:

E-mail:

Phone:

BILLING DETAILS

Company Name:*

VAT/TAX number:

Postal code: * City: *

Address: *

Country: *

Finance/Accounts or Payable Contact Person: *

GROUP REGISTRATION

Group Name / Organization:

Number of Members Registering:

Contact Person Full Name:

Contact Email Address:

Contact Phone Number:

REGISTRATION DETAILS DELEGATE 2

Firstname:

Lastname:

Job Title:

E-mail:

Phone:

MASTERCLASS FEE DS74

◯ Attendance Fee	€ 1298 / DELEGATE*
◯ Attendance Fee	€ 1498 / 2 DELEGATES*
☐ Business Communication Attendance Fee	€ 99 / delegate*

38 EUR administration charge will be applied

Participation fee includes:
- Full access to the live virtual training
- Course material
- Digital certificate
- Recording

* The offer is valid for limited number of seats only
** The recording will be shared on Vimeo and will be available for a limited time

PAYMENT METHOD

◯ Via VISA or MasterCard card with a secured link

After you send your filled registration form, you will receive a secured payment link. Follow the instructions and pay directly with your credit/debit card.

◯ Via Bank transfer

After you send us the filled registration form, our finance department will issue an invoice, so you can pay by bank transfer.

REGISTRATION CONFIRMATION & LEGAL ACKNOWLEDGMENT

☐ By filling out and returning the registration form via email to a GLC Representative, I acknowledge and agree that this constitutes a legally binding commitment, even without a physical signature. I confirm that I have read, understood, and agree to GLC Europe's General Terms & Conditions and Privacy Policy.