GLC

GLCEUROPE.COM

ADVANCED CMC MASTERCLASS

EU EVENT

ONLINE MASTERCLASS | 02-03 FEBRUARY, 2026

AT GLANCE

EVENT INTRODUCTION

Technical and regulatory requirements for developing a medicinal product are becoming stricter every day, the products themselves become more and more complex. This course will present key points in CMC which are currently the focus of Health Authorities, and which are critical for a successful developement, registration, and lifecycle of pharmaceutical products. The course covers general requirements for small molecules and biologics.

WHO SHOULD ATTEND?

- Quality assurance specialists
- Regulatory Affairs CMC authors or reviewers
- Analytical and stability laboratory managers (R&D through GMP)
- Project managers with CMC responsibilities
- Chemistry, Manufacturing & Controls (CMC) regulatory
- Product scientists and test method technical experts (R&D and QC)
- Process analytical chemists and process development scientists

HOW WILL YOU BENEFIT?

The participants will gain knowledge via lecture-type sessions, letting substantial time for Q&A and discussions. Furthermore the training places great emphasis on practical examples through case studies.

REGISTER NOW!

YOU WILL LEARN ABOUT

- Understand the different levels of requirements in CMC during development and post-approval phase
- Overview of challenges for post-approval CMC changes
- Understand what are the essential requirements for a drug substance
- Learn how to justify the choice of Registered Starting Materials (RSM)
- Learn how to set appropriate specifications for both drug substances and drug products
- Understand the pharmaceutical development section of the CTD dossier
- Learn how to justify the choice of the excipients
- Understand the requirements for packaging materials
- Overview of stability requirements

MEET THE TRAINER

Sophie Nageotte

REGULATORY CMC EXPERT

20+ YEARS OF EXPERIENCE

With over 22 years of experience in the pharmaceutical industry, Sophie has a strong experience in the CMC Regulatory field. She gained her Master's degree in analytical chemistry from Manchester University and her Chemical Engineer degree from Montpellier School of Chemistry. She went on to work in pharmaceutical development and post-marketing CMC regulatory compliance in companies such as Bayer, PregLem and Laboratoires Galderma. She gained a strong experience in the worldwide regulatory environment for the development, manufacture and control of the medicines.

Since 2015, she runs her own consultancy, delivering advice in pharmaceutical development strategies and providing support in writing IMPDs, CTD Module 3 and QOS, preparing variations and answering questions from health authorities. Her experience covers a wide range of products (small molecules and biologics) and pharmaceutical forms.

Sophie also delivers training courses on European regulations for pharmaceuticals, writing of the Module 3, how to achieve global regulatory compliance, managing transfers of manufacturing sites and preparing variations for the ASEAN region.

WHAT PEOPLE SAY ABOUT OUR TRAININGS

"High attention to detail in course content and very well delivered"

"Great course, impressed with the knowledge of the trainers and ability to answer wide variety of questions!"

"Very good training led by two knowledgeable and open experts. Excellent insight given on many complex topics. Interactive and highly useful"

DAY 1

08:55	JOINING THE COURSE
09:00	WELCOME - INTRODUCTION TO THE COURSE
	THE PLACE OF CMC IN DRUG DEVELOPMENT AND IN POST-APPROVAL LIFECYCLE MANAGEMENT
	• Different requirements at different stages • What is a QTPP? • Quality by Design • Post-approval changes and ICH Q12
10:15	BREAK
10:45	ESSENTIAL DATA REQUIREMENTS ON THE DRUG SUBSTANCE
	• GMP • Critical Quality Attributes (CQA) • Registered Starting Materials (RSM) • Control strategy
CASE STUDY I:	Setting specifications on impurities for the drug substance
12:45	LUNCH

ALL DATES AND TIMES ARE EXPRESSED IN UTC/GMT+2 ON THE AGENDA (CEST TIME ZONE).
STARTING TIME – BST 08:00 A.M.

13:45	OTHER KEY TOPICS FOR THE DRUG SUBSTANCES
	• Stability • Specificity of biologics • Lifecycle challenges
14:30	KEY POINTS FOR THE DRUG PRODUCT
	• Understanding the section 3.2.P.2 of the CTD dossier • Excipients: justifying their choice • Setting appropriate specifications for the finished product
15:15	BREAK
15:45	CASE STUDY II
	• Set specifications on a given pharmaceutical form
16:45	END OF DAY 1

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

DAY 2

08:55	JOINING THE COURSE
09:00	**KEY POINTS FOR THE DRUG PRODUCT (CONTINUED)**
	• Packaging • Stability • Lifecycle challenges
10:45	BREAK
11:00	**CASE STUDY III**
	• Prepare a QTPP (Quality Target Product Profile) for a given product
12:00	FEEDBACK/EVALUATION SESSION
12:10	END OF DAY 2

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STARTING TIME – BST 08:00 A.M.

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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 PHARMA AND BIOTECH MASTERCLASSES		US PHARMA AND BIOTECH MASTERCLASSES	
Pharma licensing negotiation MasterClass	15-18 September	Pharma licensing negotiation MasterClass	15-18 September
PSUR and RMP - Benefit Risk MasterClass with workshop	22-24 September	PSUR and RMP - Benefit Risk MasterClass with workshop	22-24 September
Entry Level CMC MasterClass	24-25 September	Setting Drug Product Specification MasterClass	06-08 October
Setting Drug Product Specification MasterClass	06-08 October	Risk based Quality management in Clinical Trials MasterClass	14-15 October
Risk based Quality management in Clinical Trials MasterClass	14-15 October	Tissue engineering: Foundations and applications MasterClass	22-23 October
Tissue engineering: Foundations and applications MasterClass	22-23 October	AI for pharma, bio, and life-sciences lawyers MasterClass	27-28 October
AI for pharma, bio, and life-sciences lawyers MasterClass	27-28 October	ICHQ7 Compliance challenges in modern API manufacturing MasterClass	04-06 November
ICHQ7 Compliance challenges in modern API manufacturing MasterClass	04-06 November	Fundamentals of Pharmacokinetics MasterClass	05-06 November
Fundamentals of Pharmacokinetics MasterClass	05-06 November	Process Validation for Biotechnological Products MasterClass	10-13 November
Key Aspects of Analytical Development MasterClass	10-11 November	Interest Rate Risk in the Banking Book (IRRBB) MasterClass	10-13 November
Process Validation for Biotechnological Products MasterClass	10-13 November	Advanced Pharma Technology Transfer MasterClass	12-14 November
Interest Rate Risk in the Banking Book (IRRBB) MasterClass	10-13 November	Pharma Contract Drafting MasterClass	17-20 November
Advanced Pharma Technology Transfer MasterClass	12-14 November	Patient engagement in gene therapy MasterClass	18-19 November
Pharma Contract Drafting MasterClass	17-20 November	PKPD in drug discovery and development MasterClass	19-20 November
Patient engagement in gene therapy MasterClass	18-19 November	Nitrosamine impurities MasterClass	20-21 November
PKPD in drug discovery and development MasterClass	19-20 November	Advanced Pharmacovigilance MasterClass	24-26 November
Advanced Pharmacovigilance MasterClass	24-26 November		

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

Advanced CMC Masterclass | 02-03 February, 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 — € 2298 / 1 or 2 DELEGATES*

☐ Business Communication Attendance Fee — € 99 / delegate*

38 EUR administration charge will be applied

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.

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