GLC

GLCEUROPE.COM

DESIGNING ROBUST CELL-BASED ASSAYS MASTERCLASS

EU EVENT

ONLINE MASTERCLASS | 04-05 FEBRUARY, 2026

AT GLANCE

EVENT INTRODUCTION

For the release of biotechnological products, potency is a mandatory critical quality attribute that manufacturers must evaluate to ensure it conforms to specifications for releasing drug substance and drug product batches. Cell-based bioassays are commonly used to determine potency. While binding assays, including non-cell-based assays, can be considered during early clinical development, regulatory bodies expect that cell-based bioassays reflecting the mechanism of action of the biotherapeutic be developed and implemented during late clinical development. These assays should then be appropriately validated before performing the process performance qualification. This Master Class addresses common bioassay formats, as well as the development and validation of bioassays.

WHO SHOULD ATTEND?

- Statisticians
- Assay development Scientists
- Bioassay Planner
- Monitoring Personnel
- Assay Managers
- Bench Scientist
- Validation Analyst

REGISTER NOW!

YOU WILL LEARN ABOUT

- Use the proper terminology of bioassays and their validation
- Know the major sources of information
- Understand biological activity vs potency and purpose of bioassays
- Understand parameters that could affect the outcome of bioassays
- Implement appropriate approaches for cell line development, cell bank establishment and testing
- Know how to design bioassays, including: fitness for use, concept of relative potency, assay optimization, determination of standard curves, statistical considerations such as number of replicates, uniformity, outliers, goodness of fit, variance, uncertainty, normality and data transformation
- Master the validation of bioassays in accordance with pre-defined acceptance criteria
- Check for robustness of bioassays
- Provide examples of bioassay formats and case studies

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 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.

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	BIOASSAY AND VALIDATION TERMINOLOGY
	REGULATORY GUIDELINES AND BIBLIOGRAPHY
	WHAT BIOASSAYS ARE AND THEIR PURPOSE?
15:30	BREAK
16:00	COMMON BIOASSAY FORMATS AND REGULATORY EXPECTATIONS FOR REFLECTING THE MECHANISM OF ACTION OF A BIOTHERAPEUTIC
	CELL LINE DEVELOPMENT, CELL BANK ESTABLISHMENT AND TESTING
	DESIGN AND DEVELOPMENT OF BIOASSAYS, INCLUDING ASSAY PARAMETERS
17:30	END OF DAY 1

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

DAY 2

13:55	JOINING THE COURSE
14:00	BIOASSAY VALIDATION
	STATISTICAL CONSIDERATIONS
	SUITABILITY TESTING
15:30	BREAK
16:00	ANALYSIS OF BIOASSAYS
	CASE STUDIES, INCLUDING THE REPLACEMENT OF IN VIVO ASSAYS WITH CELL-BASED IN VITRO BIOASSAYS
17:30	FEEDBACK/EVALUATION SESSION
17:40	END OF DAY 2

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

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	
Pharma licensing negotiation MasterClass	15-18 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
Risk based Quality management in Clinical Trials MasterClass	14-15 October
AI for pharma, bio, and life-sciences lawyers MasterClass	27-28 October
ICHQ7 Compliance challenges in modern API manufacturing MasterClass	04-06 November
Fundamentals of Pharmacokinetics MasterClass	05-06 November
Key Aspects of Analytical Development MasterClass	10-11 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
Pharma Contract Drafting MasterClass	17-20 November
Patient engagement in gene therapy MasterClass	18-19 November
PKPD in drug discovery and development MasterClass	19-20 November
Advanced Pharmacovigilance MasterClass	24-26 November

US PHARMA AND BIOTECH MASTERCLASSES	
Pharma licensing negotiation MasterClass	15-18 September
PSUR and RMP - Benefit Risk MasterClass with workshop	22-24 September
Setting Drug Product Specification MasterClass	06-08 October
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Patient engagement in gene therapy MasterClass	18-19 November
PKPD in drug discovery and development MasterClass	19-20 November
Nitrosamine impurities MasterClass	20-21 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:

+36 1 848 05 96 | marketing@glceurope.com

14+ Years of experience

600+ Events organized

4000+ Speakers

25,000 + 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

Designing Robust Cell-based Assays Masterclass | 04-05 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 — € 1298 / DELEGATE*
- ◯ Attendance Fee — € 1498 / 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