GLC

GLCEUROPE.COM

AUDIT-PROOF QC DISSOLUTION

Building Biorelevant & Discriminatory Methods Regulators Trust

EU EVENT

ONLINE MASTERCLASS | 9-11 FEBRUARY 2026

AT GLANCE

EVENT INTRODUCTION

Senior pharmaceutical professionals are under growing scrutiny from regulators on the fitness, bio-relevance, and discriminatory power of their dissolution QC methods. Traditional “compendial default” approaches are no longer enough. Agencies now expect methods that differentiate meaningful formulation changes, link to in-vivo relevance, and are robust across the product lifecycle.

WHO SHOULD ATTEND?

This masterclass is specifically designed for senior-level pharma professionals in roles such as:

- Heads/Directors/Leads of Analytical Development and QC
- Regulatory Affairs CMC Leads
- QA/QC Managers
- Technical Directors for Method Development, Validation and Lifecycle Management

TOPICS IN DEBATE

- Apply the Bio-relevance Blueprint framework to select media, apparatus, and timepoints aligned to FDA/EMA expectations
- Design discriminatory QC methods using the ‘Discriminiation Engine’ framework and ICH Q14/Q2(R2) robustness principles.
- Set clinically relevant dissolution specifications for IR, MR, and DR products, avoiding “spec squeeze” or “spec creep.”
- Craft dossier-ready justfications with the ‘StoryCraft’ Playbook, ensuring Module 3 language passes assessor scrutiny.
- Strengthen QC credibility with special studies (alcohol-induced dose dumping, NG/Gtube, Soft foods administration, BCS Solubility studies).
- Benchmark and inspection-proof QC programs with the ‘Readiness Radar’ audit checklist.
- Translate recent FDA Warning Letters and EMA queries into proactive CAPAs for your own organization.

REGISTER NOW!

MEET THE TRAINER

Pearl Pereira Nambiar

FOUNDER – REGXPERTPRO

UNIVERSITY OF MUMBAI

22+ EXPERIENCE

Pearl Pereira currently serves as a seasoned regulatory affairs professional with over two decades of experience in the pharmaceutical industry. She is widely recognized for her expertise in analytical method development, regulatory strategy, and specification management. Pearl's work is grounded in a deep commitment to data-driven decision-making, logical argumentation, and scientifically sound justifications, particularly in the context of regulatory submissions and responses to deficiencies. Pearl has been honored with accolades such as the 'Xlerator' and the 'Integrated Product Development Star' awards, which highlight her leadership in streamlining processes, accelerating timelines, and promoting collaborative team dynamics. A respected authority in her field, she is frequently consulted as the go-to expert for resolving complex technical challenges. Passionate about continuous learning, Pearl remains deeply engaged with emerging industry trends and best practices. She is also known for mentoring and building high-performing teams focused on achieving impactful results. Beyond her professional responsibilities, Pearl enjoys reading, engaging in thoughtful debates, and exploring new insights through evidence-based discussions.

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

13:55	JOINING THE COURSE
14.00	**BIO-RELEVANCE BLUEPRINT**
	• Mapping API/formulation attributes to media & apparatus • Sink vs non-sink logic, surfactant thresholds, multi-pH expectations • Guardrails: avoiding pH drift, rpm choices that preserve discrimination • Case Studies
14:35	**DISCRIMINATION ENGINE**
	• What “discriminatory power” really means for QC • Small challenge studies • DoE-lite sliders to find the “sweet spot” • Link to ICH Q14/Q2(R2) robustness principles
15:10	**SURFACTANT JUSTIFIER**
	• When surfactants help vs when they mask differences • EMA/FDA expectations on surfactant vs non-surfactant profiles • Practical concentration calibration
15.45	**BREAK**
16:00	**APPARATUS CHOICE LOGIC CARDS**
	• When to move beyond USP I/II - III/IV for MR/DR or complex products • Inspection pitfalls: floaters, oily suspensions
16:35	**TIME POINTS THAT WIN F_2 (AND WHEN F_2 FAILS)**
	• Selecting early/mid/plateau points for meaningful curves • Hands-on f_2 calculation • Alternatives when f_2 is inapplicable (model-dependent approaches)
17.10	**SPEC-SENSE FOR IR, DR & MR**
	• Selecting early/mid/plateau points for meaningful curves • Hands-on f_2 calculation
17:45	**FINAL REMARKS**
18.00	**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	**REGULATORY STORYCRAFT**
	• Converting lab data into dossier-ready language • Before/after rewrite: weak vs strong Module 3 paragraph • Trigger words that invite Day-120 queries
14:35	**CASE CLINIC: INSPECTION & WARNING LETTER LESSONS**
	• FDA WL on dissolution • EMA queries on surfactant use & irrelevant specs • CAPA playbook for dissolution governance
15:10	**THINKING DIFFERENT IN QC DISSOLUTION**
	• Bicarbonate buffer vs phosphate buffer closer mimic of intestinal physiology • Non-physiological stress-tests: alcohol, high surfactant for MR products • Safe space approach to dissolution limits avoiding spec squeeze • Tablet porosity microstructure & variability link • Surface area/volume ratio comparing profiles more scientifically
15.45	**BREAK**
16:00	**READINESS RADAR**
	• Radar scoring: apparatus, media prep, sampling, robustness, specs • Benchmark against regulatory expectations
16:35	**OOS/OOT INVESTIGATION DECISION-TREE**
	• Fast vs deep-dive paths: equipment - media - method - product - analytics • Covers blind spots: filter adsorption, gelatin cross-linking
17:45	**FINAL REMARKS**
18.00	**END OF DAY 2**

DAY 3

13:55	JOINING THE COURSE
14.00	RECAP OF DAY 2
14.15	**INTERACTIVE SESSION 1 – POLLS & RAPID KNOWLEDGE CHECKS**
14:45	**INTERACTIVE SESSION 2 – BREAKOUT CASE STUDY 1**
15.15	**BREAK**
15:45	**INTERACTIVE SESSION 3 – BREAKOUT CASE STUDY 2**
16:15	**BONUS TOPIC: LEVERAGING IVIVC/IVIVR TO STRENGTHEN QC**
	• How IVIVC/IVIVR concepts can guide biorelevant and discriminatory QC limits • Practical boundaries: When IVIVC adds value, when it does not
17.15	**WRAP UP AND Q&A**
17:45	**FINAL REMARKS**
18.00	**END OF DAY 3**

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(CET TIME ZONE)

STARTING TIME – GMT 13:00 P.M.

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	
Adaptive Design in Clinical Trials MasterClass	26-27 August
Sponsor Responsibilities in Clinical Trials MasterClass	02-03 September
Inspection readiness MasterClass	09-10 September
Pharma licensing negotiation MasterClass	11-12 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
Advanced Pharma Technology Transfer MasterClass	12-14 November
Patient engagement in gene therapy MasterClass	18-19 November
Risk Based Monitoring and the impact of ICH-GCP E6 R3 MasterClass	25-26 November
Training program for CMC leaders	29.09.2025–24.04.2026
Impurities Training Course	16 September-26 November

US PHARMA AND BIOTECH MASTERCLASSES	
Adaptive Design in Clinical Trials MasterClass	26-27 August
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ABOUT GLC

THE COMPANY

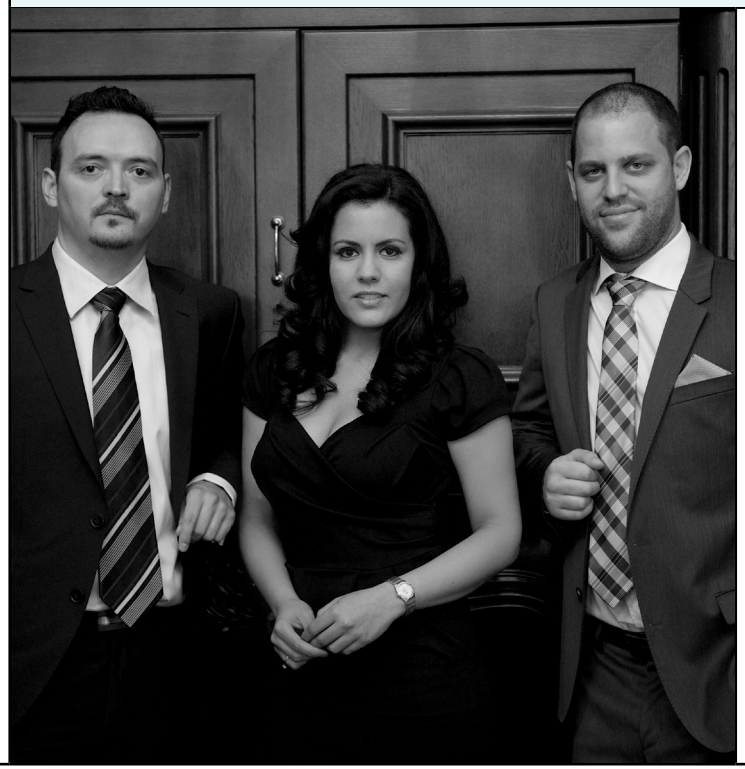
Global Leading Conferences (GLC) is an industry leader the field of business intelligence. We provide interactive & impactful business platforms and networking opportunities for senior level executives by bringing them together for B2B Conferences, Global Summits, Training & Workshops. Being customer 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+	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

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.