



METHOD DEVELOPMENT, VALIDATION AND TRANSFER WITH FOCUS ON ICH Q2(R2) AND ICH Q14 MASTERCLASS

Analytical Life Cycle Management

EU EVENT

ONLINE MASTERCLASS | 26-27 JANUARY, 2026

EVENT INTRODUCTION

The new final ICH guideline for method validation ICHQ2(R2) was put into effect in June adopted in June 2024. Together with the new ICHQ14 guideline for method development, both guidelines represent a fundamental change of direction in method development and validation, e.g. implementation of ATP (analytical target profile) and analytical lifecycle management. The WHO guidelines on transfer of technology in pharmaceutical manufacturing as well as the new draft ICH guidelines represent the new basis for the transfer of analytical methods.

WHO SHOULD ATTEND?

- Quality Control Employees
- R&D Specialists
- R&D Managers
- Quality Control Specialists
- Quality Control Managers
- Analytical Chemistry Specialists
- Analytical Chemistry Managers
- CMC Specialists

METHODOLOGY

The 1st day online Masterclass gives you practical examples for method validation. Participants can ask questions interactively during the training or in the workshop.

On the 2nd day, you will learn about the requirements for analytical method transfer and pitfalls. Participants can ask questions interactively during the training or in the workshop.

TOPICS IN DEBATE

- Introduction of ICH Q2(R2): what has changed?
- ICH Q14 and its link to method validation
- The significance of the ATP (Analytical Target Profile)
- Practical examples for method validation and method transfer
- Acceptance criteria for method validation
- Regulatory validation and transfer requirements for US and

MEET THE TRAINER



Dr. Ralph Nussbaum

HEAD QUALITY & QUALIFIED PERSON

OMEGA MANUFACTURING GMBH & CO KG

30+ YEARS OF EXPERIENCE

Dr. Ralph Nussbaum is Head of Quality and Qualified Person at Omega Pharma Manufacturing in Germany. He has extensive experience in pharmaceutical quality management and leadership. Since 2020, Dr. Nussbaum has served as Vice President of Quality Management and Managing Director, Member of the Board at Auregen BioTherapeutics GmbH in Reutlingen. Prior to that, from 2017 to 2020, he was Market Segment Leader Pharma and Site Manager at SYNLAB Analytics & Services Germany GmbH in Aachen.

A chemist by training, Dr. Nussbaum began his career in quality control at Grünenthal GmbH and later worked as Manager of Quality Assurance at CarboGen Laboratories AG. From 2003 to 2017, he held the role of Managing Director of Analytical Services, further broadening his expertise in analytical and quality operations within the pharmaceutical industry.

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

METHOD VALIDATION WITH FOCUS ON THE NEW ICH Q2(R2)

13:55	JOINING THE COURSE
14:00	WELCOME & INTRODUCTION
	<ul style="list-style-type: none"> • Overview of the masterclass • Objectives and structure • Participant expectations
14:15	ICH GUIDELINES FOR METHOD DEVELOPMENT AND VALIDATION: WHAT HAS CHANGED?
	<ul style="list-style-type: none"> • Content and focus of the new • ICH guideline on method validation • ATP and method validation • Analytical Lifecycle Management
15:30	COFFEE BREAK
15:45	PRACTICAL ASPECTS OF METHOD VALIDATION
	<ul style="list-style-type: none"> • Method validation step-by-step with practical examples for HPLC, HPLC-MS and a Bio Assay
17:00	WORKSHOP METHOD VALIDATION (PRACTICAL EXERCISES FOR PARTICIPANTS)
	<ul style="list-style-type: none"> • Prepare and present a high-level validation protocol for an analytical method
18:20	END OF DAY 1
<p>ALL DATES AND TIMES ARE EXPRESSED IN UTC/GMT+1 ON THE AGENDA (CET TIME ZONE). STARTING TIME - GMT 13:00 P.M.</p>	
<p>WE RESERVE THE RIGHT TO MAKE SLIGHT ADJUSTMENTS IN THE TRAINING PROGRAM</p>	

DAY 2

04

METHOD TRANSFER

13:55	JOINING THE COURSE
14:00	WELCOME & INTRODUCTION
	<ul style="list-style-type: none"> • Overview of the masterclass • Objectives and structure • Participant expectations
14:15	PRACTICAL ASPECTS OF METHOD TRANSFER
	<ul style="list-style-type: none"> • Method transfer step-by-step with practical examples
15:30	COFFEE BREAK
15:45	WORKSHOP METHOD TRANSFER (PRACTICAL EXERCISES FOR PARTICIPANTS)
	<ul style="list-style-type: none"> • Prepare and present a high-level transfer protocol for an analytical method.
17:00	FEEDBACK/EVALUATION SESSION
17:10	END OF DAY 2
<p>ALL DATES AND TIMES ARE EXPRESSED IN UTC/GMT+1 ON THE AGENDA (CET TIME ZONE). STARTING TIME - GMT 13:00 P.M.</p>	
<p>WE RESERVE THE RIGHT TO MAKE SLIGHT ADJUSTMENTS IN THE TRAINING PROGRAM</p>	

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 MasterClass	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:

+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

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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.

REGISTRATION DETAILS DELEGATE 1

Firstname:

Lastname:

Job Title:

E-mail:

Phone:

REGISTRATION DETAILS DELEGATE 2

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: *

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

YOUR GLC CONTACT PERSON:

DS74

danodya@glceurope.com

DATE:

GROUP REGISTRATION

Group Name / Organization:

Number of Members Registering:

Contact Person Full Name:

Contact Email Address:

Contact Phone Number:

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](#).