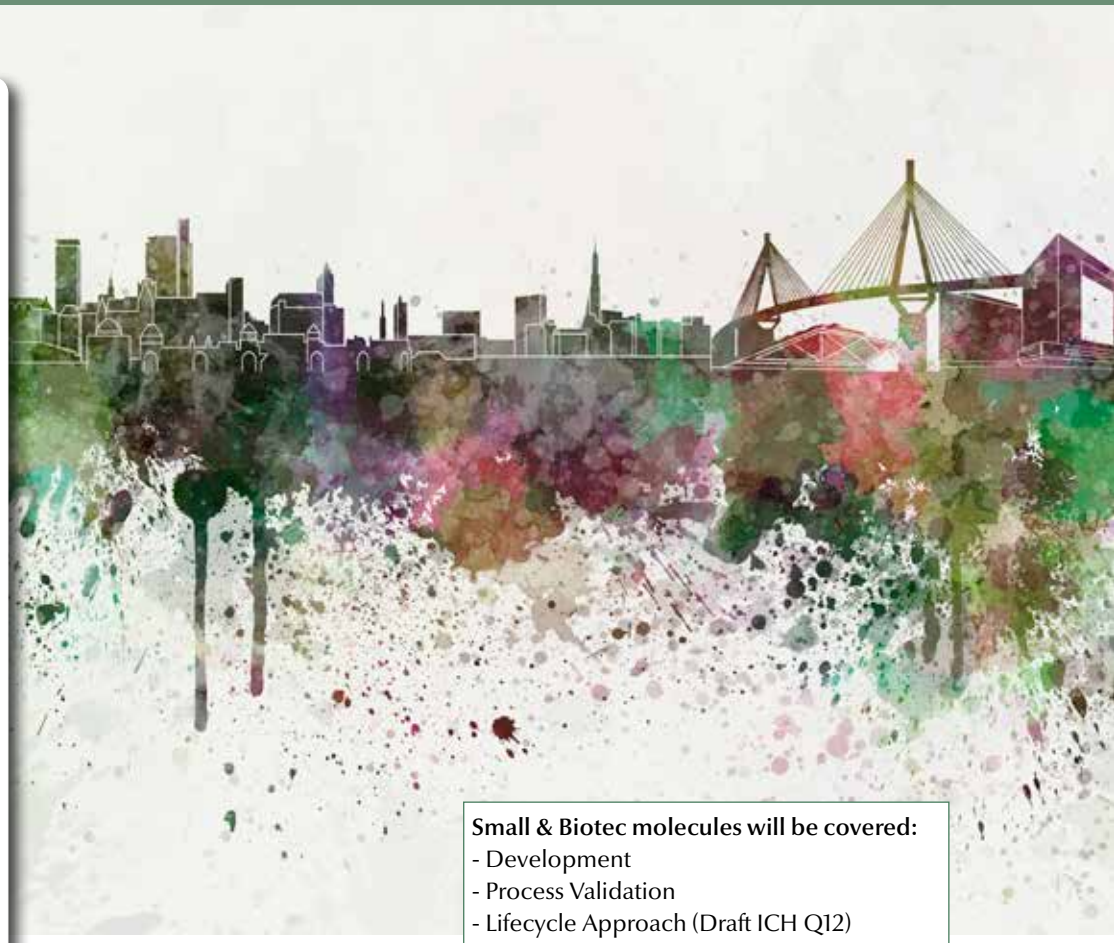
20 YEARS | ECA Academy
Your GMP/GDP Information Source

ICH Q8 / ICH Q11 Training Course

From QbD to Process Validation



Small & Biotec molecules will be covered:
- Development
- Process Validation
- Lifecycle Approach (Draft ICH Q12)
- Control Strategy / PAT / RTRT (Final Annex 17 EU GMP Guide!)

10-11 April 2019, Hamburg, Germany

Highlights

- Quality by Design (QbD)
- Quality Target Product Profile (QTPP)
- Critical Quality Attributes (CQA)
- Critical Process Parameters (CPP)
- Design Space (DS)
- Control Strategy
- Process Analytical Technology (PAT)/RTRT
- ICH Q8 and ICH Q11 (Draft ICH Q12)
- A Lifecycle Approach to Process Validation

Speakers:

Dr Hiltrud Horn
Horn Pharmaceutical Consulting

Dr Lorenz Liesum
Novartis Pharma AG

Dr Jobst Limberg
BfArM (Federal Institute for Drugs and Medical Devices, Germany)

Dr Antonio Peinado Amores
Novartis Pharma AG

Dr Hubertus Rehbaum
Dr. Rehbaum Technology Consulting

This course is recognised for the ECA GMP Certification Programme „Certified Pharmaceutical Development Manager“. Please find details at www.gmp-certification.eu

ICH Q8 / ICH Q11 Training Course

10-11 April 2019, Hamburg, Germany

Objectives

You will be updated on the latest regulatory developments and learn how to apply the respective paradigms in Pharmaceutical Development to be better able to **design strategies for the implementation of Quality by Design (QbD) according to ICH Q8 and ICH Q11.**

In workshops, you will discuss elements and methodologies associated with ICH Q8 and ICH Q11. **All this will be illustrated with examples and case studies**.

Background

The impact of ICH Q8, Q9, Q10, and Q11 is changing both the regulatory expectations and the strategies of Pharmaceutical Development, and **this impact will continue to grow, especially in view of the emerging ICH Q12 Guideline.**

The QbD concept described in ICH Q8 and ICH Q11 have to be seen as an overarching paradigm and an interdisciplinary approach across the product lifecycle. It also systematically emphasises enhanced product and process understanding throughout the product lifecycle.

Ideally, application of ICH Q8 and ICH Q11 elements already starts in the early design phase of a drug product where both patient needs and process design are considered. The QbD concept requires a comprehensive understanding of the chemical and physical nature of the individual active substance(s) and excipients, and of the way their attributes interact in the formulation and how they bare impacted by the manufacturing process. During the design phase, it is important to establish the Quality Target Product Profile (QTPP), determine the Critical Quality Attributes (CQAs), identify Critical Process Parameters (CPPs) and Material Attributes (material CQAs) and to understand how the process parameters and material attributes affect the CQAs. The relationship between process inputs (material attributes and process parameters) and the CQAs is described in the Design Space and ensured during manufacturing with an enhanced control strategy, leading to improved process understanding, greater operational flexibility and opportunities for more efficient life cycle management activities.

ICH Q8 combined with the coming Q12 will open the door to a powerful era of refined, modern and efficient pharmaceutical development and optimization for those companies who are ready to invest in this new paradigm.

Target Audience

This training course is designed for all scientists, engineers, managers and executives from Pharmaceutical and Biotech Development units and support functions to Manufacturing, including Quality Assurance and Technical/CMC Regulatory Affairs, who are involved in the implementation of ICH Q8/Q11 elements.

Programme

QbD for Drug Products: Background and Practical Aspects

- Essentials to know about QbD
- Steps for defining QTPP/CQA/CPP
- Benefits of the QbD Approach
- Practical Examples

QbD - Regulatory Perspective

- Current state of PAT & QbD implementation and regulatory challenges
- Quality by on-line (PAT) measurements
- Real time release testing: general considerations
- Going forward: ICH Q12

Interactive Sessions: QBD for Drug Products

- QTPP – CQA – CPP for different kinds of formulations, e.g. Oral formulations (Tablets, vs. Biotech vs. Vaccines)
- Typical points of discussions within teams

Development of the Drug Substance (Focus on Biotech)
- Strategies to consider for development
- Key points and potential pitfalls
- Ways to success for the submission of the dossier
- Typical questions from regulators

Development and launch of a QbD process (Drug Product)
- Lab and pilot phase investigations for criticality assessments and design space definition
- Verification of the design space and the RTRT methods at full scale
- Post approval activities and the use of a post approval change management protocol

From the design board to the implementation in the manufacturing plant: Practical examples of PAT in small and large molecules
- PAT Toolbox
- PAT as an enabler of Process Understanding and Quality Assurance
- Main milestones in the implementation of PAT for RTRT: Example in small molecules
- The big opportunities lurking around: Examples of development of PAT solutions for large molecules

Case examples: Control strategy options for a QbD process
- Case example for solid dosage form process with Real Time Release Testing (RTRT) enabled by PAT and a Design Space approach
- Case example for an small molecule API manufacturing process with PAT and SPC (Statistical Process Control) elements
- The PAT toolbox for pharmaceutical manufacturing and launches

Linking QbD and PAT towards improved process control (RTRT)
- PAT projects and the challenges with equipment manufacturers
- Technical solutions to implement the Design Space into the Control Strategy

Real Applications of PAT in Primary and Secondary Manufacturing
- Examples for Biotech Products

Continuous Process Verification and lifecycle approach of a QbD process
- Differences to the traditional validation approach
- Case example of an NDA using the alternative validation approach
- Draft ICH Q12: Life cycle management of a QbD process in the framework of ongoing process verification

Social Event

In the evening of the first conference day, you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

Speakers

Dr Hiltrud Horn, Horn Pharmaceutical Consulting, Germany
Dr Hiltrud Horn is managing director of HORN PHARMACEUTICAL CONSULTING with focus on CMC, GMP and Regulatory Affairs (EU and US). She started in pharma industry in 1990 and held several managerial positions within Hoffmann-La Roche and Knoll (now Abbott) with global responsibility within QC / QA / Regulatory Affairs / Project Management / Medical Writing. She was consultant for the biotech and life science industry at Cap Gemini Ernst & Young prior to starting her own business.

Dr Lorenz Liesum, Novartis Pharma AG, Switzerland
Lorenz Liesum studied Chemistry and Mathematics and holds a Ph.D. in Physical Chemistry from ETH Zurich. He started his industrial career as an analytical scientist in chemical and pharmaceutical development at Roche and Novartis. Since more than 10 years he is working in the field of Process Analytical Technology and was involved in regulatory QbD filings. He is leading the Statistics and PAT group within global Manufacturing Science and Technology in Novartis Technical Operation supporting the production sites globally for all statistical relevant topics and managing PAT and QbD implementation with a strong focus on advanced control strategies based on NIR spectroscopy and multivariate statistical process control.

Dr Jobst Limberg, Federal Institute for Drugs and Medical Devices, BfArM, Germany
Dr Limberg joined BfArM in 1990. From 1995 to 2005 he was head of the unit "Pharmaceutical Technology". Following an interdisciplinary reorganization in 2005, he was appointed head of regulatory unit "Cardiology". Starting 2012 he is head of section "Scientific Quality" in the department European and International Affairs. He is responsible for scientific coordination of pharmaceutical quality in the German Drug Regulatory Agency and is the nominated German member of the Quality Working Party of the European Medicines Agency (EMA). He is also involved in the national PAT group and the respective international groups at EMA in London and EDQM in Strasbourg.

Dr Antonio Peinado Amores, Novartis Pharma AG, Switzerland
After receiving his Ph. D. from the University of Barcelona, Spain, Antonio started his industrial career as Chemometrician in R&D at GSK. Since 2011 he is working for Novartis as Global Technology Expert supporting the manufacturing operations of small and large molecules in terms of PAT and data analysis. Antonio is currently the Pharmaceutical Editor of NIRnews and is leading a team in the US supporting the late-phase process development of Cell and Gene therapies.

Dr Hubertus Rehbaum, Dr. Rehbaum Technology Consulting, Germany
Dr Rehbaum received a postgraduate degree from RWTH Aachen University in Electrical Engineering (Dipl.-Ing.) and in Business Economics (Dipl.-Wirt.Ing./MBA). With his background in medical engineering, he then joined a global leader for medical products, developing hardware and software solutions for neurohabilitation systems. Following these experiences in the medical sector, he moved to the pharmaceutical industry by joining a global machine supplier in a management position. Among other responsibilities, he coordinated the developments towards continuous manufacturing and supported customer projects. During this time, he also gained in-depth understanding about pharmaceutical production processes, quality management and regulatory affairs (EMA/FDA). Today, he is working as consultant for the pharmaceutical industry, worldwide supporting various clients.

Participant's comment from the May 2018 course:

"Excellent speakers!"
Gordana Savi, Croatian Agency for Medicinal Products and Medical Devices

What are The ECA Foundation and the ECA Academy?

The European Compliance Academy Foundation (ECA Foundation) is an independent professional organisation chaired by a Scientific Advisory Board with members from the pharmaceutical industry and regulatory authorities. The ECA Foundation's goal is to support to the Pharmaceutical Industry and Regulators to promote the move towards a harmonised set of GMP and regulatory guidelines by providing information and interpretation of new or updated guidances. The ECA Academy offers professional basic and advanced education (training) programmes. All services offered by the ECA Academy and with regard to ECA Academy Memberships are solely managed by Concept Heidelberg (a leading European training and information services provider). The ECA Foundation is conceptual sponsor of the ECA Academy.

How Do You Become a Member of ECA?

By participating in one of the ECA Academy Conferences or Courses you will automatically become a ECA Academy Individual Member for two years - free of charge. More information about ECA Academy can be obtained on the Website http://www.gmp-compliance.org

What Are the Benefits of ECA?

During the membership, you enjoy

- free access to the members' area where you always find the latest update of the "GMP Guideline Manager" online version – allowing you to access a GMP tree with guidelines sorted by topics or by authority. It lets you find relevant guidelines quick and easy. And as member you can also get to this detailed tree with the GMP WebApp on your smartphone or tablet PC.
- a 200,- Euro rebate for any ECA course and conference, plus the opportunity to complete the GMP Certification Programme with an internationally recognised certificate.

GMP/GDP Certification Programme

This seminar is recognised within the GMP Certification Programme. By attending selected seminars, the participant can acquire an additional certificate. We offer the following modules:

- ECA Certified Validation Manager
- ECA Certified QA Manager
- ECA Certified API Production Manager
- ECA Certified Quality Control Manager
- ECA Certified Technical Operations Manager
- ECA Certified Computer Validation Manager
- ECA Certified Regulatory Affairs Manager
- ECA Certified Microbiological Laboratory Manager
- ECA Certified Sterile Production Manager
- ECA Certified Biotech Manager
- ECA Certified Pharmaceutical Development Manager
- ECA Certified GMP Auditor
- ECA Certified GDP Compliance Manager
- ECA Certified Packaging Manager
- ECA Certified Data Integrity Manager

On the internet at www.gmp-compliance.org you will find a text explaining which seminars are recognised for which certificates. Or you send an e-mail to info@gmp-compliance.org or a fax to +49-6221- 84 44 64 with the request for information about the GMP Certification Programme. We will then send you our brochure on the topic.

Lufthansa is Mobility Partner for all ECA Events

Lufthansa Mobility Partner

As an ECA course or conference attendee, you will receive up to 20% discounted travel fares (according to availability). And as Lufthansa German Airlines offers a comprehensive global route network linking major cities around the world you will most likely be able to benefit from these special prices and conditions.

And this is how it works: Once you registered for a course or conference you will receive a link together with your registration confirmation. Opening that link will take you to the Mobility Partner Program website where you can enter a code in the "Access to Event Booking" area you will also receive. This will take you into an online booking platform* that will automatically calculate the discount offered or provide you with an even better offer if another promotional fare is available.

We look forward to welcoming at one of our next events – and we already wish you a pleasant flight!

*Please note: You may have to enable pop-ups on the Mobility Partner Program website – otherwise the booking platform window will not open.

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg, Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

Date
Wednesday 10 April 2019, 9.00 h – 17.00 h
(Registration and coffee 8.30 h – 9.00 h)
Thursday, 11 April 2019, 8.30 h – 15.00 h

Venue
Barcelo Hamburg
Ferdinandstr. 15
20095 Hamburg, Germany
Phone +49 (0) 40 22 63 62 0
Fax +49 (0)40 22 63 62 999
hamburg@barcelo.com

Fees (per delegate plus VAT)
ECA Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable.

Accommodation
CONCEPT has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form when you have registered for the course. Reservation should be made directly with the hotel. Early reservation is recommended.

Registration
Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

Conference language
The official conference language will be English.

Organisation and Contact
ECA has entrusted Concept Heidelberg with the organisation of this event.
CONCEPT HEIDELBERG
P.O. Box 10 17 64
D-69007 Heidelberg, Germany
Phone +49 (0) 62 21/84 44-0
Fax +49 (0) 62 21/84 44 34
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content:
Dr Andrea Kühn-Hebecker (Director Operations) at +49-62 21/84 44 35, or per e-mail at kuehn@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:
Mr Niklaus Thiel (Organisation Manager) at +49-62 21/84 44 43, or per e-mail at thiel@concept-heidelberg.de.

If the bill-to-address deviates from the specification to the right, please fill out here:

_____

_____

_____

_____

_____

CONCEPT HEIDELBERG
P.O. Box 10 17 64
Fax +49 (0) 6221/84 44 34

69007 Heidelberg
Germany

Registration form (please complete in full)

ICH Q8 / ICH Q11 Training Course
10-11 April 2019, Hamburg, Germany

☐ Mr ☐ Ms Title _____

First name, surname

Company

Department

Important: Please indicate your company's VAT ID Number **Purchase Order No. (if applicable)**

Street / P.O. Box

City Zip Code Country

Phone / Fax

E-mail (please fill in)

General terms and conditions
If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees: Cancellation
- until 2 weeks prior to the conference 10 %,
- until 1 weeks prior to the conference 50 %
- within 1 week prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event.

If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
Terms of payment: Payable without deductions within 10 days after receipt of invoice.
Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing.

The cancellation fee will then be calculated according to the point of time at which we receive your message.
In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)! (As of January 2012).

German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

WA/25092018