



Speakers:



Dr Rango Dietrich
*PharmDev
Innovations*



**Dr Jochen Felix
Kepert**
Roche Diagnostics



Dr Rainer Lang
Roche Diagnostics



**Dr Line Lundsberg-
Nielsen**
NNE Pharmaplan

Small AND Biotec molecules will be covered:

- Development
- Process Validation
- Lifecycle management

ICH Q8 Training Course

From QbD to Process Validation

9-10 June 2015, Copenhagen, Denmark

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)
- ICH Q8 as a Life Cycle Approach
- New Aspects for Process Validation



ICH Q8 Training Course

9-10 June 2015, Copenhagen, Denmark

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 ICH Q8 and Quality by Design. In workshops, you will discuss elements and methodologies associated with ICH Q8. All this will be illustrated with examples and case studies.
Background	The impact of ICH Q8, Q9 and Q10 is changing both the regulatory expectations and the strategies of Pharmaceutical Development, and this impact will continue to grow. ICH Q8 and Quality by Design 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 elements already starts in the early design phase of a drug product where both patient needs and process design are considered. During the design phase, it is important to determine the Critical Quality Attributes (CQAs), identify Critical Process Parameters (CPPs) and Critical Material Attributes (CMAs) 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 greater operational flexibility with reduced regulatory filing requirements. ICH Q8 will open the door to a powerful era of refined, modern and efficient Pharmaceutical Development 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, including Quality Assurance and Technical/CMC Regulatory Affairs, who are involved in the implementation of ICH Q8 elements.
Moderator	Dr Rango Dietrich

Programme

How ICH Q8, Q9 & Q10 Guidelines work together from Development to Product Realisation

- Expectations from the guidelines and the enablers
- Product Life-Cycle Quality Management
- Are concepts and methodologies really new?
- Redesigning current approaches to match future regulatory demands

Key Concepts of QbD and how they all link together

- Quality Target Profile (QTPP)
- Critical Quality Attributes (CQAs) and Critical Process parameters (CPPs)
- The role of Material Attributes
- Design Space
- Control Strategy
- Continuous Improvement

Workshop Sessions

- QTPP – CQA – CPP
- DoE - Design Space
- Control Strategy

Design Space: from early Development to Process Validation

- Define: Target setting as pre-requisite for a design space: Quality Target Product Profile QTPP
- Do: Methodologies (DoE) and how to apply
- Evaluate: How to interpret and apply a design space
- Maintain: Product Life-Cycle Quality Management
- Conclude: How to lead the way for successful process validation
- Forget: The 3-batches paradigm

How the enhanced Control Strategy links back to the QTPP and leads to effective controls of CPPs and ensures the CQAs meet their Specifications.

- Traditional versus enhanced Control Strategy
- The link between QTPP, CQAs, CPPs, Design Space and Enhanced Control Strategy
- Implementation of the Control Strategy into Manufacturing
- Link between Control Strategy and Batch Release Strategy
- Post-approval lifecycle management

Identification of CQAs for a Biotech Product & Establishment of an Enhanced Control Strategy that ensures the CQAs meet their Specifications (Biotech).

- The link between QTPP, CQAs, CPPs, Design Space and Enhanced Control Strategy

How to apply PAT during Pharmaceutical Development

- What is PAT and how is PAT related to QbD
- Introduction to PAT tools: Process Analysers, Design of Experiments, Multivariate Data Analysis, Process Control, Knowledge Management and Continual Improvement
- Examples of PAT applications during development

QbD as a Life Cycle Approach: from Development to Process Validation and Continuous Process Verification

(Examples from both small molecules and biotech)

- Real life: Blending validation using DoE and Design Space
- Post-approval lifecycle management plan for a biotech product
- Lessons learned

Speakers



Dr Rango Dietrich, PharmDev Innovations, Germany

Dr Rango Dietrich is Managing Director of PharmDev Innovations. He is also acting as Contract Qualified Person according to EU Directive 2001/83 and §14 of German Medicines Act. His services are based on more than 20 years experience in Pharmaceutical Industry mainly focussed on development- and GMP-related aspects. He is a frequent speaker on these topics on international conferences, has filed approx 140 patents in the field and also holds a MBA from University of West London.



Dr Jochen Felix Kepert, Roche Diagnostics GmbH, Germany

Dr Jochen Felix Kepert is the Global Control Strategy Lead for Roche's QbD initiative for biotech products. He has held positions of increasing responsibilities in different analytical departments. Recently he was responsible for the development of the control strategy for the biotech product GAZYVA/ GAZYVARO.



Dr Rainer Lang, Roche Diagnostics GmbH, Germany

Dr Lang is the Technical Regulatory Lead for Roche's biotech product GAZYVA®/ GAZYVARO™. He was responsible for the drug substance part of the marketing authorization application of GAZYVA®/ GAZYVARO™ comprising a full QbD approach. That effort included interactions with major health authorities like FDA, EMA and Health Canada.



Dr Line Lundsberg-Nielsen, NNE Pharmaplan, U.K.

Dr Line Lundsberg-Nielsen is Senior QbD & PAT Consultant at NNE Pharmaplan. She has many years of experience within the pharmaceutical Industry and has a theoretical as well as practical approach to QbD and PAT from working at Novo Nordisk and Lundbeck before being a consultant. Dr Lundsberg chairs the ISPE PQLI Control Strategy Team.

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

Tuesday 09 June 2015, 9.00h – 18.00h
(Registration and coffee 8.30h – 9.00h)
Wednesday, 10 June 2015, 8.30h – 15.00h

Venue

Radisson Blu Scandinavia Hotel
Amager Boulevard 70
2300 Copenhagen S
Denmark
Phone +45 33 96 50 00
Fax +45 33 96 55 55



Fees (per delegate plus VAT)

ECA Members EUR 1,590
APIC Members EUR 1,690
Non-ECA Members EUR 1,790
EU GMP Inspectorates EUR 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
E-mail: info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content:

Mr Wolfgang Schmitt (Director Operations) at +49-62 21/84 44 39, or per e-mail at w.schmitt@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:

Ms Marion Grimm (Organisation Manager) at +49-62 21/84 44 18, or per e-mail at grimm@concept-heidelberg.de.



Social Event

On 9 June, 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.

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 Q 8 Training Course,
9-10 June 2015, Copenhagen, Denmark

☐ 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 week 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).

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.