ECA ACADEMY

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

Speakers:

Dr Rango Dietrich
PharmDev Innovations

Dr Jochen Felix Kepert
Roche Diagnostics

Dr Rainer Lang
Roche Diagnostics

Dr Line Lundsberg-Nielsen
NNE Pharmaplan

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

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

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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

- QTTP – 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:
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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.

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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:

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CONCEPT HEIDELBERG
P.O. Box 10 17 64
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69007 Heidelberg
Germany

Registration form (please complete in full)

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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)**

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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.
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- until 2 weeks prior to the conference 10 %,
- until 1 weeks prior to the conference 50 %
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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).

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