Small Molecules and **Biotech Products** will be covered in parallel sessions

ICH Q8 Master Class

Efficient Use of Quality by Design Elements

5-6 May 2011, Berlin, Germany

Speakers:

Dr Thomas Backensfeld
Bayer Schering Pharma AG, Germany

Dr Rango Dietrich
PharmDev Innovations GmbH, Germany

Dr Daniela Kasulke
Boehringer Ingelheim Pharma, Germany

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

Andrew Sinclair
Biopharm Services Ltd, U.K.

Dr Ronald Taticek
Genentech, Inc./ Roche Group, USA

Highlights

- Quality by Design (QbD)
- Quality Target Product Profile (QTPP)
- Critical Quality Attributes (CQA)
- Critical Process Parameters (CPP)
- Knowledge Management
- Design Space (DS)
- Control Strategy
- Process Analytical Technology (PAT)
- ICH Q8 as a Life Cycle Approach
- New aspects for Process Validation
- Integration in CMC Documentation (the EFPIA Mock P2 Modules)

ECA
European Compliance Academy

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

ICH Q 8 Master Class

5-6 May 2011, Berlin, 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 ICH Q8 and Quality by Design.**

In workshops, you will discuss elements and methodologies associated with ICH Q8 to use process development, knowledge management and quality risk management efficiently. **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 emphases 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 Master Class 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

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

Parallel Sessions: Working on specific tasks

1) Small Molecules:
Quality Risk Management in Pharmaceutical Development: Linking Material Attributes and Process Parameters to CQAs

- The Quality Target Product Profile (QTPP) as a starter
- Case Studies
- Design of Experiments
- What is the Data telling us?
- How to interpret data and Graphical representations
- Critical Quality Attributes (CQA) and Critical Process parameters (CPP) for pharmaceutical development of small Molecules
- Design Space and operational Flexibility

2) Biotechnology:
Integrating QbD in a Biotech Development Process

- Challenges for Biotech
- Application of Quality Risk Management
- Quality Target Product Profile (QTPP), Critical Quality Attributes (CQAs), Design of Experiments and Critical Process Parameters (CPPs)
- Design Space and operational Flexibility

3) Knowledge Management:
How does Knowledge Management support the QbD approach of continual improvement?

- Differentiation between Knowledge- and Information Management
- Quality System (ICH Q10) and it's impact to knowledge management
- Design of a Data Management concept to translate data into information: IT-Architecture, Systems and purposes, feedback loops between work areas (e.g. R&D, PD, production, clinical trials)
- Data Flow concepts, Input-Output Analysis, Data type definition

You will be able to attend 2 of these parallel sessions. Please choose the ones you would like to attend when you register for this Master Class.

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

(Examples from both small molecules and biotech)

- 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

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 Continuous Improvement 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

How to integrate ICH Q8 Elements into Development and CMC Documentation: the EFPIA Mock P2 Module

(Examples from both small molecules and biotech)

- Practical Applications of QbD for an NBE Medicinal Product
- How a P2 section might look for a parenteral product developed using a QbD approach
- Translating the Quality Target Product Profile into Product Design Elements
- Developing the formulation using Formal Experimental Design elements

Speakers

Dr Thomas Backensfeld

Bayer Schering Pharma AG, Germany

Dr Backensfeld is Head of Analytical Development at Bayer Schering Pharma AG's Global Pharmaceutical Development in Berlin. Before that he held management positions in pharmaceutical development and production. He is a member of a EFPIA Topic Group on ICH Q8 and Working Group for Mock Submissions.

Dr Rango Dietrich

PharmDev Innovations GmbH, Germany

Dr Rango Dietrich is Managing Director of PharmDev Innovations GmbH. 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-aspects including responsibility for two digit million € budgets and three digit qualified staff management.

Dr Daniela Kasulke

Boehringer Ingelheim Pharma GmbH & Co. KG, Germany

Dr Daniela Kasulke is group leader DRA CMC within the Biopharmaceutical Unit of Boehringer Ingelheim. She has more than eight years of experience in the field of regulatory affairs CMC, including both marketed biotech products and biotech products in clinical development. She has also experience in data management according to GMP. Daniela Kasulke is a member of the EFPIA Working Group for Mock Submissions.

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.

Andrew Sinclair

Biopharm Services Ltd

Andrew has over 20 years design experience in the biopharmaceutical industry, from the first recombinant insulin process through to large scale monoclonal antibody manufacturing. He has had direct experience of and responsibility for manufacturing, logistics, maintenance and capital programme management. Most recently he was Director of Engineering and Logistics at Lonza Biologics. Andrew has an MSc in Biochemical Engineering from University College London

Dr Ronald Taticek

Genentech, Inc., USA, a Member of the Roche Group

Dr Taticek is the Head of the Commercial Product Quality Stewards Group in Pharma Technical Quality Biologics at Roche. He has more than 17 years of experience working in biotechnology at Genentech, Bayer and the Biotech Research Institute (Montreal, Canada). He has held positions of increasing responsibility in Process Development, Manufacturing, Technical Regulatory and now Quality. Most recently, he led the QbD implementation effort for large molecules at Genentech. That effort included participating in the FDA QbD Pilot Program and interactions with EMA and Health Canada.

Social Event

On 5 May, 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.

GMP Certification Programme

This Master Class is recognised within the GMP Certification Programme for the module "ECA Certified Pharmaceutical Development Manager". By attending selected seminars, the participant can acquire an additional certificate. We offer the following certification 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

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.

What Is ECA?

The European Compliance Academy (ECA) is an independent educational organisation chaired by a Scientific Advisory Board with members of the pharmaceutical industry and regulatory authorities.

The ECA will provide 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.

What Are the Benefits of ECA?

First benefit: During the membership, you enjoy a 200 € discount on the regular participation fee of any European Conference organised by ECA in co-operation with CONCEPT HEIDELBERG.

Second benefit: The GMP Guidelines Manager Software with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines, will be forwarded to you when you are using your membership for a conference registration.

How Do You Become a Member of ECA?
By participating in one of the European Compliance Conferences or Courses marked with ECA, you will automatically become a member of ECA for two years – free of charge. Conferences and Education Courses organised by ECA will be realised in co-operation with CONCEPT HEIDELBERG. More information about ECA can be obtained on the Website **http://www.gmp-compliance.org**.

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
Thursday, 5 May 2011, 9.00 h – 18.00 h
(Registration and coffee 8.30 h – 9.00 h)
Friday, 6 May 2011, 8.30 h – 15.30 h

Venue
Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin
Germany
Phone +49 (0)30 2127 0
Fax +49 (0)30 2127 799

Conference fees
ECA Members EUR 1,590.- per delegate plus VAT
APIC Members EUR 1,690.- per delegate plus VAT
Non-ECA Members EUR 1,790.- per delegate plus VAT
EU GMP Inspectorates EUR 895.- per delegate plus VAT
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 HEIDELBERG 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 conference.

Please use this form for your room reservation or be sure to mention "VA 6753 ECA Course" to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel not later than 23 March 2011. Early reservation is recommended.

Registration
Via 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
CONCEPT HEIDELBERG
P.O. Box 10 17 64
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:
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 Susanne Ludwig (Organisation Manager) at
+49-62 21 / 84 44 44, or per e-mail at
ludwig@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 Master Class, 5-6 May 2011, Berlin, Germany
Please choose TWO parallel sessions:
☐ Small Molecules
☐ Biotechnology
☐ Knowledge Management

☐ 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 of Business
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 % of the registration fee.
- until 1 week prior to the conference 50 % of the registration fee.
- within 1 week prior to the conference 100 % of the registration fee.

CONCEPT 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 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. **You are not entitled to participate in the conference until we have received your payment (receipt of payment will not be confirmed)!**