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Quality by Design in Drug Product Development

A risk-based approach from start of development until submission

SPEAKERS:

Dr Michael Braun
Boehringer Ingelheim Pharma, Germany

Dr Andrea Staab
Boehringer Ingelheim Pharma, Germany

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

Dr Gerald Kindermann
F. Hoffmann-La Roche, Switzerland

10-11 October 2017, Heidelberg, Germany

HIGHLIGHTS:

- Application of QbD during different stages of drug product development
- Regulatory perspective
- Knowledge management
- Risk management and control strategy
- Reports and documentation
- Examples and case studies on DoE, PAT and statistic approaches
- Two hours of interactive workshops

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

Quality by Design in Drug Product Development

10-11 October 2017, Heidelberg, Germany

Objectives

The aim of this two-day course is to provide practical guidance on how QbD principles can be translated and implemented in drug product development. This course will deal among others with the following questions:

- What are the opportunities and challenges of applying QbD to drug product development?
- What are the current status and future expectations of QbD (ICH, FDA, EMA)?
- How can Quality Target Product Profile (QTPP) and concepts of life cycle management (ICH Q12) increase regulatory flexibility?
- What are the regulatory expectations in view of terminology and QbD related content of module 3?
- How to perform focused risk assessments for efficient development work?
- Why is it important to have a clear understanding and expectation of process performance?
- What is the impact of QbD on drug product development, scale-up and transfer?
- How can QbD also benefit marketed products?

Interactive workshops will enable delegates to apply what they have learned and to discuss the concepts in more detail. Delegates will have the opportunity to work through the whole QbD process by gaining "hands-on experience" from a number of examples and case studies.

Background

The pharmaceutical industry is currently embracing QbD concepts to help improve the robustness of manufacturing processes and to facilitate continuous improvement strategies to enhance product quality and availability throughout a product's life cycle. QbD ensures product quality and requires process performance characteristics to be scientifically designed to meet specific objectives, not merely empirically derived from the performance of test batches. Key QbD concepts are described in ICH guidelines Q8 Pharmaceutical Development, Q9 Quality Risk Management and Q10 Pharmaceutical Quality System. A new ICH guideline Q12 on Life cycle Management, which is intended to complement existing ICH Q8 to Q11 guidelines, is planned.

Risk- and science-based product development requires the support of structured tools for experimental planning and knowledge management. The documentation of the development work in risk assessments and development reports is a key to efficient compilation of the submission dossier.

Process Analytical Technology (PAT) is a key tool to an effective implementation of QbD as a way to achieve process knowledge and control. Through application of PAT during development and advanced monitoring and control options, process performance can be improved.

Initiatives from regulatory authorities like the recently published draft Annex 17 (EU GMP Guideline) on "Real Time Release Testing" emphasize the advances in the application of PAT, QbD and quality risk management (QRM) principles to pharmaceutical development and manufacturing (including quality control).

Target Audience

This course aims to provide a potential way how to meet current regulatory expectations and realize the Process Design Stage in practice. Special focus is set on the application of an alternate risk assessment approach as a guiding tool that drives drug product development. Another important aspect is adequate reporting and documentation of results that are finally summarized in the submission dossier.

This course is designed for drug product managers and scientists who are responsible for performing or reviewing activities like drug product development, process validation, scale-up and transfer, and CMC dossier preparation.

In addition, QA and regulatory affairs professionals will benefit from this course by gaining an understanding of current CMC trends. This will aid more effective multifunctional discussions on these topics within industry.

Programme

Introduction to drug product development – setting the scene

- Drug product development at a glance – from first in man to marketing authorization
- Pharmaceutical QbD: Quo vadis?
- Application of QbD principles to drug product development

Expectations from regulatory agencies

- Regulatory initiatives and approaches for supporting emerging technologies
- Concepts of Real Time Release Testing (Draft Annex 17 EU GMP Guideline)
- Harmonization of regulatory requirements (QbD parallel-assessment FDA-EMA, ICH Q8 -> Draft Q12?)
- Regulatory expectations: Lessons learned from applications so far

Knowledge Management

- Knowledge Management (KM) System - Definition and Reason
- Knowledge Management Cycle
- Explicit and Tacit Knowledge - The Knowledge Spiral
- Correlation between KM and other Processes
- Enabling Knowledge Management
- Knowledge Review - integral part of the Management Review (ICH Q10)

Quality Risk Assessment and Control Strategy

- Objectives of Quality Risk Assessment (QRA) as part of development
- Overview to risk assessment tools
- Introduction of Process Risk Map
- Introduction of risk based control strategy development

QbD Toolbox: Case studies DoE, PAT, and Basic Statistics

- Value-added use of QbD tools – generic approaches and tailored solutions
- Case studies and examples for different unit operations and variable problems

Workshop Process Risk Map & link to Control Strategy

Based on a risk assessment tool tailored to cover development needs, delegates will work on case studies of process development for a solid oral dosage form.

- From QTPP and CQA to relationship analysis of process parameters and material attributes
- Process mapping for integrated documentation of the development work
- Process Risk Map as a tool for development-focussed risk assessment

Reports and Documentation

- Development Reports
- Transfer protocols and reports
- Control Strategy and link to the submission dossier

Wrap-up & Final Discussion

The concepts and tools used over the two days will be summarized and future implications and opportunities of applying QbD principles to process development will be discussed. Delegates will be given time to ask questions on how they can apply what they have learned to their own drug product development and manufacturing.

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Train:
You can get on the train directly at the airport. Trains leave up to two times per hour and it takes less than one hour to get to Heidelberg. http://www.bahn.de

Speakers

Dr Michael Braun, *Boehringer Ingelheim Pharma GmbH, Germany*
Dr Braun is a trained pharmacist with more than 15 years of experience in Drug Product Development. He received his Ph.D. in Pharmaceutical Technology at the University of Bonn and started his career in pharmaceutical industry as Head of Pharmaceutical Development at Rentschler Pharma. In 2006 Michael joined Boehringer Ingelheim and worked in different positions with increasing responsibility within Pharmaceutical Development and R&D Project Management. Since 2014, he is Director Late Stage Drug Product Development and responsible for process development and scale-up of solid and liquid orals, parenterals and inhalative NCE products. This also includes product transfers to operations, launch support and preparation of submission documentation.

Dr Gerald Kindermann, *F. Hoffmann-La Roche, Switzerland*
Dr Kindermann joined Roche in 1996. From 2001 to 2003 he led the group for the control of incoming packaging materials where he was responsible for release analysis of packaging materials and the technical control of all packaging materials. After that he was responsible for packaging materials as Quality Manager. In 2008 he joined the Global Quality group at Roche, currently working as Head Network Support, focusing on project management.

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 Andrea Staab, *Boehringer Ingelheim Pharma GmbH, Germany*
After obtaining her PhD degree in Pharmaceutical Technology from the University of Regensburg, Dr Andrea Staab worked in different functions within Pharmaceutical Development at Aventis (2001-2005) and Boehringer Ingelheim (since 2005), covering drug product development work from early formulation to late stage process development. Since 2012, she is head of Process Science and Quality by Design Support within Late Stage Drug Product Development at Boehringer Ingelheim. Her responsibilities cover the documentation of the drug product development strategy and development work from risk-based experimental planning to submission for marketing authorization.

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☐ **Quality by Design in Drug Product Development,** 10-11 October 2017, Heidelberg, Germany

☐ **Quality by Design in API Manufacturing,** 11-12 October 2017, Heidelberg, Germany

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Date

Tuesday, 10 October 2017, 9.00 h – 17.00 h
(Registration and coffee 8.30 h – 9.00 h)
Wednesday, 11 October 2017, 8.30 h – 13.30 h

Venue

Heidelberg Marriott Hotel
Vangerowstrasse 16
69115 Heidelberg, Germany
Phone +49 (0)6221 – 908 0 | Fax +49 (0)6221 – 908 698
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Fees (per delegate plus VAT)

ECA Members € 1,490
APIC Members € 1,590
Non-ECA Members € 1,690
EU GMP Inspectorates € 845
The conference fee is payable in advance after receipt of invoice and includes conference documentation, lunch and dinner on the first day, business lunch on second day and all refreshments. VAT is reclaimable.

Would you like to save money?
If you book „QbD in Drug Product Development" AND „QbD in API Manufacturing" simultaneously, the fee for **EACH** conference reduces as follows: ECA Members € 1,290 | APIC Members € 1,390 | Non-ECA Members € 1,490 | EU GMP Inspectorates € 745

Accommodation

CONCEPT HEIDELBERG 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

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Social Event

In the evening of the first course 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.

Conference Language

The official conference language will be English.

Organisation and Contact

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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

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Quality by Design in API Manufacturing

How to connect critical quality attributes with critical process parameters

SPEAKERS:

Lígia Brás
Hovione, Portugal

Hiltrud Horn
Horn Pharmaceutical Consulting, Germany

Francois Vandeweyer
Janssen Pharmaceutica, Belgium

Elmar Wenzel
Freelance Consultant, Germany

11 – 12 October 2017, Heidelberg, Germany

HIGHLIGHTS:

- Key elements and general framework of QbD for APIs
- A risk-based approach to developing a control strategy
- How to identify and control Critical Quality Attributes in API synthesis
- Dossier requirements regarding information on the API manufacturing process
- Process Evaluation and Design Space
- Application of PAT in the API manufacturing
- Different types/elements of a control strategy

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Quality by Design in API Manufacturing

11 – 12 October 2017, Heidelberg, Germany

Objectives

During this course the principles and key aspects of Quality by Design will be discussed. You will learn

- How to identify Critical Quality Attributes
- How to design an effective risk based control strategy
- How to provide QbD related information in a regulatory submission
- How Process Analytical Technology can be applied as part of a control strategy

In an interactive workshop provides the opportunity to elaborate criticality analyses for various API syntheses.

Background

In many cases the synthesis of small molecule APIs is achieved by using multiple intermediates which themselves are produced using different processes. To ensure the API manufacturing process consistently delivers an API meeting its specifications each of these processes needs to be robust.

The Quality by Design approach aims to scientifically determine product and process characteristics derived from criteria set after analysis of the intended drug application.

These product characteristics, the so called critical quality attributes (CQAs), must be identified and in the next step the critical process parameters (CPPs) have to be determined.

Suitable approaches to identify these parameters are design of experiments (DOE) or general risk assessments e.g. FMEA. When linked to each other the CQAs and CPPs define the range within the process is considered to be robust.

This has to be demonstrated by a compilation of the relevant information in the application dossier.

Target Audience

This course is designed for all persons which are involved in the manufacture of APIs especially in process development, process validation, scale-up and transfer and CMC dossier preparation. Furthermore, the seminar will be of interest to personnel from quality assurance, regulatory affairs both from API and pharmaceutical companies and to contract manufacturers.

Programme

General framework and key elements of QbD for APIs – background and potential strategies

- What is it all about?
- What are the benefits?
- When and how should you use it?
- Practical examples with typical points of discussion

How to identify and control Critical Quality Attributes (CQAs) in API synthesis – a risk-based approach to developing a control strategy

- Severity assessment of quality attributes
- Impact levels for critical process parameters (CPPs) and critical material attributes (CMAs)
- Considerations for the API Starting material
- Design of an effective risk-based control strategy
- Examples

How to provide information on the development of the API manufacturing process – dossier requirements

- What should be done at which stage?
- Which information is relevant for the dossier?
- What are the key-points to be considered for APIs (NCE/Biotech) and their formulations
- Typical questions from Authorities

Process Evaluation and Design Space

- Changing Validation Approach
- Validation Life Cycle
- Design Space Concept

Application of PAT in the API industry

- PAT at development stages of a QbD-based development
- PAT as part of the Control Strategy in a GMP environment
- Practical examples of PAT implementations at a commercial scale in a GMP environment

Control strategies – Case studies and examples

- HA definitions
- Why and When is a control strategy needed
- Different types/elements of a control strategy
- Practical examples

Workshop

Identification and classification of CQAs in API synthesis

In this workshop delegates will elaborate criticality analyses of different APIs. As part of this analyses critical quality attributes and critical process steps within the synthesis of the APIs will be identified.

Social Event

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You can get on the train directly at the airport. Trains leave up to two times per hour and it takes less than one hour to get to Heidelberg. http://www.bahn.de

Speakers

Dr Lígia Brás
Hovione FarmaCiencia SA, Portugal
Lígia Brás, PhD, is a PAT specialist in the Operational Excellence group at Hovione (Loures, Portugal), a company with more than 50 years' experience in API development and compliance manufacture. She received both her degree in Biological Engineering and her PhD in Biotechnology from the Technical University of Lisbon, Portugal. She started working in chemometrics and PAT applications in academia in 2003. Currently, Lígia has been supporting Hovione teams on analytical technologies and statistical tools implementation to achieve manufacturing processes' efficiency targets and improve operational knowledge.

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 in Basel and Knoll (now Abbott) in Ludwigshafen 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 more than 13 years ago. She is pharmacist with a Ph.D. and holds a Diploma in Pharmaceutical Medicine (Basel). Furthermore, she is specialised pharmacist for pharmaceutical analytics and for drug information.

Francois Vandeweyer
Janssen Pharmaceutica, Belgium
Francois Vandeweyer joined Janssen Pharmaceutica (part of Johnson & Johnson) in 1981 in chemical development. Until 1995 increasing responsibilities within the organisation mainly in the Quality Control Unit. Starting from 1995 he joined the QA department. Several Senior Manager responsibilities. 2005 Sr Manager GMP Compliance Chemical Operations Belgium (sites Geel – Olen – Beerse). 2009 Director Global Compliance EMEA/AP for Johnson & Johnson.

Elmar Wenzel,
Freelance Consultant, Germany
Mr Wenzel was formerly head of API production at the Plankstadt site of AstraZeneca, now Corden Pharma. He is now freelance consultant.

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Date

Wednesday, 11 October 2017, 14.00 h – 18.00 h
(Registration and coffee 13.30 h – 14.00 h)
Thursday, 12 October 2017, 9.00 h – 15.15 h

Venue

Heidelberg Marriott Hotel
Vangerowstrasse 16
69115 Heidelberg, Germany
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Organisation and Contact

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