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

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

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

Heidelberg – Optimal Accessibility via Frankfurt

TLS:
http://www.tls-heidelberg.de

Lufthansa Bus:
http://www.transcontinental-group.com/en/frankfurt-airport-shuttles

PMJ:
http://www.pmj-fahrservice.de

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 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.

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, 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
Phone   +49 (0)6221 – 908 0
Fax   +49 (0)6221 – 908 698
email   info.heidelberg@marriott.com

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, business lunch and dinner on the first day, lunch on the second day and all refreshments. VAT is reclaimable.

Would you like to save money?
If you book „Quality by Design in API manufacturing" AND „Quality by Design in Drug Product Development" 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

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
69007 Heidelberg, Germany
Phone +49-62 21/84 44-0
Fax +49-62 21/84 44 84
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content:
Dr Gerhard Becker (Operations Director) at +49-62 21/84 44 65, or per e-mail at becker@concept-heidelberg.de.
For questions regarding reservation, hotel, organisation etc.:
Mr Ronny Strohwald (Organisation Manager) at +49-62 21/84 44 51, or per e-mail at strohwald@concept-heidelberg.de

wa/vers1/22022017

Reservation Form (Please complete in full)

☐ **Quality by Design in API Manufacturing,** 11-12 October 2017, Heidelberg, Germany
☐ **Quality by Design in Drug Product Development,** 10-11 October 2017, Heidelberg, Germany

☐ Mr   ☐ Ms

Title, first name, surname
Department
Company
Important: Please indicate your company's VAT ID Number
PO Number if applicable
Street/P.O. Box
City   Zip Code   Country
Phone   Fax   E-Mail (please fill in)

CONCEPT HEIDELBERG
P.O. Box 10 17 64
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

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

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.

📠 + 49 6221 84 44 34