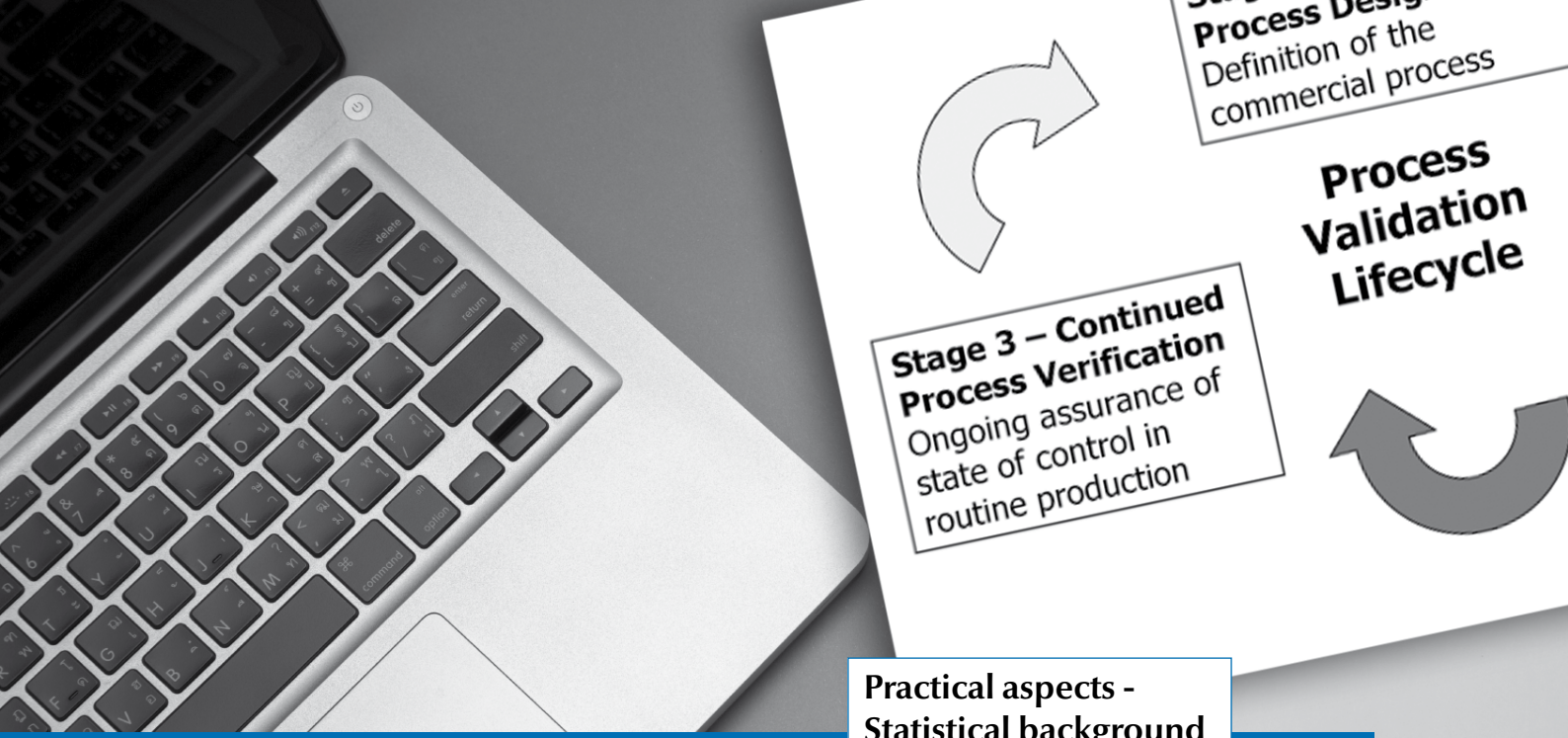

Practical aspects - Statistical background

Continued Process Verification

How to handle part 3 of the validation life cycle?

16-17 June 2015, Berlin, Germany

SPEAKERS:

Gert Moelgaard
NNE Pharmaplan, Denmark

Dr Renate Schenk-Gröninger
Boehringer Ingelheim, Germany

Dr Thomas Schneppe
Bayer Pharma AG, Germany

Dr Chris Watts
VoPal, USA
Formerly with FDA

HIGHLIGHTS:

- FDA's Process Validation guide and the principles behind
- Case Study:
  How to implement CPV of a legacy process (small molecules)
- Case Study:
  Large Molecules: Process Validation and Statistical Trending in Biopharmaceutical Manufacturing
- Parallels between Medical Device and Drug Process Validation
- Recent trends in FDA inspections, observations and warning letters
- New **Case Study CPV Protocol/Report**

ECA ACADEMY

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

Continued Process Verification

16-17 June 2015, Berlin, Germany

Objectives

With the Guidance for Industry "Process Validation: General Principles and Practices", the FDA requires a new direction. Validation is now a „Life Cycle Process" with 3 stages:

- Process Design
- Process Qualification
- Continued Process Verification

The stage 3 "Continued Process Verification" is a new step in validation. Also legacy process should be (re)validated regarding this life cycle. The start is stage 3 "Continued Process Verification". The goal of the third validation stage is continual assurance that the process remains in a state of control (the validated state) during commercial manufacture. A system or systems for detecting unplanned departures from the process as designed is essential to accomplish this goal, says the Guidance.

- But how to implement Continued Process Verification in the routine production?
- What is state of the art regarding systems for detecting unplanned departures from the process?
- How to handle the monitoring at Stage 3 (Continued Process Verification)?
- What are the differences between Continued Process Verification (FDA) and Continuous Process Verification (EMA, ICH Q8)?
- Are there parallels regarding Medical Devices?
- What statistic parameters could help

These questions are discussed, and the possibilities for implementation are covered.

Background

Since 1987 the FDA Guideline on Process Validation has been the basis for qualification and validation. Within the new FDA programme "Pharmaceutical cGMPs for the 21st Century" there was an announcement for a revision of the guideline. A new FDA Policy Guide of 2004 gives some hints as to the new validation approach. In January 2011 the new "Guidance for Industry Process Validation: General Principles and Practices" was published as final guidance. That is now FDA's „current thinking". EMA´s new Process Validation Guidance also mentions a Life Cycle Approach for Process Validation. And with the citation of ICH Q8, the possibility to do Continuous Process Verification is also mentioned.

Target Group

The addressees of the event are qualified staff charged with or responsible for validation activities, especially regarding stage 3 (Continued Process Verification) of the process validation life cycle. We mean commissioners for validation, heads of quality assurance, department heads, etc. It also addresses members of validation teams (e.g. chemists, pharmacists, microbiologists) as well as staff who is involved in process monitoring activities and consultants.

Moderator

Gert Moelgaard, NNE Pharmaplan, Denmark

Programme

Overview: The new process validation guides from FDA and EMA and the new industry guides from ISPE, PDA and ECA: content and principles

- How the concept of Process Validation is about to change
- Ongoing changes in the Quality Management philosophy
- Real-life examples

Gert Moelgaard

Parallels between Medical Device and Drug Process Validation

- Leveraging experience
- Quality System similarities
- Standard Approaches – foundation for implementation

Dr Chris Watts

Case Study: Large Molecules: Process Validation and Statistical Trending in Biopharmaceutical Manufacturing

- Introduction in Biopharmaceutical Processes
- Process development, reevaluation of commercial processes and definition of parameters
- Parameters and control
- Process Performance Validation Approach
- Trending program and choice of parameters
- Link to APR/PQR
- Case study

Dr Renate Schenk-Gröninger

Case Study: CPV Protocol/Report

- Requirements for a CPV Protocol and Report
- Case Study

Dr Renate Schenk-Gröninger

Case Study: How to implement CPV of a legacy process

- Challenges
- Experiences
- Lessons learnt

Dr Thomas Schneppe

Workshop Continued Process Verification – Process Data Evaluation and Conclusions

The delegates analyse in small groups process data regarding the validity of a legacy process.

Recent trends in FDA inspections, observations and warning letters

- Examples of expectations and enforcement
- Regulatory enforcement trends related to observations and Warning Letters

Dr Chris Watts

The future role of PAT, industrial IT and automation in continued process verification: Implementing a control strategy

- Control strategy and implications for automation solutions
- Bridging islands of information systems in manufacturing
- From data to information to knowledge: getting gold out of data
- Continued process verification: monitoring challenges
- Window to the Quality: The future role of automation and IT systems in manufacturing?

Gert Moelgaard

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.

Speakers

Gert Moelgaard
NNE Pharmaplan, Denmark
Gert Moelgaard is Vice President for Innovation & Business Development in NNE Pharmaplan. He has been working in the pharmaceutical industry since 1982 and has experience from a number of major engineering, automation and validation projects within pharmaceutical manufacturing. He has made international contributions in international conferences on automation, process validation, PAT and manufacturing excellence and has contributed to several books and technical guidelines.

Dr Renate Schenk-Gröninger
Boehringer Ingelheim Pharma GmbH & Co. KG, Biberach
Dr Schenk-Gröninger studied Pharmacy in Mainz and did their PhD-thesis at the University of Frankfurt. She is with Boehringer Ingelheim (in the past: Thomae) at the site in Biberach since 1996. She was inter alia Head of Production Head of Quality Control. Since 2004 she heads the group Process Control in Biopharmaceuticals.

Dr Thomas Schneppe,
Bayer Pharma AG, Germany
More than 20 years experience in the pharmaceutical industry. Since 2006 Bayer Pharma; Head of Mgmt. Training at Bayer Health Care - Product Supply - Compliance - Integrated Quality Mgmt.

Dr Chris Watts
Principal Consultant, VolPal, USA
Chris Watts is a principal consultant within quality and regulatory, having gained experience both from industry and FDA. **Chris was part of the team at the FDA that developed the Agency's modern approach to quality and compliance**. These included the science and risk-based approach to cGMP inspection and CMC application review, including the recent ICH Quality guidelines and the FDA guidance on Process Validation. At the FDA Chris trained many of the inspectors and reviewers on the use of these policies and practices. His consulting experience has focused on improving quality systems, regulatory strategy and providing support for life science organizations. In particular, Chris has applied his consulting expertise to organizations for application development (NDA and ANDA), as well as 483, Warning Letter and remediation actions.

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

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

Reservation Form (Please complete in full)

Continued Process Verification
16-17 June 2015, Berlin, Germany

☐ 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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Date

Tuesday, 16 June 2015, 09.30 -17.30 h
(Registration and coffee 09.00 – 09.30 h)
Wednesdy, 17 June 2015, 08.30 – 15.30 h

Venue

Steigenberger Hotel am Kanzleramt
Ella-Trebe-Str. 5
10557 Berlin, Germany
Phone +49(0)30 921 025 70
Fax +49(0)30 921 025 799

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, dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable.

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 event. Please use this form for your room reservation to receive the specially negotiated rate for the duration of your stay. 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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