Continued/Ongoing Process Verification
How to handle part 3 of the validation life cycle?

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
- The bridge between the traditional and a new life cycle validation approach - the way to continuous process verification
- NEW: Case Study From Control Strategy to Trending

SPEAKERS:

Timur Güvercinci
Merck KGaA, Germany

Dr Bettina Knapp
Boehringer Ingelheim, Germany

Gert Mølgaard
Head of ECA’s Validation Group, Denmark

Dr Thomas Schneppe
Bayer AG, Germany

Dr Chris Watts
VoPal, USA
Formerly with FDA

13-14 June 2017, Berlin, Germany

Practical aspects - Statistical background

This education course is recognised for the ECA GMP Certification Programme „Certified Validation Manager“. Please find details at www.gmp-certification.eu
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. Now, also the EU requires Ongoing Process Verification as part of a validation lifecycle.

- But how to implement Continued/Ongoing 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/Ongoing Process Verification)?
- What are the differences between Continued Process Verification (FDA) and Continuous Process Verification (ICH Q8) and Ongoing Process Verification (EU)?
- 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. In the new Annex 15 draft revision document also a Continued Process Verification, Ongoing Process Verification called, is mentioned. In the new Annex 15 revision document, valid from 1 October 2015, also a Continued Process Verification, called Ongoing Process Verification, is mentioned.

Target Group

The addressees of the event are qualified staff charged with or responsible for validation activities, especially regarding stage 3 (Continued/Ongoing 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 Mølgaard, Moelgaard Consulting, 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
- Comparision of Annex 15 revision with FDA Process Validation Guidance
- Real-life examples

Parallels between Medical Device and Drug Process Validation
- Leveraging experience
- Quality System similarities
- Standard Approaches – foundation for implementation

Case Study: From Control Strategy to Trending
- Introduction in Biopharmaceutical Processes
- Process development and definition of parameters
- Parameters and control
- Control Strategy and CPV/Trending
- Case Study
- Trending Report

Case Study: Large Molecules - Process Validation and Statistical Trending in Biopharmaceutical Manufacturing
- Process Performance Validation Approach
- Trending program and related procedures
- Link to APR/PQR
- Case Study

Recent trends in FDA inspections, observations and warning letters
- Examples of expectations and enforcement
- Regulatory enforcement trends related to observations and Warning Letters
Case Study: How to implement CPV of a legacy process
  ■ Challenges
  ■ Experiences
  ■ Lessons learnt

The bridge between the traditional and a new life cycle validation approach - the way to continuous process verification
  ■ Hybrid validation approach as a interim solution
  ■ Technology upgrade
  ■ Outlook

Workshop Continued Process Verification – Process Data Evaluation and Conclusions
The delegates analyse in small groups process data regarding the validity of a legacy process.

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?

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

Timur Güvercinci, Merck KGaA, Darmstadt, Germany
Timur Güvercinci has worked in the pharmaceutical and medical device industry for more than 10 years in various quality positions for different companies. Currently, he is working as head of QA Chemical Pharmaceutical Development. Until 2016 he was head of validation qualification and engineering in the quality assurance at Merck KGaA in Germany. Based on the different field of activities he acquired extensive experience in validation for the regulatory requirements as well as the technical implementation. Timur is a graduate engineer for pharmaceutical engineering from the Technical College of Albstadt-Sigmaringen.

Dr Bettina Knapp, Boehringer Ingelheim Pharma GmbH & Co. KG, Biberach
Dr Knapp studied Bioinformatics in Tübingen and did her PhD thesis at the University of Heidelberg. After working in different fields of statistics, she is with Boehringer Ingelheim at the site in Biberach since 2014. First working as head of Biostatistics in the Process Control of Biopharmaceuticals, she is since 2017 head of Data Processing in Quality Biopharmaceuticals.

Gert Gert Mølgaard, Moelgaard Consulting, Denmark
Gert Mølgaard has more than 25 years experience in the pharmaceutical and biotech industry, including several years of experience in process control, automation, computer systems validation and process validation as well as process engineering and consulting. He has previously worked in Novo Nordisk, Novo Nordisk Engineering and NNE Pharmaplan. From 2009-2012 Gert Mølgaard was been involved in training FDA's investigators at FDA's internal training on the 2011 Guidance on Process Validation and has contributed to several books and technical guidelines.

Dr Thomas Schneppe, Bayer AG, Germany
More than 20 years experience in the pharmaceutical industry. Since 2006 Bayer; Head of Mgmt. Training at Bayer Health Care - Product Supply - Compliance - Integrated Quality Mgmt. Currently working in the Corporate Function Process & Knowledge 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.
Tuesday, 13 June 2017, 09.30 - 17.15 h
(Registration and coffee 09.00 – 09.30 h)

Wednesday, 14 June 2017, 08.30 – 15.30 h

Venue
Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin, Germany
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Fees (per delegate plus VAT)
- ECA Members € 1,590
- APIC Members € 1,690
- Non-ECA Members € 1,790
- EU GMP Inspectorates € 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 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.

For questions regarding reservation, hotel, 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 airline penalties or other costs incurred due to a cancellation.

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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 %

Important: This is a binding registration and access 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 informing 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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