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Continued/Ongoing Process Verification

How to handle part 3 of the validation life cycle?

SPEAKERS:



Timur Güvercinci
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Dr Bettina Knapp
*Boehringer Ingelheim,
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*Head of ECA's Validation
Group, Denmark*



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Bayer AG, Germany



Dr Chris Watts
*VoPal, USA
Formerly with FDA*

**Stage 3 – Continued
Process Verification**
Ongoing assurance of
state of control in
routine production

Process Definition
Definition of the
commercial process

**Process
Validation
Lifecycle**

**Practical aspects -
Statistical background**

13-14 June 2017, Berlin, Germany

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**



Continued/Ongoing Process Verification

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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
- Comparison 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.

Easy Registration



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Reservation Form (Please complete in full)

Continued/Ongoing Process Verification

13-14 June 2017, Berlin, Germany

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Title, first name, surname

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Date

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
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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.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

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