



Speakers



Dr Rainer Gnibl
GMP Inspector for EMA



Timur Güvercinci
Merck KGaA



Jacob Johannes Hillger
Boehringer Ingelheim



Gert Moelgaard
Head of ECA's Validation Group



Dr Thomas Schneppe
Bayer Bitterfeld



Dr Ingolf Stückrath
Sanofi



Dr Chris Watts
VoPal, formerly with FDA

Modern EU and FDA Validation

Ongoing/Continued Process Verification – from
Control Strategy to Product Quality Review

19/20 May 2020, Frankfurt, Germany



Highlights

- FDA's Process Validation guide and the principles behind
- View of an EU inspector
- 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
- Case Study: SPC as tool for Continued Process Verification
- The bridge between the traditional and a new life cycle validation approach - the way to continuous process verification
- Case Study From Control Strategy to trending
- Case Study OPV program for small business

Practical aspects - statistical background

Objective

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 – **beginning from the definition of the control strategy to the Product Quality Review /Annual Product Review?**

- 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), Continuous Process Verification (ICH Q8) and Ongoing Process Verification (EU) ?
- Are there parallels regarding Medical Devices?
- What statistic parameters could help?
- Is a statistician necessary?
- How is OPV/CPV linked to PQR/APR?
- What are the expectations of an EU Inspector?

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 revision document also a Continued Process Verification, Ongoing Process Verification called, is mentioned.

In the Annex 15 revision document, valid since 1 October 2015, also a Continued Process Verification, called Ongoing Process Verification, is mentioned.

Target Audience

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.

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

Ongoing Process Verification – View of an EU Inspector

- EU process validation lifecycle approach (overview)
- EU GMP requirements on EU-OPV
- Authorities expectations regarding PQR
- Interaction and linking with EU-PQR
- Comparison of EU and US requirements to maintain status of control

Case Study: From Control Strategy to Statistical Process Control

- Introduction in biopharmaceutical processes
- Process development and definition of parameters
- Parameters and control
- Control Strategy
- Process Performance Validation Approach
- Statistical Process Control

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

- Basic Statistics
- Content of CPV protocol/report
- Trending program and related procedures
- Evaluation of Trends and CAPAs
- Link to APR/PQR

Parallels between Medical Device and Drug Process Validation

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

Recent trends in FDA inspections, observations and warning letters

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

SPC as tool for Continued Process Verification

- Continued Process Verification: Requirements
- Case Study Sanofi-Aventis

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
- Case study: OPV program for small business
 - A concept for the definition of the critical parameters/ attributes and the documentation strategy in consideration of the data integrity



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 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

Dr Rainer Gnihl, GMP Inspector, District Government of Upper Bavaria, Germany

Dr Rainer Gnihl is pharmacist and GMP Inspector for the District Government and the EMA and performs GMP inspections worldwide. Before that, he was working for the Bavarian Ministry of Environment and Health. Rainer Gnihl also holds a lectureship at the University Erlangen-Nürnberg.

Timur Güvercinci, Merck KGaA, Germany

Timur Güvercinci, graduate engineer for pharmaceutical engineering, 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 a head of QA Chemical Pharmaceutical Development.

Jacob Johannes Hillger, Boehringer Ingelheim Pharma GmbH & Co KG, Germany

Jacob Johannes Hillger has studied Biosystems Engineering and works with Boehringer since 2012 in the QA department. He is currently Head of Process Validation Life Cycle & Control Strategy Drug Substance.

Gert Moelgaard, Moelgaard Consulting, Denmark

Gert Moelgaard 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 at Novo Nordisk Engineering and NNE Pharmaplan.

Dr Thomas Schneppe, Bayer Bitterfeld GmbH, Germany

Thomas has more than 30 years GMP experience in Pharmaceutical Industry: Qualified Person, Mgmt. Training, GMP Projects, Operational Excellence in different functions at Klöckner Pentapack, Schering, Asche, Bayer and actually Bayer Bitterfeld GmbH.

Dr Ingolf Stückrath, sanofi-aventis, Frankfurt, Germany

Today Ingolf is responsible for a major insulin production facility in Frankfurt. He began his career with Aventis in 2000 and was among others Six Sigma Black Belt, was responsible for all Industrial Excellence activities at the site. In 2005 his work was recognized with the IQPC's Six Sigma IQ Excellence Award in the category "Best Defect Elimination in Manufacturing". He holds a Ph. D. in biology.

Dr Chris Watts, Principal Consultant, VolPa, 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.

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

Reservation Form (Please complete in full)

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GERMANY

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German law shall apply. Court of jurisdiction is Heidelberg.

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Date

Tuesday, 19 May 2020, 09.00 – 17.15 h
(Registration and coffee 08.30 – 09.00 h)

Wednesday, 20 May 2019, 08.30 – 17.00 h

Venue

Mercure Hotel Kaiserhof Frankfurt City Center
Kaiserstraße 62-64

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Email H8115@accor.com

Fees (per delegate, plus VAT)

ECA Members € 1,690

APIC Members € 1,790

Non-ECA Members € 1,890

EU GMP Inspectorates € 945

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/POG when you have registered for the conference. 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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