ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Validation Manager

Speakers

Dr Line Lundsberg-Nielsen
NNE

Dr Thomas Schneppe

Dr Franz Schönfeld
GMP Inspector for EMA

Dr Ingolf Stückrath
Sanofi-Aventis Deutschland

Dr Chris Watts
VoPal, formerly with FDA

Sarah Zimmet
Boehringer Ingelheim

Ongoing/Continued Process Verification

From the Control Strategy to Product Quality Review

Live Online Training on 27/28 May 2025

Practical aspects - statistical background

Highlights

- FDA's Process Validation guide and the principles behind
- View of an EU inspector
- Parallels between Medical Device and Drug Process Validation
- Recent trends in FDA inspections, observations and Warning Letters
- The future role of PAT, industrial IT and automation in continued process verification
- Case Studies:
  - From Control Strategy to Trending
  - How to implement CPV of a legacy process (small molecules)
  - Large Molecules: Process Validation and Statistical Trending in Biopharmaceutical Manufacturing
  - SPC as tool for Continued Process Verification

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 (APR)?**

- 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. 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 Annex 15 revision document, valid since 1 October 2015, also a Continued Process Verification, called Ongoing Process Verification, is now a requirement.**

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
- 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 reg. PQR and link to OPV
- Comparison of EU and US requirements reg. OPV/CPV

Case Study: From Control Strategy to Trending

- 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
- Link to IT System

Medical Device and Pharmaceuticals: Similar Expectations and Approaches

- 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 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?

Speakers

Dr Line Lundsberg-Nielsen, NNE, Denmark

Line is a scientist and runs her own consultancy business focusing on applying a science and risk based approach for pharmaceutical development, process design, technology transfer, qualification and process validation. She has many years of experience within the pharmaceutical Industry and has a theoretical as well as practical approach to QbD, PAT and RTRT from working at Novo Nordisk and Lundbeck before being a consultant. Line is an active ISPE member and has had different chairing roles and is a well-recognized international speaker and instructor.

Dr Thomas Schneppe

Thomas has more than 35 years GMP experience in Pharmaceutical Industry: Qualified Person, Mgmt. Training, GMP Projects, Operational Excellence in different functions at Klöckner Pentapack, Schering AG, Asche AG, Bayer AG, Bayer Bitterfeld GmbH and actually as freelance consulting for QM and GMP compliance.

Dr Franz Schönfeld, GMP Inspector, District Government of Upper Bavaria, Germany

Dr Franz Schönfeld is a GMP and GDP inspector at the local inspectorate for medicinal products and active substances of the District Government of Upper Franconia. He is head of the expert working group for APIs at the Central Authority of the Federal States for Health Protection.

Dr Ingolf Stückrath, Sanofi-Aventis Deutschland, 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, 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.

Sarah Zimmet, Boehringer Ingelheim, Germany

Sarah Zimmet studied human and molecular biology, started working with Boehringer Ingelheim in 2016 and is a member of Process & Cleaning Validation Drug Substance. As Validation Manager she gained a deep insight in general challenges in Continued Process Verification (stage 3) such as revalidation activities, control strategy as well as monitoring and trending.

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Reservation Form (Please complete in full)

Ongoing/Continued Process Verification – from the control strategy to Product Quality Review
Live Online Training on 27/28 May 2025

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Date of the Live Online Training
Tuesday, 27 May 2025, 09.00 - 16.45 h
Wednesday, 28 May 2025, 08.30 - 16.30 h
All times mentioned are CEST.

Technical Requirements
We use Webex for our live online training courses and webinars. At www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our events and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT system, please contact your IT department. Webex is a standard nowadays and the necessary installation is fast and easy.

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.

Registration
Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

Presentations/Certificate
The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Conference language
The official conference language will be English.

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

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