



## Speakers



Dr Rainer Gnibl  
GMP Inspector for EMA



Dr Line Lundsberg-Nielsen  
Lundsberg Consulting



Dr Thomas Schneppé



Dr Ingolf Stückrath  
Sanofi-Aventis Deutschland



Dr Chris Watts  
VoPal, formerly with FDA



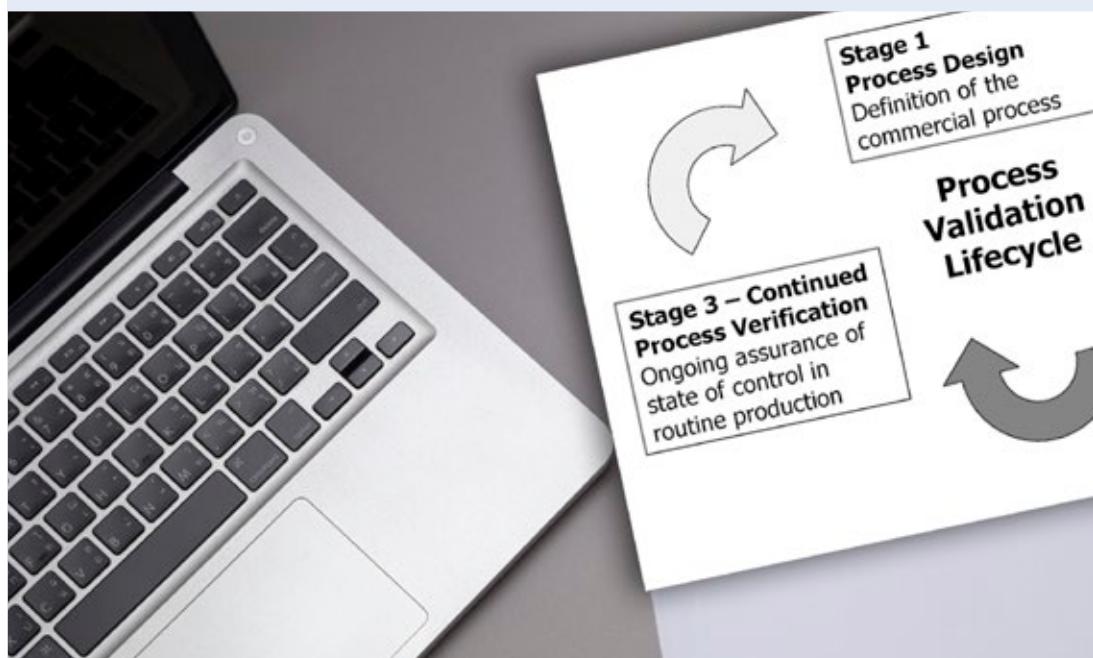
Sarah Zimmet  
Boehringer Ingelheim

# Ongoing/Continued Process Verification

From the Control Strategy to Product Quality Review



Live Online Training on 22/23 May 2024



*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

# Programme

## 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. 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

## Case Study: 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 Rainer Gnibl, GMP Inspector, District Government of Upper Bavaria, Germany

Dr Rainer Gnibl 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.

## Dr Line Lundsberg-Nielsen, Lundsberg Consulting Ltd., UK

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 Schneppé

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 most recently as a freelance consultant for QM and GMP compliance.

## 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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### Ongoing/Continued Process Verification – from the control strategy to Product Quality Review Live Online Training on 22/23 May 2024



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### Date of the Live Online Training

Wednesday, 22 May 2024, 09.00 - 16.45 h

Thursday, 23 May 2024, 08.30 - 16.30 h

All times mentioned are CEST.

### Technical Requirements

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### 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](http://www.gmp-compliance.org).

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### 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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