Speakers

Klaus Eichmüller
EU Inspector, Germany

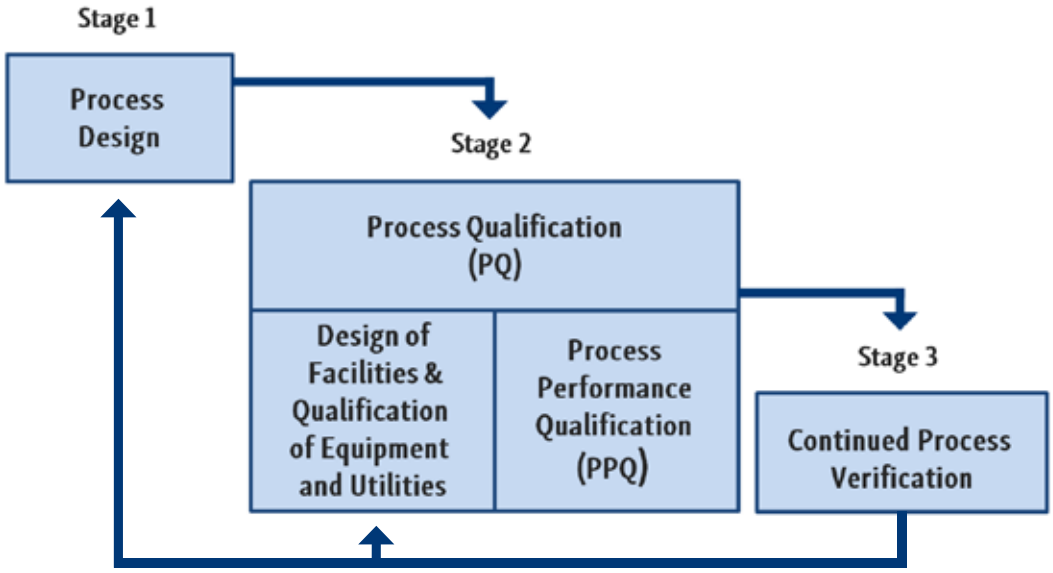
Dr Line Lundsberg-Nielsen
NNE, Denmark

Dr Thomas Schneppe

Sarah Zimmet
Boehringer Ingelheim Pharma, Germany

Process Validation

Live Online Training on 30 September/01 October 2025



Three Q & A sessions make it lively

Highlights

- EU Inspector's and FDA's Point of View
- The link between Quality by Design and Process Validation
- The benefits of applying DoE and PAT during development
- Establishing the Control Strategy
- Process Validation Life Cycle – how to implement
- Process Validation Case Study
- Ongoing Process Verification for Legacy Products

Programme

Objective

With the publication of the Guidance for Industry "Process Validation: General Principles and Practices" 2011, the FDA requires a „Life Cycle Process" with 3 stages:

- Process Design
- Process Qualification
- Continued Process Verification

The focus is on process knowledge and process understanding. Both should be a result of development and verified in routine production. The "magic" 3 batches are not mentioned any more. What is very important nowadays is the term „scientific sound", and explicit statistics are mentioned. Six Sigma elements (e.g. Design of Experiments, DoE) are also mentioned directly or indirectly. There is also a stage in routine production called „Continued Process Verification".

The EU Process Validation Guidelines incl Annex 15 of the EU GMP requires in a similar way a 3-stage life cycle approach to Process Validation: Pharmaceutical development, Process Validation and Ongoing Process Verification. In Europe 3 validation approaches are possible – traditional, continuous and hybrid.

- How can the requirements be achieved?
- How fit the FDA requirements into European guidelines and vice versa?
- How can process knowledge and process understanding be demonstrated on the basis of development studies?
- When is a process valid now?
- Which parameters can be used for knowledge and understanding studies?
- How can „Continued/Ongoing Process Verification" be realised?

These questions are at the centre of this online-course.

Background

Since 1987 the FDA Guideline on Process Validation has been the basis for qualification and validation. Within the FDA programme "Pharmaceutical cGMPs for the 21st Century" there was an announcement for a revision of the guideline. A FDA Policy Guide of 2004 gave some hints to the new validation approach. In November 2008 the "Guidance for Industry Process Validation: General Principles and Practices" was published as a draft and came into operation in January 2011. That is now FDA's „current thinking". The chapter 1 of the EU GMP Guide gives hints for more emphasises on process capabilities and varieties within process validation also in Europe. EMA´s Process Validation Guidance and also the revised Annex 15 from 2015 takes a life cycle approach to Process Validation nowadays.

Target Audience

The addressees of the event are qualified staff charged with or responsible for validation activities, such as commissioners for validation, heads of quality assurance, department heads, etc. It also addresses members of validation teams (e.g. engineers, chemists, pharmacists, microbiologists) as well as representatives of the plant engineering industry and consultants.

Programme

Day 1

Introduction

- The validation life cycle

FDA´s Point of View

- How the concept of Process Validation is about to change
- Ongoing changes in the Quality Management philosophy
- Real-life examples

The current EU Approach on Process Validation- Inspector's Point of View

- Process Validation in EU guidelines
- What has changed?
  - Revision of Chapter 1 EU GMP Guide
  - EMA´s Guidance Process Validation
  - Annex 15 revision
- Excursion QbD
- Excursion Legacy Products
- The future of Process Validation

Process Design

- Process Design
- Quality by Design, ICH Q8 and Q11
  - Quality Target Product Profile
  - Critical Quality Attribute
  - Critical Process Parameter
  - Design Space
  - Control Strategy
  - Continual Improvement
- Link between QbD the Control Strategy and Process Design

Systems and Tools for gaining Process Understanding and establishing the Control Strategy

- Process Understanding & the Control Strategy
- Quality Risk Management
- Process Analytical Technology
- Design of Experiments
- Process Analysers
- Multivariate Data Analysis

Case Study Process Design

- Stage 1
- Applying QbD principles to design a process for an oral solid dosage formulation
- Examples of the application of DoE and PAT
- Establishing the control strategy

Process Validation / Process Performance Qualification

- The purpose and principles of PV/PPQ
- EU's different approaches to Process Validation
- Number of PV/PPQ batches
- Acceptance criteria
- PV/PPQ readiness
- PV/PPQ reporting and conclusion

Case Study Process Validation / Process Performance Qualification

- Process description biotech process
- How to identify CQAs and CPPs in a biotech process
- Justifying the number of PPQ/PV batches
- Presenting and evaluating data
- Concluding the PPQ/PV activities
- Proposing a stage 3 CPV/OPV programme

Day 2

Ongoing/Continued Process Verification

- EMA: Ongoing Process Verification
- FDA: Continued Process Verification
- Statistical tools
- Monitoring plan – OPV/CPV plan
- OPV/CPV for Legacy Products

Case Study Ongoing/Continued Process Verification

- Establishing the CPV/OPV programme
- Application of relevant statistics during stage 3

Case Study Ongoing Process Verification Programme for Legacy Products

- Establishing an OPV programme for Legacy Products
- Defining the relevant Statistical Metrics
- Running, evaluating and updating the Programme

Wrap-up and considerations for Process Validation in a future Industry 4.0 manufacturing environment

- How will Process Validation evolve in light of more automated and self-optimising processes
- A holistic approach to validation – covering qualification of equipment, control systems, computer systems, processes and analytical technologies and methods
- The role of the Control Strategy

Q&A sessions

Three Q&A sessions (two on day 1 and one on day 2) ensure interaction and that your questions are answered.

Speakers

Klaus Eichmüller, Wolnzach c/o Hessian State Office for Health and Care

After working in the pharmaceutical industry, Klaus Eichmüller joined the District Government of Upper Bavaria in Munich. Since 1996 he has been working in the field of GMP Inspections of manufacturers of medicinal products and importers. He was Deputy Head of the Central Authority for Supervision of Medicinal Products in Bavaria as long as it existed and has been Head of the Division and Head of GMP/GDP/GCP/GfP - Inspectorate in Hesse since March 2014.

Dr Line Lundsberg-Nielsen, NNE, Denmark

Dr Line Lundsberg-Nielsen is a scientist and works as Managing Consultant in the department Facility Operations, Compliance Consulting at NNE. 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. Dr Lundsberg 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 most recently as a freelance consultant for QM and GMP compliance.

Sarah Zimmet, Boehringer Ingelheim Pharma, 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)

Process Validation, Live Online Training on 30 September/01 October 2025

Title, first name, surname

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German law shall apply. Court of jurisdiction is Heidelberg.

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Date of the Live Online Training

Tuesday, 30 September 2025, 09.00 – 16.00 h
Wednesday, 01 October 2025, 09.00 – 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 € 1,890
APIC Members € 1,990
Non-ECA Members € 2,090
EU GMP Inspectorates € 1,045
The conference fee is payable in advance after receipt of invoice.

Registration

Via the attached reservation form, by e-mail or by fax – or search and register directly at www.gmp-compliance.org under the number 21977.

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.

Organisation and Contact

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

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