ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Validation Manager

Speakers

Dr Christopher Burgess
Chair of ECA´s Analytical Quality Control Group, UK

Klaus Eichmüller
EU Inspector, Germany

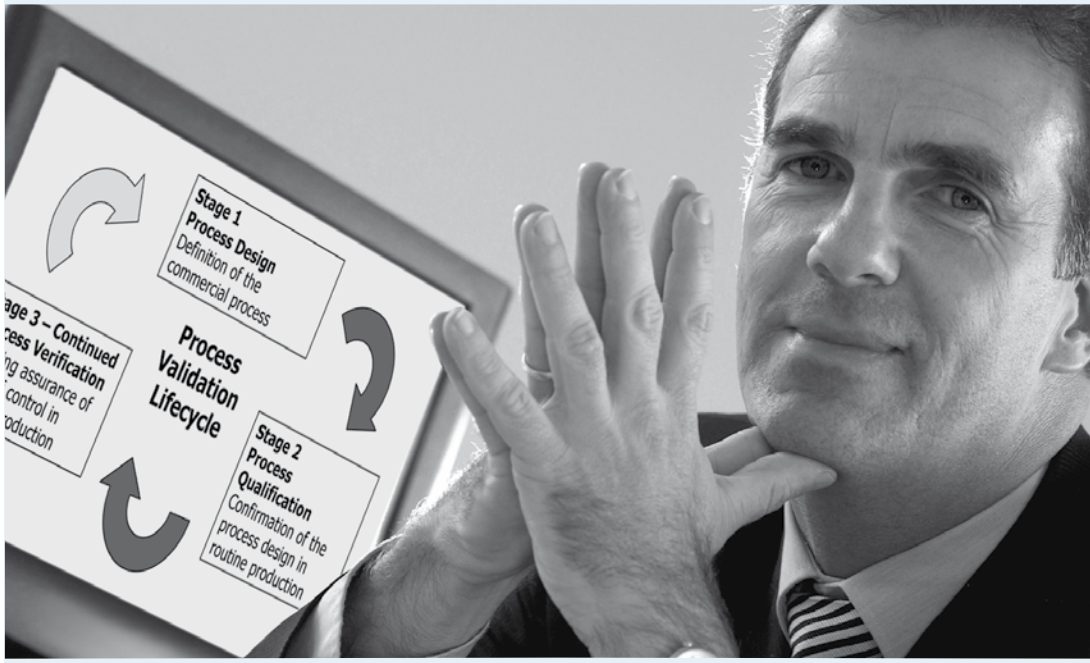
Dr Line Lundsberg-Nielsen
NNE, UK

Dr Thomas Schneppe
Bayer Bitterfeld GmbH, Germany

Process Validation

in the light of the revised Annex 15 and FDA Requirements

27/28 April 2021 | Prague, Czech Republic
06/07 October 2021 | Berlin, Germany



FDA and EU:
Assessment - Practical Aspects - Statistical Background

Highlights

- EU and FDA View
- Practical aspects on DoE
- Process validation life cycle – how to implement
- Statistical background

- Free Download: ECA's Good Practice Guide „Integrated Qualification and Validation"
- Get a free of charge Inspectors Aide memoire on Process Validation

Objective

With publication of the Guidance for Industry "Process Validation: General Principles and Practices" 2011, the FDA requires a new direction. Validation is now 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 a new stage in routine production called „continued process verification".

With the revision of Annex 15 EU GMP Guide in 2015 the EU is going in the same direction: Validation is a lifecycle with pharmaceutical development as basis and also a stage 3 is mentioned, called Ongoing Process Verification. In Europe 3 validation approaches are now possible – traditional, continuous and hybrid.

- How can the new 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?
- How can statistics 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 FDA programme "Pharmaceutical cGMPs for the 21st Century" there was an announcement for a revision of the guideline. A FDA Policy Guide of 2004 gives 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 which come into force on 1 October 2015 takes a life cycle approach to process validation.

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.

Note: The number of participants is limited to 36 persons.

Programme

FDA Thinking

- 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

- 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

Background and Environment of Process Validation: Industry View

- Process Validation in guidelines – history
- The FDA Process Validation Guidance –an overview
- European perspective
  - Annex 15 revision

Case Study Process Validation

- Role of SOP in the company QM System
- How to deal with the established 3 batch approach?
- Key aspects (Preconditions, Stages 1-3, Review)
- Further deliverables from the data and link to other company SOPs

Basics on Statistics

- An overview about statistical aspects
- What statistics do you need for modern Process Validation?

Process Design

- Quality by Design and how it is an enabler for Process Design

Systems and Tools for gaining Process Understanding and Establishing the Appropriate Control Strategy

- Quality Risk Management
- Process Analytical Technology
- Design of Experiments (including a practical factorial design for establishing the design space or the operating ranges for the process)
- How the process design is reflected in the control strategy
- Applying control strategy for stage 2, process qualification and process validation

Workshop DoE

The delegates examine a process flow diagram and generate an Ishikawa diagram to identify critical elements.

Performance Qualification Approach

- Design & qualification of facility, utilities & equipment
- Performance qualification approach
- Performance qualification protocol
- Documenting the quality baseline

PPQ Workshop

The delegates make a statistical evaluation of validation data (e.g. trend analysis, Cpk).

Continued/Ongoing Process Verification

- Process mapping & critical process variables
- Process data collection and collation
- Trend analysis & Statistical Process Control
- Deviation management & CAPA
- Change management
- Management's role in Process Validation

Continued/Ongoing Process Verification Workshop

The delegates make a High Level Risk Assessment to analyze where they are going to focus in process verification.

Speakers

Dr Christopher Burgess, Burgess Analytical Consultancy, Barnard Castle, UK

Chris Burgess is an elected member of the USP Council of Experts on General Chapters, 2010-2015 and member of the Qualified Person Association Advisory Board. During his time in industry he worked mainly for Glaxo (now GSK) in Quality Control, Quality Assurance and Analytical R&D positions.He has recently been appointed as Visiting Professor at the Strathclyde Institute of Pharmacy and Biomedical Sciences (SIPBS) within the University of Strathclyde's Faculty of Science.

Klaus Eichmüller, Wolnzach c/o Regional Council Darmstadt, GMP Inspectorate, Germany

After working in the pharmaceutical Industry Klaus Eichmüller joined the District Government of Upper Bavaria in Munich. Since 1996 he is working in the field of GMP Inspections of manufacturer 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 is now Head of the Inspectorate for Drug Products, APIs, Blood Products and Tissues in Hesse since March 2014.

Dr Line Lundsberg-Nielsen, NNE, U.K.

Dr Line Lundsberg-Nielsen is a Global Technology Partner 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 supporting QbD, PAT and PV implementation. She has practical experiences from interaction with the FDA and EMA on QbD, PAT and RTRT aspects.

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 AG, Asche AG, Bayer AG and actually Bayer Bitterfeld GmbH.

Social Event

In the evening of 27 April / 06 October, 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.

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

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CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49(0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

Process Validation in the light of the revised Annex 15 and FDA Requirements

☐ *27/28 April 2021, Prague, Czech Republic*

☐ *06/07 October 2021, Berlin, Germany*

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

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General terms and conditions
If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees:
- Cancellation until 2 weeks prior to the conference 10 %,
- Cancellation until 1 weeks prior to the conference 50 %
- Cancellation within 1 week prior to the conference 100 %.

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In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)! (As of January 2012).
German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

Date and Venue April 2021

Tuesday, 27 April 2021, 09.00 – 17.45 h
(Registration and coffee 08.30 – 09.00 h)
Wednesday, 28 April 2021, 08.30 – 16.45 h

Corinthia Hotel Prague
Kongresova 1 | 14069 Prague 4, Czech Republic
Phone +420 (261) 191 111
Email prague@corinthia.com

Date and Venue October 2021

Wednesday, 06 October 2021, 09.00 – 17.45 h
(Registration and coffee 08.30 – 09.00 h)
Thursday, 07 October 2021, 08.30 – 16.45 h

InterCityHotel Berlin Hauptbahnhof
Katharina-Paulus-Straße 5 | 10557 Berlin, Germany
Phone +49 (0) 30 288 755 0
Email berlin-hauptbahnhof@intercityhotel.de

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/POG when you have registered for the course. 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.
CONCEPT HEIDELBERG
P.O.Box 10 17 64
69007 Heidelberg, Germany
Phone +49(0)62 21/84 44-0
Fax +49(0)62 21/84 44 34
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content please contact:
Mr Sven Pommeranz (Operations Director) at
+49(0)62 21/84 44 47, or at
pommeranz@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc. please contact:
Ms Julia Grimmer (Organisation Manager) at
+49(0)62 21/84 44 44, or at
grimmer@concept-heidelberg.de.