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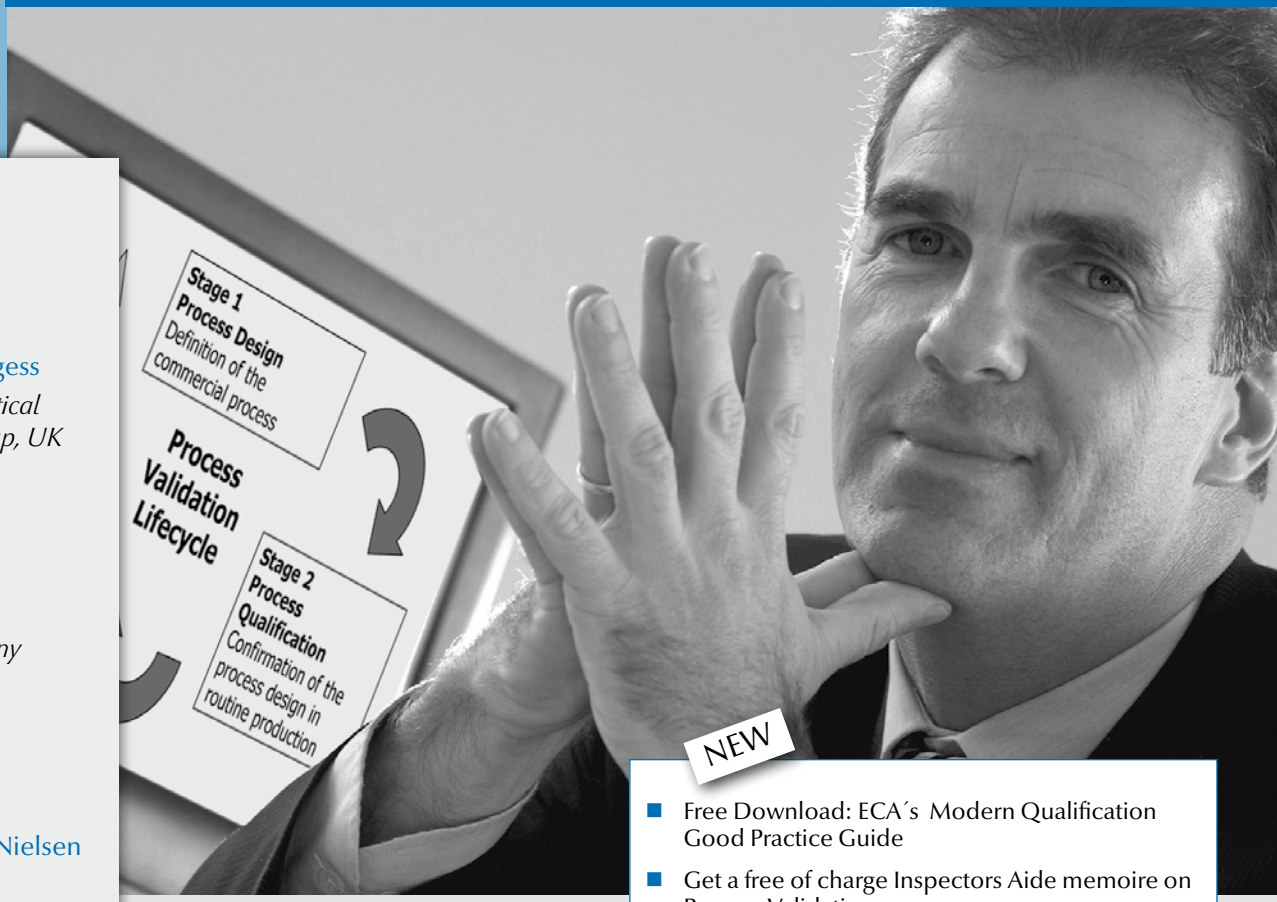
Process Validation in the light of the revised Annex 15 and FDA Requirements



SPEAKERS:

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

Klaus Eichmüller
EU Inspector, Germany

Dr Line Lundsberg-Nielsen
NNE, UK

Gert Moelgaard
Past Chairman of ISPE, Head of ECA´s Validation Group, Denmark

Dr Thomas Schneppe
Bayer Bitterfeld GmbH, Germany

NEW

- Free Download: ECA´s Modern Qualification Good Practice Guide
- Get a free of charge Inspectors Aide memoire on Process Validation

FDA and EU:
Assessment - Practical Aspects - Statistical Background

21-22 February 2019, Vienna, Austria

16-17 October 2019, Berlin, Germany

PROGRAMME:

- EU and FDA View
- Practical Aspects of DoE
- Process Validation Life Cycle – How to Implement
- Statistical Background

This education course is recognised for the ECA GMP Certification Programme „Certified Validation Manager".
Please find details at www.gmp-certification.eu

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Objectives

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 will be a new stage in routine production called „continued process verification".
With the revision of Annex 15 EU GMP Guide 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 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 to the new validation approach. In November 2008 the new "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". 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 came into force on 1 October 2015 take a life cycle approach to process validation.

Target Group

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.

Moderator

Dr. Christopher Burgess
Burgess Analytical Consultancy, UK

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 (I)

- 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 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, UK*
Dr Burgess is a Chartered Chemist and has more than 36 years experience in the pharmaceutical industry primarily with Glaxo in Quality Assurance and Analytical R&D. He is a "Qualified Person" and a member of the European QP Association advisory board. He has been appointed to the United States Pharmacopoeia's Council of Experts 2010 to 2015 and is a visiting professor of the University of Strathclyde's School of Pharmacy and Biomedical Sciences (SIPBS). In addition, he is the chairman of the ECA Analytical Quality Control Group and a member of the Executive committee of European Compliance Academy.

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 Hessen 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.

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 in Novo Nordisk, Novo Nordisk Engineering and NNE Pharmaplan. From 2009-2012 Gert Moelgaard was involved in training FDA's investigators at FDA's internal training on the 2011 Guidance on Process Validation and has contributed to several books and technical guidelines. Gert is the Head of ECA´s Validation Group.

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.

Process Validation Aide Memoire (GMP Inspectors Guide)
The Guide is developed by the Central Authority of the Länder for Health Protection with regard to Medicinal Products and Medical Devices (ZLG) – English translation. This document covers the whole spectrum of process validation regarding the Annex 15 revision The Aide Memoire is really helpful as a tool to prepare for an Authority's GMP Inspection.

Social Event

In the evening of the first course 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.

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

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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☐ 21-22 February 2019, Vienna, Austria
☐ 16-17 October 2019, Berlin, Germany

☐ Mr. ☐ Ms.

Title, first name, surname

Company | Department

Important: Please indicate your company's VAT ID Number | Purchase Order No, if applicable

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City | Zip Code | Country

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GERMANY

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German law shall apply. Court of jurisdiction is Heidelberg.

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Date and Venue February 2019

Thursday, 21 February 2019, 09.30 – 18.00 h
(Registration and coffee 09.00 – 09.30 h)
Friday, 22 February 2019, 08. 30 – 16.45 h

Radisson Blu Park Royal Palace Hotel Vienna
Schlossallee 8
1140 Vienna, Austria
Phone +43 (1) 891 10 - 0
info.parkroyalpalace.vienna@radissonblu.com

Date and Venue October 2019

Wednesday, 16 October 2019, 09.00 – 17.45 h
(Registration and coffee 08.30 – 09.00 h)
Thursday, 17 October 2019, 08. 30 – 16.45 h

Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin, Germany
Phone +49 30 21 27 0
berlin@steigenberger.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 event. Reservation should be made directly with the hotel. Early reservation is recommended.

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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