



- Update regarding Annex 15 draft revision and
- EMA Process Validation Guideline

# The New FDA/EU Approach to Process Validation

FDA and EU: Assessment - Practical Aspects - Statistical Background

14 - 15 October 2014, Berlin, Germany

## SPEAKERS:

**Dr Christopher Burgess**

*Burgess Analytical Consultancy, UK*

**Klaus Eichmüller**

*EU Inspector, Germany*

**Gert Moelgaard**

*NNE Pharmaplan, Denmark*

**Dr Thomas Schneppe**

*Bayer Pharma AG, Germany*

## PROGRAMME:

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



# The New FDA/EU Approach to Process Validation

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## Objectives

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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 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 EMA's new Process Validation Guidance and the revision of Annex 15 also modern process aspects are under discussion.

- How can the new requirements be achieved?
- How fit the new FDA requirements into European guidelines, EMA's new Process Validation Guidance and the new Annex 15 draft revision?
- 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 process verification“ be realised?
- What does "ongoing process verification" mean?
- How can statistics help?

These questions are discussed, and the possibilities for implementation are covered.

## Background

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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 as 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“. Since January 2013 the revision of chapter 1 of the EU GMP Guide is also valid. This chapter gives hints for more emphasises on process capabilities and varieties within process validation also in Europe. EMA's new Process Validation Draft Guidance mention also an Enhanced Approach and a Process Life Cycle for Process Validation. Otherwise the traditional approach is still acceptable.

Since February 2014, a new draft revision of EU GMP Annex 15 on "Qualification and Validation" is available from the EU Commission. There are some significant changes and many similarities to the US FDA Process Validation Guideline. The course will introduce the new document and compare the EU and FDA approaches.

Also in February 2014, EMA's new Process Validation Guideline was published as final version and will come into operation at the end of August 2014.

## Target Group

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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

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**Dr. Christopher Burgess**

Burgess Analytical Consultancy, UK

## Programme

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### FDA's New Thinking

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

### The new EU Approach on Process Validation

- Process validation in EU guidelines
- What is new?
  - Revision of Chapter 1 EU GMP Guide
  - EMA's new Guidance Process Validation
  - Annex 15 draft revision
- The future of process validation

### Background and Environment of Process Validation – Industry view

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

### SOP outline for 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

- Validation as a lifecycle concept
- Development prerequisites
- Criticality of Process Design
- Process definition and design space

### Design of Experiments – Principles of Defining the Design Space

- Why bother to design experiments?
- DoE versus one factor at a time
- Types of design
- Basics of a simple 2x2 factorial design
- Tutorial example of application to a chemical synthesis

### Design of Experiments – Application examples of factorial design

- Principles and practice of full 3 factor 2 level design
- Tutorial example of application to a analytical method robustness study
- Supporting Excel spreadsheet.
- Tutorial example of application of a reduced design to a excipient formulation study

#### Tutorial Workshop DoE

All delegates receive an Excel spreadsheet with the equations and detailed calculations.

### 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).

### 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

#### 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**, *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.



**Gert Moelgaard**, *NNE Pharmaplan, Denmark*

Gert Moelgaard is Vice President for Innovation & Business Development in NNE Pharmaplan. He has been working in the pharmaceutical industry since 1982 and has experience from a number of major engineering, automation and validation projects within pharmaceutical manufacturing. He has made international contributions in international conferences on automation, process validation, PAT and manufacturing excellence and has contributed to several books and technical guidelines.



**Dr Thomas Schneppe**, *Bayer Pharma AG, Germany*

More than 20 years experience in the pharmaceutical industry. Since 2006 Bayer Pharma AG; Head of Mgmt. Training at Bayer Health Care - Product Supply - Compliance - Integrated Quality Mgmt.

### 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.



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14 - 15 October 2014, Berlin, Germany

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**Internet:**  
**www.gmp-compliance.org**

**Date**

Tuesday, 14 October 2014, 09.30 – 18.15 h  
(Registration and coffee 09.00 – 09.30 h )  
Wednesday, 15 October 2014, 08.30 – 16.45 h

**Venue**

Steigenberger Hotel am Kanzleramt  
Ella-Trebe-Str. 5  
10557 Berlin, Germany  
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**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 when you have registered for the event. Please use this form for your room reservation to receive the specially negotiated rate for the duration of your stay. 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](http://www.gmp-compliance.org).

**Conference language**

The official conference language will be English.

**Organisation and Contact**

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