



■ With an EU Inspector

# The New FDA/EU Approach to Process Validation

FDA and EU: Assessment - Practical Aspects - Statistical Background

6 - 7 March 2012, Heidelberg, 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



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## Objectives

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With the new 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 the new EU campaign of the revision of the EU GMP Guide also modern process aspects are under discussion.

- How can the new requirements be achieved?
- How fit the new FDA requirements into European guidelines?
- 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?
- 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" 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 January 2011 the new "Guidance for Industry Process Validation: General Principles and Practices" was published in the final version. This is now FDA's „current thinking“. The EU Commission recently has published a draft for a revision of chapter 1 of the EU GMP Guide. This draft gives hints for more emphasises on process capabilities and varieties within process validation also in Europe.

## 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 35 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?
  - EMA Q & A Paper
  - Draft Revision of Chapter 1 EU GMP Guide
- 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

### Process Design

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

Dr Christopher Burgess

### 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

### Workshop: Process Validation

An interactive workshop to discuss and train modern process validation aspects in small groups. The workshop will take an example of a process design and explore the processes and practices to allow successful qualification and verification which could lead to a compliant process validation package

## 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

## 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

## 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**, *District Government of Upper Bavaria, 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 is Deputy Head of the Central Surveillance of Medicinal Products in Bavaria.



**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.



## Easy Registration



Reservation Form:  
**CONCEPT HEIDELBERG**  
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e-mail:  
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Internet:  
www.gmp-compliance.org

Reservation Form (Please complete in full)

### The New FDA/EU Approach to Process Validation

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Title, first name, surname

Company

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Important: Please indicate your company's VAT ID Number

Purchase Order No, if applicable

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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 %
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fee will then be calculated according to the point of time at which we receive your message. 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!).

#### Date

Tuesday, 6 March 2012, 9.30 – 18.00 h  
(Registration and coffee 9.00 – 9.30 h)  
Wednesday, 7 March 2012, 8.30 – 16.30 h

#### Venue

Crowne Plaza Hotel  
Heidelberg  
Kurfürstenanlage 1  
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#### Fees

ECA Members € 1,590.- per delegate plus VAT  
APIC Members € 1,690.- per delegate plus VAT  
(does not include ECA Membership)  
Non-ECA Members € 1,790.- per delegate plus VAT  
EU GMP Inspectorates € 895.- per delegate plus VAT  
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 or be sure to mention ECA7100 to receive the specially negotiated rate (single room € 139,- per night, incl. breakfast) for the duration of your stay. Reservation should be made directly with the hotel not later than 7 February 2012. 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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