■ **View of an EU GMP Inspector on EMA´s Process Validation Draft Document**

The New FDA/EU Approach to Process Validation

FDA and EU: Assessment - Practical Aspects - Statistical Background

NEW: Additional date in Barcelona

14 - 15 October 2013, Barcelona, Spain

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

ECA
EUROPEAN COMPLIANCE ACADEMY

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 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With EMA´s new Process Validation Draft Guidance and the revision of Annex 15 also modern process aspects are under discussion.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- How fit the new FDA requirements into European guidelines and EMA´s new Process Validation Draft Guidance?
- 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 will be discussed, and the possibilities for implementation will be 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". 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 Processs Life Cycle for Process Validation. Otherwise the traditional approach is still acceptable. Also the Annex 15 is under revision.

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 35 persons.

Moderator

Dr. Christopher Burgess
Burgess Analytical Consultancy, UK

Programme

FDA´s New Thinking

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

Basics on Statistics

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

The new EU Approach on Process Validation

- Process validation in EU guidelines
- What is new?
  - EMA Q&A Paper
  - Revision of Chapter 1 EU GMP Guide
  - EMA´s Draft Guidance Process Validation
- The future of 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.

Background and Environment of Process Validation – Industry view

- Process Validation in guidelines – history
- The new FDA Process Validation Guidance – an overview
- European perspective

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
P.O. Box 10 17 64
69007 Heidelberg
Germany

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+ 49 6221 84 44 34

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info@concept-heidelberg.de

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www.gmp-compliance.org

Reservation Form (Please complete in full)

The New FDA/EU Approach to Process Validation
14-15 October 2013, Barcelona, Spain

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Date

Monday, 14 October 2013, 09.30 – 18.15 h
(Registration and coffee 09.00 – 09.30 h)
Tuesday, 15 October 2013, 08. 30 – 16.45 h

Venue

nh-Hotel Constanza
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08029 Barcelona, Spain
Phone +34 93 281 1500
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Fees

ECA Members € 1,590.- per delegate plus VAT
APIC Members € 1,690.- per delegate plus VAT
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 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.

Conference language

The official conference language will be English.

Organisation and Contact

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