



Free Add-on: Each participant receives ECA's "Validation Good Practice Guide" with what to do and how to do recommendations

The New FDA/EU Approach to Process Validation

FDA and EU: Assessment - Practical Aspects -Statistical Background

30-31 October 2012, 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
- New: View of an EU GMP Inspector on EMA's new Process Validation Draft Document



The New FDA/EU Approach to Process Validation

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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With the new EU campaign of the revision of the EU GMP-Guide and EMA's new Process Validation Draft Guidance also modern process aspects are under discussion.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- How fit the new FDA requirements into European guidelines and EMA's new Process Validation Draft Guidance?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 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 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. That is now FDA's "current thinking". The EU Commission has published recently 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. EMA's new Process Validation Draft Guidance also mentions an Enhanced Approach and Processs Life Cycle for Process Validation. Otherwise the traditional approach is still acceptable.

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.



Free Add-on ECA's Validation Good Practice Guide

The ECA Working Group has developed a Version 1 of the Good Practice Guide on Validation. This document is intended to provide support to both regulators and industry. On one hand the Guide contains the main elements of the new approach

("what to do") but on the other hand it also serves as a supporting guide for the implementation ("how to do").

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

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.



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Easy Registration

Internet: www.gmp-compliance.org

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