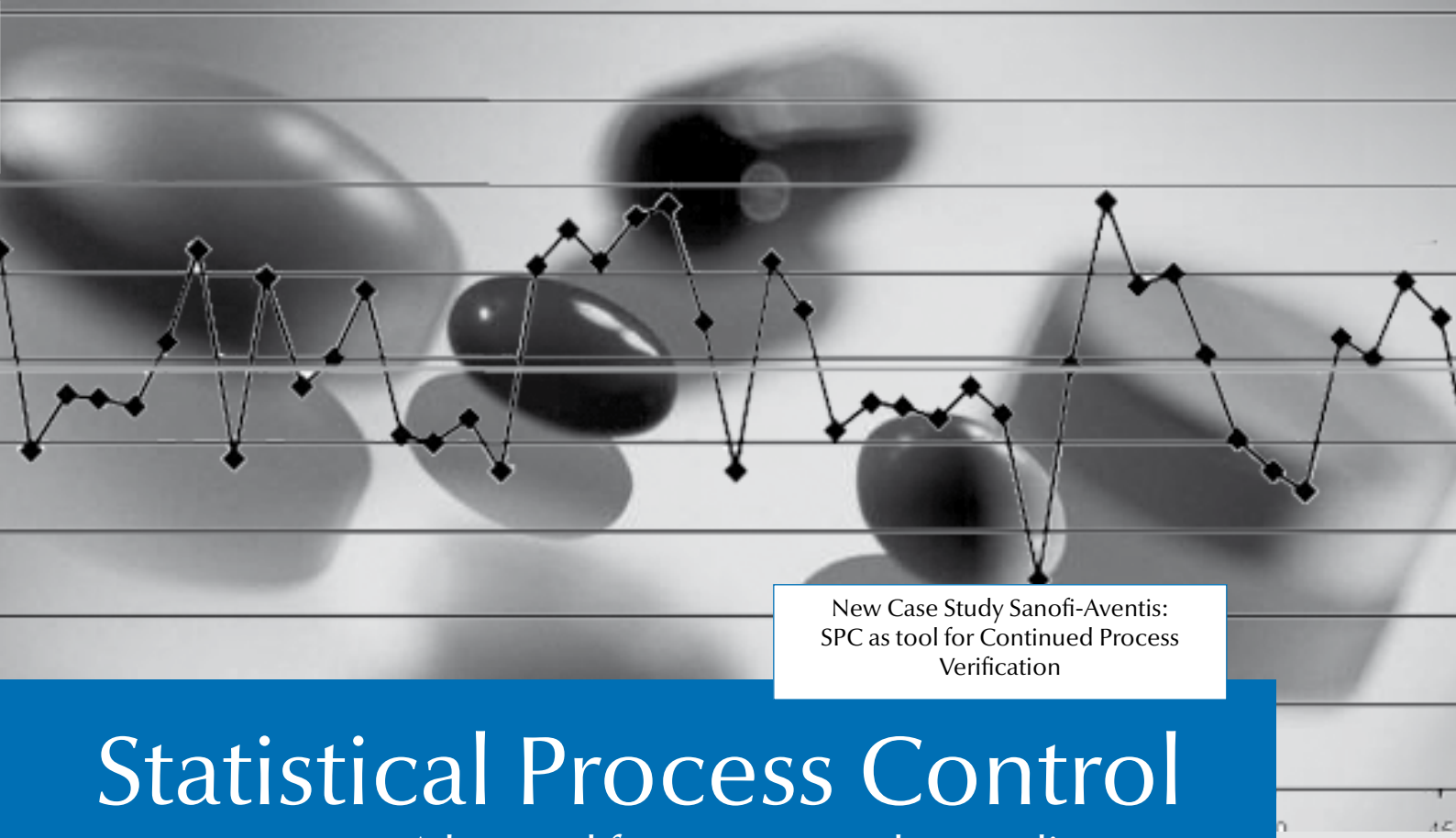

New Case Study Sanofi-Aventis:
SPC as tool for Continued Process Verification

Statistical Process Control

A key tool for process understanding in the process validation life cycle

A key tool for continuous validation

18 – 19 February 2016, Heidelberg, Germany

SPEAKERS:

Dr Ingolf Stückrath
Sanofi-Aventis Frankfurt, Germany

Dr Sven Wedemeyer
Merck KGaA, Germany

Klemens Wendl
Baxter Healthcare Ltd., Great Britain

LEARNING OBJECTIVES:

- Six Sigma
- Basic Statistic
- Process Improvement
- Process Capability
- Case Study Baxter "SPC and Trending of Microbiological Data"
- Case Study Sanofi-Aventis "SPC as tool for Continued Process Verification"
- 1 Workshop
- 2 Exercises

ECA ACADEMY

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

Statistical Process Control

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Objectives

The new process Validation life cycle is now split up into 3 stages:

1. Process Design
2. Process Qualification
3. Continued Process Verification

The new "catchword" is process understanding. Trends should be evaluated in the Stage 3.

One element to show process understanding and to monitor trends can be Statistical Process Control.

On the one hand the seminar will explain the theory of control charts e.g. how to calculate and read them. On the other hand the seminar will explore how to practically apply Control Charts, e.g. implementing control charts in production or QC and setting up a good review process. This balance of class room sessions and exercises supports a hands-on approach to manage and use Control Charts in different environments, like validation and process improvement.

Examples and case studies from the experience of the speakers will give evidence of the success and possibilities the use of Control Charts adds to your enterprise. Additionally, there is a view on the software for SPC and its GMP relevance.

Background

With the FDA Guidance on Process Validation of January 2011 the FDA gives a new interpretation of validation. Not more than 3 validation batches are the evidence that a process is valid. The FDA now expects a validation life cycle with continued process verification throughout the commercial phase. Also the EMA stated in a Question and Answer paper, that they focus on continuous validation too. Both authorities mention that a process is in statistical control and capable. One element to show this is Statistical Process Control (SPC) as mentioned by the FDA.

Also in the ICH Q9 document "Quality Risk Management" control charts and process capability are mentioned as statistical possibilities within risk assessments.

Target Audience

This course is directed to staff who is involved in process understanding and optimization (e.g. process owners, validation managers, etc.) in R&D, production and quality control. It also addresses quality assurance staff.

Note: The number of participants is limited.

Moderator

Dr Sven Wedemeyer, Merck KGaA

Workshop/Exercises

Practical trainings give the delegates the information about how control charts are used to optimise processes.

The delegates will set up a control chart (initial study). This chart will then be used to monitor a process (control to standard) and to detect changes and to analyse potential causes.

An additional workshop shows Dos and Don'ts and how to get the commitment of superiors and other teammates.

Programme

Six Sigma Definitions
- A short introduction to Six Sigma
- Six Sigma Terms

Objectives of Statistical Process Control
- Create visibility of process performance
- Increase process knowledge
- Show process stability
- Prove process capability
- Support the continuous improvement process

Some mandatory Basic Statistics
- Mean Value, Median, Range
- Standard Deviation
- Normal Distribution
- Histogram and Time Series Plot

The two Types of Variability
- Common cause variability
- Special cause variability

Control Charts
- Types of control charts
- Design a control chart
- Setting up control charts in Minitab®
- Control limits and specification limits
- Why is 3s taken as limit?
- Changing control limits

Reading Control Charts to improve the Process
- Statistical rules
- Identifying patterns
- Performance windows
- General rules

Deploying and managing SPC - Connecting SPC to Continuous Improvement

- Deployment Top-Down versus Bottom-Up
- Root cause analysis
- Paper based versus electronic control charts
- Management system / cycle

Reasons to implement Control Charts

- Link to quality control
- Link to quality assurance
- Benefits from SPC

Measurement System Analysis and SPC

- Using control charts to do a MSA
- Accuracy of data
- Triangle of Variability

NEW

SPC as tool for Continued Process Verification

- Continued Process Verification: Requirements
- Case Study Sanofi-Aventis

Exercise 1

Control chart

Setting up a Control Chart and control a process to standard manually

Workshop

Implementation of the use of a Control Chart in the local environment

- What are the Dos and Don'ts?
- How do I create commitment in senior management and my team?

Exercise 2

Control Chart

Detecting changes and analysing potential causes

Process Capability – What is the risk of failure of my process?

- Cp, Cpk versus Pp, Ppk
- Long term versus short term capability
- Process robustness

Case Study Control Charts and Trending of Microbiological Data

- Computerized systems as basis
- General use of control charts for microbiological data (Environmental monitoring, personnel monitoring, water monitoring, product bioburden)
- Distribution of microbiological data
- Minimum number of data to establish control limits
- Specify „trending rules" for microbiological data
- Frequency of Trending
- General approach on encountering a negative trend
- Case study

Speakers

Dr Ingolf Stückrath

sanofi-aventis, Germany

Ingolf began his career with Aventis in 2000 as a Trainee in an assistant plant manager programme. Until 2002 he was responsible for a fermentation plant in the insulin field of Aventis. After becoming a Six Sigma Black Belt Ingolf was made responsible for the implementation of Six Sigma at a site of 800 employees. After becoming Six Sigma Master Black Belt he became part of the Management Committee of the Site Frankfurt Biotechnology in 2004, being responsible for all Industrial Excellence activities of the site. In 2005 his work was recognized with the IQPC's Six Sigma IQ Excellence Award in the category "Best Defect Elimination in Manufacturing". In April 2007 Ingolf became Plant Head of a final processing API plant in Frankfurt/Germany, followed by a position as Head of Operations in a cell culture plant in France. Today he is responsible for a major insulin production facility in Frankfurt. Ingolf studied Biology with a major in Microbiology in Frankfurt/Germany and Anchorage, Alaska USA. He holds a Ph. D. in biology.

Dr Sven Wedemeyer

Merck KGaA, Germany

Dr Wedemeyer studied Process Engineering at the TU Clausthal and received his PhD from the same university. He joined Merck in 1999 and headed different position (e.g Assistant Plant Manger in the solids manufacturing department). Dr Wedemeyer started his Black Belt education in 2005. Since that time he is performing Six Sigma projects in manufacturing and supply chain. He is member of the Operational Excellence team leading the transformation program in Technical Operations.

Klemens Wendl

Klemens Wendl, Baxter Healthcare Ltd., Great Britain

Klemens Wendl has been with Baxter since 1999. Klemens has worked in various positions at Baxter e.g. Microbiology, Quality Assurance, Supervisor Sterility Assurance. In May 2008 he became Global Project Manager, and in this position he was responsible for the global implementation and standardisation of Statistical Process Control. At the moment he is Sterility Assurance Manager.

Social Event

On 18 February 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:
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Reservation Form:
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e-mail:
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Reservation Form (Please complete in full)

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Statistical Process Control - A key tool for process understanding in the process validation life cycle
18 – 19 February 2016, Heidelberg, Germany

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GERMANY

Date

Thursday, 18 February 2016, 9.00 – 18.00 h
(Registration and coffee 08.30 – 9.00 h)
Friday, 19 February 2016, 08.30 – 16.15 h

Venue

NH Hotel Heidelberg
Bergheimer Straße 91
69115 Heidelberg, Germany
Phone +49(0)6221 - 1327 0, Fax +49(0)6221 - 1327 100

Fees (per delegate plus VAT)

ECA Members € 1,490
APIC Members € 1,590
Non-ECA Members € 1,690
EU GMP Inspectorates € 845
The 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.

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Registration

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Conference Language

The official conference language will be English.

Organisation and Contact

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Ms Susanne Ludwig (Organisation Manager) at +49(0)62 21/84 44 44, or per e-mail at ludwig@concept-heidelberg.de.