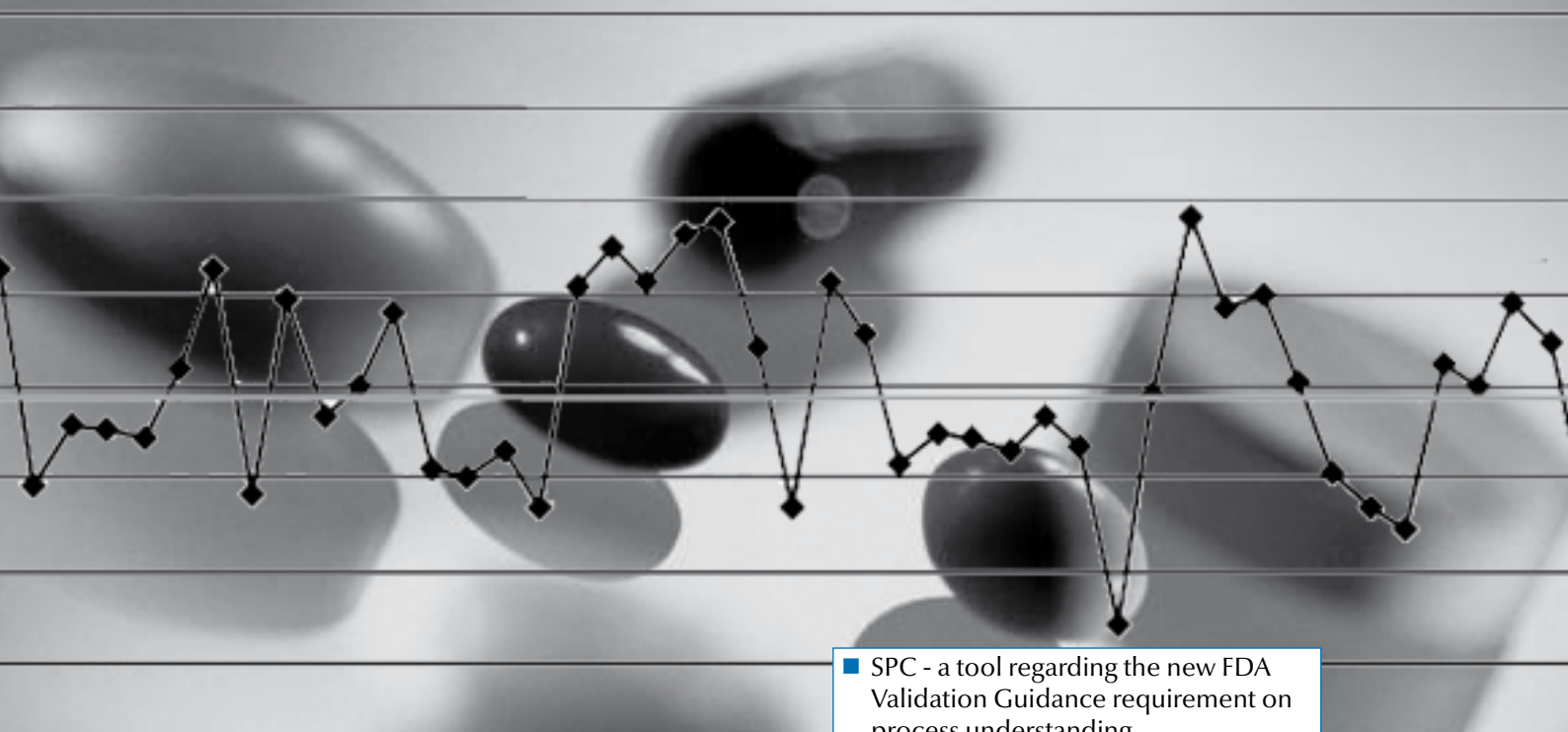


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- SPC - a tool regarding the new FDA Validation Guidance requirement on process understanding

# Statistical Process Control

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

A key tool for continuous validation

3 - 4 May 2012, Heidelberg, Germany

## SPEAKERS:

*Dr Sven Wedemeyer*  
*Merck-Serono, Germany*

*Klemens Wendl*  
*Baxter, Austria*

## LEARNING OBJECTIVES:

- Six Sigma
- Basic Statistic
- Process Improvement
- Process Capability
- Case Study SPC and Trending of Microbiological Data
- 1 Workshop
- 2 Exercises



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## Objectives

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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.

The seminar will include explanation of theory and “practical” application of Control Charts. This balance of class room sessions and exercises support 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 Chart adds to your enterprise

## Background

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With the new 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 Group

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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

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Dr Sven Wedemeyer, Merck-Serono

## Workshop/Exercises

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Practical trainings give the delegates the information about how control charts are used to optimize 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

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### 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

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

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

#### 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 get the commitment by superiors and my people

#### Exercise 2

##### Control Chart

Detecting changes and analyzing potential causes

### Case Study Control Charts and Trending of Microbiological Data

- 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

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We look forward to welcoming at one of our next events – and we already wish you a pleasant flight!

### Speakers



#### Dr Sven Wedemeyer

*Merck-Serono, Darmstadt, 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 solids manufacturing and additionally is involved in the integration of Lean & Six Sigma into Merck Pharma .



#### Klemens Wendl

*Baxter AG, Vienna , Austria*

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 is responsible for the global implementation and standardisation of Statistical Process Control.



### Social Event

On 3 May 2012 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



Reservation Form:  
+ 49 6221 84 44 34



e-mail:  
info@concept-heidelberg.de



Internet:  
www.gmp-compliance.org

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### Statistical Process Control - A key tool for process understanding in the process validation life cycle

3 - 4 May 2012, Heidelberg, Germany

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#### General terms and conditions

If you cannot attend the conference you have two options:

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2. If you have to cancel entirely we must charge the following processing fees: Cancellation
  - until 2 weeks prior to the conference 10 %
  - until 1 week prior to the conference 50 %
  - within 1 week prior to the conference 100 %.

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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

Thursday, 3 May 2012, 9.00 - 18.00 h  
(Registration and coffee 08.30 - 9.00 h)  
Friday, 4 May 2012, 08.30 - 16.00 h

#### Venue

Crowne Plaza Heidelberg  
Kurfürstenanlage 1  
69115 Heidelberg, Germany  
Phone +49 (0)6221 - 917 0  
Fax +49 (0)6221 - 917 659

#### Fees

ECA Members € 1,490.- per delegate plus VAT  
APIC Members € 1,590.- per delegate plus VAT  
(does not include ECA Membership)  
Non-ECA Members € 1,690.- per delegate plus VAT  
EU GMP Inspectorates € 845.- per delegate plus VAT  
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 or be sure to mention "ECA" 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 4 April 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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