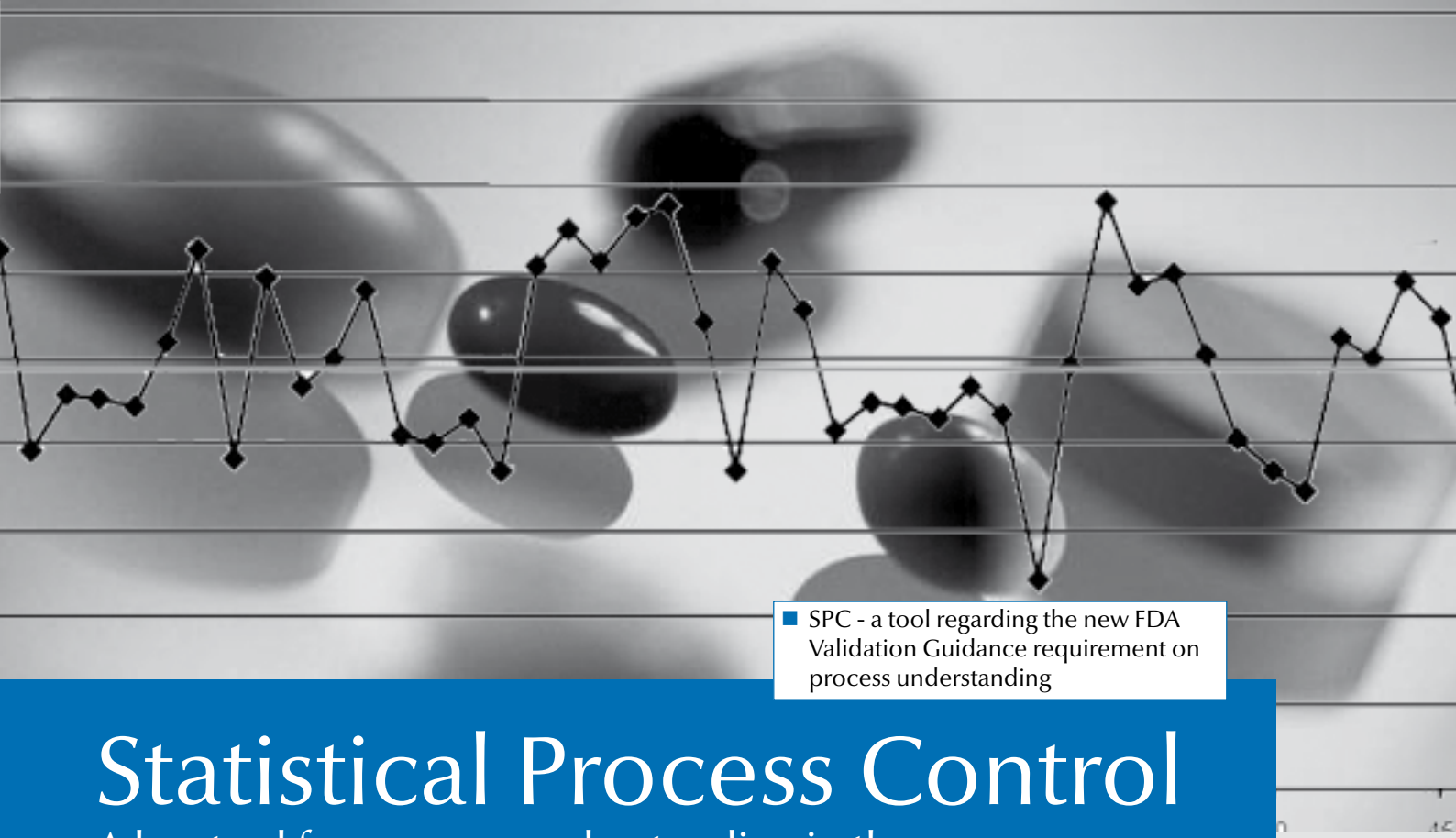

- SPC - a tool regarding the new FDA Validation Guidance requirement on process understanding

Statistical Process Control

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

A key tool for continuous validation

20 - 21 March 2014, Heidelberg, Germany

SPEAKERS:

Dr Sven Wedemeyer
Merck KGaA, Germany

Klemens Wendl
Baxter AG, Austria

LEARNING OBJECTIVES:

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

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

Statistical Process Control

20 - 21 March 2014, Heidelberg, Germany

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

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 Sven Wedemeyer

Merck KGaA, 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 manufacturing and supply chain. He is member of the Operational Excellence team leading the transformation program in Technical Operations.

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 20 March 2014 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

If the bill-to-address deviates from the specifications on the right, please fill out here:

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

Statistical Process Control - A key tool for process understanding in the process validation life cycle
20 - 21 March 2014, Heidelberg, Germany

☐ Mr. ☐ Ms.

Title, first name, surname

Company | Department

Important: Please indicate your company's VAT ID Number | **Purchase Order No. (if applicable)**

Street/P.O. Box

City | Zip Code | Country

Phone/Fax

E-Mail (please fill in)

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 %
- until 1 weeks prior to the conference 50 %
- within 1 week prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
Terms of payment: Payable without deductions within 10 days after receipt of invoice.
Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation 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)! (As of January 2012)

Date

Thursday, 20 March 2014, 9.00 – 18.00 h
(Registration and coffee 08.30 – 9.00 h)
Friday, 21 March 2014, 08.30 – 16.15 h

Venue

Crowne Plaza Heidelberg
Kurfürstenanlage 1
69115 Heidelberg, Germany
Phone +49 (0)6221 917 0
Fax +49 (0)6221 917699

Fees

ECA Members € 1,490.- per delegate plus VAT
APIC Members € 1,590.- per delegate plus VAT
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 has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form when you have registered for the course.
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

CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg, Germany,
Phone +49(0)62 21/84 44-0
Fax +49(0)62 21/84 44 34
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content:
Sven Pommeranz (Operations Director) at
+49(0)62 21/84 44 47, or per e-mail at
pommeranz@concept-heidelberg.de.
For questions regarding reservation, hotel, organisation etc.:
Ms Susanne Ludwig (Organisation Manager) at
+49(0)62 21/84 44 44, or per e-mail at
ludwig@concept-heidelberg.de.

wa/vers1/31052013