



Speakers



Dr Ingolf Stückrath
Sanofi-Aventis Frankfurt, Germany



Dr Sven Wedemeyer
Merck KGaA, Germany

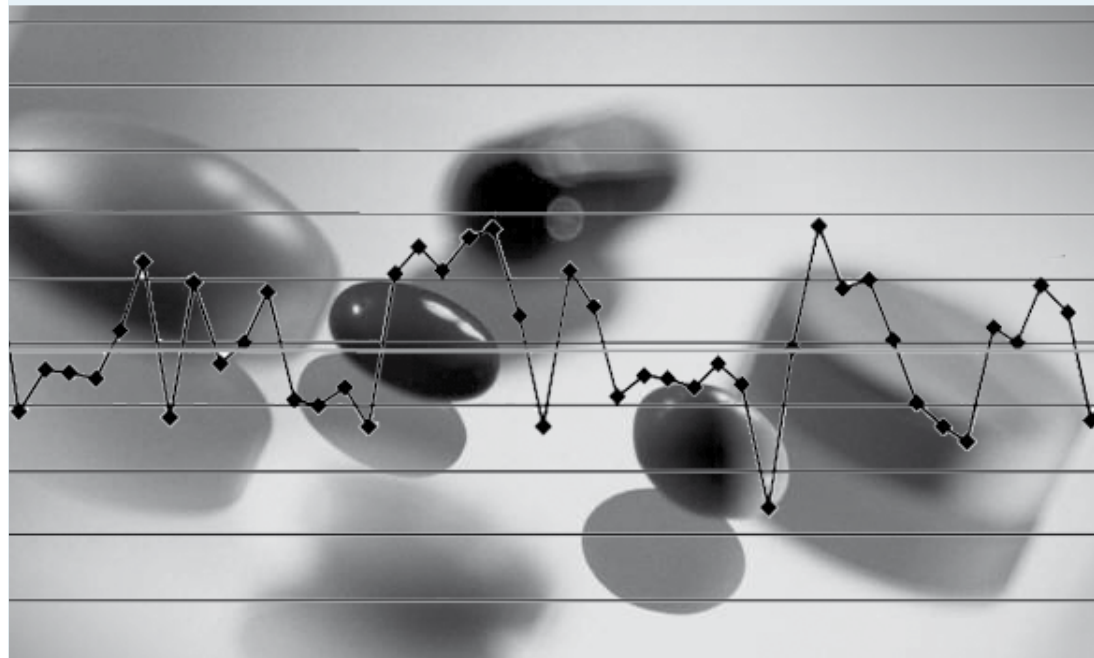


Dr Björn Wiese
Zimmer GmbH, Switzerland

Process Understanding

Statistical Process Control (SPC) as a tool to get there

24/25 March 2020 | Heidelberg, Germany



A key tool for continuous validation

Highlights

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

Free Download: ECA's Good Practice Guide
„Integrated Qualification and Validation“

Objective

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 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. This is the same in the revised Annex 15 in the EU. 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.

Social Event

In the evening of the first 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.

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.

Programm

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

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

- Trending Monitoring Data as Part of the Facility Control Concept
- Smart Setting of Alert- and Action levels
- Definition of Adverse Trends
- Periodic Data Review
- Designing a Reduced EM Program

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 Manager 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.



Dr Björn Wiese
Zimmer GmbH, Winterthur, Switzerland

From 1996 to 2000 Björn Wiese worked as project manager in R&D of Danisco Ingredients, Niebüll, Germany, and developed start up cultures. Since November 2000, he had been head of the microbiology department of Hameln Pharmaceuticals, Hameln, Germany. From 2005 - 2010 Björn worked at the pharmaceutical production site of Cilag in Schaffhausen, Switzerland. 2011 he joined Zimmer GmbH and is now Director Sterilization Technology and Analytical Testing.

Reservation Form (Please complete in full)

Process Understanding
24/25 March 2020, Heidelberg, Germany

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

Title, first name, surname

Department

Company

Important: Please indicate your company's VAT ID Number

Purchase Order Number, if applicable

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%.
 - Cancellation until 1 week prior to the conference 50%.
 - Cancellation 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.

- 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 in 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).
- German law shall apply. Court of jurisdiction is Heidelberg.

- Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

Date

Tuesday, 24 March 2020, 9.00 – 18.00 h
(Registration and coffee 08.30 – 9.00 h)
Wednesday, 25 March 2020, 08.30 – 16.30 h

Venue

Qube Hotel Bahnhof
Grüne Meile 21
69115 Heidelberg, Germany
Phone +49(0)6221 187999
Email info@qube-heidelberg.de

Fees (per delegate, plus VAT)

ECA Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895

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/POG 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

ECA has entrusted Concept Heidelberg with the organisation of this event.

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