ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Validation Manager

Speakers

Dr Ingolf Stückrath
Sanofi-Aventis, Germany

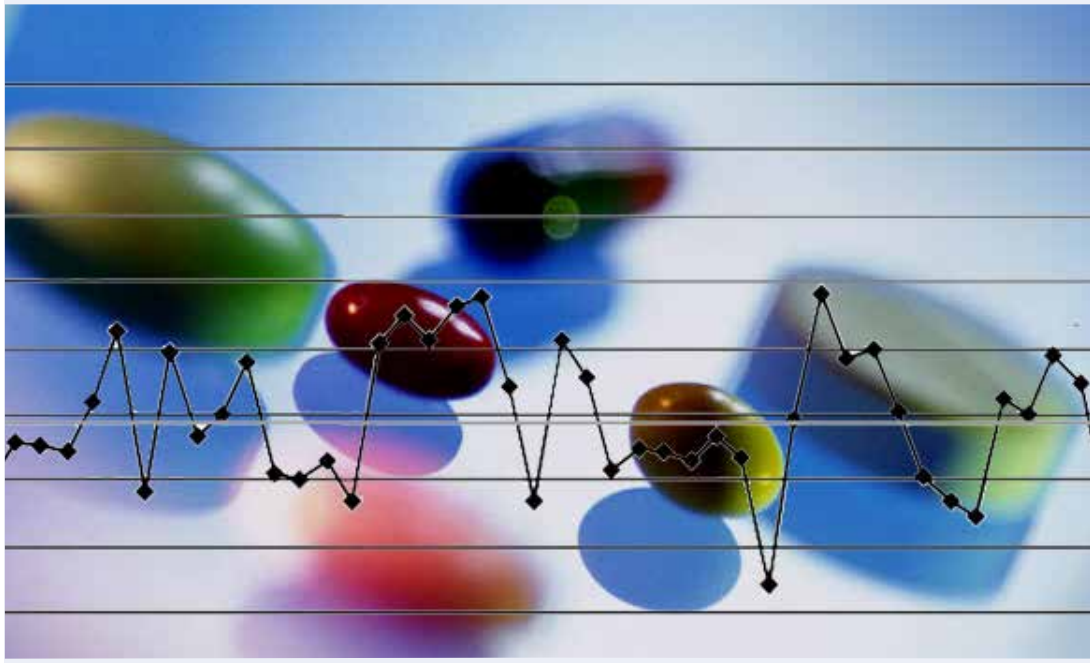
Dr Sven Wedemeyer
Merck, Germany

Dr Björn Wiese
Janssen Cilag, Switzerland

Process Understanding

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

Live Online Training on 06/07 February 2025



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"

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.

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

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

Q & A Sessions

Three Q &A sessions (two on day 1 and one on day 2) ensure interaction and that your questions are answered.

GMP/GDP Certification Scheme

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Speakers

Dr Ingolf Stückrath
Sanofi-Aventis, Germany

Ingolf began his career with Aventis, a predecessor company of Sanofi, in 2000 as an assistant plant manager in a fermentation plant in the insulin field. Following a Six Sigma Black Belt education and several successful projects Ingolf was made responsible for the implementation of Six Sigma at a site of 800 employees. After reaching the Six Sigma Master Black Belt level 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 near Paris in France. Back in Germany in 2013 he was initially responsible for a major insulin drug substance production facility before he took over the responsibility for the insulin drug substance manufacturing of Sanofi in Frankfurt. After moving to R&D in 2021 he is now managing the GMP drug substance manufacturing of all microbial derived development products of Sanofi. 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 started his Black Belt education in 2005. In 2014 he became MBB. For the last 20+ years, he has supported teams and individuals to achieve operational excellence, many times by using SPC to gain process insights and improve performance. His experience spans leadership roles in the health care and life science division of Merck on a local and global scale. In his current capacity, he leads the Project Management Office for the Quality Operation in Darmstadt.

Dr Björn Wiese
Janssen Cilag, Schaffhausen, Switzerland

Starting in November 2000, Björn had been head of the microbiology department of Hameln Pharmaceuticals, Hameln, Germany until 2005. From 2005-2010, he worked at the pharmaceutical production site of Cilag in Schaffhausen, Switzerland. From 2011 to 2022, he was Director Sterilization Technology and Analytical Testing Testing at Zimmer Biomet. Since September 2022, he has been leading the Community of Practice for Sterilization Technologies at Janssen Cilag, Schaffhausen.

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Process Understanding, Live Online Training on 06/07 February 2025

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Date Live Online Training

Thursday, 06 February 2025, 9.00 - 17.00 h
Friday, 07 February 2025, 08.30 - 12.00 h
All times mentioned are CET.

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Fees (per delegate, plus VAT)

ECA Members € 1,690
APIC Members € 1,790
Non-ECA Members € 1,890
EU GMP Inspectorates € 945
The fee is payable in advance after receipt of invoice.

Registration

Via the attached reservation form, by e-mail or by fax – or search and register directly at www.gmp-compliance.org under the number 21653.

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Conference language

The official conference language will be English.

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Organisation and Contact

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