ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Validation Manager

## Speakers

**Dr Ingolf Stückrath**
Sanofi-Aventis Frankfurt, Germany

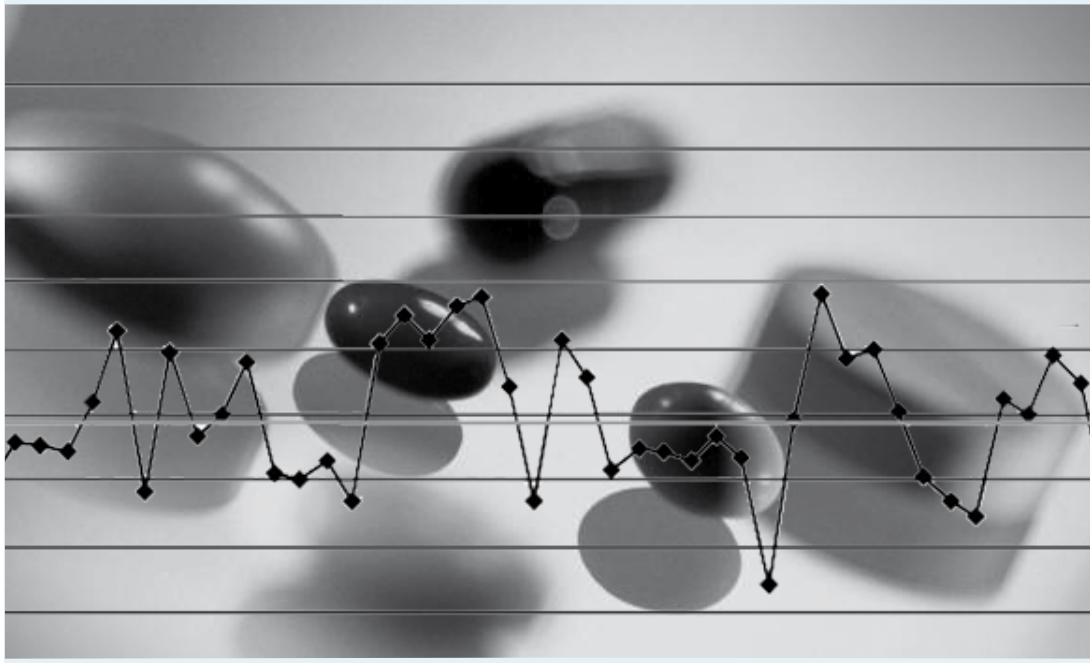
**Dr Sven Wedemeyer**
Merck KGaA, Germany

**Dr Björn Wiese**
Zimmer Biomet GmbH, Switzerland

# Process Understanding

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

## 25/26 January 2023 | 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"

# Programme

## 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

### Introduction to Six Sigma

- A short introduction to Six Sigma
- Six Sigma Terms

### Objectives of SPC and Statistical Introduction

- Create visibility of process performance
- Increase process knowledge
- Show process stability
- Prove process capability
- Support the continuous improvement process
- Mean Value, Median, Range
- Standard Deviation
- Normal Distribution
- Histogram and Time Series Plot

### The two Types of Variability and Control Charts

- Common cause variability
- Special cause variability
- 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

### Process Potential and Process Capabilities?

- Cp, Cpk versus Pp, Ppk
- long term versus short term capabilities

### Process robustness - a Tool for Process Evaluation

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

## Statistical software programs and automatically generated control charts

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

## 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

## 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 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.

### Dr Björn Wiese
Zimmer Biomet 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 Biomet GmbH and is now Director Sterilization Technology and Analytical Testing.

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Reservation Form (Please complete in full)

Process Understanding, 25/26 January 2023, Heidelberg, Germany

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## Date

Wednesday, 25 January 2023, 9.00 - 18.00 h
(Registration and coffee 08.30 - 9.00 h)
Thursday, 26 January 2023, 08.30 - 16.30 h

## Venue

NH Heidelberg
Bergheimer Strasse 91
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## 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.

## GMP/GDP Certification Scheme

Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. Simply choose any three courses within the programme according to your professional interest. Your certificate is then valid for two years. To renew it, you can pick any training from the ECA courses and conferences list within that two-years period – allowing you to broaden your knowledge in GMP and GDP compliance.

## Organisation and Contact

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