ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Validation Manager

Speakers

Dr Ingolf Stückrath
Sanofi-Aventis, Germany

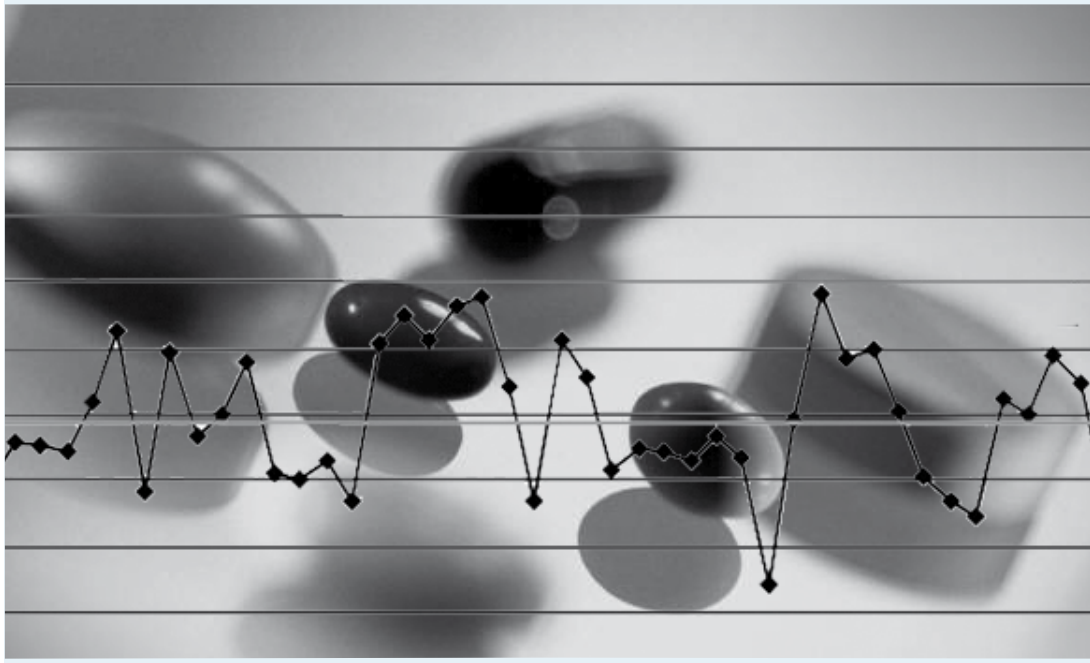
Dr Sven Wedemeyer
Merck, Germany

Dr Björn Wiese
Janssen Cilag, Switzerland

Process Understanding

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

Live Online Training on 15/16 February 2024



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

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.

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
Janssen Cilag, Schaffhausen, Switzerland

Starting in November 2000, he had been head of the microbiology department of Hameln Pharmaceuticals, Hameln, Germany until 2005. From 2005-2010, Björn 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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Reservation Form (Please complete in full)

Process Understanding, Live Online Training on 15/16 February 2024

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

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If you cannot attend the conference you have two options:
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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 July 2022).
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 Live Online Training

Thursday, 15 February 2024, 9.00 - 17.00 h
Friday, 16 February 2024, 08.30 - 12.30 h
All times mentioned are CET.

Technical Requirements

We use Webex for our live online training courses and webinars. At www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our events and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT system, please contact your IT department. Webex is a standard nowadays and the necessary installation is fast and easy.

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 message. Or you register online at www.gmp-compliance.org.

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.

You cannot attend the Live Event?

We also offer many of the training courses and conferences as recordings. This means that you can watch the videos of the event „on demand" – whenever it suits you – on our web server. It is quite uncomplicated and doesn't require any software – you simply watch the video on your browser. You can find all recorded events at www.gmp-compliance.org/recordings.

Organisation and Contact

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

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