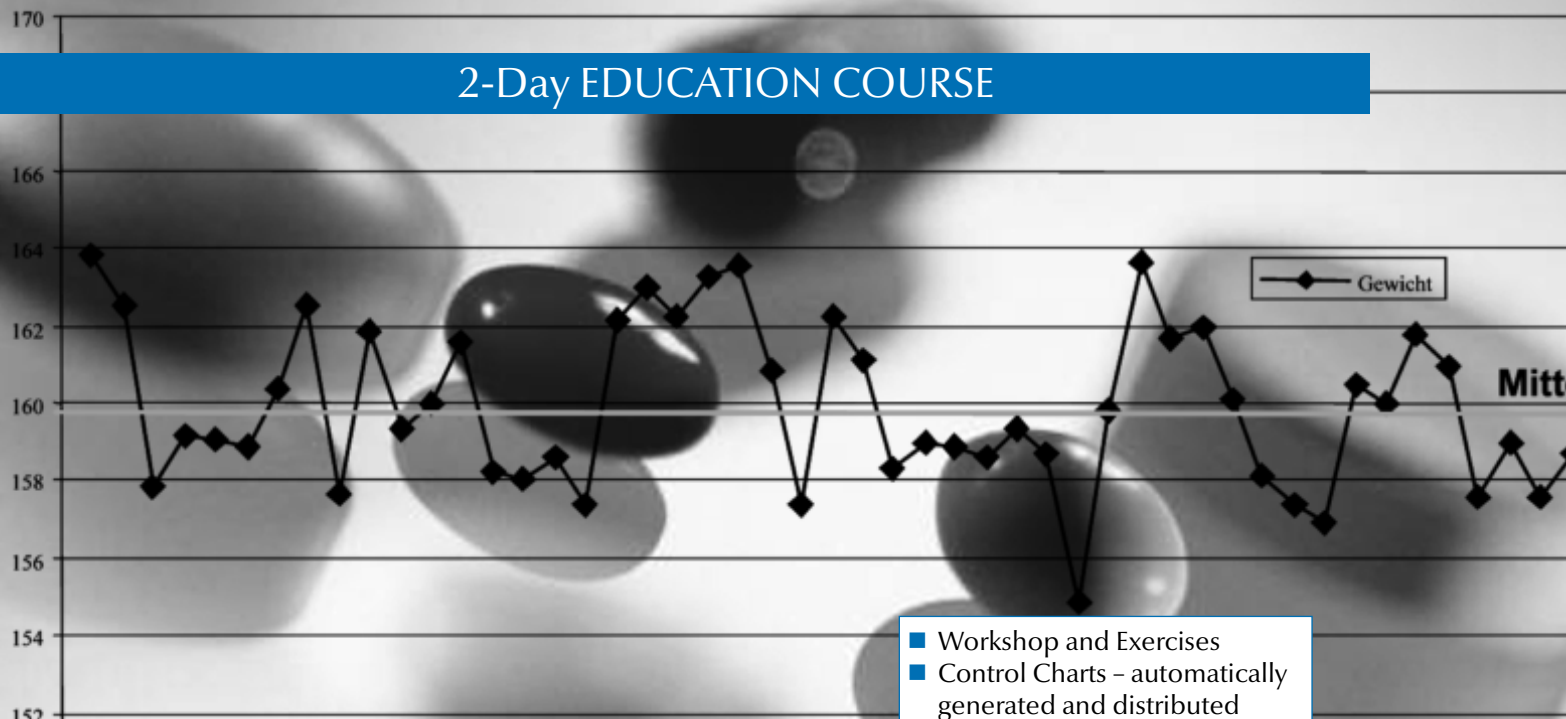


2-Day EDUCATION COURSE



- Workshop and Exercises
- Control Charts - automatically generated and distributed

Statistical Process Control

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

18 - 19 May 2010, Prague, Czech Republic

SPEAKERS:

Rolf Staal
Process Robustness Network

Klemens Wendl
Baxter

LEARNING OBJECTIVES:

- Six Sigma Definitions
- Statistical Introduction
- Control Charts
- Special Aspects with the Application of SPC
- Process Potential and Process Capability (Cpk, Ppk)
- Software Tools
- Case Study: Control Charts and Trending of Microbiological Data
- Process Robustness

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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 stage 3.

One element to show process understanding and to monitor trends can be Statistical Process Control. But:

- What is SPC?
- How and where can SPC be implemented in the field of GMP?
- Which tools are helpful?
- What is Process Robustness?
- How can you use control charts for early warnings and for monitoring?
- What is the benefit of SPC (also due to savings)

These questions will be answered in the course.

The participants learn how SPC works and get detail information on the most important control charts in the pharmaceutical industry. A case study explains practical aspects regarding microbial monitoring.

Background

With the new FDA Guidance on Process Validation of November 2008 the FDA is giving a new interpretation of validation. No longer the 3 validation batches are the evidence that a process is valid. Nowadays, the FDA expects a validation life cycle with a continued process verification in commercial phase. Also the EMEA stated in a Question and Answer paper, that they focus also on continuous validation. Both authorities want to see 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 ICH Q9 document “Quality Risk Management” are control charts and process capability mentioned as statistical possibilities within risk assessments

Target Group

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

Rolf Staal, Process Robustness Network

Workshop/Exercises

Practical trainings give the delegates the information 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).

In a workshop the delegates work out possibilities how SPC can be implemented in their companies. An additional exercise shows how a control chart can be used to identify process weakness, root cause analysis and corrective actions as teamwork.

Programme

Six Sigma Definitions

- A short introduction to Six Sigma
- Six Sigma Terms

Exercise 1

Control chart

The participants establish a control chart for individual values and moving ranges. This initial study and the approach “control to standard” are being discussed to demonstrate the benefit of control charts to improve and to monitor existing processes.

Statistical Introduction

- Goals and activities of SPC
- Variability
- The two types of variability
- A process which is “in statistical control”
- Frequency distribution, its limits
- Histogram
- Standard deviation
- Process definition
- Statistic rules

Control Charts

- Attribute and variable data
- Definition of SPC
- Overview of control charts
- Sense and nonsense of Attribute-Control charts

Workshop

Possibilities of application of SPC in the pharmaceutical industry

In small groups the delegates work out how SPC can be applied in their companies, setting up project descriptions.

Special Aspects in the Application of SPC

- When to calculate new control limits?
- How to handle positive and negative measurements
- Possible problems which can occur with SPC
- The link between the process and the measurement process
- Simulation of over-adjusting and how to prevent it

Process Potential and Process Capability

- Efficiency of SPC
- Potential Problems
- Cpk
- Ppk

Exercise 2

Simulation of a Pharmaceutical Process

With the help of control charts the delegates optimise a process which is not in statistical control.

Software Tools

- Overview
- Basic statistics
- Control Charts
 - Initial study
 - Control to standard
 - Calculating new control limits
 - Customizing

Control Charts, Automatically Generated

- Automatically generated control chart as tool for early warning systems and monitoring
- Case studies

Case Study

Control Charts and Trending of Microbiological Data

- 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

Process Robustness

- Definitions/model
- Benefit of Process Robustness
- Data analysis and the interpretation
- Strategies within projects

GMP Certification Programme

This seminar is recognised within the GMP Certification Programme. By attending selected seminars, the participant can acquire an additional certificate. We offer the following certification modules:

- Certified Quality Assurance Manager – Pharmaceutical Production (ECA)
- Certified Quality Assurance Manager – API Production (ECA)
- Certified Quality Control Manager (ECA)
- Certified Pharmaceutical Engineering Manager (ECA)

Speakers



Rolf Staal

Process Robustness Network, Niedernhausen, Germany

After 11 years as Process Improving Engineer in the US, Mr Staal worked as Director Process Excellence at Aventis Pharma AG.

He developed a method for measuring and improving process robustness whose index is now used for implementing the strategy. To improve processes he also introduced Six Sigma worldwide. In addition to quality and process improvements this also resulted in a general cultural change and cost savings of 20 Million Euro. Since 2004 Mr Staal has been working as an independent consultant.



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 18 May 2010 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.



- Certified Computer Validation Manager (ECA)
- Certified Regulatory Affairs Manager (ECA)
- Certified Validation Manager (ECA)

On the internet at www.gmp-compliance.org you will find a text explaining which seminars are recognised for which certificates. Or you send an e-mail to info@gmp-compliance.org or a fax to +49-6221-84 44 64 with the request for information about the GMP Certification Programme. We will then send you our brochure on the topic.

Easy Registration



Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany



Reservation Form:
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Statistical Process Control - A key tool for process understanding in the process validation life cycle

18 - 19 May 2010, Prague, Czech Republic

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 - until 2 weeks prior to the conference 10 %
 - until 1 week prior to the conference 50 %
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Date

Tuesday, 18 May 2010, 9.00 - 18.00 h
(Registration and welcome coffee 08.30 - 9.00 h)
Wednesday, 19 May 2010, 08.30 - 16.00 h

Venue

Dorint Hotel Don Giovanni Prague
Vinohradská 157A
130 20 Prague 3
Tel. +420 2 6703 1111
Fax +420 2 6703 6717

Fees

Non-ECA Members € 1,690.- per delegate plus VAT
ECA Members € 1,521.- per delegate plus VAT
APIC Members € 1,605.- per delegate plus VAT
(does not include ECA Membership)
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 HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form when you have registered for the event. Please use this form for your room reservation or be sure to mention "VA 6264 ECA Event" to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel not later than 16 April 2010. 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

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