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Live Online Training

Speaker

Dr Joachim Ermer
Ermer Quality Consulting, Germany

Monitoring and Trending in Quality Control and Production

Live Online Training on 08 November 2022

Highlights

- Distribution of Data
- Error Types
- Outlier Tests and Trend Tests
- Statistical Control Charts and Out-of Expectation limits
- Suitable Parameters for Monitoring of Analytical Performance
- Out-of Trend in Stability Studies

Objectives

This Live Online Training provides fundamentals with respect to

- the statistical distribution of data
- the selection, generation, and use of statistical control charts

Recommendations are given
- for identification of results outside of expectation (OOE) and outside of trends (OOT)
- for analysis of trends

The seminar covers the monitoring of product and process data, as well as analytical performance data and stability results.

Background

In order to ensure quality, safety, and efficacy of pharmaceuticals, an appropriate control of the capability of the manufacturing process (EU GMP Guide Part 1, Annex 15), as well as of the analytical performance (EU GMP Guide Part 1, Chapter 6, Quality Control (6.16), FDA Method Validation Guidance) is important, during the whole lifecycle. A regular evaluation is expected, e.g. as Annual Quality Review (FDA, 21CFR 211.180(e)) or Product Quality Review (EU GMP Guide 1.10). The importance of a monitoring of analytical performance to identify proactively failures and adverse trends is discussed in the FDA-Guidance „Analytical Procedures and Methods Validation for Drugs and Biologics“ (2015) and also in the draft of the new ICH guideline Q14 „Analytical procedure development“.

Unlike the rules established for investigation of results outside of specification (OOS), no detailed advice is provided by the authorities in case of results outside of expectation or outside of trends. However, this opens up the flexibility to establish suitable monitoring and trending programs of own choice.

Target Audience

This Training is aimed at executives and employees from quality control and analytical development as well as quality assurance and production responsible for evaluation and monitoring of analytical results.

Programme

„Normal“ Distribution of Data

- Regulatory expectations to the quality of product and analytical results
- Error types: random and systematic errors
- Distribution of data
- Capability indices
- Outlier tests
- Trend tests
- Appropriate consideration of variability contributions (manufacturing and analytics, precision levels)

Statistical Control Charts and OOE Limits

- Statistical basics and out-of-control rules
- Control chart types and their appropriate selection (individuals and means, moving range, CUSUM, range, standard deviation control charts)
- Software
- Practice check: Always statistics?
- Statistical and empirical OOE limits
- Suitable parameter to monitor analytical performance

Workshop Control Charts

OOT in Stability Investigations

- Regulatory requirements (EU-GMP-Guide)
- Identification of stability OOT by means of
  - Prediction intervals
  - Regression control charts
  - Time-point approach

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Speaker

Dr Joachim Ermer
Ermer Quality Consulting, Germany

Dr Ermer worked for almost 30 years in various positions in industrial Quality Control. His responsibilities included head of laboratory within the analytical drug development at Hoechst AG, Frankfurt, Germany, a global function as Director of Analytical Processes and Technology at Aventis, head of Quality Control and head of QC Lifecycle Management Frankfurt Chemistry, Sanofi, Germany, and Sanofi Global Reference Standard Coordinator. Since December 2020, he serves as consultant for topics of pharmaceutical analytics and Quality Control. Dr Ermer is member of the Ph.Eur. Working Group "Chromatographic Separation Techniques" and of the USP Expert Committee "Measurement and Data Quality". He authored more than 50 publications on analytical topics and is editor and author of the two editions of the book "Method Validation in Pharmaceutical Analysis. A Guide to Best Practice" (Wiley-VCH, 2005 and 2015)

Your Benefit:
Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires: „... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,...". This is why you receive an acknowledged participant certificate, which lists the contents of the seminar in detail and with which you document your training.


CERTIFICATE

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- Regulatory Affairs
- Sterile Manufacturing
- IT / Computer Validation
- Good Distribution Practice (GDP)
- Data Integrity
- Packaging
- Medical Devices und
- Technical Operations

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Reservation Form (Please complete in full)

Monitoring and Trending in Quality Control and Production
Live Online Training on 08 November 2022

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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Date of the Live Online Training
Tuesday, 8 November 2022, 14.00 h – 17.30 h CET

Technical Requirements
We use Webex Events for our live online training courses and webinars. At https://www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our trainings 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 € 590
APIC Members € 640
Non-ECA Members € 690
EU GMP Inspectorates € 590
The fee is payable in advance after receipt of invoice.

Registration
By e-mail 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.

Ordering Recordings
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.

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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