ECA Academy
Your GMP/GDP Information Source

Live Online Training

Speaker

Dr Bernd Renger
Bernd Renger Consulting, Germany

Handling OOS Results

Live Online Training on 26 April 2022

Highlights

- OOS: US/FDA and MHRA Guidelines and European Regulatory Expectations
- Handling OOS Results in the QC Laboratory and beyond
- Specific Cases of OOS Results
  - OOS Results of Discrete/Attribute Data
- Handling OOS Results in the Microbiological Laboratory
- Strategies not to generate OOS Results
- OOS Results Scenarios

Objective

This Live Online Training provides practical advice on how to deal with OOS Results. You will get to know the European Regulatory Expectations and what FDA and European guidelines tell us about handling OOS Results. During the training the following aspects will be covered:

- Repeated Testing, Retesting, reporting of results
- How to perform investigations on different levels
- Limit Excursions of critical process parameters
- OOL (out-of-limits) results in monitoring
- OOS Results of Discrete/Attribute Data
- OOS results in microbiological testing
- What makes a good OOS SOP?

Participants will get OOS case studies upfront. During the training options how to deal with the results will be discussed and possible solutions will be suggested.

Background

Since the often cited Barr ruling (Wolin Judgement) of February 1993 pharmaceutical companies all around the world have implemented procedures and strategies on how to deal with results that do not comply with their predetermined specifications. Although 27(!) years have passed since that judgement and although in the meantime FDA and MHRA have published guidances about OOSs, the investigation of OOS results continues to be a hot topic in FDA inspections. The incorrect handling and investigation of OOS results is still frequently cited in Warning Letters.

The **ECA Working Group on Analytical Quality Control** decided to address these aspects and developed a harmonised **guideline SOP** on managing analytical deviations within the laboratory including OOS, OOE and OOT results. It encourages the application of a consistent and scientifically sound approach to trend analysis as part of a QMS. The current Version 2 is available for all ECA members on the ECA members area.

Target Audience

This Live Online Training is recommended for all levels of technical staff and managerial personnel dealing with out-of-specification results, including analytical laboratories, contract laboratories, and uality Assurance/Quality Control personnel.

Programme

Regulatory Requirements for Handling OOS Results

- FDA and MHRA Guidelines and European Regulatory Expectations
- Key points and scope of the different guidelines

Handling OOS Results in the QC Laboratory – and beyond

- Responsibilities and how to deal with OOS results
- Lab scale investigation – full scale investigation
- Repeated testing, retesting, reporting of results
- Appropriate and inappropriate uses of averaging test data

Specific Cases of OOS Results

- OOS Results of Discrete/Attribute Data and Microbiological OOS Results
- OOS results in testing of attributes and dichotomic tests
- Limit excursions of critical process parameters
- OOL (out-of-limits) results in monitoring
- OOS results in microbiological testing
- OOE or OOS results in validation, calibration and SSTs

Handling OOS Results in the Microbiological Laboratory

- Micro OOS Results of Products
- OOS Results in Environmental Monitoring

Strategies not to Generate OOS Results

- Test procedures and specifications
- Meaningful SSTs
- Acceptance limits for the variability among replicates
- Sampling and averaging
- Deviations during testing

Workshop – OOS Results Scenarios

- Real OOS case studies will be presented upfront
- Options how to deal with the results will be discussed
- Possible solutions will be suggested

Speaker

Dr Bernd Renger
Bernd Renger Consulting, Germany

Dr Bernd Renger started at Hoechst AG. Since then, he has held several quality management positions at Mundipharma, Byk Gulden (now Takeda) and Baxter BioScience in Vienna and Vetter Pharma-Fertigung. He was a member of the European Compliance Academy (ECA) Advisory Board and is Immediate Past Chair of the European QP Association.

This could be of interest for you as well

Would you like to train a larger group of participants in your company?

We offer practice-oriented GMP/GDP training courses on:

- Basic GMP
  - APIs (ICH Q7)
  - Medicinal Products
  - Biopharmaceuticals
- Quality Assurance
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- Good Distribution Practice (GDP)
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- Packaging
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- Technical Operations

You will find a time schedule for each training course at https://www.gmp-compliance.org/training/gmp-gdp-in-house-trainings

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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GERMANY

Reservation Form (Please complete in full)

Handling OOS Results, Live Online Training on 26 April 2022

Title, first name, surname

Department

Company

Important: Please indicate your company's VAT ID Number

Purchase Order Number, if applicable

City

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Phone / Fax

E-Mail (Please fill in)

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If you cannot attend the conference you have two options:
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German law shall apply. Court of jurisdiction is Heidelberg.

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Date of the Live Online Training

Tuesday, 26 April 2022, 09.00 – 16.45 h CEST

Technical Requirements

For our Live Online Training Courses and Webinars, we use Cisco WebEx, one of the leading suppliers of online meetings. At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer 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 € 890
APIC Members € 950
Non-ECA Members € 990
EU GMP Inspectorates € 495
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.

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Organisation and Contact

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

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