Academy
Your GMP/GDP Information Source

Live Online Training

Speaker

Dr Joachim Ermer
Ermer Quality Consulting,
Germany

Identification and Management of OOT and OOS Results

Live Online Training on 27 September 2022

Highlights

- Regulatory “out-of” definitions
- Error types
- Establishing OOT-limits for release testing
- Establishing OOT-limits for stability testing
- Impact of OOT-results in stability studies
- Management of OOT and OOS results in the Quality Control laboratory
- Appropriate response to OOS observations in inspections

Objective

Out-of-specification (OOS) test results and their appropriate management is an important topic in pharmaceutical Quality Control and inevitably in the focus of any inspection and audit. The purpose of the seminar is providing an overview on regulatory expectations, which are mainly based on the FDA Guidance for Industry "Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production", as well as practical recommendations for a GMP-conform investigation.

Background

Although the FDA-Guidance on OOS-results provides detailed instructions how to manage results outside specification, observations and deficiencies dealing with OOS results is still a major issue in inspections, FDA 483s and Warning Letters.

In the speaker's experience, an important aspect is to establish a clear terminology to facilitate understanding of the investigation phases and the appropriate testing approaches.

Of course, "prevention is better than cure". For this purpose, it is important to avoid OOS-results, for example by means of a suitable identification of atypical or out-of-trend (OOT) results. The participants will learn how to identify OOT-results and how to establish suitable OOT-limits

Target Audience

This Live Online Training is aimed at executives and employees from quality control, quality assurance, production, regulatory and audit functions who want to gain a better understanding of the GMP requirements for the management of OOS-results and how to establish OOT-limits to better prevent OOS-results.

Programme

Definition of OOT and OOS Results

- Regulatory "out-of" definitions
  - atypical, suspect, out-of-trend, out-of-expectation, out-of-specification
- Reportable value
- Error types (random, systematic)
  - How can they be distinguished?
- Normal or abnormal?
  - (Normal) distribution of data

Establishing OOT Limits for Release Testing

- Statistical approaches
- Empirical approaches
- Control charts

Establishing OOT Limits for Stability Testing

- Impact of OOT results in stability studies (ICH studies, ongoing stability)
- Introducing a second dimension ("normal" stability trend)
- Statistical approaches
  - 95% prediction interval of the linear regression
  - Regression control chart
  - Time-point method

Management of OOT and OOS Results in the Quality Control Laboratory

- FDA-Guidance and European requirements (EU GMP Guide, MHRA, PIC/S)
- Importance of a clear terminology (reportable value, re-analysis, retest, re-sampling)
- Investigation pathway: OOS identification & decisions
- Phase I: Initial laboratory investigation
- Phase II: Full scale investigation
  - Phase IIA: Review in production
  - Phase IIB: Additional laboratory testing (retests, averaging)
- Variability and OOS
- Reporting and documentation
- Appropriate response to OOS observations in inspections

Workshop

Evaluation and commenting of OOS examples

Speaker

Dr Joachim Ermer
Ermer Quality Consulting, Bensheim, Germany

Following study of biochemistry and PhD thesis in enzyme kinetics at the Martin-Luther-University Halle-Wittenberg, and a post-doc scholarship in Cambridge, UK, 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 Focus Group "Analytics and Quality Assurance", International Association of Pharmaceutical Technology (APV), 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).

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

Mr John Doe

has completed a two day ECA Course on 5 to 6 December 2019 in Barcelona, Spain covering the following subject

ECA - Lab Data Integrity - Meeting FDA & EU Concerns
Part 2: Self Inspections and Audits to Confirm Effective Data Integrity Controls

Contents of the course:

- Introduction to Course
- Data Integrity Self Inspections and Audits for Hybrid and Electronic Systems
- Workshop 1
- Risk Assessment and Roadblocks
- Workshop 2
- Audit of an Excel Spreadsheet
- Workshop 3
- Auditing a Hybrid Stereotaxic System
- Workshop 4
- Auditing a Networked Laboratory System - Audit Trail Review
- Workshop 5
- Electronic Signature Auditing
- Workshop 6
- Preparing for the Data Integrity Audit
- Workshop 7
- Data Integrity and Findings During a Laboratory Audit and Planning the Closing Meeting
- Workshop 8
- Feedback to the Auditee
- Review of the Course and Key Learning Points

Heidelberg, 6 December 2019

ECA Academy

Why not online?

GMP/GDP seminars, webinars and e-learning

Take advantage of the wide range of „on demand" training opportunities offered by the ECA Academy. You can use various online offers at any time without software installation. There is an extensive selection of courses available. Simply book online - with a certificate of completion, of course. Find out more at https://www.gmp-elearning.com and https://www.gmp-compliance.org/recordings.

If the bill-to-address deviates from the specifications on the right, please fill out here:

_____

_____

_____

_____

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

Identification and Management of OOT and OOS Results
Live Online Training on 27 September 2022, 14.00 h - 18.00 h CEST

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

E-Mail (Please fill in)

General terms and conditions
If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees:
- Cancellation until 2 weeks prior to the conference 10 %,
- Cancellation until 1 weeks prior to the conference 50 %
- Cancellation within 1 week prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event.
If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERGwill not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
Terms of payment: Payable without deductions within 10 days after receipt of invoice.
Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message.
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 January 2012).
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 of the Live Online Training
Tuesday, 27 September 2022, 14.00 h – 18.00 h CEST

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
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.

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.

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

CONCEPT HEIDELBERG
P.O.Box 10 17 64
69007 Heidelberg, Germany
Phone +49(0)62 21/84 44-0
Fax +49(0)62 21/84 44 34
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content please contact:
Dr Gerhard Becker (Operations Director) at
+49(0)62 21/84 44 65, or at
becker@concept-heidelberg.de.

For questions regarding organisation please contact:
Mr Rouwen Schopka (Organisation Manager) at
+49(0)62 21/84 44 13, or per e-mail at
schopka@concept-heidelberg.de.