



Speaker



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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).

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

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Date of the Live Online Training

Tuesday, 27 September 2022, 14.00 h – 18.00 h CEST

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Fees (per delegate, plus VAT)

ECA Members € 590

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Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

Presentations/Certificate

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Conference language

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Organisation and Contact

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

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