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GMP Webinar
Strategic Prevention of Lab Errors

Strategic Measures to Prevent Unconfirmed OOS Results in QC-Laboratories

Date:
Thursday, 29 September 2022, 14.00 – 15.30 h CEST

Speaker:
Dr Karl-Heinz Bauer, Boehringer Ingelheim

ECA has entrusted CONCEPT HEIDELBERG with the organisation of this webinar.

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Background
Laboratory tests are performed on active pharmaceutical ingredients, excipients and other components, in-process materials, and finished drug products. The investigation of out-of-specification (OOS) results is an important part of the work undertaken in QC-laboratories and continues to be a hot topic in authority inspections. The incorrect handling and investigation of OOS results are still frequently cited in FDA Warning Letters.
Unconfirmed OOS results (= lab errors) require a full and often time-consuming OOS investigation with a predefined procedure to find the root cause and to define CAPAs.
Against this background, it is essential to thoroughly investigate unconfirmed OOS results and make every effort to prevent the recurrence.

Educational Objectives
In this webinar, you will get to know strategies to investigate unconfirmed OOS results and you will learn how to define strategic measures to significantly reduce the probability of such results.
The following topics are addressed:
- Terms, definitions and requirements to prevent errors in QC-laboratories,
- The role of quality risk management,
- Error sources and error analysis in the laboratory and strategic measures,
- Integrated error management and error culture,
- Tools for root cause analysis (Ishikawa, 5W, FTA etc.).

Target Audience
This webinar is aimed at all levels of technical staff and managerial personnel dealing with OOS results. Those are for example persons working in
- Incoming goods control,
- Control of finished drug products,
- Analytical development,
- API and excipient testing,
- Contract laboratories.

Speaker

Dr Karl-Heinz Bauer, Boehringer Ingelheim
Dr Bauer holds a PhD in pharmaceutical engineering and has been with Boehringer Ingelheim for more than 25 years. He has held various senior management positions in quality assurance, quality control and pharmaceutical manufacturing. During this time, he successfully introduced the Continuous Improvement Process into the quality department. In addition, he was responsible for the balanced scorecard of the quality unit.
Since January 2020, he has taken over a strategic, international quality management position. In addition to that, Dr Bauer works now for many years as a speaker, consultant and coach in the pharmaceutical industry.

Fees (plus VAT)
Single participation: € 249.- for ECA Members
Single participation: € 299,- for non-ECA Members
(This fee does not include the ECA Membership. You will find more about the ECA Membership at https://www.gmp-compliance.org/about-the-academy).

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You have colleagues who also want to participate in the webinar? Then register yourself and your colleagues as a GROUP! You can view the webinar either together (e.g. in a conference room, etc.) or also each individually on your own PC.

Group Participation (fee per person):
3-10 Persons EUR 254,15
11-20 Persons EUR 224,25
more than 20 Persons EUR 194,35

Registration
By e-mail or online on the Internet at www.gmp-compliance.com. In order to avoid misunderstandings, please indicate the exact address and the full name of the participant. You will receive your access data by e-mail in due time prior to the event.

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Important: Deadline for registration is
28 September 2022 at 12.00 h

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