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GMP Webinar
Stability of Test Solutions

Date:
Thursday, 24 February 2022, 14.00 – 15.30 h CET

Speaker:
Dr Joachim Ermer, Ermer Quality Consulting

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

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Background
According to EU GMP Guide Part 1, Chapter 6, Quality Control and US 21 CFR 211.160, analytical procedures must be designed to ensure that drug products meet the quality standards and the specifications with respect to strength and purity defined in the marketing authorisation. This includes a suitable control of analytical procedure components such as reagents, solvents, standard and sample preparations to ensure an accurate and reliable analytical result. Thus, the shelf-life and storage conditions of standard and sample solutions should be demonstrated, as discussed in the USP General Information Chapter <1226>"Verification of compendial procedures".

Educational Objectives
Besides regulatory expectations, the Webinar provides recommendations with respect to stability investigations of test solutions for qualitative and quantitative use. Suitable stability study designs, data calculations and assessments will be presented, in order to achieve a reliable and traceable shelf-life determination.

The following topics will be covered:
- Requirements to solutions for qualitative and quantitative use
- Corresponding addition to USP General Information Chapter <1226> "Verification of compendial procedures" (valid December 1, 2019)
- What changes are acceptable for qualitative and quantitative use?
- Appropriate evaluation of stability results. Why is the assessment of individual results not suitable?
- Evaluation of stability data by averaging and regression
- Determination of the shelf-life of standard and sample solutions

Target Audience
The webinar targets executives and staff in quality control laboratories and quality assurance, who want to get an overview on GMP requirements with respect to stability and expiry dating of reagents, solvents, standard and sample preparations, as well as their efficient practical implementation.

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 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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Single participation: € 249.- for ECA Members
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Group Participation (fee per person):
3-10 Persons € 254,15
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from 21 Persons € 194,35

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