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GMP Webinar
Quality-by-Design Method Development – Replication Strategy
Optimisation of the reportable value precision

Date:
Thursday, 30 September 2021, 14.00 – 15.30 h CEST

Speaker:
Dr Joachim Ermer, Ermer Quality Consulting

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

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Background

In the last two decades, the ICH process has emphasised the assurance of quality, safety, and efficacy of pharmaceutical products during the whole life cycle (ICH Q8-12, EU and FDA Guidelines on process validation). Applying the same principles to analytical procedures comes naturally and has been proposed by EFPIA/PhRMA working groups as well as USP Expert Panels since 2010, in several publications. The generally encouraging feedback resulted in the draft of a USP General Information Chapter <1220> "Analytical Procedure Life Cycle" [Pharm. Forum 46(5) 2020]. Such analytical lifecycle aspects will also be included in the revision of the ICH Guidline Q2 "Validation of analytical procedures" and the new Guideline Q14 "Analytical Procedure Development" – which face unfortunately further delay.

An important aspect of the analytical lifecycle management is a systematic (quality-by-design) method development to gain an enhanced understanding of the procedure's performance. This is the basis to establish measures and controls of sensitive parameters in order to ensure the required performance during routine application. One aspect of this Analytical Control Strategy is a science-based establishment of the number of replicates of the routine method, i.e. the replication strategy.

Educational Objectives

Repeated injections and preparations of sample and reference standard are often generically defined, or based on "tradition". This Live Online Training provides the scientific and statistical background to optimise the precision of the reportable value of an analytical procedure to ensure its fitness for purpose. Impacting factors regarding the optimisation of variability by averaging will be discussed, providing practical orientation and recommendations for a QbD-replication strategy. Further, potential conflicts and solutions with regard to the current FDA-Guidance on OOS results are discussed.

The following topics will be covered:

- Statistical background – precision of the mean (standard error)
- Application to multiple precision levels & bioassays
- What is the practical effect of increasing the number of determinations (dependence on relative variance contributions)
- Optimisation under consideration of the uncertainty (confidence interval of precision)
- Prerequisites for an appropriate establishment of the replication strategy (reliability of the variance contributions from precision studies)
- Consideration of regulatory expectations- FDA (CDER) "averaging issue"

Target Audience

The webinar is aimed at executives and employees from analytical development, Quality Control, Quality Assurance, regulatory, and production who are interested in approaches of continual improvement of analytical procedures as the basis to efficiently control the quality of pharmaceutical products and manufacturing processes, or in current discussions regarding the Analytical Control Strategy.

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).

Fees (plus VAT)

Single participation: € 249.- for ECA Members
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Participation of a Group

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 € 254,15
11-20 Persons € 224,25
from 21 Persons € 194,35

Registration

By mail, fax, 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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Presentation/Certificate

The presentation will be made available to you prior to the Webinar as a PDF file. After the Webinar, we will automatically send you a certificate of participation.

Organisation/Contact

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Important: Deadline is 12 noon on 29 September 2021
Please register at www.gmp-compliance.org