ECA Academy
Your GMP/GDP Information Source

GMP Webinar
Statistical Simulations for Enhanced Understanding of Analytical Performance

Date:
Monday, 09 September 2024, 14.00 – 16.00 CEST

Speakers:
Dr Christopher Burgess
Dr Joachim Ermer

This webinar is included free of charge for all participants of the ECA course "Practical Statistical Tools for Analytical Laboratories" on 01/02 October 2024 in Barcelona, Spain. If you decide to book the course in Barcelona after attending the webinar, the webinar fee will be credited.

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

CONCEPT HEIDELBERG GmbH
Rischerstrasse 8
69123 Heidelberg, Germany
Phone +49 (0) 6221 - 84 44 0
Fax +49 (0) 6221 - 84 44 64
info@concept-heidelberg.de

Background
A comprehensive understanding of the performance of an analytical procedure is a key element in the enhanced (Quality-by-Design) development approach described in the new ICH Guideline Q14 "Analytical Procedure Development", but is also beneficial in more traditional approaches to method development and validation. Besides the identification and (as far as possible) elimination of systematic bias (thus ensuring accuracy), an appropriate knowledge of the random variability (common cause variation) is essential, as this error type contributes to all other performance characteristics.
Having established a reliable knowledge of the respective precision, statistical simulations can facilitate to evaluate the consequences to other performance attributes or investigations, such as calibration models, design of precision or transfer studies, reportable values etc. This approach allows to perform a large number of (simulated) "experimental" investigations, to gain a "feeling" on the interplay of precision, number of determinations, as well as acceptance criteria.

Educational Objectives
The participants will learn what statistical simulations are and how they can be applied to relevant questions in pharmaceutical analysis, such as

- Expected spread of data, standard deviations, means
- Interplay of standard deviation, number of determinations, and specification limits
- Link between variability contributions of precision levels and expected mean difference (e.g. for transfer of analytical procedures)

The participants will receive an Excel file with simulation worksheets, which will be explained in the webinar and which can be used later for own applications.

Target Audience

- Analytical laboratory managers and their colleagues charged with the day to day management and evaluation of laboratory data throughout the lifecycle, i.e. in method development, validation, transfer, specification setting, batch release and stability, continuous performance verification and change control.
- QA, manufacturing and regulatory affairs professionals

Speakers

Dr Christopher Burgess
Burgess Analytical Consultancy Ltd., UK
He is a Chartered Chemist and has more than 45 years' experience in the pharmaceutical industry initially with Glaxo in Analytical R&D, Quality Control and Quality Assurance followed by 25 years in international consultancy. He is a "Qualified Person" in the European Union. He was appointed to the United States Pharmacopoeia's Council of Experts 2010 to 2025 and is a visiting professor at the University of Strathclyde's School of Pharmacy and Biomedical Sciences (SIPBS). In addition, he is the chairman of the ECA Analytical Quality Control Group and a member of the Extended board of European Compliance Academy Foundation. He was a member of the USP Expert Panel which developed General Chapter <1220> and is chairman of the JSC revising General Chapter <1058>.

Dr Joachim Ermer
Ermer Quality Consulting, Germany
He has 30 years of experience in pharmaceutical analytics including development products, global responsibilities as Director of Analytical Processes and Technology, Head of Quality Control, and Head of QC Lifecycle Management Frankfurt Chemistry at Sanofi. From 2010 till 2020, he was also responsible for the central reference standard group of Sanofi. He is member of the USP Expert Committee Measurement and Data Quality, and of the Chromatographic Separation Techniques Working Party of the European Pharmacopoeia. Since December 2020, he works as a consultant for topics of pharmaceutical analysis and Quality Control.

Fees (plus VAT)
Single participation: € 399,- for ECA Members
Single participation: € 349,- for non-ECA Members
(This fee does not include the ECA Membership. You will find more about the ECA Membership at www.gmp-compliance.org/about-the-academy).

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 € 359,10
11-20 Persons € 319,20
more than 20 Persons € 279,30

Registration
By e-mail – or search and register directly at www.gmp-compliance.org under the number 21251. 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.

Technical Requirements
We use Webex for our live online training courses and webinars. At www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our events 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.

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.

You cannot attend the Live Event?
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 Markus Funk, phone +49(0)6221 / 84 44 40
Email: funk@concept-heidelberg.de

For questions regarding organisation please contact:
Mr Niklaus Thiel, phone +49(0)6221 / 84 44 43
Email: thiel@concept-heidelberg.de

Register at
www.gmp-compliance.org/training/gmp-course-conference/eca-webinar-statistical-simulations

CF/10062024