IFAPP
Pharmaceutical Medicine

IFAPP WEBINAR

Date: 30th June 2025
Time schedule:
05.00-07.00 AM EST
10.00-12.00 AM GMT
12:00-02:00 PM CEST
07.00-09.00 PM JST

The speakers

Rebecca Stanbrook

BPharm (hons), MRPharmS, FFRPS, DipRQA, FRQA

ICH – GCP Revision

Gabriele Schwarz

a graduated pharmacist, joined the German Federal Institute for Drugs and Medical Devices (BfArM) in 2001

Good Clinical Practice (GCP) is the international scientific and ethical standard for the conduct of interventional clinical trials. The ICH E6 Guideline, published in the mid-1990s, established a harmonised understanding of GCP.

New trial designs, new technology and the greater use of different data sources required a comprehensive revision of the guideline. This seminar will familiarise participants with the key aspects of this revision.

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ICH – GCP Revision

Rebecca is the EFPIA Topic lead for ICH E6(R3) Expert Working Group, the group responsible to rewriting the Good Clinical Practice Guideline, the global standard for the conduct of clinical trials.

Rebecca has worked at a number of pharmaceutical companies in various roles across all aspects of the pharmaceutical industry and as a regulator at the Medicines and Healthcare products Regulatory Agency. To date she has over 30 years' experience in the industry or as a regulator.

Rebecca Stanbrook

Gabriele is currently BfArM's GCP Strategy Expert and represents the EU in the ICH E6(R3) Expert Working Group. For more than a decade and a half, until the end of 2022, Gabriele was Head of BfArM's GCP Inspection Unit and responsible for BfArM's GCP inspection activities, particularly in the context of international pre-approval inspections coordinated by the Europe Medicines Agency.

Over the years, she has contributed to the development of a considerable number of European and international guidelines, such the OECD 'Recommendation on Clinical Trial Governance', the ICH E6(R2) and (R3) Guideline on 'Good Clinical Practice' and the ICH E19 Guideline on a 'Selective Approach to Safety Data Collection in Specific Late-stage Pre-approval or Post-approval Trials'.

Gabriele Schwarz

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Follow-up workshop

This webinar will be followed by a virtual workshop on "Practical challenges of implementing ICH-GCP(R3) in your clinical trials" on 18th September 2025 from 10:30 am CEST to 3:00 pm CEST. The speakers will be Ingrid Klingmann, MD, PhD, PharmaTrain, Belgium, and Elisabeth Reus, Swiss Tropical and Public Health Institute, Switzerland.

REGISTER IN ADVANCE FOR THIS WEBINAR

AFTER REGISTERING, YOU WILL RECEIVE A CONFIRMATION EMAIL CONTAINING INFORMATION ABOUT JOINING THE WEBINAR.

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