Implications and Opportunities
ICHQ2(R2): Validation of Analytical Procedures
ICHQ14: Analytical procedure development

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Webinar for members of EIPG in conjunction with PIER and University College Cork

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Wednesday 15th June 2022 at 17.00 CEST (16.00 BST)

About the Speaker

Phil Borman is a fellow of the Royal Society of Chemistry with over 25 years of experience in the pharmaceutical industry having obtained a Masters in Chemistry from Manchester University, a Masters in Applied Statistics from De Montfort (Leicester) University and a Doctorate in Sciences for his work in pioneering and developing Quality by Design (QbD) approaches for analytical procedures. Phil is currently a Director and Senior Fellow at GlaxoSmithKline where he is accountable for the ongoing development and implementation of Quality by Design. Phil pioneered the adaptation of QbD principles to Analytical procedures and has published widely in the field of Analytical Chemistry. He currently co-leads the EFPIA ICHQ2(R2)/Q14 support team as well as being a member of the USP Measurement and Data Quality Expert Committee and British Pharmacopoeia (MHRA) Analytical Quality by Design Working party.

Overview of Webinar

The revision of ICHQ2(R1): Validation of Analytical Procedures and the development of ICHQ14: Analytical Procedure Development reached the key ICH milestone of Step 2 publication for public consultation in March 2022. The combined topic Q2(R2)/Q14 represents an opportunity to provide guidance on how to apply enhanced development approaches (‘Quality by Design’) to analytical procedures and how to use the knowledge obtained to support routine use of procedures. Q2(R2)/Q14 will also have the potential to facilitate the selection or identification of development approaches that will reduce the risk incurred by post-approval changes to analytical procedures discussed in ICHQ12: Pharmaceutical product Lifecycle Management. This webinar will explain why these guidelines are being developed as well as highlighting the implications and opportunities.

Learning Outcomes

By the end of this webinar, you will be able to understand:

- How Quality by Design can be applied to Analytical Procedures (“Analytical Quality by Design” or AQbD) and learn about key concepts such as the Analytical Target Profile (ATP)
- What has changed in the revision of ICHQ2(R1) and what opportunities this may provide
- The purpose of ICHQ14 and what this new guideline means for the pharmaceutical industry

To Join the Webinar

Please register for the event by filling out the Registration Form. **The instructions will be shown on the screen when you submit the form**. Further instructions will be sent by an invitation e-mail.

Continuing Education

A certificate of attendance will be issued after the webinar. The session will be an hour of Continuing Education.