



# ICH Q12 Product Lifecycle Management: Open road or dead end?

Graham Cook



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

*Tuesday 18<sup>th</sup> April 2023 at 17.00 CEST (16.00 BST)*

## About the Speaker

Graham Cook recently retired from Pfizer where he led Pfizer's Quality Intelligence and Compliance Information team. He was the chair of the European Federation of Pharmaceutical Industries and Associations (EFPIA) Manufacturing and Quality Expert Group (MQEG) from 2016-2021 and was the EFPIA Topic Lead for ICH Q12 Product Lifecycle Management.

He was appointed to the British Pharmacopoeia Commission between 2010 and 2021 and chairs the Medicinal Chemicals (MC2) Expert Advisory Group and the Analytical Quality by Design Working Party. Between 2012-2018 he was Chairman of the American Society for Testing Materials (ASTM) International E55 Technical Committee developing pharmaceutical manufacturing standards and continues to serve as a member of the E55 Executive Committee. He was a past chair of Pfizer's Quality by Design Council and previous roles include Technical Director supporting Wyeth Europa Manufacturing and External Supply, and Director Formulation Development for Wyeth Consumer Healthcare (Richmond, Virginia, USA). Graham is a pharmacist with a Ph.D. in pharmaceuticals.

## Overview of Webinar

The ICH Q12 Product Lifecycle Management guideline reached step 4 in the ICH process in November 2019 – where are we with the adoption of this guideline? This webinar will explain the context for the development of the guideline, provide an overview of the content, and discuss the opportunities and implications for implementation of Q12 by industry and regulators.

## Learning Outcomes

Webinar attendees will gain understanding of:

1. Why Product Lifecycle Management is a global issue.
2. What kind of a guideline is Q12 – Who is it for? What regulatory tools and enablers are described in it?
3. Some considerations for using Q12.

## To Join the Webinar

Please register by [filling out the Registration Form](#).

**Streaming details of the event will be shown on your screen at the time of your registration.**

## Continuing Education

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