ICH Q8 Pharmaceutical Development Guideline: From regulatory principles to practical experience

8th Sept 2021

Final Programme

This is a foundation course to introduce the ICH Pharmaceutical Development (Q8) guideline.

This ICH-recognised training will be run online because of the limitations caused by the on-going pandemic. The online meeting schedule will be used where the lectures will be either pre-recorded and made available to the delegates online prior to the meeting (via the King's electronic learning platform called KEATS) or given online live during the day. For the pre-recorded lectures, the online-live meeting will focus on the Q&A/discussion session where each speaker will provide a short 10 min summary of their lecture and a 20 min Q&A.

10:00-10:05	*Introduction & Welcome*	**Dr Andrew Chan**
10:05-11.15	*Online Live Presentation* *An introduction to ICH Q8:* *Background ⇨ Overview ⇨ Regulatory Perspective* *Followed by a short Q&A*	**Dr Karin Boon (MHRA) & Dr Mustafa Zaman (MHRA)**
11:15-11:45	*A case study of implementing the ICH Q8 guideline 1: Solid dosage formulation*	**Dr Terry Ernest (GSK)**
11:45-12:15	*A case study of implementing the ICH Q8 guideline 2: Liquid dosage formulation*	**Dr Dave Elder (Consultant)**
12:15-12:45	*A case study of implementing the ICH Q8 guideline 3: Biotech products*	**Dr Ray Nims (MC Pharma)**
12:45-13:30	*Further Q&As*	**Panel**

Dr David Elder

JPAG/Consultant

Dr. Elder has 44 years of service within the pharmaceutical industry, with Sterling, Syntex and 23 years with GSK. He is now an independent CMC consultant and has broad based experience in formulation (including stabilization strategies) and analytical method development.

Dr. Elder obtained his PhD in crystallography from the University of Edinburgh. Dr. Elder is a visiting professor at King's College, London. He is a Fellow of the RSC and chartered chemist and scientist. He is an expert member of the British Pharmacopoeia. He is the immediate past chair of JPAG (Joint Pharmaceutical Analysis Group). He is a member of the Editorial Advisory Board for the Journal of Pharmaceutical Sciences and the European Pharmaceutical Review. He has published 18 book chapters, 160 papers in international journals and has presented 19 webinars and over 182 presentations at national/international symposia. He has 9 patents to his name.

He has co-edited a book on the Analytical Characterisation and Separation of Oligonucleotides and their Impurities (with George Okafo and Mike Webb) and a second on the ICH Quality Guidelines (with Andy Teasdale and Ray Nims).

Dr Karin Boon

Medicines and Healthcare products Regulatory Agency

Karin obtained her Pharmacy degree at the University of Marburg, Germany and subsequently her PhD at the University of Greifswald, Germany. After working as a postdoctoral researcher at the Weatherall Institute of Molecular Medicine in Oxford, UK she joined the Medicines and Healthcare products Regulatory Agency (MHRA) in 2010.

Her current role at the MHRA is as a Leading Senior Pharmaceutical Assessor in a Product Lifecycle Assessment Team within the Licensing Division; she is responsible for evaluating, assessing and providing scientific advice on both UK (national) and European Marketing Authorisation Applications and post-approval variations for anti-infectives, products used in obstetrics and gynaecology and products for treatment of genitourinary conditions. She has a special interest in paediatric formulations on both national and EU level.

Dr Mustafa A. Zaman

Medicines and Healthcare Products Regulatory Agency (MHRA)

Mustafa qualified as a Pharmacist after initially gaining a BPharm (Hons) degree and later a PhD in Drug Delivery – both from King's College London. With over 17 years' experience Mustafa sees success as derived through efficiently interpreting, utilising, advocating and influencing current regulatory frameworks/policy/guidance in combination with developments to existing products and new innovations. Almost 9 of these years have been spent working as a Chemistry Manufacturing and Controls (CMC) Assessor / Reviewer for the UK Medicines & Healthcare Products Regulatory Agency (MHRA).

Mustafa has worked with several international companies including PAREXEL International Consulting (UK), GSK (UK), GENPACT (UK), POLUS Inc. (South Korea) and Scendea Ltd (UK). Mustafa also holds four academic (Honorary) posts at three UK Universities.

Mustafa has experience in leading strategic, technical and/or process issues for a wide range of therapeutic areas and product types, including new chemical entities, generic products, combination products, drug-device combinations and clinical trials applications. Some of his current interests include: Quality-by-Design (QbD), GMP/sterile products, local drug delivery, paediatric medicine, bioequivalence, and Over-The-Counter (OTC) medicine.

Mustafa's current role at the MHRA is as a Senior Pharmaceutical Assessor in a Product Lifecycle Assessment Team within the Licensing Division; he is responsible for evaluating, assessing and providing scientific advice on both UK (national) and European Marketing Authorisation Applications and post-approval variations for Gastro-intestinal, Blood, Nutrition, Pain and OTC Medicines.

Dr Terry Ernest

GSK

Terry Ernest is a senior fellow, director and product development team leader at GSK with a wide range of formulation and process development expertise. Experienced in dosage form design for a variety of dose forms e.g. solid oral, oral liquid, topicals, steriles. Product transfer from R&D to Commercial and between commercial sites. Process and Equipment Validation. Leadership, matrix working and project planning.

Subject matter expert in age appropriate dosage form design with a number of publications and conference presentations.

Specialties: Expertise in modified release technologies, bioenhancement technologies and paediatric dosage form design.

Dr Raymond Nims

RMC Pharmaceutical Solution

Raymond Nims has, since 2009, served as a consultant/subject matter expert to the pharmaceutical industry in the areas of viral testing, viral safety, animal-derived materials risk assessment, and Quality. From 2006 to 2009, Ray was a subject matter expert at Amgen, directing viral and mycoplasma testing of raw materials and products, and was a business process owner for Amgen's global contract analytical testing lab outsourcing program. From 1994 to 2006, Ray was employed by BioReliance, directing viral safety, endotoxin, and cell line identity studies for biologics cell line characterization, raw material testing, and product lot release testing. He currently serves on the editorial board for the BioProcessing Journal, and has served on the ad hoc advisory boards for USP chapters 1237, 1050, and 1050.1. He is a generalist in the biomedical sciences, with a publication list spanning a wide range of areas in chemistry, carcinogenesis, biochemistry, pharmacology, toxicology, and virology.