ICH Q6A Specifications: How to write a successful specification for new chemical drug substances and new chemical drug products

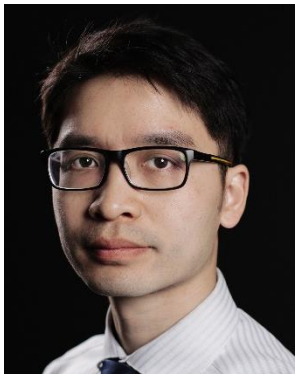
24th Nov 2022

Final Programme

This is a foundation course to introduce the ICH (Q6A) guideline.

This ICH-recognised training will be run online. 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 from the host*	**Dr Andrew Chan (KCL)**
10:05-10:45	*Online Live Presentation* *An introduction to ICH Q6A: Background ⇨ Overview ⇨ Regulatory Perspective*	**Dr Karin Boon (MHRA)**
10:45-11:15	*Online Live Presentation* *ICH Q6A: An introduction to setting specifications for product types (TBC)*	**Dr Mustafa A. Zaman (Granzer Regulatory Consulting & Services GmbH)**
11:15-11:25	*Short - Q&A*	**Panel**
11:25-11:30	*5 min break*	
11:30-12:00	*A case study of implementing the ICH Q6A guideline 1: Solid dosage formulations*	**Dr Terry Ernest (GSK)**
12:00-12:30	*A case study of implementing the ICH Q6A guideline 2: Semi-solids and APIs*	**Dr Dave Elder (Consultant)**
12:30-13:00	*A case study of implementing the ICH Q6A guideline 3: Inhaled and nasal products*	**Mr Mark Parry (Intertek Melbourn)**
13:00-13:05	*5 min break*	
13:05-13:35	*The future of ICH Q6A*	**Dr Matt Popkin** **Dr Cristiana Campa (GSK)**
13:35-14:00	*Further Q&As*	**Panel**



Dr K. L. Andrew Chan

King’s College London

Andrew obtained his MEng (2001) and PhD (2004) in Chemical Engineering at Imperial College London. He then became a research associate in Prof Kazarian's group between 2004 and 2012 including time as an EPSRC Life Science Interface (LSI) fellow between 2006 and 2009. While an EPSRC LSI fellow, he spent 1 year (2007) in Rutgers University, Newark, USA, with Prof Richard Mendelsohn's group as a visiting researcher.

In 2012 and 2018, Andrew respectively acquired the Lectureship and Senior Lectureship in Pharmaceutical Molecular Spectroscopy in the Institute of Pharmaceutical Science at King’s College London. He has been the Director of Postgraduate-Taught MSc course in Pharmaceutical Sciences at KCL since 2019 and has hosted ICH-recognised training since 2021.

In 2014, he joined as a committee member, and has served as the Event Secretary since 2019, in the Joint Pharmaceutical and Analysis Group (JPAG). He is an editorial board member of Scientific Reports. He has published over 90 peer-reviewed research articles and book chapters primarily in the development of novel applications of Fourier Transform Infrared (FTIR) spectroscopy for testing pharmaceutical formulations and biological systems. Some of his current research interests including the application of FTIR spectroscopy and imaging to study live cells-drug interactions and co-amorphous formulation for enhancing the stability and dissolution properties of class II drugs.

Dr Karin Boon

Medicines and Healthcare products Regulatory Agency (MHRA)

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

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 19 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 10 of these years have been spent working for the UK Medicines and Healthcare products Regulatory Agency (MHRA). Mustafa's role at the MHRA was a Senior Pharmaceutical Assessor for Healthcare Quality and Access (HQA) where he was responsible for evaluating, assessing and providing scientific advice on both UK (national) and European Marketing Authorisation Applications and post-approval variations for Pain, Gastrointestinal, Nutrition, Musculoskeletal, Obstetrics & Gynaecology Medicines.

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), Analytical QbD, GMP/sterile products, local drug delivery, paediatric medicine, bioequivalence, and Over-The-Counter (OTC) medicine.

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 David Elder

JPAG/Consultant

Dr. Elder has 45 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).

Mark Parry

Intertek Melbourn

Mark Parry has worked with Intertek Melbourn for 20 years after graduating from Cambridge University and currently works as the Technical Director supporting the wide range of analytical, formulation and product development activities across the company.

Mark has worked in a range of pharmaceutical analysis and formulation development areas with a particular focus on inhaled and nasal drug products. Mostly working in the pre-approval stages, Mark's background includes extensive experience with product and formulation development, as well as method development and validation, stability studies, and pharmaceutical development activities for a wide range of clients across the pharmaceutical industry.

Dr Matthew Popkin

GSK

Dr Popkin is a Senior Director, CMC Excellence at GSK.

He works at the interface of Product Development and Supply, manufacturing & CMC regulatory. He helps develop CMC strategy for GSK products, with a focus on Quality by Design (QbD).

He is formally a manager and project leader in GSK Product Development, based in the UK.

Specialties: Chemistry, inhaled dose forms, oral dose forms, Design Space, CPV, process validation, CMC regulatory, pharmaceuticals, QbD, delivery, ICH, English, French, Italian, cGMP, leadership, manufacturing, pharmaceutical development, chemical engineering, management, materials management, process engineering, project management, publicity, quality, safety, scientific, team management, technical training and technical transfer.