Programme

09.30 - 09.55 Coffee and Registration

09.55 - 10.00 Welcome
10.00 - 10.30 British Pharmacopoeia Update and a Radiopharmaceuticals Opportunity (Steve Hoare, MHRA)
10.30 - 11.00 ICH M4Q(R2): Evolution or Revolution? (Marine Joly-Battaglini, PharmDev Consulting)
11.00 - 11.30 Round up of ICH Quality Guidance Updates (Lisa Hinchliffe, LangAllan CMC Regulatory Solutions Ltd)
11.30 - 12.00 The USP and Our Strategy: Commitment to 2030 (Christian Zeine, USP)
12.00 - 12.30 IPQ round up of Global Regulatory Topics (Janine Jamieson, IPQ)

12.30 - 13.30 Lunch

13.30 - 14.00 Revisiting SUPAC: FDA's Approach to Modernising Post-Approval Change (Paul Dickinson, SEDA)
14.00 - 14.30 Combination Products as a Cross-Functional Hot Topic: Evolution, Current Realities and Future Considerations for Drug Development Teams (Abha Raveau-Violette, Combination Products and Medical Devices Ltd)
14.30 - 15.00 Regulatory and Analytical Aspects of the Global Helium Crisis (Stuart Williams, Dove Analytics)

15.00 - 15.30 Coffee

15.30 - 16.00 Point of Care Manufacture (James Rickard, Richmond Research Institute)
16.00 - 16.30 Strengthening UK Regulatory Science: Outcomes and Lessons from the CERSI Phase I Programme (Walkiria Schlindwein, CERSI, De Montfort University, Leicester)
16.30 - 17.00 Enabling regulated pharmaceutical manufacturing in space (Matt Heath, MHRA)

17.00 Drinks reception

Abstracts

Dr Paul Dickinson - Founder and Chief Scientist, Seda Pharmaceutical Development Services

FDA's Scale-Up and Post-Approval Changes (SUPAC) guidances have provided a risk-based framework for evaluating manufacturing, formulation, scale and site changes for almost 30 years. In March 2026, FDA opened a public docket seeking information on their continued utility and suggestions for potential revision. FDA recognised that, while the core principles remain relevant, pharmaceutical science, manufacturing technologies and approaches to quality risk management and lifecycle management have evolved considerably. This presentation will review the scope and origins of SUPAC, the specific questions raised by FDA and the principal themes emerging from stakeholder responses. These include potential consolidation of the guidances, clearer classification of changes, broader product coverage and improved alignment with ICH Q9(R1) and ICH Q12. The presentation will also briefly consider how related FDA thinking on the Biopharmaceutics Risk Assessment Framework may inform the evaluation of product changes and their potential relevance to clinical performance.

Dr Matt Heath - Innovation Specialist, MHRA

Commercial access to orbit and increasingly capable automated platforms is creating new opportunities to explore pharmaceutical manufacturing in microgravity. Potential applications span drug discovery, product development and manufacturing, including improved formulations, protein crystallisation, cell and tissue-based technologies, and other advanced therapies. This presentation will explore how the UK is preparing for this emerging field through early engagement between regulators, government, and industry. It will draw on a use case of protein crystallisation, including progress in the testing of an automated and potentially scalable approach, while highlighting the value of proportionate, evidence-led regulatory engagement while the technology and market continue to mature. It will consider the further proof-of-concept evidence, regulatory clarity and targeted collaboration needed to support responsible development, alongside joint work by MHRA and the UK Space Agency.

Steve Hoare - Standards & Regulatory Governance, MHRA

In addition to providing an update on the latest developments with the British Pharmacopoeia, the session will showcase the support that MHRA is providing to raise the profile of Radiochemical expertise in the UK

Marine Joly Battaglini - PharmDev Consulting

After more than 20 years of use, the Common Technical Document (CTD) is undergoing a major update with ICH M4Q(R2). While the revision aims to modernize the presentation of quality information and support greater global harmonization, its impact extends far beyond dossier structure.

From an industry perspective, ICH M4Q(R2) presents opportunities to improve the clarity, consistency, and lifecycle management of quality submissions, while also raising practical implementation challenges for dossier authors, CMC teams, and regulatory organizations. This presentation will explore the key changes introduced by the guideline, discuss their anticipated impact on pharmaceutical companies, and highlight how industry can prepare for the transition. The key question for the industry is no longer whether M4Q(R2) will change

the CTD, but whether it will fundamentally change how quality dossiers are created, maintained, and assessed.

Abha Raveau-violette - Combination Products and Medical Devices Ltd

Combination products are an increasingly important hot topic for drug development teams, requiring early alignment across medicinal product, device, quality, regulatory, clinical and commercial considerations.

This presentation will explore their evolution, current development and regulatory realities, and future considerations as products, technologies and expectations continue to evolve. It will highlight key regulatory and technical elements, including the medicinal product/device interface, design controls, risk management, CMC and quality considerations, submission strategy and lifecycle management.

The session will also discuss why successful combination product development depends on strong cross-functional relationships, clear ownership and effective collaboration to support patient-centred and regulator-ready strategies.

James Rickard - Chief Scientific Officer, Richmond Research Institute

Point of Care Manufacture – a case study in the real world for delivery of a POCM product in clinical trials. Where legislation is providing a framework other products reach patients for better outcomes.

Prof Walkiria Schlindwein - De Montfort University, Leicester

This presentation provides an overview of the emerging outcomes of the CERSI Phase I programme, with a focus on the Digital CMC CERSI. It highlights collaboration, knowledge exchange and the development of regulatory science capability. Key outputs include an industry survey, a computational model assessment framework, pharmaceutical case studies, and supporting training and digital resources. The presentation considers how these outputs can support more consistent regulatory assessment of innovative technologies, alongside lessons and opportunities for future collaboration across the CERSI network.

Dr Stuart Williams - Dove Analytics

The pharmacopoeial and regulatory landscape needs to adapt to a rapidly changing situation with global helium supply and prices that will continue to escalate almost exponentially over the next one or two decades making the continued use of helium untenable. We need to remove ourselves from the dependency on helium for analytical work that can be replaced with other gases with no loss of testing quality. The HA’s and Pharmacopoeia need to facilitate this change with minimal effort and disruption since the amount of work to remediate all registrations world-wide for residual solvents would be a paralysing activity for both the industry and the regulators. A pragmatic approach is required, and this presentation will discuss the global supply chain and forecasts, the current regulatory status, the practical impact in the lab and a proposed way forward.

Dr Christian Zeine - Scientific Affairs EMEA, USP

Following a short introduction to USP from its beginnings in 1820, the contribution describes USP’s strategic vision for 2030 and its response to changes in the global pharmaceutical environment. USP’s commitments focus on expanding access to quality medicines and biologics, addressing quality challenges, strengthening supply-chain resilience, advancing digital technologies and supporting sustainability. It also showcases the USP Small Molecules Pipeline, a public platform that improves transparency and enables stakeholders to follow and contribute to monograph development, emerging standards, Pharmacopeial

Forum proposals, published standards, and reference-material releases.

Speaker biographical details



Dr Paul Dickinson - Founder and Chief Scientist, Seda Pharmaceutical Development Services

Dr Paul A. Dickinson, BPharm (Hons), PhD, is Founder and Chief Scientist of Seda Pharmaceutical Development Services. A pharmaceutical scientist specialising in biopharmaceutics and clinical pharmacology, his work centres on translating drug product performance into clinically meaningful outcomes and regulatory strategy. He has extensive experience applying biopharmaceutic principles, dissolution science, clinical pharmacology and CMC knowledge across all stages of drug development, supporting programmes from early development through to regulatory approval. Paul has contributed to the successful approval of multiple medicinal products and regularly supports interactions with global regulatory authorities. He has also played a central role in the growth of Seda, helping develop an integrated scientific organisation that combines biopharmaceutics, clinical pharmacology and CMC expertise to support efficient, science-led pharmaceutical development.



Dr Matt Heath - Innovation Specialist, MHRA

Matt Heath is a Non-Clinical Innovation Specialist at the MHRA, providing scientific and regulatory expertise in the development of innovative products and supporting innovative regulatory pathways. He has 20 years' experience in R&D and drug development, including progressing assets from proof of concept through clinical development and commercialisation. He has authored more than 40 scientific publications and is a co-inventor of multiple patents.



Steve Hoare - Standards & Regulatory Governance, MHRA

Steve Hoare is Head of Standards and Regulatory Governance at the Medicines and Healthcare products Regulatory Agency (MHRA) and is supporting the Agency's Partnerships Group in the development of its Sustainability Policy. Steve is the Scientific Director and Secretary for the British Pharmacopoeia, which sets the minimum standards for Quality for medicines marketed in the UK (and recognised in over 100 countries). An analytical chemist by training, and Fellow of the Royal Society of Chemistry, Steve has a background in Quality roles in the pharmaceutical industry, and formerly policy director for a biopharmaceutical trade association, leading on both regulation and sustainability. Steve is active in the development of international approaches to sustainability in standards setting



Dr Janine Jamieson - IPQ

After 18 years as a Pharmaceutical Assessor in the Licensing Division of MHRA assessing variations and medical devices incorporating ancillary medicinal substances, Janine joined IPQ, International Pharmaceutical Quality, in 2016 at the same time as relocating to Sweden. She is a member of TOPRA and enjoys promoting Quality topics at their Regulatory Intelligence and Combination Product Special Interest Networks. Janine's main focus at IPQ is on the interface between drug and device regulation and she enjoys sharing the valuable regulatory intelligence from conferences globally arranged by membership-based organizations with the ultimate aim of helping towards regulatory strengthening and convergence. She also enjoys visiting the beautiful cities and art galleries where the conferences are held and looks forward to new travels!



Marine Joly Battaglini - PharmDev Consulting
Marine is a pharmacist by training with about 15 years of experience in the pharmaceutical industry, holding different positions in CMC development and commercialization of new drugs. Her experience includes projects spanning from chemically synthesized products with oral and topical routes of administration (liquid and semisolid dosage forms) and parenteral products, including monoclonal antibodies.

Marine has been responsible for regulatory submissions to the US FDA, EMA, and Health Canada, as well as other regulatory agencies in Asia, Middle East, and the LATAM region. Marine has also developed expertise in the creation and revision of monographs for the European and United States Pharmacopeias.



Abha Raveau-violette - Combination Products and Medical Devices Ltd
Abha Raveau-Violette is the Founder and Principal Consultant at CPMD Consulting Ltd., a specialist consultancy focused on combination products and medical devices. She has over 17 years' experience across pharmaceutical and medical device organisations, with expertise spanning regulatory strategy , device development and lifecycle management.
Abha has held senior leadership roles in combination products and medical devices, including at AstraZeneca, Sandoz, Teva and B. Braun. She supports companies in navigating the complex interface between medicinal product and device requirements across the US, EU, UK and other global markets, with a particular focus on translating regulatory expectations into practical development and lifecycle strategies.



James Rickard - Chief Scientific Officer, Richmond Research Institute
James Rickard is Chief Scientific Officer of Richmond Research Institute (RRI), where he leads research that advances the science of clinical trials through collaborative programmes spanning multiple therapeutic areas. He is responsible for shaping the Institute's scientific strategy, fostering academic and industry partnerships, and driving research that improves the design, delivery and impact of clinical studies.

James brings more than 20 years of experience across hospital pharmacy, clinical research, biotechnology and academia. He began his career in NHS hospital pharmacy, progressing through large London teaching hospitals before becoming Deputy Chief Pharmacist at Barts Health NHS Trust, where he led pharmacy manufacturing and research and development services across five sites, managing more than 100 staff. Throughout his career, he has supported over 400 clinical trials, with several translational project now in pivotal studies.

He later joined a biotechnology start-up as Chief Scientific Officer, leading the development of regenerative cell therapies and pioneering manufacturing technologies. During this time, he played a key role in translating scientific innovation into commercial value and contributed to changes in UK medicines legislation to support emerging advanced therapies.

Alongside his role at Richmond, James is a Senior Visiting Lecturer in Pharmaceutics at King's College London and serves as a Senior and Expert Advisor to the Department of Health and Social Care through his position on the British Pharmacopoeia Commission.

James is passionate about advancing clinical research to address unmet patient need and developing innovative approaches that improve how treatment success is measured, helping to deliver better outcomes for patients.



Prof Walkiria Schlindwein - De Montfort University, Leicester
Professor Walkiria Schlindwein is an educator and researcher at De Montfort University’s Leicester School of Pharmacy, specialising in pharmaceutical development and Quality by Design (QbD). She trained as a chemical engineer in Brazil before earning a PhD in Chemistry from the University of Leicester and a DSc from the Federal University of Rio de Janeiro. Her research connects polymer science, hot-melt extrusion and QbD to advance the design and manufacture of medicines. She established DMU’s pioneering MSc in Pharmaceutical Quality by Design and works closely with international industry partners and regulators. She also serves on the CMAC Advisory Board and leads a work package within the Digital CMC Centre of Excellence in Regulatory Science and Innovation (CERSI), a UK government-funded programme led by the University of Strathclyde.



Dr Stuart Williams - Dove Analytics
Independent consultant for method design and validation, OOS investigations, and analytical problems with a Doctorate in Organic Synthesis from Bristol and a postdoc in Environmental Analytical at the University of Queensland in Australia.
Worked in a variety of industries, including the mineral industry, ecotoxicology, petroleum and pharmaceuticals and API manufacturing analytics where he is the ex-Analytical Science and Technology Head at the Novartis UK manufacturing site in Grimsby. His special scientific interests are in HPLC, GC and MS methods with his most notable analytical publication being a review of "Ghost Peaks in Gradient HPLC" published in the Journal of Chromatography in 2004.



Dr Christian Zeine - Scientific Affairs EMEA, USP
Christian Zeine joined USP in 2019 as Senior Manager in the Scientific Affairs Group for the EMEA region, with a focus on Small Molecules, USP's General Chapters and Impurities. In his job, he collaborates with scientific experts and stakeholders and is responsible for protecting and growing USP's scientific reputation in the region and globally. Before joining USP, Christian worked for seventeen years in the field of pharmaceutical reference standards with a focus on impurities, and before that in the IVD (In Vitro Diagnostic) industry. His scientific expertise includes impurity testing, reference standards characterization and adjacent fields. Christian has published several articles and white papers on topics such as impurities, overview of (certified) reference materials and the use of reference standards in method development and validation.
He earned his Ph.D. degree in Organosilicon Chemistry from the University of Muenster, Germany.

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