CRED: Medical Product Regulation in the United Kingdom

Part 1: Medicinal Product Regulation in the United Kingdom

22 July 2025, London and Online

Time	Session	Speaker
09:15	**Registration**	
09:25	**Welcome from TOPRA**	
09:30	**Introductions – presenters and delegates**	**Marc Bailey**, *Cambridge Scientifix Ltd*
09:40	**Background and Overview of Medicines Regulation in the UK** **History** • Including actions prompted by medical tragedies, pre-Brexit role and work sharing in EU **Structure of the Agency** • What the Agency regulates, its responsibilities and functions (incl. R&D) • Key partners and advisory bodies within the UK, governance • Global collaboration and partnering arrangements (e.g. WHO, IMCRA, IMDRF, ICH, IPRP)	**Marc Bailey**, *Cambridge Scientifix Ltd*
10:00	**MHRA as Sovereign Regulator** • Challenges and Opportunities for a standalone regulator ○ What needs to change (Clinical and MD regulation, vs what can remain aligned with EU regulatory precedence, the NI Agreement) • The MHRA Today (Corporate Plan and People Strategy) • MHRA Interfaces (Submission Portal) and the planned-for Regulatory Connect	
10:30	**Small Populations** • Rare diseases and Orphan Drugs • Paediatrics	**Daniel O'Connor**, *ABPI*
11:00	**Tea and Coffee – 1st Break**	
11:15	**Clinical Trials in the UK** • Anticipated changes to the GB/UK regulation • Combined review procedure with the HRA • How commercial clinical studies are set up and managed within the NHS network	

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12:15	**Lunch**	
13:15	**The GB Marketing Authorisation Application Dossier** • Particulars of Module 1 • Labelling	
13:30	**Marketing Authorization Pathways** • Legal bases, and routes: 150-day national assessments, rolling reviews, unfettered access procedure, international partnerships (Orbis, ACCESS). • The International Recognition Procedure, UK-wide regulation under the Windsor Framework from Jan 2025	
13:50	**Early Access Procedure** • Regulatory flexibilities for ATMPs and gene therapy products	**Rehma Chandaria** *Catapult Cell and Gene Therapy*
14:10	**ABPI Code of Practice**	
14:30	**Tea and Coffee – 2nd Break**	
14:40	**Medicine-Medical Device Combination Companion Diagnostics**	
15:10	Post-Authorisation Activities • Lifecycle considerations • Post-authorisation commitments and real-world data (RWD) • Variation procedures • Reclassification	**Daniel O'Connor**, *ABPI*
15:30	**Product Safety (Pharmacovigilance)** • PV requirements, RMP, Yellow card, PSUR	**Marc Bailey**, *Cambridge Scientifix Ltd*
16:00	**Consolidation** • Panel Discussion and Q&A	**All Available Speakers**
16:30	**Close**	

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