LIFE SCIENCES FUTURE FORUM FULL DAY BOOTCAMP

Thursday 20 June 2024
9.30 AM–5.15 PM BST

Complimentary regulatory training day for junior lawyers and new joiners on the EU and UK regulatory framework for medicinal products

Time	Seminar	Speaker
9.00 AM	**Coffee and Registration**	
9.30	Welcome	Eleri Williams Chris Bates
9.40 – 10.30	Overview of the UK and EU pharmaceutical legal framework ▪ What is a medicinal product ▪ Life cycle of a medicinal product ▪ Overview of the regulatory framework and EU pharma strategy ▪ The main institutions in the UK and EU ▪ The position in the UK post-Brexit	Alexander Roussanov Anna Pothof Eleri Williams
10.30 – 11.20	**Pre-authorisation** Clinical trials ▪ Current EU framework and key terminology ▪ Clinical trials in the UK post-Brexit ▪ Overview of liabilities	Adela Williams Ana González- Lamuño
11.20 – 11.40	**Coffee Break**	
11.40 – 12.30	Obtaining a Marketing Authorisation ▪ General principles ▪ EU procedures ▪ UK procedures post-Brexit ▪ Legal bases for authorization ▪ Exemptions to requirement for marketing authorisation	Chris Bates Eftychia Sideri Sofia Holmquist
12.30 – 1.15	**Post-authorisation** Pharmacovigilance ▪ Definition and legal framework ▪ Pharmacovigilance Activities (focused primarily on MAH) Pharmacovigilance in the UK post-Brexit	Alexander Roussanov

1.15 – 2.00	**Lunch**	
2.00 – 2.40	Incentives and Rewards: Regulatory and IP ▪ Patent exclusivity ▪ Regulatory data protection and marketing protection ▪ Global marketing authorisation, new active substances ▪ Orphan medicines and marketing exclusivity ▪ Supplementary Protection Certificates (SPCs) ▪ Paediatric research and rewards	Jackie Mulryne Beatriz San Martin
2.40 – 3.10	Supply chains and parallel trade ▪ Import, manufacture and distribution of active substances ▪ Manufacture and importation of finished products ▪ Wholesale distribution of finished products ▪ Brokering ▪ Parallel trade	Eftychia Sideri Zahrah Kazim
3.10 – 3.30	Regulation on Substances of Human Origin (SoHO) ▪ Overview of new requirements	Jackie Mulryne Eleri Williams
3.30 – 3.50	**Afternoon Break**	
3.50 – 4.30	Promotion and Advertising ▪ EU and UK Legislative & self-regulatory frameworks ▪ Definition of advertising ▪ Permitted activity prior to grant of MA ▪ Interactions with HCPs after grant of MA ▪ Employee use of social media	Libby Amos-Stone Katya Farkas
4.30 – 5.15	Pricing and reimbursement in the UK ▪ The Voluntary Scheme and the Statutory Scheme ▪ Drug Tariff ▪ Health technology assessments (NICE) ▪ Public procurement	Adela Williams Chris Bates
5.15	**Drinks, Canapés and Networking**	