Programme For 1-Day Pharmaceutical Legislation & Guidance Update Course

Note: Programme for This Day Will Be Revised in Early 2022 to Accommodate Recently Changed and Proposed Revisions to Legislation and Guidance Impacting Medicines.

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Time	Session No. 12 May 2022	Content
08.30 – 09.00		Registration and Welcome Coffee
09.00 – 09.10	1	Welcome and Objectives
09.10 – 10.00	2	Changes to EU Legislation and Guidance: • The CT Regulation 536/2014 ○ Associated GMP legislative changes • Veterinary Medicines Regulation 2019/6 • Medical Devices Regulation 2017/745 impact on Combination Products • EMA Reflection Paper on GMP and MA Holders • Nitrosamine Impurity Guidelines • Water Quality Guideline
10.00 – 10.20		***Refreshment Break***
10.20 – 11.00	3	Changes to EU GMP • Implementation of HBELs • Revision of Annexes 1 and 13 • New Annex 21 • ATMPS: Q&A on GMP For The Manufacturing Of Starting Materials Of Biological Origin
11.00 – 11.45	4	The impacts of 'Brexit' on medicinal product movement between EEA and U.K.
11.45 – 12.30	5	Data Integrity: strategy for compliance
12.30 – 13.30		***Lunch Break***
13.30 – 14.15	5a &b	Teamwork: Data Integrity Exercise

14.15 – 15.00		ICH Changes
		• ICH organisation and current membership
		• New and developing guidelines
		  ○ Q12, 13 and 14
		  ○ Revision of Q2, and 9

15.00 -15.15		***Refreshment Break***
15.15 – 16.00	7	Changes to USA Legislation and Guidance • FDA Organisation • Nitrosamine guidance • New Final and Draft Guidance for Industry
16.00		Conclusion and Close