Pharmaceutical Legislation and Guidance update

NFS, Oslo, Thursday 21 May 2024

Time	Session No.	Content
08:30 – 09:00		Registration and Welcome
09.00 – 09.10	1	Introduction and Objectives
09.10 – 09.45	2	Global changes: • Artificial Intelligence (AI) • Decentralised Manufacturing
09.45 – 10.30	2	Changes to EU Legislation and Guidance: • New Human commercial medicines Directive and Regulation • Veterinary medicines GMP legislation • New Variations guideline • Propose legislation for Biotech and Critical medicines • Regulation 2025/40 for Packaging
10.15 – 10.30		*Refreshment Break*
10.30 – 11.30	3	Changes to EU GMP Guidance • Titanium Dioxide (TiO_2) in Medicinal Products • European Pharmacopoeia changes • Revision of GMP Chapters 1 and 4 • Revision of GMP Annexes 3, 4, 5 11 & 15 • EFPIA foreign inspections survey
11.30 -12.30		*Lunch*
12.30 – 13.00		EU/EEA – UK Supply Chains
13.00 – 13.45		ICH and other International Changes • ICH organisation; new members and observers • Recent draft and final guidance: M4Q(R2), M7, Q1/Q5C, Q3E, • Other recent publications from PIC/S, WHO, ICMRA, IPEC, etc. New African Medicines Agency
13.45 – 14.30	6	Changes to USA Legislation and Guidance • FDA management changes • OPQ State of Pharmaceutical Quality report • QMM update • Benzene contamination • New Final and Draft Guidance for Industry

Time	**Session No.**	**Content**
14.30 – 14.45		*Break*
14.45 – 15.30	7	Quality Culture and its Impact on the PQS
15.30 – 16.00	8	Teamwork: Are we ready for these changes?
16.00		Final questions, Conclusion and Close