

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 – 10.15	2	Changes to EU Legislation and Guidance: • EU legislation for human commercial medicines • Propose legislation for Biotech and Critical medicines • Veterinary GMP • Regulation 2025/40 for Packaging
10.15 – 10.30		<i>Refreshment Break</i>
10.30 – 11.30	3	Changes to EU Guidance • Titanium Dioxide (TiO₂) in Medicinal Products • European Pharmacopoeia changes • Revision of GMP Chapters 1 and 4 • Revision of GMP Annexes 4, 5 & 11
11.30 -12.30		<i>Lunch</i>
12.30 – 13.15		Norwegian Health Authority (NOMA) update
13.15 – 13.45		EU/EEA – UK Supply Chains post 'Windsor Framework'
13.45 – 14.30	6	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. • EFPIA foreign inspections survey • New African Medicines Agency
14.30 – 14.45		<i>Break</i>

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14.45 – 15.30	7	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management changes • OPQ State of Pharmaceutical Quality report • QMM update • Benzene contamination • New Final and Draft Guidance for Industry
15.30 – 16.00	8	Teamwork: Are we ready for these changes?
16.00		Final questions, Conclusion and Close