**Pharmaceutical Legislation and Guidance update**

**NFS, Oslo, 24 May 2024**

| **Time** | **Session No.** | **Content** |
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| 08:30 – 09:00 |  | Registration and Welcome |
| 09.00 – 09.10 | 1 | Introduction and Objectives |
| 09.10 – 10.10 | 2 | Changes to EU Legislation and Guidance:   * EU strategy for Human Medicines   + Proposed new Directive and Regulation * Propose legislation for Packaging and SoHO * EMA role in managing shortages * Ph.Eur. recent changes * EMA Reflection Paper on AI |
| *10.10 – 10.30* |  | *Refreshment Break* |
| 10.30 – 11.00 | 3 | Changes to EU GMP Guidance   * Remote QP Certification * Nitrosamine Impurities guidance * Titanium Dioxide in medicines * Proposed ban on PFAS * Revision of GMP Annexes 4, 5 & 11 * EFPIA foreign inspections survey |
| 11.00 – 11.30 | 4 | Impact of Brexit on medicines moving between EEA and UK   * The post-Brexit trade agreement * The difference between Northern Ireland and Great Britain   + The ‘Windsor Framework’ * New and revised UK legislation and guidance * Exporting medicines from UK to EEA * Importing medicines from the EEA into the UK |
| 11.30 -12.15 |  | Norwegian Health Authority (NOMA) update by Renana Rabe |
| *12.15 – 13.15* |  | *Lunch* |
| 13.15 – 14.00 | 6 | ICH and other International Changes   * ICH organisation; new members and observers * Recent final guidance: M7(R2), Q2(R2), Q9(R1), Q13 and Q14 * Revision of Q1/Q5C, Q5(R2) and new Q3E * Other recent publications from PIC/S, WHO, ICMRA, IPEC, etc. * New African Medicines Agency |
| 14.00 – 14:45 | 7 | Changes to USA Legislation and Guidance   * OPQ State of Pharma. Quality annual report * QMM * New FDA consultations; AI, point-of-care manufacturing and NDSRI AI limits * Measures to address drug shortages * New Final and Draft Guidance for Industry |
| *14.45 – 15:00* |  | *Break* |
| 15.00 – 15:45 | 8 | Teamwork: Are we ready for these changes? |
| 15:45 – 16.00 |  | Final questions, Conclusion and Close |