**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
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| *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
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| 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
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| 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
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| 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* New Final and Draft Guidance for Industry
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| *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 |