Pharmaceutical Law and Guidance

Norsk Farmasøytisk Selskap, Oslo, Norway

PROGRAMME

Monday

08.30 – 09.00	Registration
09.00 – 09.10	Session 1: Welcome and Objectives
09.10 – 09.30	Session 2: Teamwork 1: What do we want Medicines to do?
09.30 – 10.10	Session 3: Introduction to Medicines Law
10.10 – 10.30	***Refreshment Break***
10.30 – 11.15	Session 4: EU Law – An Overview
11.15 – 12.00	Session 5: Marketing Authorisations and Dossiers: EU and USA
12.00 – 13.00	***Lunch***
13.00 – 13.30	Session 6: Teamwork 2: Role and Activities of the EMA
13.30 – 14.00	Session 7: Regulatory Framework for Investigational Medicinal Products (IMPs) EU and USA
14.00 – 14.30	Session 8: Post Approval Changes and Variations
14.30 – 15.00	Session 8a: Teamwork 3: EU MA Variations
15.00 – 15.15	***Refreshment Break***
15.15 – 15.45	Session 8b: Teamwork 3: EU MA Variations; Feedback
15.45 – 16.15	Session 9: Manufacturing and Wholesale Dealers Authorisations
16.15 – 17.00	Session 10: Teamwork 4: EU GDP Guidelines

Tuesday

08.30 – 09.00	Feedback – Key Learning Points from Day1
09.00 – 10.00	Session 11: The Role of the Qualified Person (QP): The Revised Annex 16
10.00 – 10.15	***Refreshment Break***
10.15 – 11.15	Session 12: Teamwork 5: Qualified Person Scenarios
11.15 – 12.15	Session 13: Regulatory Control of Starting Materials
12.15 – 13.15	***Lunch***
13.15 – 14.00	Session 14: Teamwork 6: API QP Declaration Scenarios
14.00 – 14.45	Session 15: International Council for Harmonisation (ICH) – Organisation, Role and Recent Quality Guidance
14.45 – 15.00	***Refreshment Break***
15.00 – 15.30	Session 16: Teamwork 7: Complaint Scenario
15.30 – 16.00	Session 17: Recalls – EU and US Laws
16.00 – 16.30	Session 18: Teamwork 8: Product Recalls
16.30 – 17.00	Session 19: Mutual Recognition Agreements of Inspection

Wednesday

08.30 – 09.00	Feedback – Key Learnings from Day 2
09.00 – 10.00	Session 20: Data Integrity
10.00 – 10.15	***Refreshment Break***
10.15 – 11.00	Session 21: Teamwork 9: Data Integrity Scenarios
11.00 – 11.45	Session 22: Medical Devices Regulation 2017/745
11.45 – 12.00	Session 23: Q&A and Close of NSF
12.00 – 13.00	***Lunch***
13:00 – 17.00	Norwegian Medicines Agency briefing