Pharmaceutical Legislation Update

Norsk Farmasøytisk Selskap, Oslo, Norway

PROGRAMME

Thursday 31 May 2018

08.30 – 09.00	Course Registration
09.00 – 09.10	Session 1: Welcome and Objectives
09.10 – 10.00	Session 2: Changes to EU Legislation and Guidance: • The CT Regulation 536/2014 • GMP Legislative Changes • Medical Devices Regulation • EU-USA MRA • Brexit impact
10.00 – 10.20	***Refreshment Break***
10.20 – 11.00	Session 3: Changes to EU GMP • Revision of Annexes 1 & 17 • New Annex 21
11.00 – 11.45	Session 4: Pack 'Safety Features'; Serialisation and Tracing
11.45 – 12.45	***Lunch***
12.45 – 13.30	Session 5: Data Integrity: • EMA, FDA, MHRA, PIC/S and WHO Guidance
13.30 – 14.15	Session 5a & b: Teamwork: ALCOA Exercise
14.15 – 15.00	Session 6: ICH Changes • ICH re-organisation • ICH Q3D • ICH Q12
15.00 – 15.15	***Refreshment Break***

15.15 – 16.00	Session 7: Changes to USA Legislation and Guidance
	• PAG Initiative
	• New Final and Draft Guidance for Industry
	  ○ Combination Products
	  ○ Quality Agreements
	  ○ Quality Metrics

16.00	Conclusion and Close