THE NORWEGIAN QP-COURSE 2012

20 – 22 November 2012

Draft Programme V1 as at 29 August 2012
med forbehold om endringer

20 November 2012		
Time		**Programme**
08.30 - 09.00		Registration and Coffee
09.00 - 09.30		Introduction and Objectives
09.30 - 10.15	Lecture 1	EU Law - An Overview
10.15 - 10.30		Refreshment Break
10.30 - 11.00	Groupwork 1	What do We Know?
11.00 - 11.30	Lecture 2	GMP Legislation in EU and USA
11.30 - 12.00	Groupwork 2	The EU GMP Directives - Discussions
12.00 - 13.00		Lunch
13.00 - 13.30	Groupwork 2 cont	The EU GMP Directives - Feedback
13.30 - 13.45	Introduction to Groupwork 3	Clinical Manufacture and Packaging: An Overview
13.45 - 14.15	Groupwork 3	What are the Key Differences between Commercial and Clinical Operations?
14.15 - 14.30		Refreshment Break
14.30 - 15.00	Lecture 3	Key Considerations for the Clinical QP
15.00 - 15.45	Lecture 4	The Qualified Person - Code of Practice (Including clarification of QP Role vs. QA, QC, Production and Senior Management)
15.45 - 17.00	Groupwork 4	QP Scenarios (QP Code of Practice and QP Role vs Management)
21 November 2012		
09.00 - 09.45	Lecture 5	The Batch Manufacturing Record
09.45 - 10.30	Lecture 6	Batch Certification – What Gives a QP Confidence?
10.30 - 11.15	Groupwork 5	Batch release Scenarios (including refreshments)
11.15 - 12.00	Groupwork 6	QP Scenarios: To Release or Not
12.00 - 13.00		Lunch
13.00 - 13.20	Lecture 7	A review of 2011 recalls in the EU and US (including Recall Laws)
13.20 - 14.20	Groupwork 7	Complaint Scenario

14.20 - 14.35		Refreshment Break
14.35 - 15.00	Lecture 9	Counterfeits – a growing threat!
15.00 - 15.30	Lecture 10	Inspections and Inspectorates
15.30 - 16.15	Groupwork 8	Inspection Priorities
16.15 - 17.00	Lecture 11	Quality Management Systems: Overview (incl.. a short overview of ISO 9001:2008)
22nd November 2012		
09.00 - 09.30	Lecture 12	Management of Electronic Documents
09.30 - 10.00	Groupwork 9	What Must improve? Our Top Three
10.00 - 11.00	Lecture 13	Risk-Based Decision Making: Practical Application of Risk Assessment (*to include refreshment break at a suitable point)*
11.00 - 11.45	Groupwork 10	Risk-Based Decision Making Scenarios
11.45 - 12.00	Lecture 14	What benefit Does the QP Bring or Should Bring, and How does the QP Keep up to Date?
12.00 - 13.00		Lunch break

NOMA Module - (13.00 to 16.00 on Thursday 22 November)

13.00 - 13.45	Lecture 15	NOMA; Norwegian Regulations-QPs + the New Paradigm for the Regulation of Pharmaceuticals and the QP
13.45 - 14.15	Lecture 16	Norwegian Recalls
14.15 - 14.30		Refreshment Break
14.30 - 15.15	Lecture 17	NOMA: Good Distribution Practice and Cold Chain Management
15.15 - 15.45		Panel Discussion (Q & As)
15.45 - 16.00		Course Close