**APPENDIX 2**

**The Norwegian QP Course**

**13 – 15 May 2013**

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| **Tuesday 13 May 2014** |
| 08.30 – 09.00 | Registration and Refreshments |
| 09.00 – 09.30 | Session 1 | Introduction and Objectives |
| 09.30 –10.15 | Session 2: | Lecture 1: EU-Law - An Overview(Including Supply Chain Legislation) |
| 10.15 – 10.30 | *Refreshment Break* |
| 10.30 –10.45 | Session 3:  | Groupwork 1: What Do We Know? |
| 10.45 – 11.30 | Session 4:  | Lecture 2: GMP Legislation in EU and USA |
| 11.30 – 12.00 | Session 5:  | Groupwork 2: The EU GMP Directives Discussions |
| 12.00 – 13.00 | *Lunch* |
| 13.00 – 13.30 | Session 5 cont:  | Groupwork 2: The EU GMP Directives - Feedback |
| 13.30 – 13.45 | Session 6:  | Introduction to Session 7: Clinical Manufacture and PackagingAn Overview |
| 13.45 – 14.15 | Session 7:  | Groupwork 3: What are the Key Differences between Commercial and Clinical Operations? |
| 14.15 – 14.30 | *Refreshment Break* |
| 14.30 –15.00 | Session 8:  | Lecture 3: Key Considerations for the Clinical QP |
| 15.00 - 15.45 | Session 9: | Lecture 4: The Qualified Person - Code of Practice (Including Clarification of QP Role vs. QA, QC, Production and Senior Management) |
| 15.45 –17.00 | Session 10:  | Groupwork 4: QP Scenarios (QP Code of Practice and QP Role : Management Interface) |
| **Wednesday 14 May 2014** |
| 09.00 – 09.45? | Session 11: | Lecture 5: The Batch Manufacturing Record and Batch Certification – What Gives a QP Confidence when Releasing? |
| 09.45 – 10.30? | Session 12:  | Groupwork 5: Current Issues/Hot Topics for the QP |
| 10.30 – 10.45 | *Coffee* |
| 10.45 – 12.00 | Session 13:  | Groupwork 6: QP Scenarios, (e.g. Batch Release, Supply Chain, GMP/GDP) |
| 12.00 – 13.00 | *Lunch* |
| 13.00 – 13.20 | Session 14:  | Lecture 6: Counterfeits – a Growing Threat! |
| 13.20 – 14.20 | Session 15:  | Groupwork 7: Your Company Receives a Complaint! (Scenario) |
| 14.20 – 14.35 | *Refreshment Break* |
| 14.35 – 15.00 | Session 16:  | Lecture 7: Inspections and Inspectorates |
| 15.00 – 15.30 | Session 17:  | Lecture 8: Recall Laws – Including a Review of Reasons for Recalls |
| 15.30 –16.15 | Session 18:  | Groupwork 8: Inspection Priorities |
| 16.15 –17.00 | Session 19:  | Lecture 9: Quality Management Systems: Overview (Including a Short Overview of ISO 9001:2008) |
| **Thursday 15 May 2014**  |
| 09.00 – 09.30  | Session 20:  | Lecture 10: Management of Electronic Documents  |
| 09.30 – 09.45  | Session 21: Lecture 11 | Lecture 11: Risk-Based Decision Making – Part 1: Risk Ranking  |
| 09.45 –10.00 | *Refreshment Break* |
| 10.00 – 10.45  | Session 22: | Groupwork 9: Using Risk Ranking – Supplier Audit Priorities |
| 10.45 – 11.00 | Session 23: | Lecture 12: Risk-Based Decision Making – Part 2: Risk Assessment  |
| 11.00 – 11.45 | Session 24:  | Groupwork 10: Risk- Based Decision Making Scenarios  |
| 11.45 – 12.00  | Session 25: | Lecture 13: What Benefit Does the QP Bring or Should Bring, and How does the QP Keep up to Date? |
| 12.00 – 13.00  | *Lunch* |
| **NOMA Module (**13.00 – 16.00) |
| 13.00 – 13.45 | Session 26: | Lecture 14: NOMA: Norwegian Regulations – QPs + the New Paradigm for the Regulation of Pharmaceuticals and the QPCovered by NSF & NOMA |
| 13.45 – 14.15 | Session 27: | Lecture 15: Norwegian RecallsCovered by NSF & NOMA |
| 14.15 – 14.30 | *Refreshment Break* |
| 14.30 – 15.15 | Session 28:  | NOMA: Good Distribution Practice and Cold Chain ManagementCovered by NSF & NOMA (will include Reference Paper – Good Distribution Practices) |
| 15.15 – 15.45 | Session 29:  | Panel Discussion (Q & As) |

**Draft Programme Half Day Law Update**

**May 2014**

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| **Time****Thurs pm option** | **Time****Fri pm** | **Session No.** | **Content** |
|  | 09.00 – 09.10 | 1 | Welcome and Objectives |
| To follow | 09.10 – 10.15 | 2 | Changes to EU Legislation and Guidance: |
|  | *10.15 – 10.35* |  | *Refreshment Break* |
|  | 10.35 – 11.15 | 3 | Changes to EU GDP GuidelinesInteractive Session  |
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|  | *11.15 – 12.15* | *4* | Changes to EU GMP Guidelines |
|  | 12.15 – 12.45 | 5 | International Changes - a brief review* ICH,
* PIC/S
* USA/FDA
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|  | 12.45 – 13.00 |  | Q&A Session |
|  | 13.00 |  | Conclusion and Close |