**APPENDIX 2**

**The Norwegian QP Course**

**13 – 15 May 2014**

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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 Packaging  An 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 QP  Covered by NSF & NOMA |
| 13.45 – 14.15 | | Session 27: | | | | | Lecture 15: Norwegian Recalls  Covered by NSF & NOMA |
| 14.15 – 14.30 | | *Refreshment Break* | | | | | |
| 14.30 – 15.15 | | Session 28: | | | | | NOMA: Good Distribution Practice and Cold Chain Management  Covered 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 Guidelines  Interactive Session |
|  |  |  |  |
|  | *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 |
|  | 12.45 – 13.00 |  | Q&A Session |
|  | 13.00 |  | Conclusion and Close |