HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

GMP Conference
12th November 2014
The Crowne Plaza Hotel, Santry Demesne, Santry, Dublin 9

7:30	**Registration Opens**
9.00	**Welcome**

Morning Programme

9.15	**Session 1: Regulatory Update**
	This session will include updates on GMP guidance and legislation
9.45	**Session 2: Computerised Systems Validation**
	This session will provide an overview of considerations regarding the computerized system validation lifecycle and will include commonly seen GMP deficiencies in this area.
10:15	**Questions & Answers - Session 1 & 2**
10.45	**Morning Break - Tea/Coffee**
11:15	**Session 3: Falsified Medicines Directive - Safety Features Update**
	This session will provide an update regarding the delegated act(s) setting out the details relating to the unique identifier.
11.45	**Session 4: Quality Defect Investigations & Product Recalls**
	This session will include information about how the HPRA investigates quality defect reports and our application of ICH Q9 Quality Risk Management principles in such investigations, as well as the implications of the revised Chapter 8 for manufacturers.
12:30	**Questions & Answers – Session 3 & 4**
13:00	**Lunch Break**

Parallel Sessions

The remainder of the programme will include parallel sessions covering specialist topics relevant to manufacture and market compliance. Parallel sessions have been incorporated to facilitate greater interaction. An overview of the specialist topics is provided below. Q&A will be incorporated into each parallel session.

Attendees may choose either session A or B.

14.00 Parallel Session 1A

Sterile Manufacture

Topics to Include:

- *Visual Inspection*
- *Contamination Control Strategy – Microbiological, Particulate & Pyrogen*
- *Aseptic Process Control – Current Expectations on Critical Elements*

14.00 Parallel Session 1B

Non-Sterile / General Manufacture

Topics to Include:

- *Data Integrity: Laboratory & Production Environment – Manual & Automated Systems*
- *Utilities & Bulk Storage – Management & Control*
- *Outsourcing – Responsibilities & Controls*

15.15 *15 Minute Break - Changeover between Parallel Sessions*

15.30 Parallel Session 2A

Market Compliance

Topics to Include:

- *MA Compliance Reviews – Implications for Manufacturers*
- *Overview of the HPRA's Sampling & Analysis (S&A) Programme – Its Relevance for Manufacturers*

15.30 Parallel Session 2B

Cleaning / Cleaning Validation

Topics to Include:

- *Updates to Chapters 3 & 5*
- *Updates to Toxicological Guidance*
- *Cleaning Validation Issues*

16.45 Close of Conference

****** Please note that this agenda may be subject to change ******