

## IRISH MEDICINES BOARD

### GMP & Market Compliance Information Day 23<sup>rd</sup> October 2008

**7:30- 8:30**      **Registration**

**8:30 – 12:30**    **Morning Programme**

**8.30-8.45:**      **Welcome and Opening Address**  
*Pat O'Mahony, CEO, IMB*

The morning programme will include presentations on topics of general interest to all manufacturers.

**8.45-9.30:**    **Session 1: “What’s New in the GMPs”**

*This session will explore the current state of revision of the EU GMPs and associated annexes, specifically focussing on general aspects relevant to all manufacturers. This will also include some general EU updates and information on the new system for Manufacturing Authorisations.  
(Speaker: Paul Sexton)*

**9.30-10.30:**    **Session 2: “PQRs/ On-going Stability/ Feed-Back from Inspection”**

*PQRs and on-going stability testing were topics covered during our information day in 2006 as new GMP requirements. This session will discuss and provide feedback on these areas in context of observations from our inspection programme during the past 2 years.  
(Speaker: Lorraine Nolan, IMB; Victor Garvin, IMB)*

**10.30-11.00:**    **Morning Break**

**11.00-11.45:**    **Session 3: “Using Your Self-Inspection Programme to Maximum Effect”**

*This session will explore the concept of the “self-inspection programme” and how to maximise this to drive continuous improvement. This will include recommendations for development of self-inspection as a means for identification of commonly observed GMP deficiencies.  
(Speaker: Kevin O'Donnell, IMB)*

**11.45-12.30:**    **Session 4: “Materials Management and Assuring the Supply Chain”**

*Discussion of the vendor audit programme and regulatory requirements, control of incoming materials, reduced sampling and reduced testing.  
(Speaker: Cormac Dalton)*

**12:30–14:00**    **Lunch**

## **14:00 to 16:30 Afternoon Programme**

The afternoon programme will include parallel sessions covering specialist topics relevant to manufacture and market compliance. An overview of the specialist topics, including relevant attendees is provided below. The number of parallel sessions covered on the day may change pending assessment of interest in the proposed topic. There will be a short break between parallel session 1 and parallel session 2.

### **14:00-15:00: Parallel Session 1**

- **Sterile Manufacturing Issues**  
Annex 1 and areas of focus for GMP inspections involving sterile products.  
(Chair: Stan O'Neill  
Speakers: Greg McGurk; Ger Sheridan)

**OR**

- **PAT/Quality By Design**  
Discussion of PAT initiatives and developments from a regulatory and industrial perspective.  
(Chair: Mike Morris, Chief Scientific Advisor, IMB  
Speakers: Connor McSweeney, Pfizer Ireland Pharmaceutical; Chris Cullen, IMB)

### **15.15-16.15: Parallel Session 2**

- **Selected Market Compliance Activities**  
The Sampling & Analysis Programme - Important findings from API sampling activities performed by IMB at finished product manufacturers  
The Quality Defect & Recall Programme - Key Features & Expectations  
(Chair: Lorraine Nolan  
Speakers: Laura Hickey, IMB; Aoife Farrell; IMB)

**OR**

- **API Manufacturing Issues**  
Commonly Observed Deficiencies; EDQM Inspection Programme for API sites.  
(Chair: Chris Cullen  
Speakers: Cormac Dalton; Victor Garvin)

### **16.15-16.30: Closing Remarks**

(John Lynch, Director of Compliance, IMB)