IRISH MEDICINES BOARD

GMP & Market Compliance Information Day
September 27th 2012
The Crowne Plaza Hotel, Santry Demesne, Santry, Dublin 9

7:30	**Registration**	
9.00	**Welcome and Opening Address**	

Morning Programme

Consisting of a short general forum session followed by the first parallel session after the coffee break

9:15	**Introduction to Voting Pads**	***Facilitator:*** *Cormac Dalton*
	Some general instructions on use of the voting pads and collection of general information – e.g. what types of organizations are represented in the audience etc.	
9.30	**Session 1: Regulatory update**	***Speaker:*** *Paul Sexton*
	This session will include updates on GMP guidance and legislation	
10:00	**Session 2: Quality Management Considerations**	***Speaker:*** *Chris Cullen*
	This session will include discussion of the use of ICH Q10 by manufacturers	
10:30	**Questions & Answers - Sessions 1 & 2**	
10:45	**Morning Break - Tea/Coffee**	

Parallel Sessions

The remainder of the programme will include parallel sessions covering specialist topics relevant to manufacture and market compliance. More 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.***

Choose Session 1A or 1B

11:15	**Parallel Session 1A**	***Session Coordinator:*** *Chris Cullen*
	Falsified Medicines Directive*:* *This session will explore the practical implementation of those aspects of the FMD legislation which come into force in 2013.*	
	Speaker	***Title of Presentation***
	Chris Cullen	*Falsified Medicines Directive*
	Anne Hayes	*Starting Materials - Changes from FMD*
11:15	**Parallel Session 1B**	***Session Coordinator:*** *Lorraine Nolan*
	Improving Quality Risk Management Activities: Addressing the Problems of Subjectivity & Uncertainty	
	Speaker	***Title of Presentation***
	Kevin O'Donnell	*Improving Quality Risk Management activities to better support GMP Activities*
12:30	**Lunch Break**	

IRISH MEDICINES BOARD

	Choose Session 2A or 2B	
14:00	**Parallel Session 2A**	***Session Coordinator:*** *Cormac Dalton*
	Cleaning Validation – challenges old and new: *Exploring traditional approaches and new developments in this area*	
	Speaker	***Title of Presentation***
	Cormac Dalton	*New Product Introduction and Assessing the Residues*
	Victor Garvin	*Cleaning Validation - Facility & Equipment Considerations & Potent Materials*
	Sarah O'Meara	*Cleaning Validation - The Toxicological Approach*
14:00	**Parallel Session 2B**	***Session Coordinator:*** *Kevin O'Donnell*
	Market Compliance *Current Issues*	
	Speaker	***Title of Presentation***
	Aoife Farrell	*Quality Defects - Recent Trends*
	Rob Smyth	*Updates to the IMB Guide to Reporting of Quality Defects*
	Kevin O'Donnell	*Regulatory Compliance Inspections at MAH Offices - implications for manufacturers*
15:15	*15 Minute Break - Changeover Between Parallel Sessions*	
	Choose Session 3A or 3B	
15:30	**Parallel Session 3A**	***Session Coordinator:*** *Greg McGurk*
	Sterile and Biological Manufacturing: *This session will examine current trends in deficiencies, environmental monitoring and the introduction of rapid microbiology methods.*	
	Speaker	***Title of Presentation***
	Greg McGurk	*Rapid Micro Methods*
	Denise Coakley	*Deficiencies*
	Paul Moody	*Environmental Monitoring*
	Gerard Sheridan	*Aseptic Process Validation*
	Gerard Sheridan	*Steam in Place (SIP)*
	Paul Moody	*Applicability of Annex 1 to manufacture of a Biological Drug Substance*
15:30	**Parallel Session 3B**	***Session Coordinator:*** *Paul Sexton*
	Process Validation – challenges old and new: *Exploring traditional approaches and new development in this area.*	
	Speaker	***Title of Presentation***
	Catherine McHugh	*Objectives and impact of the draft revision of the EMA PV guidance*
	Paul Sexton	*Current GMP Guidance & revision of Annex 15*
	Kevin O'Donnell	*Process Validation Deficiencies*
16:45	**General Audience Feedback on the day :**	
	At the conclusion of parallel session number 3 the chairpersons for each of the groups (3A and 3B) will put some general questions to the audience for feedback on the event. The feedback will be recorded anonymously via the voting pads.	
17:00	**Close of Meeting**	