



IRISH MEDICINES BOARD

**GCP SEMINAR
JANUARY 27TH 2010
CAMDEN COURT HOTEL
DUBLIN**

10.00	Registration	
10.45	Welcome address	Pat O'Mahony Chief Executive IMB
	Session I Chairperson: Elaine Breslin Clinical Assessment Manager	
11.00	Clinical Trials in Ireland - Regulatory Framework	Peter Kiely Senior Medical Officer
11:20	Overview of IMB's Approach to Inspection of Good Clinical Practice	Deirdre O'Regan GCP/Pharmacovigilance Inspection Manager
11:40	Compliance with the Clinical Trial Protocol	Sinead Curran GCP/Pharmacovigilance Inspector
12.20	Q&A	
12:30	Session Overview	
	12.45 – 13:45 Lunch	
	Session II Chairperson: Joan Gilvarry Director of Safety Monitoring	
13:45	Safety Reporting	Donna McGowan GCP/Pharmacovigilance Inspector
14:05	Q&A	
14:15	Informed Consent, Clinical Trial Subjects	Sinead Curran GCP/Pharmacovigilance Inspector
14:35	Q&A	
14:45	Investigational Medicinal Product Management	Deirdre O'Regan GCP/Pharmacovigilance Inspection Manager
15:05	Q&A	
15:15	Training and Delegation of Trial Duties	Donna McGowan GCP/Pharmacovigilance Inspector
15:35	Q&A	
15:45	Session Overview	