Agenda for the HPRA Information Day - GCP for Investigational Medicinal Product Trials

Tuesday, 23rd October, Camden Court Hotel, Dublin 2

TOPIC	TIME
Opening/Welcome	
A message from the HPRA	09:30
Session 1: Update on legislation and guidance – *Chair, Mr John Lynch, Director of Compliance*	
Update on Clinical Trials Regulation EU No 536/2014 *Agnieszka Przybyszewska – Senior Medical Officer*	09:45
Good Clinical Practice – review of recent and future changes to relevant guidance *Sinead Curran – GCP/PV inspection manager*	10:00
Q&A session	10:45
Tea & Coffee – 30 mins	11:00
Session 2: GCP inspections and compliance – Chair, Ms Anne Hayes, Inspection manager	
Overview of HPRA GCP inspections and common findings *Peter Twomey, GCP/PV inspector*	11:30
Expectations for GCP compliance: data integrity *Marie Callaghan, GCP/PV inspector*	12:00
Q&A session	12:45
Lunch – 60 mins	13:00
Session 3: Clinical trial sponsorship: focus on non-commercial sponsors – Chair, Dr. Elaine Breslin, Clinical assessment manager	
Sponsoring a clinical trial, expectations for quality systems, risk management and monitoring *Sinead Curran – GCP/PV inspection manager*	14:00
Pharmacovigilance systems *Peter Twomey, GCP/PV inspector*	14:50
Investigational medicinal product management *Marie Callaghan, GCP/PV inspector*	15:40
Q&A session	16:00
Close	16:30