HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Agenda for Compliance Information Day - GCP for Investigational Medicinal Product Trials

Tuesday, 23rd October, Camden Court Hotel, Dublin 2
Time 09:30-16:30 (registration desk opens 08:30)

TOPIC	TIME
Opening/Welcome	
A message from Dr Lorraine Nolan, CEO	09:30
Session 1: Update on legislation and guidance	
Update on Clinical Trials Regulation EU No 536/2014	09:45
Good Clinical Practice – review of recent and future changes to relevant guidance	10:00
Q&A session	10:45
Tea & Coffee – 30 mins	11:00
Session 2: GCP inspections and compliance	
Overview of HPRA GCP inspections and common findings	11:30
Expectations for GCP compliance: protocol compliance and data integrity	12:00
Q&A session	12:45
Lunch – 60 mins	13:00
Session 3: Clinical trial sponsorship: focus on non-commercial sponsors	
Sponsoring a clinical trial, expectations for quality systems, risk management and monitoring	14:00
Pharmacovigilance systems	14:50
Investigational medicinal product management	15:40
Q&A session	16:00
Close	16:30