



Agenda for the Irish Medicines Board (IMB) IVD Information Day 2010

Date: 12 February 2010
Location: Irish Medical Devices Association (IMDA), IBEC, Confederation House, 84/86 Lower Baggot Street, Dublin 2.
Time: Registration will take place from 9.00am to 9.30am.
The IVD Information Day will begin at 9.30am

Session 1: Chairperson: Dr. Joan Gilvarry; Director of Human Products Safety Monitoring

Topic 1: *General Introduction to the IMB*
Speaker: Mr. Pat O'Mahony, Chief Executive; IMB
Time: 9.30am – 9.40am (10 mins)

Topic 2: *IVD Legislation – Current and Future Developments*
Keynote Speaker: Ms. Ann O'Connor, Director of Human Products Authorisation and Registration; IMB
Time: 9.40am – 10.15am (35 mins)

Topic 3: *Impact of International Issues on future IVD developments*
Keynote Speaker: Mr. Benny Ons, Director RA/RC/QM; BD Biosciences Europe
Time: 10.15am - 10.50am (35 mins)

Q&A session

Tea/Coffee: 11.10am-11.30am

Session 2: Chairperson: Mr. Wilf Higgins; Member of Advisory Committee for Medical Devices (ACMD)

Topic 4: *Auditing of IVD manufacturers and key issues to date*
Speaker: Ms. Mairead Finucane, Medical Devices Auditor; IMB
Time: 11.30am-12.05pm (35 mins)

Topic 5: *The National Vigilance System for IVDs*
Speaker: Dr. Judith Martin, IVD Product Manager; IMB
Time: 12.05pm-12.40pm (35 mins)

Q&A session

Lunch 1.00pm-2.15pm

Session 3: Chairperson: Ms. Ann O'Connor; Director of Human Products Authorisation and Registration

Topic 6: *Case Studies on IVD Vigilance Issues & Group Discussion*
Speakers: Mr. Stephen Lee, Principal Medical Device Specialist; MHRA
Dr. Judith Martin, IVD Product Manager; IMB
Time: 2.15pm-3.30pm

Close of meeting: IMB (3.30pm)