30 October 2015
EMA/INS/PhV/724709/2015
Compliance and Inspections

Agenda - 2015 Pharmacovigilance Inspectors Working Group training course

09-11 November 2015, London, United Kingdom

09 November 2015, 08.30 – 18.00
10 November 2015, 09.00 – 17.30
11 November 2015, 09.00 – 15.00

Chair: Anabela Marcal

Human medicinal products

Day 1 – Monday 09 November 2015 08.30 – 18:00

Time	Topic	
08:30-09:30	Registration (All)	
Human session, day 1, morning, room 2A		
09:30-10:00	Welcome 1.1H Introduction: HEALTH & SAFETY INFORMATION Presentation of the agenda and format of the course, training purpose and objectives.	
1H. Inspection planning and preparation, conduct and follow-up		
10:00–10:25	1.2H Inspection preparation	
10:25-11:55	**Workshop 1H** Exercises on pharmacovigilance inspection preparation, conduct and follow-up. Groups (lists to be provided)	
11:55-12:15	Coffee break	

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Time	Topic	
12-15-12:45	Feedback session	
12:45-13:45	Lunch break	
Human session, day 1, afternoon, room 2A		
2H. Inspection of RMPs, signal detection, PSUR & Interaction with PRAC/Assessors		
13:45-14:10	2.1H Assessor presentation	
14:10-14:35	2.2H Strengthen Collaboration for Operating Pharmacovigilance in Europe (SCOPE)	
14:35-14:55	Q&A	All
14:55-15:20	2.3H Regulatory procedures and product information updates timelines	
15:20-15:30	Q&A	All
15:30-15:50	Coffee break	
15:50-17:15	**Workshop 2H** • Inspecting safety variations / PIL updates Groups (lists to be provided)	All
17:15-17:50	Feedback session	
17:50-18:00	Summary and conclusions of day 1	All

Day 2 – Tuesday 10 November 2015 09.00 – 17.30

Time	Topic	
Human session, day 2, morning, room 2A		
09:00-09:10	Introduction to day 2	
3H. Databases – how can inspectors use the information available		
09:10-09:35	3.1H Data analysis and case processing – feedback from users and consideration on additional use of this tool	
09:35-11:00	**Workshop 3.1H** Data analysis and case processing exercise Groups (lists to be provided)	All
11:00-11:30	Coffee break	
11:30-12:00	3.2H WEB-RADR: Recognising Adverse Drug Reactions - Project update	
12:00-12:30	Q&A	All

Time	Topic	
12:30-13:30	Lunch break	
Human session, day 2, afternoon, room 2A		
3H. Databases *(session continues)*		
13:30-13:55	3.3H Computer validation	
13:55-14:10	Q&A	
14:10-14:35	3.4H Medical Literature Monitoring and impact on MAHs	
14:35-15:50	Q&A	All
15:50-16:10	Coffee break	
16:10-17:10	**Workshop 3.2H** • EV/EVDAS demonstration and discussion of queries	All
17:10-17:20	Feedback session / Q&A	All
17:20-17:30	Summary and conclusions of day 2	
ORGANISED ACTIVITY/DINNER IN LONDON		

Day 3 – Wednesday 11 November 2015 09.00 – 15.00

Time	Topic	
Human session, day 3 morning, room 2A		
09:00-09:10	Introduction to day 3	
4H. Clinical trials and safety reporting		
09:10-09:35	4.1H Non-interventional clinical trials and safety reporting	
09:35-09:55	Q&A	All
5H. PSMF and third party inspections		
09:55-10:20	5.1H PSMF & third parties (safety data exchange agreements, audits etc.)	
10:20-10:30	Q&A	All
10:30-10:50	Coffee break	
10:50-12:00	**Workshop 5H** Inspections of third parties • PSMF and third parties / licencing partners & cross referring to other PSMF(s) and PhV systems; • PSMF and audits; • Inspection of third parties managing studies /having specific	All

Time	Topic	
	pharmacovigilance responsibilities; • Follow-up of pharmacovigilance inspections. Groups (lists to be provided)	
12:00-12:30	Feedback session	All
12:30-13:30	Lunch break	
Human and Veterinary session, day 3 afternoon, room 2A		
1HV International collaboration / PICs activities		
13:30-13:55	1.1HV International collaboration / PICs activities	
13:55-14:20	Q&A	All
Closing session, day 3 afternoon, room 2A		
14:20-15:00	General discussion and conclusions of training course. Evaluation forms completion & distribution of certificates	All