



30 October 2015
EMA/INS/PhV/724710/2015
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: Sophia Mylona

Veterinary medicinal products

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

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



Time	Topic	
12:15-12:45	Feedback session	
12:45-13:45	Lunch break	
Veterinary session, day 1, afternoon, room 2D		
2V. Inspection follow up - how to handle corrective and preventive action(s) (CAPA)		
13:45-14:10	2.1V Inspection follow-up and how to handle CAPA	
14:10-14:25	2.2V CAPA handling practical examples	
14:25-14:35	Q&A	All
3V. Inspection findings: grading and common areas of findings		
14:35-15:00	3.1V Categorisation of CVMP requested inspection findings	
15:00-15:15	Q&A	
15:15-15:45	Coffee break	
15:45-17:00	Workshop 3V Categorisation and grading of pharmacovigilance inspection findings Groups (lists to be provided)	All
17:00-17:30	Feedback session	
17:30-18:00	Summary and conclusions of day 1	All

Day 2 – Tuesday 10 November 2015 09.00 – 17.30

Time	Topic	
Veterinary session, day 2, morning, room 2D		
09:00-09:10	Introduction to day 2	
4V. Quality Management Systems		
09:10-09:35	4.1V Quality Management Systems – what are the minimum criteria	
09:35-09:55	Q&A	All
09:55-12:00 <i>Coffee break</i> 10:40-11:00	Workshop 4V Exercises on Quality Management Systems Groups (lists to be provided)	All
12:00-12:30	Feedback session	All

Time	Topic	
12:30-13:30	Lunch break	
Veterinary only session, day 2, afternoon, room 2D		
5V. Multiple entities and fulfilment of pharmacovigilance activities		
13:30-14:00	5.1V Multiple MAH entities and fulfilment of requirements (DDPS, PSURs, SOPs) – How does it work? MA Transfers contracts, roles and responsibilities	
14:00-14:20	Q&A	All
14:20-15:30	Workshop 5V Practical examples / case scenarios for discussion <ul style="list-style-type: none"> Contracts and minimum requirements (CAPs/NAPs including MRP and DCP) and distributors (Volume 9B guidance and expectations) Multiple DDPSs/PSURs / Repeat use MRP cases 	All
15:30-15:50	Feedback / conclusion session	
15:50-16:20	Coffee break	
6V. Risk-based inspection planning		
16:20-16:45	6.1V Risk-based inspection planning	
16:45-17:00	Q&A	All
17:00-17:30	Summary and conclusions of day 2	All
ORGANISED ACTIVITY/DINNER IN LONDON		

Day 3 – Wednesday 11 November 2015 09.00 – 15.00

Time	Topic	
Veterinary session, day 3 morning, room 2D		
09:00-09:10	Introduction to day 3	
7V. Databases – how can inspectors use the information available		
09:10-10:40	Workshop 7V EV-Vet/DWH exercise	All
10:40-11:00	Feedback session / Q&A	
11:00-11:30	Coffee break	
11:30-12:00	7.1V Computer validation for non-experts	

Time	Topic	
12:00-12:30	Q&A	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