03 October 2017
EMA/INS/PhV/174813/2017
Committees and Inspections

Agenda - 2017 Pharmacovigilance Inspectors Working Group Training Course

16 - 18 October 2017, London (UK)

16 October 2017, 09:00 – 17:30
17 October 2017, 09:00 – 18:00
18 October 2017, 09:00 – 15:00

(Co)-Chair: Sophia Mylona (EMA)/Calogero Cannavó (EMA)

Day 1 – Monday 16 October 2017 09:00 – 17:30

H only sessions / V only sessions

Time	Topic	Speaker
09:00 – 10:00	Registration and coffee (All)	
10:00 – 10:30	**00.HV Welcome and introduction (H+V session,)** HEALTH & SAFETY INFORMATION Presentation of the agenda and format of the course, training purpose and objectives.	Sophia Mylona (EMA)
10:30 – 11:00	**1.1HV EU NTC platform update (H+V session)**	Sheila Kennedy (EMA)
11:00 – 12:30	**2.1HV PhV inspection of third parties/contractors and contracts (H+V session)** • The approach of SUKL and common inspection findings. • MHRA experience of pharmacovigilance service provider	Zuzana Chomátová - CZ (SUKL), Kiernan Trevett – UK (MHRA),

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Time	Topic	Speaker
	inspections. • Approaches of Vet NCAs – Questionnaire. Q&A/Discussion	Andrea Whinchenbach - DE (BVL)
12:30 – 13:30	**Lunch**	
13:30 - 16:30	**2.2HV Group exercise / Workshop (H+V session)*)*** Panel/Coordinator: Calogero Cannavó (EMA), Sophia Mylona (EMA) Groups (lists to be provided) H group topics: • to develop check list/guidance how to inspect the third parties/contractors; • to develop Q&A regarding contracts; • MAs transfers: points to be considered; • other topics submitted by inspectors. V group topics: • to develop something for the veterinary MAHs/QPPVs; • MAs transfers: points to be considered; • to look into existing guidance and propose updates or identify potential gaps in the guidance; • other topics submitted by Inspectors.	
16:30 – 17:00	**Wrap-up by group leaders** and coffee break	
17:00 – 17:10	AOB – PIC/S update	Mandeep Rai – UK (MHRA)
17:10 – 17:30	Summary and conclusions of day 1	

H only sessions / V only sessions

Day 2 – Tuesday 17 October 2017 09:00 – 18:00

Time	Topic	Speaker
09:00 – 09:15	Introduction to day 2	
09:15 – 11:15	**3.1HV Signal management (H+V session)** • Future signal management process following the release of the EudraVigilance (EV) data for MAHs in Nov 2017 and inspectors' expectations. • Inspecting signal management activities and example findings. Q&A/Discussion	Rodrigo Postigo (EMA), Julie Durand (EMA), Kiernan Trevett – UK (MHRA), Claire Longman – UK (MHRA)
11:15 – 11:30	**Coffee break**	
11:30 – 13:00	**3.2H Workshop on signal management of human medicinal products (H session)** Panel /Coordinator: Rodrigo Postigo (EMA), Julie Durand (EMA), Calogero Cannavó (EMA) Groups (lists to be provided) • Signal detection at inspection – example cases for discussion - future approach? • Risk minimizations measures from RMPs - example cases for discussion – Questionnaire.	
11:30 – 13:00	**3.2V Workshop on signal management/Surveillance of veterinary medicinal products (V session)** Panel/Coordinator: Laura Patten (EMA), Raquel Gopal (EMA) Groups (lists to be provided) • Signal detection at inspection – Basic knowledge for inspectors. • How to verify tools for SD developed by MAH.	
13:00 – 14:00	**Lunch**	
14:00 – 14:05	**Group photo**	
14:05 – 16:00	**4.1HV Harmonisation in grading of findings (H+V session)** Member State presentations (findings/case scenarios).	CZ, DE, DK, FR, IE, IT, HR, NL, PT, SE, UK

Time	Topic	Speaker
	How would you grade the deviation?	
16:00 – 16:30	**Coffee break** **Wrap-up by group leaders**	
16:30 – 17:30	**5.1HV NON EU authorities presentations (H+V session)** • FDA program alignment: Impact on post-marketing adverse drug experience inspections. • Post-marketing investigation and pharmacovigilance systems of Japan. • Pharmacovigilance inspection approach in South Africa. • TGA's recent pharmacovigilance inspection pilot program.	Namita Kothary - US (FDA), Maho Hoshi- Japan (PMDA), Noriko Tomita - Japan (PMDA), Mlungisi Wondo - South Africa (Medicines Control Council of SA), My Di Luu – Australia (TGA)
17:30 – 18:00	Summary and conclusions of day 2	
ORGANISED SOCIAL EVENT		

Day 3 – Wednesday 18 October 2017 09:00 –15:00

H only sessions / V only sessions

Time	Topic	Speaker
09:00 – 09:15	Introduction to day 3	
09:15 – 10:15	**6.1H Art.57/ XEVMPD (extended EudraVigilance medicinal product dictionary) (H session)** • Art.57 data reports for NCAs. • Practical examples where information from Art.57 has been used for inspection.	Calogero Cannavó (EMA), Loris Piccolo (EMA), Sofia Zastavnik (EMA), Thorsten Frank Jørgensen - DK (DKMA)
09:15 – 10:15	**6.1V DDPS assessment/CAPA management: harmonisation** • DDPS – harmonization of assessments (V session). • Before and after the inspection: how to deal with non-compliance after CAPA.	Lisa Woods – IE (HPRA), Yvonne Mein - DE (BVL), Raquel Gopal (EMA)
10:15 – 10:35	**Coffee break**	
10:35 – 12:00	**7.1H Workshop on EV/EVDAS - MedDRA coding -ADR reporting (H session)** • Q&A	Thomas Paternoster-Howe (EMA)
10:35 – 12:00	**7.1V Workshop on EVVet/DWH - VeDDRA coding - ADR reporting (V session)** • Q&A	Laura Patten (EMA), Gillian Diesel – UK (VMD), Anita Bottger – NL (MEB), Hector Duran – ES (AEMPS) Raquel Gopal (EMA),
12:00 -12:30	General discussion and conclusions of training course. Distribution of certificates. Evaluation forms provided electronically.	All
13:00 – 15:00	Only for coordinators and group leaders to consolidate the outcome/actions of the training.	Coordinators and group leaders