



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

12 October 2016  
EMA/858631/2015  
Compliance and Inspections

## 2016 EU GCP Inspectors Working Group Workshop PROGRAMME

17-19 October 2016, room 3A, EMA, London (UK)

Chair: Ana Rodriguez Sanchez Beato

### HEALTH & SAFETY INFORMATION

In accordance with Agency policy, delegates are to be shown a slide show with health and safety and emergency information and procedures. This is to be displayed at the start of this meeting using the Crestron system as delegates are entering the meeting room. In addition, the chairperson or meeting secretariat is to draw the delegates' attention to the slideshow and point out the nearest fire exit(s), which are marked where the room has two or more exits. Should there be an evacuation during the meeting, staff will guide delegates out of the building via the nearest fire exit.



**Day 1 – Monday 17 October 9:00-17:00**

Time	Topic	Speaker
09:00-09:25	Welcome and Introduction with training purpose and objectives	
09:25-10:30	<b>1. Inspections of ATMP- inspectors' and assessors' perspectives</b>	
	Specifics of ATMPs in clinical trials and examples of findings	
	Factors that affect the risk-benefit balance	
10:30-11:00	Q&A	All
11:00-11:20	Coffee Break	
	<b>2. Inspections of oncology trials-inspectors' and assessors' perspectives</b>	
11:20-12:30	Factors that affect the risk benefit balance in Oncology Trials	
	Oncology trials: Examples of inspection findings	
12:30-13:00	Q&A	All
13:00-14:00	Lunch Break	
14:00-15:30	<b>BREAK OUT Session A</b> – discussions on case studies on inspections of ATMPs and oncology trials	
15:30-15:50	Coffee Break	
15:50-16:50	Feedback session	All
16:50-17:00	Conclusions and feedback on Day 1	All

**Day 2– Tuesday 18 October 9:00-17:00**

Time	Topic	Speaker
09:00-09:05	Introduction to day 2	
	<b>3. Optimising the writing of inspection findings and conclusions of inspection reports</b>	
09:05-09:50	Report writing	
09:50-10:15	Assessors' perspective	
10:15-10:45	Q&A	All
10:45-11:15	Coffee Break	
11:15-13:00	<b>BREAK OUT Session B</b> – practise with writing inspection findings- case studies	
13:00-14:00	Lunch Break	
14:00-15:00	Feedback session	All
	<b>4. Topics of interest discussed at GCP IWG meetings</b>	
15:00-15:20	Presentation of topics & Q&A session part I	
15:20-15:50	Coffee Break	
15:50-16:50	Presentation of topics & Q&A session part II	
16:50-17:00	Conclusions and feedback on day 2	
18:00 – 22:30	<b>Social event</b>	

**Day 3– Wednesday 19 October 9:00-13:30**

Time	Topic	Speaker
09:00-09:05	Introduction to day 3	
9:05-10:40	<b>5. Inspection findings- impact and grading</b>	
	EU and international perspectives	
	Short Q&A after each presentation	
10:40-10:50	Coffee Break	
10:50-11:50	<b>BREAK OUT Session C-</b> case studies/discussion points on grading of findings with practical examples	
11:50-13:00	Feedback session	All
	Presentation of the results of the pre-training exercise	
13:00-13:30	Conclusions of workshop and distribution of certificates	