9 October 2015
EMA/104761/2015
Compliance and Inspections

2015 EU GCP Inspectors Working Group workshop programme

12-14 October 2015, EMA, London (UK), Room 3A

Chair: Ana Rodriguez

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 12 October 09:00-17:00

Time	Topic	Speaker
09:00-09:25	Welcome and Introduction with training purpose and objectives	Anabela Marcal (Head of Inspections and Compliance Department) Ana Rodriguez (Head of the Clinical and Non Clinical Compliance Service, EMA)
	1. Electronic Data Integrity	
09:25-11:00	What is 'Data Integrity'? • GCP Framework and Expectations for Data Integrity • Management Governance & Quality Culture • Example Health Authority Observations for Data	Monica Cahilly (Green Mountain Quality Assurance, LLC)

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Time	Topic	Speaker
	Integrity	
11:00-11:20	Coffee Break	
11:20-12:30	Key Principles for Inspecting for Data Integrity: • Good Documentation Practices for Paper and Electronic (continued) • Case Studies & Examples	Monica Cahilly (Green Mountain Quality Assurance, LLC)
12:30-13:30	Lunch	
13:30-15:30	Key Principles for Inspecting for Data Integrity: • 'Critical Thinking' Skills for Data Review • Reviewing Electronic & Paper Data and 'Metadata' • Hands-on Case Studies Electronic and Paper	Monica Cahilly (Green Mountain Quality Assurance, LLC)/ ALL
15:30-15:50	Coffee Break	
15:50-16:50	Key Principles for Inspecting for Data Integrity: • Data Life Cycle & Data Governance	Monica Cahilly (Green Mountain Quality Assurance, LLC)/ ALL
16:50-17:00	Summary and Conclusions of day two	ALL
	Social Event at EMA promenade	

Day 2 – Tuesday 13 October 09:00-17:00

Time	Topic	Speaker
09:00-09:05	Introduction to day 2	Ana Rodriguez (EMA)
	2. Electronic Data Integrity	
09:05-09:15	Key Principles for Inspecting for Data Integrity: • Data Life Cycle & Data Governance- Introduction to breakout session on Data process Maps	Monica Cahilly (Green Mountain Quality Assurance, LLC)
09:15-10:15	**BREAK OUT Session A-** group discussions of case studies on **Data Process Maps**	ALL
10:15-11:00	Feedback	ALL
11:00-11:20	Coffee Break	
11:20-12:30	Inspections of Facilities (e.g., Central Labs / CROs) and Quality Management Systems • Identifying 'Red Flags' • Case Studies & Examples	Monica Cahilly (Green Mountain Quality Assurance, LLC)
12:30-13:30	Lunch	
13:30-15:30	Validation for Data Integrity	Monica Cahilly (Green

Time	Topic	Speaker
	• Cloud Computing • Case Studies & Examples	Mountain Quality Assurance, LLC)/ ALL
15:30-15:50	Coffee Break	
15:50-16:50	Conclusion Discussion—Questions & Answers & Comments	Monica Cahilly (Green Mountain Quality Assurance, LLC)/ ALL
16:50-17:00	Summary and Conclusions of day two	ALL

Day 3 – Wednesday 14 October 09.00-13:00

Time	Topic	Speaker
09:00-09:05	Introduction to Day 3	Ana Rodriguez (EMA)
	3. GCP inspection findings and their impact	
09:05-10:05	**BREAK OUT Session B**- group discussions of case studies on specific inspection findings	ALL
10:05-11:10	Feedback	Group Leaders
	4. International Collaboration	
11:10-11:30	Ebola Vaccine Trial Applications	Nartekuor Nartey-Armooh, (Ghana FDA)
11:30-11:45	Coffee Break	
	5. Update on new EU Clinical Trial legislation	
11:45-12:10	5.1 The new Clinical Trial Regulation- what is changing?	Ana Rodriguez, (EMA)
12:10-12:30	5.2 Overview of the GCP Implementing Act	Caroline Attard/ Maja-Leon-Grzymkowska, (EC via T-con)
12:30-12:45	Q&A	
12:45-13:00	Summary and Conclusions of Workshop	Ana Rodriguez (EMA)
	Distribution of Certificates and closure of workshop	Ana Rodriguez (EMA)

Abbreviations:
CSR: Clinical Study Report
CSV: Computer Systems Validation
EU: European Union
EEA: European Economic Area
MAA: Marketing Authorisation Application
MS: Member State
Q&A: Questions and Answers
RP: Reflection Paper
SDV: Source Data Verification
TMF: Trials Master File