



8 October 2015  
EMA/499514/2015

## Agenda - Workshop on GCP compliance in BE trials/generics

15 October 2015, London, UK, Room 3A<sup>1</sup>, 09:00-16:30

Chair: Anabela Marcal (EMA)

Co-Chair: Gaëtan Rudant (ANSM)

Item	Topic		Time
	Registration		08:30-09:00
	Welcome and introduction of workshop purpose and objectives.	<i>Introduction</i>	09:00-09:10
1.	Proposal regarding common practices by the sponsor for: - CRO selection criteria - Quality assurance and quality control before (selection) and during the conduct of the trial, as applicable.	<i>Presentation</i>  <i>Break out session: Points for discussion (All)</i>  <i>Conclusions (All)</i>	09:10-9:25  09:25-09:55  09:55-10:25
	<b>Coffee break</b>		<b>10:25-10:45</b>
2.	Proposal regarding common practices by the MAH for due diligence of licenced-in dossiers (including contractual aspects), (understand the processes in place and discuss best practices).	<i>Presentation</i>  <i>Break out session: Points for discussion (All)</i>  <i>Conclusions (All)</i>	10:45-11:00  11:00-11:30  11:30-12:00
3.	Industry assessment of hurdles to information sharing between companies.	<i>Presentation</i>	12:00-12:30
	<b>Lunch</b>		<b>12:30-13:30</b>

<sup>1</sup> Break-out sessions in meeting rooms 3A, 3G, 3H, 3J, 3K



Item	Topic	Time	
4.	Definition of a common trigger point for the reporting of breaches to competent authorities that were revealed during CRO audits (current situation and future requirements for the notifications of serious breaches in the context of the new CT Regulation).	<i>Presentation</i>	13:30-14:00
5.	CRO closure: mechanisms to ensure data retention for further verification/responsibilities.	<i>Presentation</i>	14:00-14:30
	<b>Coffee break</b>		<b>14:30-14:50</b>
6.	How to improve transparency and communication of inspection findings.	<i>Presentation</i>	14:50-15:20
7.	Proposals by the regulatory authorities to communicate expectations and best practices.	<i>Presentation</i>	15:20-15:50
8.	Next steps		15:50-16:10
9.	Summary and conclusions		16:10-16:30