EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

9 October 2015
EMA/670206/2015

Agenda – Forum on bioequivalence inspections

14 October 2015 – Room 2A, - 14:00-18:00

Chair: Maria Antonietta Antonelli (EMA)

Co-Chairs: Olivier Le Blaye (ANSM)

Item	Preliminary draft agenda	Initials	Mins
	Registration and welcome coffee	EMA	13:30–14:00
1.	Welcome and practical information	Introduction	14:00-14:05
2.	Update on the 9th Workshop on Recent Issues in Bioanalysis (9th WRIB)	Presentation	14:05-14:20
3.	Handling of a volunteer management system - inspector expectations for computerized system	Presentation	14:20-14:50
4.	Level of documentation when setting up a LCMS system (documentation for mobil phases, preparation of subject samples etc.)	Presentation	14:50-15:20
5.	How to handle the internal control on balances (documentation regarding the internal control)	Presentation	15:20-16:00
	Picture and coffee break		16:00-16:20
6.	- eCRFs in BE trials – experiences? - Source data verification of laboratory values of screening/end of trial values at the clinical laboratory – is it worth to do spot-checks on this in certain cases? - Source data verification of laboratory values of screening/end of trial values at the clinical laboratory – is it worth to do spot-checks on this in certain cases? - PK samples and IMPs BE trials – to be kept a certain time period after CSR finalized? (no requirements to do so?) - Bankruptcy of CROs to be inspected – archiving of trial/source data	Presentation	16:20-16:50

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7.	Loss of audit trail functionality – issue associated with Analyst® 1.4.2 and Windows	Presentation	16:50-17:20
8.	Online BE trial inspections training course	Presentation	17:20-17:30
9.	A.O.B.		17:30-17:50
10.	End of Forum	EMA	17:50-18:00

For preparation of the Forum: please bring any useful inspection tools (excel, word etc based, on USB stick) with you, if you like to present and share them.