



FOCUS GROUP MEETING

CVMP BIOEQUIVALENCE GUIDELINE (REVISION)

6 May 2009, EMEA, Room 3A
13.00 – 17.00h

AGENDA

TIME	AGENDA TOPIC	
13.00	Welcome	M. Holzhauser-Alberti (Chairman EWP)
13.15	Main changes to the guideline: • Introduction and scope • Aspects related to the <i>in vivo</i> design • BCS system	F. Hulten (EWP) K. Törneke (CVMP) P.-H. Overhaus (QWP)
14.00	Topics identified by Interested Parties (IFAH Europe) • Biowaivers • Statistica Analysis • Study Design • Others (API bioequivalenceconsideration, evaluation of separate enantiomers)	E. de Ridder (Elanco) U. Sent (BIV) R. Hunter (Elanco) M. Bobey (Merial)
14.45	TEABREAK	
15.15	Detailed discussion of changes to the Guideline	All
16.45	Final comments and conclusions	M. Holzhauser-Alberti