19 April 2016
EMA/INS/189297/2016
Compliance and Inspections

Agenda

EU workshop on ICH Q3D from a quality perspective

5th April 2016, European Medicines Agency, London, Room 3A

Co-Chairs: Sven-Erik Hillver and Michael James

Timing	Subject	Speaker
09:00 – 09:10	**Opening**	Anabela Marcal (EMA)
09:10 – 09:40	**Introduction**	John Kauffman (FDA)
09:40 – 10:20	**Safety block:** Development of safe levels of elemental impurities	Dominique Masset (ANSM)
10:20 – 10:40	**Coffee break**	
10:40 – 11:20	Administration by other routes and other safety aspects	Anja Slikkerveer (Astellas Pharma Europe B.V.)

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Timing	Subject	Speaker
11:20 – 11:40	Discussion and Questions	
11:40 – 12:30 12:30 – 12:40	**Quality block:** Risk Assessment Discussion and Questions	Sven-Erik Hillver (MPA)
12:40 – 13:40	**Lunch break**	
13:40 – 14:10 14:10 – 14:30 14:30 – 14:50	Controls of Elemental Impurities Calculation Options Discussion and Questions	Michael James (GSK) John Kauffman (FDA)
14:50 – 15:20	**Coffee break**	
15:20 – 17:00	Case Studies	Andrew Teasdale (AstraZeneca) and Laura Rutter (GSK)

EU workshop on ICH Q3D from a quality perspective

6th April 2016, European Medicines Agency, London, Room 3A

Co-Chairs: Sven-Erik Hillver and Michael James

Timing	Subject	Speaker
09:00 – 09:40 09:40 – 10:10	**Regulatory and Pharmacopoeia Block:** EU Regulatory Perspective and Expectations CEPs and Q3D	Sven-Erik Hillver (MPA) Hélène Bruguera (EDQM)

Timing	Subject	Speaker
10:10 – 10:30	Discussion and Questions	
10:30 – 11:00	**Coffee break**	
11:00 – 11:40 11:40 – 12:00	Ph.Eur. and Q3D Discussion and Questions	Bruno Spieldenner (EDQM)
12:00 – 13:00	**Lunch break**	
13:00 – 15:30	Group Exercise on Implementation Challenges	
15:30 – 16:00	**Closing remarks**	