

## 2013 European Medicines Agency/IFAH-Europe Info Day

'THE LATEST DEVELOPMENTS'  
IN SCIENTIFIC REVIEW, LEGISLATION AND MARKETING AUTHORISATION PROCEDURES

7-8 March 2013, European Medicines Agency (EMA), London

### Programme

#### Thursday 7<sup>th</sup> March 2013

13:30	<i>Registration open</i>	
14:00	Introduction and Welcome	David Mackay, EMA
<b>Session I: Scientific Developments</b>		<u>Chair:</u> Rick Clayton, IFAH-Europe
14:10	<b>CVMP work plan for 2013</b> (30')	Anja Holm, chair CVMP
14:40	<b>Pharmacovigilance</b> (20') - Latest developments	Peter Ekström, chair PhVWP-V
15:00	- Industry view (20')	<i>Yvonne Hausmann, IFAH-Europe (tbc)</i>
15:20	Panel discussion with all speakers; (20') Questions & Answers	
15:40	<a href="#">Tea and Coffee</a>	

#### Session II: Scientific Developments

Chair: Kornelia Grein, EMA

16:10	<b>Immunologicals</b> (20') - Latest developments	Nikolaus Križ, EMA
16:30	- Industry perspective (20')	Ariane van de Moer, IFAH-Europe
16:50	<b>Application of 3Rs in safety studies</b> (20') - incl. VICH, EPAA	Nicholas Jarrett, EMA
17:10	Panel discussion with all speakers; (30') Questions & Answers	
17:45	<a href="#">Cocktail reception, followed by supper at 19:00</a>	

#### Friday 8<sup>th</sup> March 2013

#### Session III: EU Procedural Updates

Chair: David Mackay, EMA

09:00	<b>E-presentations</b> (20') - Latest developments	Kornelia Grein, EMA
09:20	- Industry perspective (20')	Michael Colmorgen, IFAH-Europe
09:40	<b>Packaging and labelling</b> (20') - Opportunities and trends	Emily Drury, EMA
10:00	<b>Variations &amp; worksharing</b> (20') - Regulatory perspective	Melanie Leivers, EMA
10:20	- Industry perspective (20')	Remon van Aubel, IFAH-Europe
10:40	Questions (20')	
11:00	<a href="#">Tea and coffee</a>	

**Session IV: Future Legislation and international affairs**

11:20	<b>Veterinary antimicrobials:</b> state of play and future developments (20')
11:40	<b>Global trends and benchmarking</b> (20')
12:00	<b>VICH / Outreach</b> (20')
12:20	<b>An Agency on the move</b> (20')
12:40	Questions (20')
13:00	Close of the meeting

Chair: Declan O'Brien, IFAH-Europe

Martinus Nagtzaam, European Commission

Barbara Freischem, IFAH

Brigitte Boenisch, IFAH-Europe

David Mackay, EMA

Rick Clayton/Kornelia Grein