22 June 2017
EMA/274950/2017

Workshop on generation and use of Health Based Exposure Limits (HBEL)

Managing the risk of cross contamination during the manufacture of medicinal products

20 - 21 June 2017, Room 2D

Chair: David Cockburn, EMA

Health and safety information

In accordance with Agency policy, delegates will be shown a slide show with health and safety and emergency information and procedures. This is displayed at the start as delegates are entering the meeting room. In addition, the chairperson or meeting secretariat will draw the delegates' attention to the slideshow and indicate where the nearest fire exit(s) to the meeting room are. Should there be an evacuation during the meeting, staff will guide delegates out of the building via the nearest fire exit, and assist anyone with mobility impairment.

Time	Topic	
20 June 2017 – HBEL determination, Regulatory proposals and Industry feedback		
09:30	Introduction	David Cockburn, EMA
09:45	Background on development and implementation of guide to HBEL and Q&A	Graeme McKilligan, MHRA, UK
10:15	Application of the Q&A on identifying Highly Hazardous products, justification for this proposed approach – how to use the Q&A, data sources for manufacturers, benefits of this approach	Roland Frötschl, BfArM, Germany
11:00	**Break**	
11:15	Inspection findings on Health Based Exposure Limits and Cross Contamination	Graeme McKilligan, MHRA, UK
12:00	HBEL – an industry perspective Introduction Setting HBEL at different stages of the product life-cycle	 John Berridge, ISPE Bruce Naumann,

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

Time	Topic	
	Key points to recognise quality in HBEL and associated monograph	ISPE Ester Lovsin-Barle/ Peter Boeddeker, PDA
13:00	**Lunch**	
13:45	Summary of feedback from recent public consultation on Q&A	Graeme McKilligan, MHRA
14:15	Summary of main industry concerns from recent public consultation on Q&A	John Berridge, ISPE
14:45	Discussion of key issues from industry and other comments received on the Q&A: • Q&A 2 - Use and applicability of "Highly Hazardous" categories • Q&A 3 – Use of OEL/OEB to determine whether a product is "Highly Hazardous". • Q&A 4 - Continued availability of 1/1000th of a dose approach • Q&A 6 - Setting cleaning limits • Q&A 7, 8 & General comment - Further specific guidance required for veterinary manufacturers • Q&A 14 Use of TTC in establishing HBEL – concerns over applicability • Any other specific points for discussion that stakeholders wish to raise.	Graeme McKilligan, MHRA
15:30	**Break**	
15:45	Continue discussion of key issues from industry and other comments received on the Q&A	
17:15	Reflection on day 1 and opportunities for day 2	David Cockburn, EMA
17:30	**Close Day 1**	
21 June 2017 - Use of HBEL in risk management and next steps		
08:30	Continue discussion of key issues from industry and other comments received on the Q&A and matters arising from day 1.	
09:30	Use of HBEL within risk management to determine organisational and technical controls required. Risk related to the hazard. Inspectors' perspectives and expectations. Key risks/issues, 'road map' of expected approach.	Graeme McKilligan, MHRA Heike Cartensen, LasD Jean-Luc Golnez, AFMPS
10:45	**Break**	
11:00	Evaluation of HBELs and Potential Impact on Cleaning Limits Veterinary case study: Application of HBEL in cleaning validation Use of HBEL in risk assessment	Gretchen Allison, EFPIA Andreas Engwicht-Lassmann, IFAH Stephanie Wilkins, ISPE

Time	Topic	
13:15	**Lunch**	
14:00	Steps to develop and communicate 'road map' Consideration of further actions required: • Applicability to APIs and API intermediate stages • Consistency of application by inspectors • Need and development of training for inspectors and industry • Discussion on options and opportunities to provide training.	Graeme McKilligan. MHRA
16:15	Review	David Cockburn, EMA
16:30	**Close**	

Appendix 1 – List of participants

Name	NCA
Jean-Luc Golnez	Federal Agency for Medicines and Health Products (AFMPS) - Belgium
Christel Raffournier	National Agency for the Safety of Medicine and Health Products (ANSM) - France
Thomas Erlich	
Maryline Buggin-Daubie	National Veterinary Medicines Agency (ANSES) - France
Roland Froetsch	The Federal Institute for Drugs and Medical Device (BfArm) - Germany
Heike Cartensen	LasD/Schleswig-Holstein - Germany
Gavin Ryan	Health Products Regulatory Authority (HPRA) - Ireland
Paul Sexton	
Adele Romani	Italian Medicines Agency (AIFA) - Italy
Teresa Cortellino	
Judit Feher	Malta Medicines Authority - Malta
Graeme McKilligan	Medicines and Healthcare Products Regulatory Agency (MHRA) – United Kingdom
Helen-Marie Dunmore	
Philip Rose	

Name	Industry Association representative
Gretchen Allison	EFPIA – European Federal of Pharmaceutical Industries and Associations
Graham Cook	
Bjorn Dahl	
Nigel Hamilton	
Steven Spanhaak	
Anja Slikkerveer	
John Berridge	ISPE – International Society for Pharmaceutical Engineering
Bruce Naumann	
Stephanie Wilkins	
Jaume Colomer	IFAH – International Federation for Aninal Health
Andreas Engwicht-Lassman	

Name	Industry Association representative
Martin Folger	
Nicolas Luzin	
Koen Nauwelaerts	Medicines for Europe
Hendrik Schlehahn	
Kenneth Farrugia	
Ian Cutting	
Ester Lovsin-Barle	PDA – Pharmacists Defence Association

Name	European Medicines Agency
David Cockburn	Manufacturing and Quality Compliance
Brendan Cuddy	Manufacturing and Quality Compliance
Nicholas Jarrett	Veterinary Department
Milton Bonelli	Clinical Pharmacology and Non-clinical Support Office
Jean-Marc Vidal	Clinical Pharmacology and Non-clinical Support Office
Lydia Dias	Manufacturing and Quality Compliance