ACCELERATING GLOBAL DELETION OF THE ABNORMAL TOXICITY TEST.
PLANNING COMMON NEXT STEPS.
OCTOBER 14TH, 2021 - 12:30 -16:45 CEST

AGENDA

Time	Topic	Speakers/Panelists/Moderators
12:30	Welcome Opening remarks	• Laura Viviani, (AFSA, HSI Director of Biologicals) • Kirsty Reid (EFPIA, Director Science Policy)
12:40	Keynote speeches (15 min per speaker) • The Global Challenge of post-approval changes and how to address it. • Removal of the ATT from the European Pharmacopoeia • Q&A (10)	 • Thierry Gastineau (SANOFI PASTEUR, Global Quality Head of Innovation, Culture & Engagement) • Catherine Milne (EDQM, Head of section Biological Standardisation)

HUMANE SOCIETY INTERNATIONAL

AFSA ANIMAL-FREE SAFETY ASSESSMENT COLLABORATION

efpia European Federation of Pharmaceutical Industries and Associations

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13:20	Roundtable: Global perspectives on ATT deletion	Moderator: • Shahjahan Shaid, GSK (Program Manager and Head of 3Rs) Participants: • EFPIA – Mark van Ooij (Scientific Director, Drug Substance Development Vaccines and Process Development Department, Infectious Diseases & Vaccines TA, Janssen Vaccine Technology) • DCVMN – Leena Madhuri (Quality Control Lead, Indian Immunologicals) • WHO –Dianliang Lei (Technical Specifications and Standards unit of Health Product Policy and Standards) • HealthCanada – Dean Smith (Associate Director in the Center for Biologics Evaluation (CBE)) • CBER/FDA - Robin Levis (Deputy Director of the Division of Viral Products in the Office of Vaccines Research and Review at CBER/FDA) • Bill & Melinda Gates Foundation – Philippe-Alexandre Gilbert (Senior Program Officer CMC) • *50 mins*

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14:10	Break	

14:15	Open session: **Many countries many approaches, how far are we for a global alignment**
	
	Current status of ATT
	Dialogue bewteen Industries and regulators
	Plans for deletion/barriers
	
	Find common local approaches to support deletion and how global player can support the process –> to help next session
		Moderator:
		• Joris Vandeputte (IABS)
		
		Panelists:
		• 10' - Japan – **Takuo Mizukami** (National Institute of Infectious Diseases) *starts first with question 1* // **Yoshihisa Shirasaki** (GSK/Japan)
		• 25' - China – RDPAC repr. (**Jack Xie /J&J,** Xiantang Li/Pfizer US; James Ooi/Novartis China, Ying-ying Zhou/Merck US) // Prof. Yang (Tsinghua University)
		• 15' - Russia – **Alla Trapkova** (FSBI SCEEMP) // Viktor Aleksandrovich Dmitriev (General Director ARFP) // Elena Sakanyan (Microgen)
		• 10' - India – Dr. Jai Prakash (Sr. Principal Scientific Officer, IPC)// Dr. **Sunil Goel** (Additional Director QC, Serum Institute of India)
		• 10' – Indonesia - Eniek Suwarni (NQCLDF, Indonesia FDA) // **Amrullah Aninditio Subagio** (Quality Control, BioFarma)
		• 5' - South Korea – **Kyung Jin Jung** (Korea Institute of Toxicology)
		
		There is enough time in case we go longer (1 h 10 min /1 h 25 min)

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15:40	Break	
15:50	Collaborative session: defining next step *Aim: The participants should concretely work on identified actions (global vs country/region specific).*	Moderator: • Vaughn Kubiak (IABS) Send notes to Rajinder and Philippe
16:20	Closing remarks: Importance of regulatory alignment What's coming next and thank	Rajinder Suri (CEO, DCVMN), Philippe-Alexandre Gilbert (Bill & Melinda Gates Foundation) Laura Viviani, (AFSA, HSI Director of Biologicals) Kirsty Reid (EFPIA, Director Science Policy)

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