2021 PDA Aseptic Animal Health Conference
Online
26-27 October 2021

Tuesday, 26 October 2021

Conference Portal Opens: Create your User Profile & Get Oriented & Join the Virtual Exhibition		
12:30	Welcome & Introductions	Falk Klar, *PDA Europe*
12:35	**LIVE:** Welcome from the Chairs	Mai Huynh, *U.S. FDA* Martin Müllner, *Boehringer Ingelheim*
12:40	Keynote: Companion vs Cattle Animals – How Veterinary Manufacturing is Impacted	Luc Pisarik, *Boehringer Ingelheim*
Updates in the Regulatory Landscape		**Moderators:** Martin Müllner, *Boehringer Ingelheim* Mindy Hoskins, *WEST*
13:00	**LIVE Session Introduction**	
13:05	Jurisdiction between USDA and U.S. FDA	Kate Huebner, *U.S. FDA* Matt Erdman, *USDA*
13:25	The One Health Initiative in the US	Marianne P. Martinson, *U.S. FDA*
13:45	Regulation (EC) 2019/6: the driving force for change in European VMP registration	Klaus Hellmann, *Klifovet AG*
14:05	LIVE Q&A, Discussion	
14:35	**Break & Virtual Exhibition**	

Module II

Tuesday, 26 October 2021

Drug and Supply Shortages in the Animal Health Industry		**Moderators** Mai Huynh, *U.S. FDA* Mike Schäfers, *Aenova Group*
15:05	**LIVE Session Introduction** *The pandemic has resulted in several shortages of commodities that impact our lives one way or the other. As supply chain becomes more and more complex due to globalization, shortages of*	

	ingredients and/or non ingredients supplies (e.g. vials, stoppers, sterilizing filters, single use bags, tubing, etc.) have forced all of us to react and adapt differently. Shortage of drugs for use in human has been a highlight throughout the pandemic; veterinary medicinal drugs are not an exception.	
15:10	U.S. Veterinary Drug Shortages: Industry Views on Potential Changes to Regulatory Policy	Jeanne Greenwald, *Intervet*
15:30	PDA Task Force on Quality Risk Management: Managing Supply Shortages	Tiffany Baker, *ValSource*
16:50	**LIVE Q&A, Panel Discussion**	Jeanne Greenwald, *Intervet* Tiffany Baker, *ValSource* Arnel B. Peralta, *U.S. FDA* Renée Blosser, *U.S. FDA* Mai Huynh, *U.S. FDA* Mike Schäfers, *Aenova Group*
16:20	**Break & Virtual Exhibition**	

Module III

Tuesday, 26 October 2021

Interactive Experience: Working Groups **Implementation of the Annex 1 Revision in the Animal Health Industry**		**Moderators** Martin Folger, *Boehringer Ingelheim* Olivier Chancel, *Boehringer Ingelheim*
16:50	**LIVE Session Introduction** *The revision of the EU GMP Annex 1 will be published soon. New requirements are included that are applicable not only to the Human Health Industry but also to the Veterinary Industry. Within this session, we will have the chance to listen to two case studies on hot topics discussed in the new Annex 1: Contamination Control and Barrier Systems. Following the presentations 2 workshop groups in separate live video chat rooms will offer a deep dive into the challenges faced in the Animal Health sector specifically. Choose your topic and join the discussions with the experts.*	
16:55	*Topic 1 - Contamination Control* Contamination Control Through Efficient Cleaning and Disinfection - A Case Study	Subrata Chakraborty, *GxPFONT Consulting Group*
17:15	*Topic 2 – Barrier Systems* Differences in the Contamination Control Strategy using Barrier Systems - A Case Study	Richard Denk, *SKAN*

17:35	LIVE Q&A, Discussion	
17:50	Group 1 **Contamination Control** • What differences are apparent between Human and Animal Industry and how does this impact the implementation of the new guidelines? • How can companies be compliant and what strategy along the whole supply chain will be feasible? • How does QRM relate to the proposed, revised Annex 1 CCS?	Group 2 **Barrier Systems** • What is the typical set-up currently in Animal Health Manufacturing Facilities and how can the proposed requirements be met in each set-up? • Is the trend towards closed or open RABS? • What specifications does equipment need to have specifically in the veterinary industry?
18:20	LIVE: Summary of Working Groups by Moderator groups	
18:30	**End of Conference Day 1 and Live Poster Lounge**	
18:30 – 19:30 CEST: Networking Event – Poster Lounge		

Module IV:

Tuesday, 26 October 2021

12:00 CEST: Conference Portal Opens: Create your User Profile & Get Oriented & Join the Virtual Exhibition		
13:00	**Development, Testing and Aseptic Processing of Veterinary Products**	**Moderators:** Alexander Trautmann, *A&O Pharma* Luc Pisarik, *Boehringer Ingelheim*
LIVE Session Introduction Session description		
13:05	Overview of the Fundamental Principles Governing Aseptic Processing	Tony Dinis, *CEVA*
13:25	Monocyte Activation Test: A Comprehensive Approach to Assessing Pyrogenic and/or Non-pyrogenic Contaminants in Biologics and Medical Device	Flobert Tanga, *Baxter Healthcare*

13:45	Case Study: Flexible Fill/Finish Line for Multiple Veterinary Products at High Outputs	Laura Moody, *Syntegon Pharma Technology*
14:05	LIVE Q&A, Discussion	
14:30	**Break & Virtual Exhibition**	

Module V

Wednesday, 26 October 2021

15:00	**Novel Approaches in the Animal Health Industry**	**Moderators** Marit Lemke, *Elanco* Hanjo Hennemann, *VeroVaccines*
LIVE Session Introduction *This module provides insight into new approaches for R&D in the animal health industry. It spans across early research (antimicrobial drug resistance), platforms (recombinant antibody discovery), analytical development (shortening development timelines using simulations) to late phase development activities (decision on sustainable packaging).*		
15:05	An Approach to Sustainable Packaging in the Animal Health Space	Elke Wagner, *Elanco Animal Health* Uwe Müller, *Elanco Animal Health*
15:25	Case Study – Computational Simulation Support for Injection Device Development	Max Rehpenning, *Elanco Animal Health* Jeremy Hemmingway, *Stress Engineering Services*
15:45	Species-Specific Therapeutic Antibodies as New Treatment Options in Veterinary Medicine	Markus Waldhuber, *Adivo*
16:05	Exploring Microbial Virulence Factors: Roles as Potential Therapeutic Targets and Relationships to Antimicrobial Drug Resistance	Heather Harbottle, *U.S. FDA*
16:25	LIVE Q&A, Discussion	
17:00	**LIVE** Conference Closing & Summary	Mai Huynh, *U.S. FDA* Martin Müllner, *Boehringer Ingelheim*
17:15	**LIVE** Thank You Remarks and Farewell	Falk Klar, *PDA Europe*

Agenda is subject to change without notice