

ANIMAL HEALTH

— REGULATORY AFFAIRS —

PHARMA • BIO • NUTRITION



Day 1: Tuesday, September 16

K-State Olathe | 22201 West Innovation Drive Olathe, KS 66061

Time	Topic and Presenter	Location
8 a.m.	Check-in	Lobby
Keynote 8:30 - 10 a.m.	Opening Keynote: The Adversarial and Collaborative Facets of Regulatory Affairs: Opportunities and Challenges , Carlos Gonzalez, Ph.D., Hill's Pet Nutrition <i>This presentation will address challenges faced by a variety of stakeholders in balancing regulatory compliance and oversight with supporting agribusiness and ensuring safe, effective products are available and affordable.</i>	Great Plains B
10 - 10:15 a.m.	Break	
Session One Breakouts 10:15 - 11:30 a.m.	 Navigating and Understanding AAFCO , Dan King, Minnesota Department of Agriculture, AAFCO <i>Develop an understanding of AAFCO's role in ingredient regulations, their history as an organization, the resources they provide, and how to engage with them as a professional.</i>	Great Plains B
	 Introduction to the FDA , Rob Hunter, Ph.D., Animal Health Consultant <i>Understanding how CVM operates is critical to being an effective professional in animal health. This presentation will review the history of the FDA and the process of getting a drug to market through the agency's processes.</i>	221A
	 Introduction to the USDA , Norm Brown, M.S., Animal Health Consultant <i>This breakout provides an introduction to understanding the CVB, including history and how regulations became law. Discussion will focus on why Congress decided veterinary virus serums and toxins would be regulated by the USDA and also more about the structure of the agency and how it functions today.</i>	221B
11:30 a.m. - 12:30 p.m.	Lunch, sponsored by 	Bistro
Session Two Breakouts 12:30 - 1:45 p.m.	 Regulatory Jenga: Navigating Import and Export Regulations in Animal Nutrition with the USDA , Lyn Huffaker, D.V.M., Ph.D., LH Solutions <i>Gain a closer understanding of how USDA APHIS handles export and import of animal origin products, such as feeds, pet foods and ingredients. Learn about regulatory hurdles and some of the common mistakes that may cause delays and disruptions.</i>	Great Plains A
	 Animal Supplements and Legal Risk Considerations , Bill Bookout, National Animal Supplement Council Todd Harrison J.D., Venable, LLP <i>To maximize economic success of any business venture, it is critical not to step on any potential landmines that may cause significant disruption to your business. In this session, get a clear look at how animal supplements are regulated and where the legal risks hide. Learn how to navigate product claims, stay compliant and avoid common pitfalls that can disrupt your business.</i>	Great Plains B
	 Panel: NexGen Products , Matt Zehnder, PastureBio Rob Hunter, Ph.D., Moderator Terrell Suddarth, Hilltop Bio Kevin Carrick, Ph.D., USP <i>New technologies are presenting new challenges for companies and the agency in getting products to market efficiently. Join these panelists as they share about their journeys in development and navigating the process to market, as well as how other organizations support the research and work.</i>	221A
	 Licensing New Products through CVB: Continuum of Studies Needed , Helen Smith, M.S., Kemin <i>Pitfalls in pushing ahead with submissions and studies without having the necessary information for the product is an ongoing challenge. The course will provide an understanding of the process for licensing a veterinary vaccine with USDA/CVB.</i>	221B

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Time	Topic and Presenter	Location
1:45 - 2 p.m.	Break	
Session Three Breakouts 2:15 - 3:30 p.m.	 Import and Export of Nutrition Ingredients with the FDA , Tim Lombardo, EAS Consulting Group <i>Join us for a practical look at FDA regulations for importing food and nutrition ingredients into the U.S. This course will outline the specific food regulations required at each stage in the import process from manufacturing in the foreign facility to distribution in the U.S. and whose responsibility it is for each activity.</i>	Great Plains A
	 Panel: CRO Selection and Oversight , Rob Hunter, Ph.D., Moderator Kyle Kappeler, Attentive Science Dominic Warrino, Ph.D., KCASBio <i>The value of using a CRO is best utilized when the sponsor and CRO develop clear communication and shared goals. Hear from two CROs on questions to ask and how to make the most of the relationship to develop a quality product and efficient process.</i>	221A
	 Qualification and Validation of Equipment for FDA, USDA and Medical Devices , Terrie Jo Hamtak, Merck Animal Health (retired) Sandy Dixon, Plastikon Healthcare <i>Validation requirements differ between USDA and FDA for vaccines, medical devices and drugs. Learn the differences and how to use a project specific validation plan with URS documents to provide a well laid out approach to managing project deliverables.</i>	221B
3:15 - 3:45 p.m.	Break	
3:30-4 p.m.	Speaker Panel and Day One Wrap-up	Great Plains B
5:30-7 p.m.	Networking Dinners RSVPs are required <i>Join us for dinners hosted across various KC restaurants by subject matter experts.</i>	Off-site

Helpful hints

- Our guest wifi is available for your convenience: **KSUGuest**
- Luggage storage is available on Thursday in Office 210.
- **Need a space to work?** The Bistro and Student Success Center are available for your use. If you need a private space, please ask a team member for assistance.

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Day 2: Wednesday, September 17



Time	Topic and Presenter	Location
8:30 - 9 a.m.	Research and Networking Breakfast , Sidharth Babu, Sensory and Consumer Sciences Madison Bermisderfer, Animal Science Logan Diller, Animal Science Ashlee Gibbons, Animal Science	Great Plains B
9 - 10:15 a.m.	Standing in the Storm: Maintaining your Mojo in the Midst of Uncertainty, Jim Bishop, M.S., Conjunction Leadership <i>You don't need another productivity hack. You need a life that actually works; where energy, space and purpose coexist. This keynote delivers a fresh framework for leaders who are high performing and highly tired. Attendees will understand the relationship between energy, clarity and sustainable success; be introduced to a practical margin-building framework for themselves and their teams; and, walk away with tools to protect mojo and align daily work with deeper meaning.</i>	Great Plains B
10:15 - 10:30 a.m.	Break	
Session One Breakouts 10:30 - 11:45 a.m.	Panel: Value of Interdisciplinary Approaches to Developing Nutrition Products Amanda Anderson, Elanco Kelly Foos, J.D., Post Consumer Brand Haley Larson, Ph.D., K-State Olathe Moderator - Kathy Gross, Ph.D., PAS, Dip. ACAN, K-State <i>Silos occur when teams or departments operate independently with limited interaction, leading to duplicated efforts, misalignment of goals, and wasted resources. Silos create significant obstacles, including poor communication, reduced efficiency, and barriers to innovation. An interdisciplinary approach facilitates innovation while ensuring regulatory compliance, consumer protection, and faster, more strategic market access.</i>	Great Plains B
	A Conversation on the Developing Technology of Monoclonal Antibodies Jay Peterson, Elanco Facilitator - Norm Brown, M.S., Animal Health Consultant <i>This facilitated conversation will provide an initial understanding of monoclonal antibodies use in animal health and a discussion of the most recent developments in the technology.</i>	221A
	USDA and FDA Compliance Through Facility Design, Sandra Bachamp, M.S., P.E. Novel Engineering and Consulting <i>Understanding facility design features in response to regulatory compliance or process requirements is a challenge. Join us to learn more about facility needs, including general arrangement and utilities, that help ensure compliance.</i>	221B
11:45 a.m. - 12:45 p.m.	Lunch/Break	Bistro
12:45 - 2:15 p.m.	Professional Skills Workshop: Translating Expertise: Professional Skills for Scientific Minds, Brent Mayabb, D.V.M., M.S., Royal Canin <i>People with a scientific, technical or medical background can sometimes struggle in business-oriented conversations. Their methods of communication are highly effective in settings with scientific peers but often fail to work with business colleagues. This interactive workshop will provide learners with tangible communication processes and tools, including a stakeholder mapping process, the SBI feedback method, and the 5 Languages of Appreciation framework.</i>	Great Plains B

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Day 2: Wednesday, September 17



Time	Topic and Presenter	Location
2:15 - 2:30 p.m.	Break	
Session Two Breakouts 2:45 - 4 p.m.	 Regulatory Innovation in Action: The SRIS Pathway and the AAFCO–K-State Olathe Partnership for Ingredient Review , Haley Larson, Ph.D., K-State Olathe <i>Recent changes in the animal nutrition regulatory landscape have opened the door to modernizing how new ingredients are evaluated for use in animal feed and pet food. The newly established Scientific Review of Ingredient Submissions (SRIS) pathway—a partnership between AAFCO and Kansas State University—recruits, trains, and engages industry thought leaders to review ingredient definitions for inclusion in AAFCO's Official Publication, the FDA-recognized listing of approved feed ingredients for livestock and pet food.</i>	Great Plains A
	 Global Efforts: Changing Pharmacovigilance Landscape , Martin Tiemann, D.V.M., Boehringer-Ingelheim Animal Health U.S. <i>A brief description of the history of Global Pharmacovigilance, an oversight of existing regulations and a summary of ongoing PV activities within Industry Associations.</i>	221A
	 Leveraging Bioassays for Quality Control and Regulatory Considerations in Animal Health Biologics , Maria Dashek, D.V.M., Ph.D., DACPV, Promega <i>Enhance your understanding of how bioassays can be used to ensure product quality and regulatory compliance. This session also will equip participants with knowledge of cutting-edge tools for biologics development offering real-world case studies demonstrating best practices and common pitfalls in bioassay implementation.</i>	221B
4 - 4:30 p.m.	Day Two Wrap-up Session	Great Plains B
4:30 - 6 p.m.	Social After Hours Off-site	Austin's Bar and Grill 11180 S. Lone Elm Drive Olathe, KS 66061 <i>(across the street from campus)</i>

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Day 3: Thursday, September 18



Time	Topic and Presenter	Location
8:30 - 9:30 a.m.	Industry Resources Panel Breakfast , Sponsored by AHC, AHI, ADA, GADA, BioNexus, AAIV	Great Plains B
9:30 - 9:45 a.m.	Break	
Session One Breakouts 9:45 - 11 a.m.	 Understanding Ingredient Approval Pathways , Leah Wilkinson, AFIA <i>Gain the latest updates and insights in the animal ingredient review process. New pathways, changing definitions, and legislation proposals make navigating the latest information an ever-changing challenge.</i>	Great Plains A
	 Understanding ADUFA/AGDUFA Fees , Stephanie Batliner, Bimeda Kathy Vannatta, Phibro <i>During this presentation, plan to learn about the differences of ADUFA and AGDUFA fees, their history and how to understand what is needed.</i>	221A
	 Navigating the Regulatory Pathways of Novel Oral Biologics: Scaling a Scientific Discovery into Manufacturing at Scale and Setting up Quality Control , Jolieke van Oosterwijk, Ph.D., M.S., MCB, US Biologic	221B
11 - 11:15 a.m.	Break	
Session Two Breakouts 11:15 a.m. - 12:30 p.m.	 Licensing and Registration for US Pet Food Producers and Suppliers , Cheryl Iverson, Merieux Lifesciences <i>How to navigate through licensing and registrations for pet foods in the US.</i>	Great Plains B
	 CMC Overview , Stephanie Batliner, Bimeda <i>In this session, Drug Substance and Drug Product technical elements for CMC technical sections for veterinary drugs for registration with FDA-CVM will be explored and discussed. This includes considerations for analytical methods and formulation development, selection of packaging, scale up and post-approval changes.</i>	Great Plains A
	 Clinical Efficacy vs. Study Claims , Melinda Poole, D.V.M., Poole Veterinary Consulting <i>In pharmaceutical development, clinical efficacy and study claims are related but distinct concepts, and understanding the difference is important for interpreting results and marketing statements. Clinical efficacy is the proven, measured effect in well-controlled clinical trials. Study claims are the takeaways and marketing statements derived from that data which may or may not match the strength of the actual evidence.</i> <i>From a regulatory perspective, clinical efficacy shows whether the drug produces the intended clinical benefit in the target patient population. It is the actual, measurable therapeutic effect of a drug in controlled clinical trials and is derived from predefined endpoints in trial protocols (most often those that show a clinical benefit or endpoint vs a biomarker). These are core to regulatory approval and label indications.</i>	221A
	 Innovation to Organization: From Compliance in a Post-licensure Setting , John Brooke, Ph.D., MPH, US Biologic	221B
12:30 - 1:30 p.m.	Lunch/Break	



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Time	Topic and Presenter	Location
Case Study Working Groups 1:30 - 3 p.m.	 Working Group A: Elements of a Label: Livestock and Companion Animals, Kathy Gross, Ph.D., PAS, Dip. ACAN, K-State Garret Ashabrunner, Ph.D., K-State Olathe <i>Both livestock and companion animal nutrition labels often leave more questions than answers. In this workshop, participants will have the opportunity to practice identifying key characteristics of labels and how to make them regulatory compliant.</i>	Great Plains A
	 Working Group B: Labeling and the FDA, Rob Hunter, Ph.D., Animal Health Consultant Jennifer Schofield, D.V.M., CPH, Elanco <i>Apply what you've learned by practicing with a pharmaceutical label ready for market. Catch the mistakes and make suggestions to make sure you've met the regulatory requirements needed to pass inspection of the label.</i>	221A
	 Working Group C: Writing an Outline for Production (USDA), Norm Brown, M.S., Animal Health Consultant Terrie Jo Hamtak, Merck Animal Health (retired) <i>Writing an outline for production is a long process that requires accuracy and know-how to follow through to completion. Take the process step-by-step to gain an understanding of how to prepare and complete a full outline of production for CVB licensure.</i>	221B
3 - 3:30 p.m.	Closing Remarks and Conference Wrap Up	Great Plains

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Have questions? Ask to speak to a Success Coach, email ksuolathe@ksu.edu or call 913-307-7373.



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