The Veterinary Drug Approval Process and FDA Regulatory Oversight (com) A

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Organizer : METRICSTREAM INC - NewYorkEventsList

Venue :

Location : Kansas CityKansas City, MOUnited States,
Kansas , MO , US, ZIP: United States

Description

The Veterinary Drug Approval Process and FDA Regulatory Oversight

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REGISTER TODAY!

The U.S. Food and Drug Administration's Center for Veterinary Medicine or CVM is responsible for the approval of veterinary drug products intended for both family pets and food-producing animals. However, FDA does not regulate all products intended for animal use. Jurisdiction over animal products including licensed biologics such as vaccines is shared with a number of other federal agencies. For example, animal vaccines, animal disease diagnostic devices and some animal biologics are regulated by the U.S. Department of Agriculture's Animal and Plant Health Inspection Service or APHIS; and products such as flea and tick collars are regulated by the Environmental Protection Agency.

This seminar on veterinary medicine regulations will provide attendees with an understanding of FDA's veterinary drug approval process. This two day interactive course will cover:

- Premarket approval process
- Various sections of a New Animal Drug Application
- Strategies for navigating the FDA approval process and for expending product approval
- The nature of shared jurisdiction over veterinary products in certain cases

Seminar Fee Includes:Lunch
AM-PM Tea/Coffee
Seminar Material
USB with seminar presentation
Hard copy of presentation
Attendance Certificate
$100 Gift Cert for next seminar

Learning Objectives:

Upon completing this course on veterinary medicine regulations participants will:

- Understand how the U.S. Food and Drug Administration regulates veterinary drug product.
- Understand how FDA's Center for Veterinary Medicine is organized.
- Discuss the process by which veterinary drug products are reviewed and approved.
- Learn how to open an INAD File and request fee waivers.
- Obtain a working knowledge of various sections included within an NADA.
- Develop a deep understanding of what is needed to substantiate product characterization,

target safety and effectiveness.
- Analyze FDA's rules governing chemistry, manufacturing and controls or CMC.
- Understand the various components of an animal field study to support product approval.
- Discuss the difference between FDA's various user fees and fee waivers.
- Identify the elements of an FDA compliant label.
- Develop a corporate compliance strategy covering labeling, marketing and advertising.
- Problem solving methods to mitigate regulatory enforcement risks.
- Explain how jurisdiction is split between various Federal agencies in a certain cases.
- Learn how animal feed, veterinary devices, OTC drug products and nutritional supplement are regulated in the U.S.

Who will Benefit:

This course is designed for people tasked with developing and maintaining an animal health company's product portfolio and responsible for overseeing a company's regulatory strategies. This includes individuals responsible for overseeing regulatory affairs, developing veterinary drug products, evaluating new technologies or applications, and those tasked with ensuring corporate compliance. Among others, this includes:

- Personnel new to the Animal Health Industry
- CRO professionals
- Entrepreneurs looking to add value to their products
- Regulatory professionals
- Compliance professionals
- U.S. Agents of Foreign Corporations
- Process owners
- Document control specialists
- Record retention specialists
- Legal Professionals
- Financial Advisors and Institutional Investors
- Consultants, Inspectors and cGxP Experts

AGENDA

DAY 01(8:30 AM - 4:30 PM)

- 08.30 AM - 09.00 AM: Registration
- 09.00 AM: Session Start
- Introduction to the FDA Veterinary Drug Approval Process
- Introduction to Veterinary Drug Approval process
    - FDA's jurisdiction and Center's relevant to Animal Health
        - Center for Food Safety and Applied Nutrition (CFSAN)
        - Center for Drug Evaluation and Research (CDER)
        - Center for Veterinary Medicine (CVM)
    - Specifics of CVM
    - Intro to the FDCA, AMDUCA, ADAA, MUMS, etc and guidance (GFI)
        - Overview of FDCA and regulations
        - Introduction to FDA GFI
- Overview of Veterinary Drug Develpment
    - Discovery/Acquisition
        - Preliminary Patent Protection Concerns
    - Submissions
        - Open INAD File
        - NADA (8 sections)
            - 5 Major Technical Sections
            - Chemistry, Manufacturing and Controls (CMC)
            - Safety (target animal safety study)
            - Efficacy (field study)
            - Human Food Safety (human food safety studies for food-producing animals)
            - Environmental Impact (EA/CE)
    - Brief Description of cGxP (GMP, GLP, & GCP)
- Approval Process: Chemistry, Manufacturing Controls, Environmental Impact & Managing Clinical Trials
    - CMC
        - API: name, structure, properties
        - API manufacturing
        - Clinical Trial material
        - Final Formulation
    - Target Animal Safety
        - Content and format
        - Final Study Reports
        - Monitoring and Reporting Adverse Drug Events
    - Human Food Safety
        - Analysis of Drug Residues
        - Toxicology
        - Residue Chemistry
        - Microbial Food Safety
        - Regulatory Method Relied Upon by Sponsor
    - Effectiveness
        - Dosage Characterization

        - Substantial evidence (e.g. dose confirmation and clinical field studies)
        - All other information related to effectiveness
        - Proposed effectiveness-related labeling
        - Effectiveness Guidance Documents
        - The 7 Major Phases of Animal Field Studies
        - Planning
        - Study Initiation
        - In-life Activities
        - Site close-out
        - Data management
        - Biostatistical analysis
        - Report writing
    - Environmental Impact
        - Categorical Exclusions
        - Environmental Assessments (EA)
        - Common EA Components
        - Environmental Impact Statements (EIS)
    - Labeling 21 CFR requirements
    - FOI
    - AOI

DAY 02(8:30 AM - 4:30 PM)

- Animal Drug User Fees and Related Fee Waivers
    - Veterinary Drug User Fees and Fee Reductions and Waivers
        - Animal Drug User Fee Act (ADUFA) – Applies to Innovators Only
        - Animal Generic Drug User Fee Act (ADGUF) – Applies to Generic Manufacturers
        - ANADA sections
            - CMC
            - BE (Safety & Efficacy)
            - HFS
            - All others
        - Types of User Fees
            - Animal Drug Application and Supplement Fee
            - Animal Drug Product Fee
            - Animal Establishment Fee
            - Animal Drug Sponsor fee
        - Types of Fee Waivers and Reductions
        - Procedures, Timing and FDA Evaluation of Waivers or Reductions
    - FDA decision on approval
- Introduction to FDA's Regulation of Veterinary Feed, OTC Drugs and Supplements

    - Animal Feed
        - GRAS
        - Feed Labeling
        - AAFCO
        - Veterinary Feed Directive (VFD)
    - Veterinary OTC Drugs and Nutritional Supplements
        - Regulatory Agencies
        - CVM Compliance Policy - CPG 690.150 & CPG 690.100
    - Veterinary Medical Devices CPG 655.100
- USDA (CVB, APHIS, FSIS) & EPA
    - USDA's Animal and Plant Health Inspection Service
        - Virus Serum Toxin Act
            - Animal vaccines
            - Animal biologics
            - Animal disease diagnostic devices
    - EPA
        - Flea & Tick Products
        - Insect Repellants such as Equine Fly Sprays
        - State Registrations
- Non-Approval-Related Considerations
    - Extra-Label Drug Use
    - Compounding
    - Noncompliance and Enforcement
        - FDA Enforcement Authority over Development, Manufacture, Marketing, and Distribution
            - FDA's Office of Regulatory Affairs (ORA): Responsible for field activities, imports, inspections, and enforcement policy
            - Local, State, and Tribal governments
            - CVM's Office of Surveillance and Compliance
        - Types of Enforcement Actions
    - Pharmacovigelence
    - Post-approval submissions
        - CMC
        - Safety
        - Efficacy

SPEAKER

Rob Hunter
Veterinary Drug Development Specialist

Seminar Instructor Rob Hunter has 20 years of veterinary and human drug development experience with NASA, Pfizer, Elanco, Parnell, and Provetica. He has contributed to the approvals for Revolution®, Dectomax®, Ovugel®, and Pulmotil®, with others currently in development or under regulatory review. Internationally recognized subject matter expert on pharmacokinetics, antimicrobial PK/PD, interspecies allometry, drug metabolism, bioequivalence, and tissue residues/human food safety along with corresponding bioanalytical support. Dr. Hunter has served on and chaired several AHI committees and represented the U.S. veterinary pharmaceutical industry on the VICH bioequivalence expert committee. He has represented various companies at CVM/FDA, EMA/CVMP, APVMA, VDD (Canada), NVQRS/QIA (South Korea), Thailand FDA, NVAL (Japan), Ministry of Agriculture (Vietnam), and IVDC (China) regarding specific products, issues, and/or policies.

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