



VETERINARY BIOLOGICS TRAINING PROGRAM



INSTITUTE FOR
INTERNATIONAL
COOPERATION IN
ANIMAL BIOLOGICS

an OIE collaborating center

MAY 13 - 23, 2014

The Institute for International Cooperation in Animal Biologics (IICAB) is offering the Veterinary Biologics Training Program beginning May 13, 2014 in Ames, Iowa. The course is sponsored by the USDA Animal and Plant Health Inspection Service's (APHIS) Center for Veterinary

Biologics (CVB). The USDA sponsors have concentrated their veterinary biologics training into one consolidated course per year. Individuals interested in obtaining veterinary biologics training at USDA facilities in Ames are strongly encouraged to obtain that training through this course.

COURSE OBJECTIVES:

This course will give participants an overview of the scientific principles of vaccines and vaccination and of the USDA regulatory process for assuring the purity, safety, potency, and efficacy of veterinary biologics.

AUDIENCE:

Intended participants are from biologics companies and government regulatory programs. In the past 18 years, more than 1500 individuals from the United States have attended the Program, along with more than 600 international participants.

BLOCK 1: IMMUNOLOGY AND PRINCIPLES OF VACCINATION

Block 1 is intended for individuals who have not recently studied immunology who want an overview and update of immunology as it applies to resistance to infectious diseases. *Presented by James A. Roth, IICAB, Iowa State University*

TUESDAY, MAY 13

2226 College of Veterinary Medicine

1:00 p

Welcome and Introduction of the Course and Participants

1:30 p - 5:00 p

Basic Immunology
Introduction, Phagocytosis, Complement System

WEDNESDAY, MAY 14

2226 College of Veterinary Medicine

8:30 a

Basic Immunology
Interferons, Lymphocytes, Antibodies and Antigens, Cell-Mediated Immunity

11:50 a

Lunch

1:00 p - 5:00 p

Basic Immunology
Antigen Processing and Presentation, Lymphocyte Antigen Recognition, Activation and Effector Mechanisms, Lymphocyte Circulation, Mucosal Immunity

THURSDAY, MAY 15

2226 College of Veterinary Medicine

8:30 a - 11:50 a

Basic Immunology
Fetal and Neonatal Immunity, Mechanisms of Hypersensitivity, Evaluation of Cell-Mediated Immunity

11:50 a

Lunch – Certificate Presentations

1:00 p - 5:00 p

Comparative Immunology
Principles of Vaccination – Vaccine Safety and Efficacy

FRIDAY, MAY 16

2226 College of Veterinary Medicine

8:30 a - 11:50 a

Vaccine Safety and Efficacy (continued)
Overview of Biotechnology Derived Biologics – Adjuvants

No Lunch Provided

BLOCK 2: PROCEDURES FOR ENSURING VACCINE SAFETY AND EFFICACY

Block 2 will review the requirements and processes for licensing/registration and testing of veterinary biological products and the inspection and compliance process. *Presented by USDA CVB Staff.*

MONDAY, MAY 19

2226 College of Veterinary Medicine

8:30 a

Welcome and Introduction of Participants

9:30 a

Instructions to Participants

9:40 a

Break

9:55 a

Introduction to the Center for Veterinary Biologics (CVB)

10:25 a

Quality Manufacturing Standards for Veterinary Biologics

11:05 a

Break

11:20 a

Introduction to the CVB – Policy, Evaluation & Licensing (PEL)

12:05 p

Lunch

Optional Presentation: Brucellosis

1:00 p

General Licensing Requirements in the United States

1:45 p

Break

2:00 p

Outlines of Production

3:00 p

Break

3:15 p

Efficacy Requirements & Interference Studies

4:15 p - 4:45 p

Regulatory Considerations for Nucleic Acid-Mediated Veterinary Vaccines

TUESDAY, MAY 20

2226 College of Veterinary Medicine

8:30 a

Statistical Considerations for Vaccine Trials

9:20 a

Break

9:35 a

Licensing of Veterinary Diagnostic Test Kits

10:25 a

Importation of Biological Products for Distribution and Sale

10:55 a

Break

11:10 a

Regulating Products of Biotech Origin

12:00 p

Lunch

Optional Presentation: Veterinary Stockpile

1:00 p

Summary Information Format and Risk Analysis

1:50 p

Safety Requirements

2:25 p

Break

2:40 p

In vitro Potency Testing of Live and Inactivated Vaccines

3:30 p

Autogenous Biologics

4:10 p **Break**
4:25 p - 4:55 p Poultry Specific Licensing Issues

WEDNESDAY, MAY 21

2226 College of Veterinary Medicine

8:30 a Master Seed Testing (Viral, Bacterial, Recombinant)
9:10 a United States Vaccine Label Regulations
9:50 a **Break**
10:05 a FDA-EREA Regulations and CVB
10:30 a Regulatory Consideration for Transgenic Plant-Derived Vet Biologics
11:05 a **Break**
11:15 a Review of New Products
12:00 p **Lunch**
1:00 p Aquaculture Biologics
2:00 p - 5:00 p USDA NCAH Tour

THURSDAY, MAY 22

2226 College of Veterinary Medicine

8:30 a Introduction to the CVB – Inspection & Compliance (IC)
9:00 a CVB Inspection Program
9:30 a **Break**
9:45 a Compliance Activities
10:25 a Overview of CVB Website
11:05 a **Break**
11:20 a Inspection Categories
12:00 a **Lunch** – Certificate Presentations
1:00 p Product Inspection and Release
1:40 p Record Keeping and Documentation
2:20 p **Break**
2:35 p Common Errors and Other Form 2008 Uses
3:15 p Pharmacovigilance
3:55 p **Break**
4:05 p - 4:50 p Exporting Products from the United States

FRIDAY, MAY 23

2226 College of Veterinary Medicine

8:30 a CVB Panel Discussion
9:30 a **Break**
9:40 a Quality Assurance and Quality Management
10:20 a **Break**
10:30 a Inspection Workshop
12:00 p **Lunch**
1:00 p APHIS Form 2008 Workshop
2:00 p **Break**
2:15 p - 3:15 p Sample Evaluation Workshop

For more information please contact the IICAB Office: Institute for International Cooperation in Animal Biologics,
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