



Veterinary Biologics Training Program



The Institute for International Cooperation in Animal Biologics (IICAB) is offering a nine-day Veterinary Biologics Training Program beginning May 12, 2009 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 OBJECTIVE: 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.

INTENDED PARTICIPANTS: The intended participants are regulatory officials from countries throughout the

world and biologics company employees. Over 946 industry representatives and 436 international representatives from 78 countries have attended portions of the Program in the last thirteen years. The number of participants is limited for some sections of the course and government regulatory officials receive priority acceptance into the Program.

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 12

Location: 2226 College of Vet Med

- 1:00 p Welcome and Introduction of the Course and Participants
- 1:30 p Basic Immunology
Introduction, Phagocytosis, Complement system
- WELCOME RECEPTION

Wednesday, May 13

Location: 2226 College of Vet Med

- 8:30-11:50 a Basic Immunology
Interferons, Lymphocytes, Antibodies and antigens, Cell-mediated immunity
- 11:50 a LUNCH
- 1:00-5:00 p Basic Immunology
Antigen processing and presentation, Lymphocyte antigen recognition, activation and effector mechanisms, Lymphocyte circulation, Mucosal immunity

Thursday, May 14 Location: 2226 College of Vet Med

- 8:30-11:50 a Basic Immunology
Fetal and neonatal immunity, Mechanisms of hypersensitivity, Evaluation of cell-mediated immunity
- 11:50 a LUNCH Certificate Presentations

BLOCK 1
(con't)

1:00-5:00 p Comparative immunology
Principles of vaccination
Vaccine safety and efficacy

Friday, May 15

Location: 2226 College of Vet Med

8:30 a-11:50 a Vaccine safety and efficacy (cont), 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 will review the inspection and compliance process.

Presented by USDA CVB Staff.

Monday, May 18

Location: 2226 College of Vet Med

8:30 a Welcome and Introduction of Participants
9:30 a Instructions to Participants
9:40 a BREAK
9:50 a Introduction to the Center for Veterinary Biologics
10:20 a Quality Manufacturing Standards for Veterinary Biologics
Parallels: 9CFR and GMP and Harmonization
11:00 a BREAK
11:10 a Introduction to Policy, Evaluation and Licensing (PEL)
12:00 p LUNCH Optional Presentation: Brucellosis Serology
1:00 p General Licensing Requirements
145 p BREAK
1:55 p Outline of Production
2:40 p BREAK
2:50 p Efficacy Requirements
3:40-4:00 p Interference Studies
EVENING WELCOME RECEPTION AT REIMAN GARDENS FOR ALL ATTENDEES

Tuesday, May 19

Location: 2226 College of Vet Med

8:30 a Statistical Considerations for Vaccine Trials
9:30 a BREAK
9:40 a Regulating Products of Biotech Origin
10:20 a BREAK
10:30 a Summary of Information Format/Risk Analysis
11:30 a Regulatory Considerations for Nucleic Acid-Mediated Veterinary Vaccines

BLOCK 2**(con't)**

12:00 p	LUNCH Optional Presentation: Aquaculture Optional Presentation: Statistical Considerations of Vaccine Trials: Examples
1:00 p	Safety Requirements
1:30 p	APHIS Label Requirements
2:10 p	BREAK
2:20 p	In vitro Potency Testing of Live/Inactivated Vaccines
3:10 p	BREAK
3:20 p	Statistical Considerations for Potency Tests

Wednesday, May 20**Location: 2226 College of Vet Med**

8:30 a	Autogenous Vaccines
9:10 a	Poultry Specific Licensing Issues
9:40 a	BREAK
9:50 a	Summary: Review of a New Product Submission
10:35 a	BREAK
10:45 a	Diagnostic Kits: Registration & Licensing Issues
11:15 a	FDA-Export Reform and Enhancement Act and CVB
11:40 a	Agent Biosecurity and Reference Management
12:00 p	LUNCH Optional Presentation: National Veterinary Stockpile/Avian Influenza Biologics Optional Presentation: Plant Derived Biologics
1:00 p	Importation of Product for Sale/Distribution in the US
1:25 p	Pre- and Post-license Biologics Testing at CVB
2:00 p	BREAK
2:10 p	ELISA Technology
3:00 p	BREAK
3:10 p	Master Seed Testing
3:50 p	Molecular Techniques

Thursday, May 21**Location: 2226 College of Vet Med**

8:30 a	Introduction to Center for Veterinary Biologics, Inspection and Compliance (IC)
9:00 a	CVB-IC Inspections
9:30 a	BREAK
9:40 a	Inspection Categories

BLOCK 2**(con't)**

10:50 a	BREAK
11:00 a	Good Documentation Practices
11:50 a	LUNCH Certificate Presentations and Optional Presentation: Quality Assurance
1:00 p	Compliance Activities
1:40 p	BREAK
1:50 p	Inspection Workshop
3:20 p	BREAK
3:30 p	Pharmacovigilance
4:05-5:00 p	Export Products from the US
EVENING	BARBECUE for all attendees at Dr. Roth's home

Friday, May 22**Location: 2226 College of Vet Med**

8:30 a	Panel Discussion—CVB Management
9:30 a	BREAK
9:40 a	Product Inspection and Release
10:25 a	Common Errors & Other 2008 Uses
11:00 a	BREAK
11:10 a	Select Agents
11:40 p	LUNCH Video Tour of CVB Laboratory
1:00 p	APHIS Form 2008 Workshop
1:50 p	BREAK
2:00 p	APHIS Form 2008 Workshop (cont)
2:40 p	BREAK
3:00-4:30 p	Sample Evaluation Workshop

*For more information please contact the IICAB Office:
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