



Veterinary Biologics Training Program



The Institute for International Cooperation in Animal Biologics (IICAB) is offering a eleven-day Veterinary Biologics Training Program beginning May 9, 2007 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 730 industry representatives and 350 government officials from 75 countries have attended portions of the Program in the last eleven 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

Wednesday, May 9

Location: ISU College of Veterinary Medicine

8:30 a	Welcome and Introduction of the Course and Participants
9:00 a	Basic Immunology Introduction, Phagocytosis, Complement system
11:50 a	LUNCH
1:00-5:00 p	Basic Immunology Interferons, Lymphocytes, Antibodies and antigens, Cell-mediated immunity

Thursday, May 10

8:30 a	Basic Immunology Antigen processing and presentation, Lymphocyte antigen recognition, activation and effector mechanisms, Lymphocyte circulation, Mucosal immunity
11:50 a	LUNCH
1:00-4:30 p	Basic Immunology Fetal and neonatal immunity, Mechanisms of hypersensitivity, Evaluation of cell-mediated immunity, Overview of avian immunology

BLOCK 1

Friday, May 12

(con't)

8:30 a	Overview of aquatic animal immunology
9:00 a	Principles of vaccination Vaccine safety and efficacy
11:50 a	LUNCH – Certificate Presentations
1:00-4:30 p	Vaccine safety and efficacy (cont), Overview of biotechnology derived biologics Adjuvants

BLOCK 2

Monday, May 14

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.

8:30 a	Welcome and Introduction of Participants
9:20 a	Instructions to Participants
9:30 a	BREAK
9:40 a	Introduction to the Center for Veterinary Biologics
10:10 a	Introduction to Policy, Evaluation and Licensing (PEL)
10:50 a	BREAK
11:00 a	General Licensing Requirements
11:50 a	LUNCH Optional Presentation: Brucellosis Serology
1:00 p	GMP vs. CVB Quality Standards
1:40 p	BREAK
1:50 p	Outline of Production
2:40 p	BREAK
2:50 p	Efficacy Requirements
3:40 p	Interference Studies
4:00 p	BREAK
4:10- 5:00 p	Statistical Considerations for Vaccine Trials

Tuesday, May 15

8:30 a	In vitro Potency Testing of Live/Inactivated Vaccines
9:20 a	BREAK
9:30 a	Statistical Considerations for Potency Tests
10:40 a	BREAK
10:50 a	Autogenous Vaccines
11:30 a	Demonstration of the CVB website
11:50 a	LUNCH Optional Presentation: Aquaculture

BLOCK 2

(con't)

1:00 p	Safety Requirements
1:30 p	APHIS Label Requirements
2:00 p	BREAK
2:10 p	Summary of Information Format/Risk Analysis
3:00 p	BREAK
3:10 p	Summary: Review of a New Product
3:40 p	Licensing Procedures and Workflow
4:10-4:40 p	Poultry Specific Licensing Issues

Wednesday, May 16

8:30 a	Diagnostic Kits: Registration & Licensing Issues
9:00 a	Regulating Products of Biotech Origin
9:40 a	BREAK
9:50 a	Plant Derived Biologics
10:30 a	BREAK
10:40 a	DNA Vaccines
11:15 a	Pre- and Post-license Biologics Testing at CVB
11:50 a	LUNCH Optional presentation: Cancer Biologics
1:00 p	Importation of Product for Sale/Distribution in the US
1:40 p	BREAK
1:50 p	FDA- Export Reform and Enhancement Act and CVB
2:30 p	US Perspectives of International Harmonization of Veterinary Biologics
3:10 p	BREAK
3:20 p	Avian Influenza Biologics
4:00 p	National Veterinary Stockpile
4:30-5:00 p	Agent Biosecurity and Reference Management

Thursday, May 17

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
10:50 a	BREAK
11:00 a	Good Documentation Practices
11:50 a	LUNCH/Optional Presentation: Quality Assurance

1:00 p	Inspection Workshop
2:30 p	BREAK
2:40 p	Investigations
3:20 p	Export Products from the US
4:10 p	BREAK
4:20-5:00 p	Pharmacovigilance

Friday, May 18

8:30 a	CVB Panel Discussion—PEL & IC Section Leaders
9:30 a	BREAK
9:45 a	Product Inspection and Release
10:15 a	Common Errors & Other 2008 Uses
10:50 a	BREAK
11:00 a	Select Agents
11:50 a	LUNCH Certificate Presentations
1:00 p	APHIS Form 2008 Workshop
1:50 p	BREAK
2:00 p	APHIS Form 2008 Workshop (cont)
2:40 p	BREAK
2:50-4:30 p	Sample Evaluation Workshop

BLOCK 3

Potency and Safety Testing and Diagnostic Test Kit Evaluation

Block 3 will review the principles and procedures for laboratory testing of biologics and diagnostic test kits.

Presented by USDA CVB Staff

Monday, May 21

Room 2780-Pathology Lab

8:30 a	Master Seed Virus Testing and Viral Vaccines Potency Testing Room 1010-Anatomy
11:00 p	Sterility with Mycoplasma Demonstration
12:00 p	LUNCH Room 2025 –BMS Lab PM
1:15-5:00 p	ELISA Technology: Participants select: 1) Basic ELISA Workshop 2) Advanced ELISA Lecture

Tuesday May 22

GROUP A

Room 2107-VMPM Lab

8:30 a	SDS-PAGE/Western Blot Laboratory and Demonstration
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BLOCK 3

(con't)

12:00 p LUNCH
1:15-4:45 p SDS-PAGE/Western Blot Laboratory and Demonstration
(cont.)

GROUP B

Room 2780-Pathology Lab

8:30 a Poultry Virology Laboratory and Demonstration
12:00 p LUNCH
Room 2025 – BMS Lab
1:15-4:45p Molecular Techniques, Bioinformatics and PCR,
Laboratory and Demonstration

Wednesday, May 23

GROUP B

Room 2107-VMPM Lab

8:30 a SDS-PAGE/Western Blot Laboratory and Demonstration
12:00 p LUNCH
1:15-4:45 p SDS-PAGE/Western Blot Laboratory and Demonstration
(cont.)

GROUP A

Room 2780-Pathology Lab

8:30 a Poultry Virology Laboratory & Demonstration
12:00 p LUNCH
Room 2025 – BMS Lab
1:15-4:45 p Molecular Techniques, Bioinformatics and PCR
Laboratory & Demonstration

Thursday, May 24

International attendees only:

8:00 a Tour of a small biologics production company.
11:30 a-2:00 p LUNCH

*For more information please contact the IICAB Office:
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