



Veterinary Biologics Training Program



The Institute for International Cooperation in Animal Biologics (IICAB) is offering an eleven-day Veterinary Biologics Training Program beginning May 10, 2006 in Ames, Iowa. The course is co-sponsored by the USDA Animal and Plant Health Inspection Service's (APHIS) Center for Veterinary Biologics (CVB) and National Veterinary Services Laborato-

ries (NVSL), and the Iowa State University (ISU) College of Veterinary Medicine. The USDA has 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 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 645 industry representatives and 310 government officials from 71 countries have attended portions of the program in the last ten 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 Wednesday, May 10

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

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 p	Information Resources in the ISU College of Veterinary Medicine
1:45-5:00 p	Basic Immunology
	Interferons, Lymphocytes, Antibodies and Antigens, Cell-Mediated Immunity

Thursday, May 11

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)

8:30-9:00 a	Overview of Aquatic Animal Immunology
9:00-11:50 a	Principles of Vaccination Vaccine Safety and Efficacy
11:50 a	LUNCH
1:00-4:30 p	Vaccine Safety and Efficacy (cont), Overview of Biotechnology Derived Biologics Adjuvants

BLOCK 2

Monday, May 15

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.

8:30-9:20 a	Welcome and Introduction of Participants
9:20-9:30 a	Instructions to Participants
9:40-10:00 a	Demonstration of CVB Website
10:00-11:00 a	Introduction to Center for Veterinary Biologics—Policy, Evaluation and Licensing (PEL)
11:10-11:50 a	General Licensing Requirements
11:50 a	LUNCH/Optional Presentation: Brucellosis
1:00-1:50 p	Outline of Production
2:00-2:35 p	Efficacy Requirements
2:35-3:25 p	Interference Studies
3:35-4:50 p	Statistical Considerations for Vaccine Trials

Tuesday, May 16

8:30-9:20 a	Statistical Considerations for Potency Tests
9:30-10:10 a	Registration of Diagnostic Kits
10:20-11:10 a	Safety Requirements
11:30-12:00 p	Regulating Products of Biotech Origin
Noon	LUNCH/Optional Presentation: Aquaculture
1:00-1:30 p	Summary of Information Format/Risk Analysis
1:40-2:30 p	APHIS Label Requirements
2:40-3:30 p	Poultry Specific Licensing Issues
3:40-4:10 p	Drug Export Reform and Enhancement Act

BLOCK 2 **Wednesday, May 17**

(con't)	8:30-9:20 a	US Perspectives of International Harmonization of Veterinary Biologics
	9:20-9:50 a	Importation of Product for Sale/Distribution in the US
	10:00-10:50 a	<i>In Vitro</i> Potency Testing of Live/Inactivated Vaccines
	11:00-11:50 a	Example Review of a New Product
	11:50 a	LUNCH/Optional presentations: 1) Cancer Biologics
	1:00-1:50 p	Introduction to the Center for Veterinary Biologics, Policy, Evaluation and Licensing Lab (PEL)
	2:00-2:40 p	DNA Vaccines
	2:50-3:20 p	Plant Derived Biologics
	3:30-3:55 p	<i>Laboratory Testing</i>
	3:55-4:20 p	Agent Biosecurity and Reference Management
	4:20-5:00 p	Select Agents

Thursday, May 18

	8:30-9:00 a	Introduction to Center for Veterinary Biologics, Inspection and Compliance (IC)
	9:00-9:30 a	CVB-IC Inspections
	9:45-10:50 a	Inspection Categories
	11:00-11:50 a	Good Documentation Practices
	11:50 a	LUNCH/Optional Presentation: Quality Assurance
	1:00-2:30 p	Inspection Workshop
	2:40-3:20 p	Export Products from the US
	3:20-4:15 p	Pharmacovigilance
	4:15-5:00 p	Investigations

Friday, May 19

	8:30-9:30 a	CVB Panel Discussion
	9:45-10:15a	Product Inspection and Release
	10:25-11:00 a	Product Inspection and Release (Part 2)
	11:00-11:50 p	Autogenous Products
	11:50 a	LUNCH
	1:00-1:50 p	APHIS Form 2008 Workshop
	2:00-2:40 p	APHIS Form 2008 Workshop (cont)
	2:50-3:50 p	Sample Evaluation Workshop
	4:00-4:30 p	Sample Evaluation Workshop (cont)

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 22

- 8:30-11:00 a Master Seed Virus Testing & Viral Vaccines Potency Testing
11:00-12:00 p Sterility with Mycoplasma Demonstration
12:00 p LUNCH
1:15-5:00 p ELISA Technology:
Participants Select:
1) Basic ELISA Workshop
2) Advanced ELISA Lecture

Tuesday and Wednesday, May 23 & 24

GROUP A on Tuesday, GROUP B on Wednesday

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

GROUP B on Tuesday, GROUP A on Wednesday

- 8:30-12:00 p Poultry Virology Laboratory & Demonstration
12:00 p LUNCH
1:15-4:45 p Molecular Techniques, Bioinformatics and
PCR Laboratory & Demonstration

Thursday, May 25, International attendees only:

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

*For more information please contact the IICAB Office:
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