



VETERINARY
BIOLOGICS
TRAINING
PROGRAM



INSTITUTE FOR
INTERNATIONAL
COOPERATION IN
ANIMAL BIOLOGICS

a WOAHA collaborating center

MAY 13 - 17, 2024

MONDAY, MAY 13

Gateway Conference Center

8:30 a	Welcome/Introductions
9:40 a	Introduction to the Center for Veterinary Biologics (CVB)
10:10 a	Break
10:30 a	Overview of the CVB Website
10:50 a	Quality Manufacturing Standards for Veterinary Biologics
11:30 a	Introduction to the CVB Policy, Evaluation and Licensing (PEL)
12:15 p	Lunch
1:15 p	General Licensing Requirements in the United States
2:00 p	Outlines of Production
3:00 p	Break
3:20 p	Master Seed/Master Cells/Backpassage
3:45 p - 4:30 p	Efficacy Requirements and Interference Studies

TUESDAY, MAY 14

Gateway Conference Center

8:30 a	Statistical Considerations for Vaccine Trials
9:10 a	Safety Requirements
9:50 a	Break
10:10 a	Serial Release Testing
10:30 a	Potency Tests
11:30 a	Potency Specifications and Product Dating
12:00 p	Lunch
1:00 p	Jurisdiction: Products and Permits
1:30 p	Risk Management
2:10 p	Break
2:30 p	Poultry Specific Licensing Issues
3:00 p	Platform and Prescription Platform Biologics
3:30 p	US Vaccine Label Regulations
4:00 p - 4:30 p	Outlines of Production and Labels Workshop
5:00 p	Welcome Reception at Reiman Gardens for All Attendees

WEDNESDAY, MAY 15*Gateway Conference Center*

8:30 a	Immunomodulator Products
9:15 a	Aquaculture Biologics
9:50 a	Break
10:10 a	Conventional and Autologous Cancer Products
10:40 a	Licensing of Veterinary Diagnostic Test Kits
11:30 a	FDA-EREA Regulations and CVB
11:45 a	IABS Membership Offer
12:00 p	Lunch
1:00 p	Overview of the CVB Laboratory
2:20 p	Break
2:40 p - 4:00 p	General Question and Answer Session

THURSDAY, MAY 16*Gateway Conference Center*

8:30 a	Introduction to the CVB-Inspection and Compliance (IC)
9:00 a	CVB Inspection Program
9:30 a	Compliance Activities
10:10 a	Break
10:30 a	Inspection Categories
11:10 a	Inspection Workshop
12:00 p	Lunch
1:00 p	Product Inspection and Serial Release
1:40 p	APHIS Form 2008 Workshop
2:30 p	Sample Submission and Retention
3:00 p	Break
3:20 p	Export Certification
3:50 p - 4:30 p	Export Certification Workshop
5:00 p	IICAB Dinner at ISU Alumni Center for All Attendees

FRIDAY, MAY 17*Gateway Conference Center*

8:30 a	CVB Panel Discussion
9:30 a	Record Keeping, Documentation and Process Deviation
10:20 a	Break
10:40 a	Quality Assurance and Quality Management
11:10 a	Root Cause Analysis Workshop
12:00 p	Lunch
1:00 p	Regulatory Flexibility and Firm Requests
1:40 p	Autogenous Biologics
2:25 p	Break
2:45 p - 3:25 p	Pharmacovigilance