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WOAH Collaborative Centre Reports Activities 2024

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CENTRE INFORMATION

*Title of WOAHCollaborating Centre	Vaccine Evaluation in the Americas
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*Name Director of Institute (Responsible Official):	Dr. Matthew M. Erdman
*Name (including Title and Position) of Head of the Collaborating Centre (WOAH Contact Point):	Dr. Matthew M. Erdman, Science Advisor, APHIS, Diagnostics & Biologics
*Name of the writer:	Dr. Amy F. Gill

TOR 1 AND 2: SERVICES PROVIDED

1. Activities as a centre of research, expertise, standardisation and dissemination of techniques within the remit of the mandate given by WOAHC

Category	Title of activity	Scope
		Various products were imported from a

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Diagnosis, biotechnology and laboratory (true)	The Center for Veterinary Biologics (CVB), Inspection and Compliance activities for international veterinary biologics manufacturers.	total of nine countries (France, New Zealand, Canada, Argentina, Spain, Israel, United Kingdom, The Republic of South Korea, and Serbia) and were evaluated for market release within the United States for a total of 276 lots for over 570 million doses.
Vaccines (true)	Veterinary Biologics Training Program	Annual 5-day in person training program in partnership with the USDA APHIS Center for Veterinary Biologics on the USDA regulatory process for assuring the purity, safety, potency, and efficacy of veterinary biologics
Vaccines (true)	The Center for Veterinary Biologics (CVB) approved the first RNA particle vaccine for use in felines.	The Center for Veterinary Biologics (CVB) approved the first monovalent RNA particle vaccine against Feline Leukemia Virus for administration in cats.

TOR 3: HARMONISATION OF STANDARDS

2. Proposal or development of any procedure that will facilitate harmonisation of international regulations applicable to the main focus area for which you were designated

Proposal title	Scope/Content	Applicable Area
Harmonization of Title 9 Code of Federal Regulations (9CFR) and Good Manufacturing Practices (GMP)	Working to demonstrate the 9 CFR regulations for U.S. Veterinary Biologics have the same results as Good Manufacturing Practices (GMP) regulations utilized by many foreign trading partners by addressing "quality" in U.S. regulations. This will enable trading partners to find specific GMP requirements to help facilitate the export of biologics.	Veterinary Products
Harmonization of Title 9 Code of Federal Regulations and Pharmacovigilance	Working to demonstrate the 9 CFR regulations for U.S. Veterinary Biologics have the same results as International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) Pharmacovigilance Guidelines GL24, 29, 30, 35, 42.	Veterinary Products
Veterinary Biologics Training Program	CVB and Institute for International Cooperation in Animal Biologics (IICAB): Training on the USDA Process for regulating veterinary biologics and diagnostics.	Veterinary Products

3. In exercising your activities, have you identified any regulatory research needs* relevant for WOA?H?

No

4. Did your Collaborating Centre maintain a network with other WOA?H Collaborating Centres (CC), Reference Laboratories (RL), or organisations designated for the same specialty, to coordinate scientific and technical studies?

Yes

Name of WOA?H CC/RL/other organisation(s)	Location	Region of networking Centre	Purpose
International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) Outreach Forum	Amsterdam, Netherlands	América Asia y el Pacífico Europa	VICH Outreach Forum is a VICH initiative with the main objective of providing a basis for wider international harmonization of technical requirements, improve information exchange and raise awareness of VICH and VICH guidelines with non-VICH countries/regions. The Outreach Forum is composed of countries and regional organizations that have expressed an interest in the work of VICH and are motivated to participate in the activities of the VICH Outreach Forum. Currently approximately 14 countries and four regional organizations are participating (or have been invited).
International Association of Biological Standards	Lyon, France	África América Asia y el Pacífico Europa	Meeting with International Association of Biological Standards along with other subject matter experts on Veterinary Use of Phages.
Council on Biologic and Therapeutic		América	The Council on Biologic and Therapeutic Agents (COBTA): advised the American Veterinary Medical Association Board of Directors in promoting interest in the

Agents (COBTA)	Chicago, Illinois, USA		efficacy and proper use of veterinary biologic and therapeutic units and updates for CVB response to Avian Metapneumovirus and Highly Pathogenic Avian Influenza.
U.S. Animal Health Association Annual Meeting	Nashville, Tennessee, USA	América	The CVB provided a presentation entitled, "Veterinary Biologics for Emerging Animal Diseases" to the attendees at the 2024 U.S. Animal Health Association Annual Meeting.
Food and Agriculture (FAO) of the United Nations Global Conference on Animal Health Innovation, Reference Centres, and Vaccines	Rome, Italy	África América Asia y el Pacífico Europa Oriente Medio	The CVB provided a presentation entitled, "Regulation of Veterinary Biologics in the United States" to the attendees at the 2024 Food and Agriculture (FAO) of the United Nations Global Conference on Animal Health Innovation, Reference Centres, and Vaccines.
European Medicines Agency (EMA) Committee for Veterinary Medicinal Products (CVMP) VeDDRA subgroup meeting.	Virtual	África América Asia y el Pacífico Europa Oriente Medio	The CVB participated in a videoconference to the attendees at the 2024 European Medicines Agency (EMA) Committee for Veterinary Medicinal Products (CVMP) VeDDRA subgroup meeting.
American Association of Swine Veterinarians (AASV) Committee on Influenza	Nashville, Tennessee, USA	América	The mission of this committee is to review and study the issues and science surrounding the threats to swine and human health by influenza. The committee will assist the Board in the development of policies, position statements and educational resources.
			The CVB provided a presentation entitled,

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American Association of Swine Veterinarians (AASV) Annual Meeting	Nashville, Tennessee, USA	América	"Vaccine Platforms: What's Currently Available" to the attendees at the 2024 American Association of Swine Veterinarians (AASV) Annual Meeting.
International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) Working Group: Extraneous Agent Testing for Master Seeds/Cells and Ingredients of Animal Origin for veterinary biologics.	Amsterdam, Netherlands	América Asia y el Pacífico Europa	The CVB participates as a Subject Matter Expert for writing new VICH guidelines for wider international harmonization of technical requirements, improve information exchange and raise awareness of VICH and VICH guidelines with non-VICH countries/regions.
Vaccine Evaluation in the Americas: USDA APHIS Center for Veterinary Biologics and the Institute for International Collaboration in Animal Biologics (IICAB).	Ames, IA USA	América	Training on the USDA regulatory process for veterinary biologics, outreach to veterinary biologics regulators and companies in the Americas and beyond. Harmonization of veterinary biologics regulations.

TOR 4 AND 5: NETWORKING AND COLLABORATION

5. Did your Collaborating Centre maintain a network with other WOAHO Collaborating Centres, Reference laboratories, or organisations in other disciplines, to coordinate scientific and technical studies?

No

TOR 6: EXPERT CONSULTANTS

6. Did your Collaborating Centre place expert consultants at the disposal of WOAHO?

Yes

Name of expert	Kind of consultancy	Subject
Mark Pagala, Melisse Schilling, David White	Chapter revisions and reviews	WOAH Terrestrial Chapters

<p>Randy Atchison, Alethea Fry, Lora Gurley, Morgan Hennessey, Nichole Hines-Bergeron, Jeff Nelson, Mark Pagala, Connie Schmellik-Sandage, Garrett Smith, Alexandra Scupham, Barbara Sheppard, Albert Van Geelen, David White</p>	<p>Chapter revisions and reviews</p>	<p>WOAH Biological Chapters</p>
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TOR 7: SCIENTIFIC AND TECHNICAL TRAINING

7. Did your Collaborating Centre provide advice/services to requests from Members in your main focus area?

Yes

The CVB hosted, for four days, delegates from the Animal and Plant Quarantine Agency (APQA) of South Korea to provide training in areas of whole genome sequencing of master seeds (WGS) and antimicrobial resistance detection (AMR) related to regulatory processes. The CVB hosted and participated with USDA National Veterinary Services Laboratory and the National Animal Disease Center.

8. Did your Collaborating Centre provide scientific and technical training, within the remit of the mandate given by WOA, to personnel from WOA Members?

Yes

a) Technical visit : 0

b) Seminars : 148

c) Hands-on training courses: 0

d) Internships (>1 month) : 0

Type of technical training provided (a, b, c or d)	Content	Country of origin of the expert(s) provided with training	No. participants from the corresponding country
B	Veterinary Biologics Training Program, in-person, 5-day course	Argentina (3); Australia (2); Brazil (4); Canada (5); Chile (2); Ecuador (1); France (1); Germany (1); Great Britain (1); Japan (2); Korea (3); Paraguay (1); Saudi Arabia (2); Singapore (2); Spain (2); South Africa (2); Thailand (2); U.S (112)	148

TOR 8: SCIENTIFIC MEETINGS

9. Did your Collaborating Centre organise or participate in the organisation of scientific meetings related to your main focus area on behalf of WOA?

No

TOR 9: DATA AND INFORMATION DISSEMINATION

10. Publication and dissemination of any information within the remit of the mandate given by WOAHA that may be useful to Members of WOAHA

a) Articles published in peer-reviewed journals:

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Scupham, Alexandra J., Tong, Christopher. Detection of equine parvovirus-hepatitis and efficacy of governmental regulation of equine biologics purity: JVDI. Online November 6, 2024. <https://journals.sagepub.com/doi/10.1177/10406387241292343>

b) International conferences:

c) National conferences:

d) Other (Provide website address or link to appropriate information):

11. What have you done in the past year to advance your area of focus, e.g. updated technology?

1. IICAB continued efforts to move software that was running on old on-site web server technology to current technologies in the Azure cloud computing platform. In addition, IICAB revised online content to meet new accessibility guidelines. For the Veterinary Biologics Program, IICAB and CVB are working together to modify the agenda to better meet participants needs.

2. CVB continues to improve our internal Quality Management system. Development and maintenance of a formally registered Quality Management System (QMS) confirms to the public and industry, both on a national and on an international basis, that the CVB is committed to a robust quality program. The CVB was initially certified to the ISO 9001 standards September 4, 2007, and is currently registered to these standards through March 7, 2026.

3. CVB continues to improve our on-line platform for Pharmacovigilance reporting and monitoring.

12. Additional comments regarding your report: