

# OIE Collaborating Centres Reports Activities

## *Activities in 2021*

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<b>Title of collaborating centre:</b>	Vaccine Evaluation in the Americas
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<b>Name of Director of Institute (Responsible Official):</b>	Dr. Byron E. Rippke
<b>Name (including Title and Position) of Head of the Collaborating Centre (formally OIE Contact Point):</b>	Dr. Byron E. Rippke, Director, Center for Veterinary Biologics
<b>Name of writer:</b>	Ms. Elizabeth A. Latcham, Staff Assistant

**ToR: To provide services to the OIE, in particular within the region, in the designated specialty, in support of the implementation of OIE policies and, where required, seek for collaboration with OIE Reference Laboratories**

**ToR: To identify and maintain existing expertise, in particular within its region**

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

Diagnosis, biotechnology and laboratory	
Title of activity	Scope
Inspection and Compliance activities for international veterinary biologics manufacturers.	Various products were imported from a total of 9 countries (France, Canada, New Zealand, Argentina, Spain, Israel, United Kingdom, Serbia, and South Korea) and were evaluated for market release within the United States for a total of 293 lots for over 400 million doses
Vaccines	
Title of activity	Scope
The Center for Veterinary Biologics licensed the first African Swine Fever diagnostic biological product license.	<p>The product license was issued to Tetracore, Inc., Est. 644, for detection of African Swine Fever Virus DNA from samples of whole blood (EDTA) and spleen samples. This is the first diagnostic product licensed by CVB for ASF. The kit demonstrated the ability to detect 22 of 24 known viral strains (samples unavailable for genotypes XVIII and XXIV), and has primers and probes designed to detect all strains. The license carries the following restrictions:</p> <p style="padding-left: 40px;">a. Sale and use in the United States restricted to laboratories approved by State and Federal (USDA) animal health officials.</p> <p style="padding-left: 40px;">b. Domestic distribution and use shall be under the supervision or control of USDA, APHIS, Veterinary Services, as part of an official USDA animal disease control program.</p>

**ToR : To propose or develop methods and procedures that facilitate harmonisation of international standards and guidelines applicable to the designated specialty**

**2. Proposal or development of any procedure that will facilitate harmonisation of international regulations applicable to the surveillance and control of animal diseases, food safety or animal welfare**

Proposal title	Scope/Content	Applicable area
<p>Harmonization of Title 9 Code of Federal Regulations (9CFR) and Good Manufacturing Practices (GMP)</p>	<p>Working to demonstrate the 9 CFR regulations for U.S.</p> <p>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 make it easier for trading partners to find specific GMP requirements to help facilitate the export of biologics.</p>	<p><input checked="" type="checkbox"/> Surveillance and control of animal diseases  <input type="checkbox"/> Food safety  <input type="checkbox"/> Animal welfare</p>

***ToR: To establish and maintain a network with other OIE Collaborating Centres designated for the same specialty, and should the need arise, with Collaborating Centres in other disciplines***

***ToR: To carry out and/or coordinate scientific and technical studies in collaboration with other centres, laboratories or organisations***

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

No

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

Yes

Name of OIE CC/RL/other organisation(s)	Location	Region of networking Centre	Purpose
American Association of Swine Veterinarians (AASV) Committee on Influenza	Perry , IA	<input type="checkbox"/> Africa <input checked="" type="checkbox"/> Americas <input type="checkbox"/> Asia and Pacific <input type="checkbox"/> Europe <input type="checkbox"/> Middle East	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.
American Association of Swine Veterinarians (AASV) Committee on Transboundary and Emerging Diseases (CTED)	Perry, IA	<input type="checkbox"/> Africa <input checked="" type="checkbox"/> Americas <input type="checkbox"/> Asia and Pacific <input type="checkbox"/> Europe <input type="checkbox"/> Middle East	To explore issues associated with transboundary and emerging diseases of swine domestically and internationally. The purpose of the committee is to inform the AASV membership and relevant stakeholders regarding the status of swine diseases and the development and implementation of strategies to respond to current and future animal health events.
America Veterinary Medical Association (AVMA) Council on Biologics and Therapeutic Agents (COBTA) and Clinical Practitioners Advisory Committee (CPAC)	Schaumburg, IL	<input type="checkbox"/> Africa <input checked="" type="checkbox"/> Americas <input type="checkbox"/> Asia and Pacific <input type="checkbox"/> Europe <input type="checkbox"/> Middle East	CPAC advises the BOD and promotes in the efficacy and proper use of biologics and therapeutic agents. They serve as an informational and advisory on issues pertaining to biologics and therapeutic agents. They advise the BOD in formulating positions concerning proposed or existing rules, regulations, and legislation and maintain awareness of activities and proposed actions by divisions of state and national governments concerned with veterinary biologics and therapeutic agents.
PREEMPT program	U.C. Davis	<input checked="" type="checkbox"/> Africa <input checked="" type="checkbox"/> Americas <input checked="" type="checkbox"/> Asia and Pacific <input checked="" type="checkbox"/> Europe <input checked="" type="checkbox"/> Middle East	The U.S. Defense Advanced Research Projects Agency funds PREEMPT which is a initiative that seeks to preserve the health of U.S. Troops and communities around the world by containing emerging infectious diseases in animal populations before they can threaten humans.: <a href="https://www.preemptproject.org/about">https://www.preemptproject.org/about</a>
Forum on Microbial Threats Systematizing the One Health Approach in Preparedness and Response Efforts for Infectious Disease Outbreaks: A Virtual Workshop	Washington, D.C.	<input checked="" type="checkbox"/> Africa <input checked="" type="checkbox"/> Americas <input checked="" type="checkbox"/> Asia and Pacific <input checked="" type="checkbox"/> Europe <input checked="" type="checkbox"/> Middle East	The National Academies' forum on Microbial Threats is hosting this virtual workshop to examine ways to systemize and integrate the One Health approach as part of outbreak prevention, detection, preparedness, and response efforts. This workshop will explore multi-sector collaboration mechanisms, community engagement strategies, workforce development, and policies that can effectively implement the core capacities and interventions of One Health principles.

<p>Held a virtual meeting with the Roslin Institute and R(D)SVS, University of Edinburg, Scotland, to discuss porcine circovirus and vaccine needs for the swine industry.</p>	<p>University of Edinburg, Scotland</p>	<p><input type="checkbox"/>Africa  <input type="checkbox"/>Americas  <input type="checkbox"/>Asia and Pacific  <input checked="" type="checkbox"/>Europe  <input type="checkbox"/>Middle East</p>	<p>The Roslin Institute and R(D)SVS, University of Edinburg, Scotland, aims to enhance the lives of animals and humans through world class research in animal biology. The meeting was to discuss porcine circovirus and vaccine needs for the swine industry with subject matter experts from the USDA, Center for Veterinary Biologics.</p>
<p>2021 ISPE Global Pharmaceutical Regulatory Summit - Remote/Distant Assessments, Audits, and Regulatory Guidance hosted by International Society for Pharmaceutical Engineering. Speakers from the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA) and Pharmaceutical Inspection Co-Operations Scheme (PIC/S)</p>	<p>Bethesda, MD</p>	<p><input checked="" type="checkbox"/>Africa  <input checked="" type="checkbox"/>Americas  <input checked="" type="checkbox"/>Asia and Pacific  <input checked="" type="checkbox"/>Europe  <input checked="" type="checkbox"/>Middle East</p>	<p>presented guidance used to ease the impact of disruptions caused by COVID-19 and the difficulty of on-site inspections during the pandemic. The benefits and pitfalls to remote audits were discussed. Interacting with like regulatory agencies regarding best practices and limitations of remote inspections.</p>
<p>VICH and VICH Extraneous Agent Master Seed Testing Subgroup For Viral Agents</p>	<p>Belgium</p>	<p><input type="checkbox"/>Africa  <input checked="" type="checkbox"/>Americas  <input checked="" type="checkbox"/>Asia and Pacific  <input checked="" type="checkbox"/>Europe  <input type="checkbox"/>Middle East</p>	<p>VICH is a trilateral (EU-Japan-USA) program aimed at harmonizing technical requirements for veterinary biological products.</p>
<p>Canadian Swine and Poultry Infectious Diseases Research Center at the University of Montreal</p>	<p>University of Montreal</p>	<p><input type="checkbox"/>Africa  <input checked="" type="checkbox"/>Americas  <input type="checkbox"/>Asia and Pacific  <input type="checkbox"/>Europe  <input type="checkbox"/>Middle East</p>	<p>Forum on Porcine Reproductive and Respiratory Syndrome: looking back and looking forward, what do we see? Keynote speakers provided presentations on epidemiology, diagnostics, vaccinations, and genetics.</p>
<p>World Organization for Animal Health (OIE) Focal Point Seminar and the Committee of the Americas for the Harmonization of Registration and Control of Veterinary Medicines (CAMEVET)</p>	<p>Paris, France</p>	<p><input checked="" type="checkbox"/>Africa  <input checked="" type="checkbox"/>Americas  <input checked="" type="checkbox"/>Asia and Pacific  <input checked="" type="checkbox"/>Europe  <input checked="" type="checkbox"/>Middle East</p>	<p>The American Committee for Veterinary Medicines (CAMEVET) is a regional project which aims to facilitate the harmonization of standards, records, and control of veterinary medicines among member countries.</p>

**ToR: To place expert consultants at the disposal of the OIE.****5. Did your Collaborating Centre place expert consultants at the disposal of the OIE?**

Yes

Name of expert	Kind of consultancy	Subject
Dr. Albert Van Geelen	Review of Chapter 1.3. Diseases, Infections, and Infestations Listed by the OIE and Chapter 8.16. Infection with Rinderpest Virus	OIE Manual of Standards  for Diagnostic Tests and Vaccines
Dr. Bruce Thomsen	Review of Chapter 1.8. Application for Official Recognition by the OIE of Risk Status for BSE and Chapter 11.4. Bovine Spongiform Encephalopathy (BSE)	OIE Manual of Standards  for Diagnostic Tests and Vaccines
Dr. Sabrina Swenson	Review of Chapter 3.1. Introduction to Recommendations on Veterinary Services and Chapter 3.2. Quality of Veterinary Services	OIE Manual of Standards  for Diagnostic Tests and Vaccines
Dr. Matthew Erdman	Review of Chapter 6.12. Zoonoses Transmissible by Non-Human Primates	OIE Manual of Standards  for Diagnostic Tests and Vaccines
Dr. Bruce Carter	Review of Chapter 8.8. Infection with Foot and Mouth Disease Virus and Chapter Number and Title: Chapter 3.9.3 Classical swine fever (infection with classical swine fever virus)	OIE Manual of Standards  for Diagnostic Tests and Vaccines
Dr. Barbara Sheppard	Reviewed 20 chapters related to aquaculture.	OIE Manual of Standards  for Diagnostic Tests and Vaccines

<p>Dr. Geetha Srinivas</p>	<p>Represented the U.S. on the  Committee of Veterinary Medicines for  the Americas (CAMEVET)</p>	<p>Information sharing, trade facilitation, and  harmonization of the registration of  veterinary biological products.</p>
<p>Dr. Bryon Ripcke</p>	<p>Represented the U.S. at a Veterinary  International Conferences on  Harmonization (VICH)</p>	<p>Information sharing, trade facilitation, and  harmonization of the registration of  veterinary biological products.</p>
<p>Dr. Sabrina Swenson</p>	<p>Subject matter expert for OIE adhoc  group</p>	<p>Import of semen form countries not free  from Porcine Reproductive and Respiratory  Syndrome (PRRS)</p>
<p>Dr. Barbara Sheppard</p>	<p>Subject matter expert for OIE adhoc  group</p>	<p>Aquatic animals</p>
<p>Dr. Jeffrey Nelson</p>	<p>Subject matter expert for OIE adhoc  group</p>	<p>Equine Piroplasmosis</p>

***ToR: To provide, within the designated specialty, scientific and technical training to***

**personnel from OIE Member Countries****6. Did your Collaborating Centre provide scientific and technical training, within the remit of the mandate given by the OIE, to personnel from OIE Member Countries?**

Yes

a) Technical visits: 0

b) Seminars: 1

c) Hands-on training courses: 0

d) Internships (&gt;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. Institute for International Cooperation in Animal Biologics (IICAB)	Online sessions of the Collaborating Centre of Diagnosis of Animal Diseases (OIE), Veterinary Biologics Training Program were posted October 1 - November 30, 2021. With a live Question and Answer session on October 29, 2021. This program gave participants an overview of the USDA regulatory processes assuring the purity, safety, potency, and efficacy of veterinary biologics. Representatives from the USDA, CVB present information on the requirements and processes for licensing and testing of veterinary biological products and the inspection and compliance process for production, release and post-marketing surveillance. The program is made available to both domestic and international attendees is co-sponsored by the Iowa State University College of Veterinary Medicine and USDA, CVB.	Argentina, Brazil, Canada, China, Germany, Great Britain, Netherlands, Puerto Rico, United States, South Africa,	72

**ToR: To organise and participate in scientific meetings and other activities on behalf of the OIE****7. Did your Collaborating Centre organise or participate in the organisation of scientific meetings on behalf of the OIE?**

No

**ToR: To collect, process, analyse, publish and disseminate data and information relevant to the designated speciality****8. Publication and dissemination of any information within the remit of the mandate given by the OIE that may be useful to Member Countries of the OIE**

a) Articles published in peer-reviewed journals: 2



A Review of Guidelines for Evaluating a Minor Modification to a Validated Assay  
World Health Organisation for Animal Health (OIE) Diagnostic test validation science Vol. 40(1), 2021

The Statistical Endeavors of Andrew Carnegie  
Chance, vol. 34, issue 4, pp. 12-17 (Nov. 2021) published by American Statistical Association

b) International conferences: 0

c) National conferences: 0

d) Other

(Provide website address or link to appropriate information): 2

Veterinary Vaccines: Principles and Applications, Chapter 11: The Manufacture of Veterinary Vaccines:  
Manufacturing Facilities

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<https://onlinelibrary.wiley.com/doi/abs/10.1002/9781119506287.ch11>

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Final Product

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<https://www.wiley.com/en-bm/Veterinary+Vaccines:+Principles+and+Applications-p-9781119505952>

**9. Additional comments regarding your report:**