

Renee M. Schnurr

PROFESSIONAL SUMMARY

Public servant for 34 years, specializing in the inspection and regulation of veterinary biological products following the USDA good manufacturing practices as specified in Title 9, Code of Federal Regulations (9 CFR), Parts 101-121 and the Virus-Serum-Toxin Act (VSTA), 21 USC, 151-159. I have over 22 years of supervisory experience with both professional and support staff.

WORK EXPERIENCE

Consultant, EDGE Veterinary Vaccines Consulting Group October 2025-Present

Advise established and start-up companies on facility requirements, compliance with the regulations, market release process, inspection findings, and export certification related to veterinary biological products.

Director, Inspection and Compliance

November 2021-April 2025

Center for Veterinary Biologics, United States Department of Agriculture, Ames, Iowa

Duties:

- Formulated, organized, directed, controlled and executed a national program for inspection of veterinary biological products and facilities.
- Developed policies, plans, procedures and programs to assure compliance with the VSTA, including the functions of inspections, investigations, market release of product, export certification, compliance plans, and pharmacovigilance.
- Provided leadership in the development of complex, scientific standard for the construction and maintenance of manufacturing, testing, and storage facilities and equipment for veterinary biological products.
- Responsible for the inspection of international manufacturing sites requesting to permit veterinary biological product for sale and distribution in the United States.
- Conducted international inspections for veterinary biologics used in USDA programs.

Section Leader, Inspection

June 2006-November 2021

Center for Veterinary Biologics, United States Department of Agriculture, Ames, Iowa

Duties:

- Developed and implemented policy in accordance with the VSTA and 9 CFR for three functional areas: inspections, market release of product, and export certification.
- Approved personnel, budget and other resources associated with the three functional areas of inspection, market release and export certification.
- Responsible for the review of inspection reports for policy, accuracy and consistency.
- Conducted domestic and international inspections, including prelicensing establishments, investigations, and select agent inspections.
- Trained CVB staff and establishment employees regarding the acceptability of facilities, equipment, processes and personnel engaged in the production and testing of veterinary biological products to ensure compliance with the VSTA and 9 CFR.

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- Served as Management Champion, Project Leader and Subject Matter Expert on a formal and informal Business Process Improvement Team annually. Projects included:
 - Inspection Took Kit – improvement of process for both CVB and the regulated industry and documented innovative practices used for inspection as developed by all team members.
 - Virtual and Remote Record Inspections – first developed in response to travel restrictions related to COVID.
 - Electronic receipt of Export Certificates – improved customer service.
 - Electronic processing of Facility Documents – streamlined the process and allowed for easier submission of the foundational documents.
 - Collaborated with regulated industry to align Veterinary Services Memorandum 800.91, Inspection of U.S. Veterinary Biologics Licensed and Permitted Establishments with international standards to facilitate international registration of US manufacturing sites and allow issuance of GMP Inspection Certificates, recognizing the methods of good manufacturing practices specified in the 9 CFR and VSTA.

Assistant Director, Inspection and Compliance

January 2003-June 2006

Center for Veterinary Biologics, United States Department of Agriculture, Ames, Iowa

Duties:

- Financial Management – drafted budgets for CVB program FY2002-2006.
- Human Capital Management – developed new positions within Inspection and Compliance to meet needs of Center.
- Member of CVB Directorate.

Team Leader, Product Inspection

July 1999-January 2003

Veterinary Biologics Program-Veterinary Biologics Field Operations/Center for Veterinary Biologics, United States Department of Agriculture, Ames, Iowa

Duties:

- Managed the day-to-day processes for Product Market Release and Firm Requests including implementation of policy and provided information to support regulatory defensible decisions by self and other Specialists.
- Conducted inspections and performed submission review related to inspection and compliance issues for several licensed and prelicensed entities.
- Developed positions related to the creation of the Center for Veterinary Biologics (2002).

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Senior Biologics Specialist

December 1994-July 1999

Veterinary Biologics Program-Veterinary Biologics Field Operations, United States Department of Agriculture, Ames, Iowa

Duties:

- Conducted inspections and reviewed submissions related to inspection and compliance issues that were more complex in nature.
- Responsible for certification of export documents.
- Reviewed and implemented business process improvements including the following practices:
 - Streamlined the reporting of first serial autogenous product using summary formats – decreasing the use of CVB resources and providing increased customer service. Replaced by NCAH Portal Electronic submissions.
 - Co-authored guideline VSM 800.87, Guidelines for Licensing Establishments with Separated Premises when the new policy to allow multiple licensed sites on one establishment license was implemented.

Biologics Specialist

July 1991-December 1994

Veterinary Biologics Program-Veterinary Biologics Field Operations, United States Department of Agriculture, Ames, Iowa

Duties:

- Responsible for conducting on-site inspections, review of market release documents, responding to firm requests, review and filing of facility documents, investigations of licensed and unlicensed entities and authoring regulatory correspondence.
- Served as a mediator between employees at Veterinary Biologics Field Operations (now known as Inspection and Compliance). Facilitated discussions to de-escalate conflict between employees and find workable solutions to create a collaborative working environment.

Quality Control Technician

May 1988-July 1991

Ambico, Inc., Dallas Center, Iowa

Duties:

- Conducted in-process testing on bulk antigens used in the preparation of veterinary vaccines.
- Conducted all final product testing for porcine modified live virus vaccines and killed bacterins in accordance with the 9 CFR and filed Outlines of Production.
- Conducted extraneous agent testing on ingredients of animal origin (serum/trypsin) in accordance with the 9 CFR regulations.
- Collected firm testing and retention samples and as an authorized government sampler, collected final samples for government retention and submission.
- Developed and implemented testing procedures for new products.

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Research Laboratory Technician

May 1987-May 1988

Veterinary Medical Research Institute, Ames, Iowa

Duties:

- Developed protocols for studies related to viral swine research
- Developed and maintained monoclonal antibodies for rotavirus and TGE
- Carried out research testing – titrations, PAGE gels, animal studies
- Managed daily laboratory activities for three graduate students

EDUCATION

Bachelor – Sciences and Humanities May 1987

Major – Microbiology

PUBLICATION

Coauthor and facilitator for Chapter 11, The manufacture of veterinary vaccines; Manufacturing Facilities, in the Veterinary Vaccines: Principles and Applications 1st Edition, in conjunction with the Food and Agriculture Organization of the United Nations (FAO).

AWARDS (Selected)

USDA Secretary's Award for Customer Service and USDA Honor Award for Excellence

For an exceptional level of innovation in efficiently serving USDA's customers through business process improvements for the veterinary biologics program

NVSL-CVB Women's History Award

Recognition by peers for leadership, teamwork, enthusiasm and commitment to equal opportunity

APHIS Administrator's Civil Rights Award

Providing innovative methods for training and experience to lower graded staff (leveraging diversity)