

Paul J. Hauer DVM, MS, PhD
Partner, EDGE VCG, LLC

Education:

Doctor of Philosophy Degree in Veterinary Microbiology from Iowa State University in 2002
Masters of Science Degree in Immunobiology from Iowa State University in 1994
Doctor of Veterinary Medicine Degree from Iowa State University in 1984
Undergraduate courses: Three years pre-veterinary medicine at Iowa State University.

Work Experience:

2022-present: Partner, Edge Veterinary Vaccines Consulting Group. Job includes advising established and start-up companies how to deal with the USDA's regulatory structure for licensing veterinary biologics.

2015- 2022: USDA, APHIS, Center for Veterinary Biologics, Policy, Evaluation and Licensing. Director. Job responsibilities included the management and oversight of all aspects related to licensing and testing of veterinary biologicals in the United States. Job duties also included extensive interaction with biologics manufacturers, animal health researchers, State Animal Health officials and international regulatory agencies.

2014-2015: USDA, APHIS, Center for Veterinary Biologics Policy, Evaluation and Licensing. Senior Staff Veterinarian. Job responsibilities included reviewing and approving data submitted to support licensure of veterinary biological products and development of policy and licensing considerations for veterinary biologicals.

2007-2014: USDA, APHIS, National Veterinary Services Laboratories Associate Director. Job responsibilities included sharing management responsibilities for the USDA's only national veterinary diagnostic reference laboratory. The facilities are located in Ames, Iowa and Plum Island, New York and employ approximately 350 personnel.

2004-2007: USDA, APHIS, Center for Veterinary Biologics Licensing and Policy Development. Section Leader, Bacteriology. Job responsibilities included supervision of all policy development, licensing, data review, and regulatory testing conducted on bacterial veterinary biological products licensed by or presented for licensure to the USDA.

2001-2004: USDA, APHIS, Center for Veterinary Biologics Licensing and Policy Development. Senior Staff Veterinarian. Job responsibilities included reviewing and approving data submitted to support licensure of veterinary biological products and development of policy and licensing considerations for veterinary biologicals.

1990-2001: USDA, APHIS Center for Veterinary Biologics Laboratory, Veterinary Medical Officer in the Biologics Bacteriology Section. Job responsibilities included assignment and supervision of regulatory testing of veterinary bacterins, toxoids, antibody products, and diagnostic test kits. The position included responsibility for testing the efficacy and safety of veterinary biological products made using recombinant DNA technology.

1988-1990: United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) Field Veterinary Medical Officer in Sedalia Missouri. Job duties consisted of implementing federal veterinary disease eradication and animal care programs in west central Missouri. The job included supervisory responsibility for 4 animal health technicians.

1984-1988: Clinical Veterinarian in mixed animal practices in Galena, Illinois and Preston, Minnesota. Job duties included the clinical practice of veterinary medicine in busy, progressive, multi-veterinarian clinics.

Select Publications:

Erdman, MM, Clough, NE, Hauer, PJ. 2020. Review of updated regulations and product license categories for veterinary vaccines in the United States. *JAVMA*. 257/11
<https://doi.org/10.2460/javma.2020.257.11.114211.1142>

Thiele TL, Stuber TP, Hauer PJ. 2013. Detection of *Clostridium sordellii* strains expressing hemorrhagic toxin (TcsH) and implications for diagnostics and regulation of veterinary vaccines. *Vaccine*. Oct 17;31(44):5082-7. doi: 10.1016/j.vaccine.2013.08.065. Epub 2013 Sep 7.

Ingebritson AL, Roth JA, Hauer PJ *Erysipelothrix rhusiopathiae*: association of Spa-type with serotype and role in protective immunity. *Vaccine*. Mar 16;28(13):2490-6. doi: 10.1016/j.vaccine.2010.01.041. Epub 2010 Jan 29.

Hauer PJ, Yeary TJ, Rosenbusch RF. 2006. Evidence of the protective immunogenicity of native and recombinant *Clostridium haemolyticum* phospholipase C (beta toxin) in guinea pigs. *Vaccine*. 24:124-132.

Hauer PJ, Yeary T, Rosenbusch, RF. 2004. Cloning and Molecular Characterization of the Beta Toxin (phospholipase C) Gene of *Clostridium haemolyticum*. *Anaerobe*. 10:243-254.

Hauer PJ, Clough NE. 1999. Development of monoclonal antibodies suitable for use in antigen quantification potency tests for clostridial veterinary vaccines. *Dev. Biol. Stand.* 101:85-94.

Hsieh HV, Stewart B, Hauer P, Haaland P, Campbell R. 1998. Measurement of *Clostridium perfringens* beta-toxin production by surface plasmon resonance immunoassay. *Vaccine*. 16(9-10):997-1003.

Hauer PJ. 1998. New ways for testing the quality of erysipelas vaccines and antisera-The US approach. *Pharmeuropa*. 98-1:8-22.

Clough NE, Hauer PJ, Whitaker MS, Henderson LM. 1998. Use of a sandwich ELISA for antigen quantitation of erysipelas bacterins. *Pharmeuropa*. 98-1:60-64.