Carol P. Gibbs PhD
Senior Consultant, EDGE VCG, LLC

Education:
NIH Postdoctoral Fellow, Rockefeller University, 1984-1987: Genetic analysis of antigenic variation in *Trypanosoma brucei*.
Doctor of Philosophy Degree in Microbiology and Public Health, Michigan State University, 1984
Bachelor of Arts Degree in Biology, Frostburg State University, 1978

Work Experience:
2022-present: Senior Consultant, Edge Veterinary Vaccines Consulting Group. Assisting established and start-up companies with regulatory requirements for licensure of veterinary biologics with the USDA, including license plans, study protocols and reports, Outlines of Production, labeling, training, and post-licensure issues.

2008-2021: USDA, APHIS, Center for Veterinary Biologics, Policy, Evaluation and Licensing. Senior Staff Microbiologist. Reviewed and approved data and related materials submitted by veterinary vaccine and diagnostic test manufacturers in support of licensure of veterinary biological products. Participated in the development of policy and licensing considerations for veterinary biologicals; authored and co-authored Veterinary Services Memoranda and CVB Public Notices. Provided scientific support for laboratory projects related to the development and improvement of assays. Participated in the development of VICH guidelines and authored updates to the OIE Terrestrial Manual.

2004-2008: Director of Quality Control and Regulatory Affairs, Lohmann Animal Health International, Inc. (poultry vaccine manufacturer). Served as USDA liaison and was Responsible Official for Select Agent registration. Responsible for ensuring compliance with regulatory requirements in the licensure and manufacture of veterinary vaccines. Coordinated efficacy and safety studies as well as *in vitro* and *in vivo* product testing. Provided scientific review of proposed new products and assisted with technical support for the manufacturing facility and quality control laboratory.

2002-2004: Project Manager, Lohmann Animal Health GmbH & Co. KG (poultry vaccine manufacturer). GMP production and testing of viral master and working seeds, planning of safety and efficacy testing of recombinant viral vaccines, development of DIVA ELISA. Responsible for facility compliance with laws regulating work with genetically modified organisms.

1998-2002: Head of Quality Assurance, Manager of Regulatory Affairs, Creatogen AG (start-up, contract generation of recombinant bacterial strains using a variety of bacterial vectors). Set up the GLP Quality Control Laboratory and developed assays for bacterial reference stocks and construct testing. Established and implemented quality control systems for the R&D division and the quality control laboratory. Responsible for regulatory aspects of pre-clinical trials and for facility compliance with laws regulating work with genetically modified organisms. Provided scientific review of proposed and ongoing projects.

1992-1998: Laboratory Leader, Bacterial Genetics, Immuno AG (human vaccine manufacturer). Led a team responsible for the genetic characterization, epitope mapping, and population analysis of protective antigens, and expression of the antigens in vector systems. Developed and validated PCR assay used in Phase I clinical trial.

1987-1991: Staff Scientist, Max Planck Institute for Infection Biology: Basic research into the genetic analysis of antigenic variation and mechanisms of immune escape in *Neisseria gonorrhoea*.

Select Publications:

Gibbs, C.P., P. Foley, M. Reising, A. Gill, D. Siev, and M. Schilling. 2021. The manufacture of veterinary vaccines: Control of final product. In: S. Metwally, G. Viljoen and A. El Idrissi (eds), Veterinary Vaccines: Principles and Applications. John Wiley & Sons Limited, UK. pp. 161-168.

Ingebritson, A.L., C.P. Gibbs, C. Tong, and G.B. Srinivas. 2015. A PCR detection method for testing Mycoplasma contamination of veterinary vaccines and biological products. Lett. Appl. Microbiol. 60(2):174-180.

Kupsch, E.-M., D. Aubel, C.P. Gibbs, A.F. Kahrs, T. Rudel, and T.F. Meyer. 1997. Construction of the Hermes shuttle vector system: a versatile system useful for genetic complementation of transformable and non-transformable Neisseria mutants. Mol. Gen. Genet. 250: 558-569.

Gibbs, C.P., I. Livey, and F. Dorner. 1996. The role of recombination in OspC variation in Lyme disease Borrelia. Acta Dermatovenerologica A.P.A. 5:179-183.

Livey, I., C.P. Gibbs, R. Schuster, and F. Dorner. 1995. Evidence for the role of lateral transfer and recombination in OspC variation in Lyme disease Borrelia. Mol. Microbiol. 18:257-269.

Rudel, T., J.P.M. van Putten, C.P. Gibbs, R. Haas, and T. F. Meyer. 1992. Interaction of two variable proteins (PilE and PilC) required for pilus-mediated adherence of Neisseria gonorrhoeae to human epithelial cells. Mol. Microbiol. 6:3439-3450.

Bihlmaier, A., U. Römling, T.F. Meyer, B. Tümmler, and C.P. Gibbs. 1991. Physical and genetic map of the Neisseria gonorrhoeae strain MS11 chromosome. Mol. Microbiol. 5:2529-2539.

Bhat, K.S., C.P. Gibbs, O. Barrera, S.G. Morrison, F. Jähnig, A. Stern, E.-M. Kupsch, T.F. Meyer, and J. Swanson. 1991. The opacity proteins of Neisseria gonorrhoeae strain MS11 are encoded by a family of 11 complete genes. Mol. Microbiol. 5:1889-1901.

Meyer, T.F., C.P. Gibbs, and R. Haas. 1990. Variation and control of protein expression in Neisseria. Ann. Rev. Micro. 44:451-477.

Gibbs, C.P., B.Y. Reimann, E. Schultz, A. Kaufmann, R. Haas, and T.F. Meyer. 1989. Reassortment of pilin genes in Neisseria gonorrhoeae occurs by two distinct mechanisms. Nature. 338:651-652.

Gibbs, C., R. Haas, and T.F. Meyer. 1988. Structural and functional modulation of gonococcal surface proteins. Microbial Path. 4:393-399.

Gibbs, C.P. and G.A.M. Cross. 1988. Cloning and transcriptional analysis of a variant surface glycoprotein gene expression site in Trypanosoma brucei. Mol. Biochem. Parasitol. 28:197-206.

Tanaka, A., C.P. Gibbs, R.R. Arthur, S.K. Anderson, J.J. Kung, and D.J. Fujita. 1987. DNA sequence encoding the NH2-terminal region of the human c-src protein: implications of sequence divergence among src-type kinase oncogenes. Mol. Cell. Biol. 7:1978-1983.

Cully, D.F., C.P. Gibbs, and G.A.M. Cross. 1986. Synthesis of variant surface glycoprotein expression site associated gene products in Escherichia coli and Trypanosoma brucei. Mol. Biochem. Parasitol. 21:189-197.

Gibbs, C.P., A. Tanaka, S.K. Anderson, J. Radul, J. Baar, A. Ridgway, H.J. Kung, and D.J. Fujita. 1985. Isolation and structural mapping of a human c-src gene homologous to the transforming gene (v-src) of Rous sarcoma virus. J. Virol. 52:19-24.

Gibbs, C.P., K. Nazerian, L.F. Velicer, and H.J. Kung. 1984. Extensive homology exists between Marek disease herpesvirus and its vaccine virus, herpesvirus of turkeys. Proc. Natl. Acad. Sci. 81:3365-3369.