



Curriculum Vitae

**Barbara J. Potts, Ph.D.**  
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**EXPERIENCE**

**Biologics Consulting Group, Inc., Senior Consultant**  
San Francisco, CA (Nov 2009 - present)

**Genentech, Inc., Director, Quality Control Biology and Raw Materials**  
*Director, Virology (new role 2004), Principal Scientist, South San Francisco, CA (Jul 2000 – Oct 2009)*

- Directed scientific and compliance activities for microbiology, raw materials, virology, mycoplasma, potency environmental monitoring, cell bank testing for adventitious agents, nucleic acid methods and method development in molecular biology.
- Responsibilities included serving as the Project Team Leader for the BSE Task Force providing updates to the GMP Core Team, support senior management in TSE related presentations to Genentech's Executive Committee and Board of Directors.
- Additional responsibilities included developing Quality/Regulatory strategies in the field of virology and new technologies for the detection of mycoplasma.
- Responsible for providing technical review for IND and BLA/CTD submissions and responses to regulatory questions and a member of the risk assessment steering committee.
- Established and implement policy, guidance and technical documents for the control of CHO cell banking, TSE, adventitious agents and parvovirus cross contamination.
- Established a generic COA for master and working cell banks and a sustainable and transparent system that is usable by Quality, Manufacturing and Process Development for the adventitious agent testing of CHO cell banks.
- Established and chaired the Raw Material Review Board that included cross functional GNE staff from Regulatory Affairs, Process Development, Procurement, QA, QC and Materials Management to assess GMP raw material specifications and reduced testing.
- Project Team Leader for the cross functional TSE Task Force for Genentech, Inc.
- Established a safety improvement program for Quality Control that included a training program and safety audit program that is sustainable and transparent.
- Participated in and provided leadership in a team that established bioburden limits for CHO and *E. coli* commercial and clinical products.
- Provided development opportunities for staff that resulted in four publications in peer review journals and job rotations in departments outside of QC.
- Prepared cell substrate safety sections for two BLA submissions and multiple INDs.



- Developed a rapid detection assay using touchdown PCR for the detection of mycoplasma for routine lot release of CHO products. This reduced the testing time from 28 days to 8 hours resulting in savings on product manufacturing.
- Worked with Roche to convert this PCR assay into a commercial kit.
- Served in a leadership role to get this PCR assay approved by the FDA CDER and worked with Roche to get the assay and the commercial kit approved by the EMEA.
- Leader of the PDA Mycoplasma Task Force that is producing a technical report on alternative testing for mycoplasma and the development of the standardization of a filter for mycoplasma removal.
- Co editing with Dr. Len Hayflick a special set of nine of mycoplasma publications for the journal Biologics.

**Viomed Laboratories**, *Technical Consultant in Xenodiagnosics*, Minnetonka, MN and **College of Veterinary Medicine**, *Director, Center for Excellence in XenoDiagnosics*, St. Paul, MN (1998 - June 2000).

- Administered and coordinated xenodiagnostic-related research and service functions of the center and at ViroMed.
- Interacted with regulatory agencies, the biotechnology industry, and veterinary, medical and animal owner communities.
- Developed a basic research program in swine infectious disease and risk assessment of xenozoonotic agents.
- Developed peptide-based ELISA for the detection of circovirus, porcine CMV, and swine HEV.
- Developed TaqMan PCR assay for the detection of circovirus, porcine CMV, and swine HEV.
- Project manager for two contracts.

**Tektagen, Inc.**, *Director of Retrovirology*, Malvern, PA (1995-1998)

- Established and directed Human Retrovirology contract services program, including research, development, assay development, and validation studies under cGMP/GLP guidelines.
- Developed study plans, direct research, and prepare GMP/GLP reports for inclusion in IND applications.
- Worked with multiple biopharmaceutical firms as consultant in Human Retroviral Studies and Xenotransplantation.
- Participated with a Xenotransplantation firm with pre IND meetings with the FDA.
- Established human retroviral and xenodiagnostic research programs under cGMP and GLP guidelines.
- Established nucleic acid detection methods for determining viral load in clinical studies (bDNA, RNA/DNA hybridization).
- Project leader for multiple programs requiring cGMP/GLP studies for clinical trials.
- Consultant for biotechnology companies on how to interpret the Code of Federal Regulations (CFRs) and Points to Consider for virology studies.



**United Biomedical, Inc.**, *Director of Virology, Vaccine Program*, Hauppauge, NY (1992-1994)

- Established and directed Human Retrovirology program for development of an HIV-1 vaccine and immune-based therapy. Manage two contracts and three grants.
- Established BL-1, BL-2, and BL-3 projects and facilities for study of HIV-1 from international sites for pre-clinical and clinical studies.
- Project leader for development of an HIV-1 vaccine targeted for international trials. IND filed and Phase 1 clinical trials completed. Participate in pre IND meetings with the FDA.
- Project leader for development of an immune-based therapy for HIV-1 post-exposure prophylaxis.
- Principal investigator on two NIAID grants.

**Repligen Corp.**, *Research Scientist, Principal Investigator – Virology*, Cambridge, MA (1989-1992).

- Directed human and simian retrovirology program for basic research leading to the development of an HIV-1 vaccine and of humanized mouse monoclonals for therapeutic use.
- Managed two grants
- Established HIV-1 assays to evaluate vaccine and therapeutic candidates.
- Project leader for development of monoclonal antibodies as therapeutic reagents.
- Principal investigator on two NIAID grants.

**National Institute of Allergy and Infectious Disease**, *Senior Staff Fellow, Laboratory of Molecular Microbiology, Intramural Research Program*, Bethesda, MD (1987-1989).

- Perform independent basic research on mechanisms of HIV-1 and HIV-2 infection and destruction of monocytes and bone marrow stem cells.
- Identified mechanism of stem cell destruction by HIV-1 and HIV-2 in the bone marrow.
- Identified type of cell susceptible to HIV-1 infection in the human placenta.

**National Institute of Neurological & Communicative Disorders and Stroke**, *Staff Fellow, Infectious Diseases Branch, Intramural Research Program*, Bethesda, MD (1984-1987).

- Perform independent basic research on pathogenesis of pestiviruses in the central nervous system of an animal model (sheep) and humans.
- Identified a possible human pestivirus associated with birth defects

**Department of Microbiology, University of Tennessee**, *Post-doctoral Trainee*, Knoxville, TN (1981-1984)

- Performed independent research on protein chemistry of coronaviruses (human, porcine, bovine) and pestivirus.

**Department of Pathology/Neurology, University of California, *Pre-doctoral Fellow/Graduate***, San Francisco, CA (1978-1981).

- Performed independent research on pathogenesis of pestiviruses in the central nervous system of sheep. Established Koch's postulates for a virus.

#### **EDUCATION**

Ph.D. *Experimental Pathology*, University of California, San Francisco, CA (1981)

M.S. *Zoology*, Montana State University, Bozeman, MT (1970)

B.S. *Zoology*, Montana State University, Bozeman, MT (1967)

#### **HONORS AND AWARDS**

2005	Genentech, Inc. Diversity Champion Award
2004	Genentech, Inc. Safety Team Thinking Outside of the Box Award
2004	Genentech, Inc. Safety Team Outstanding Contributor
1988	NIH Director's Award for special efforts on the recruitment and employment of the physically handicapped employees in NINCDS, NIH.
1982	Teratology Society Young Investigator Award
1981-1983	HEW Public Health Service National Research Service Award
1981	Teratology Society - Full Member
1970	Sigma XI

#### **GRANT ADMINISTRATION/ REVIEW/COMMITTEE MEMBERSHIP**

2003 to 2007	Genentech, Inc. Institutional Biosafety Committee
2005	NIAID grant review for "HIV/AIDS Clinical Trials Networks" (vaccine)
2004 to 2008	The Secretary of Health and Human Services Advisory Committee on Xenotransplantation
2004	NIAID grant review for "Virology Project Bioshield"
2004	NIAID contract review for "Assessing the Safety of Cell Substrates and Vaccine Components"
2004	NIAID Special Emphasis Panel for "Cooperative Research for the Development of Vaccines, Adjuvants, Therapeutics and Diagnostics For Biodefense and SARS" Grant review.
2002	NIAID Special Emphasis Panel on "HIV Vaccine Design and Development". Grant review.
2000-2002	NIAID Special Emphasis Panel: "Novel HIV Therapies Integrated Preclinical/Clinical Program"
1999-2000	Porcine Cytomegalovirus: A Risk for Xenotransplantation. University of Minnesota, AHC Faculty Development Grant. Co-Principle Investigator.
1994 – 1998	AIDS and Related Research Study Section member (ARR-1) Division of Research Grants
1993 – 1998	NIH Study Section Reviewer: SBIR Special Study Section
1991 – 1995	HIV-1 Specific Immunity and Maternal-Fetal Transmission: 1R01 A132469-01. Principle Investigator on subcontract for determining humoral immune responses.
1990 – 1995	Neutralization Resistant Variants of HIV: 5R01 A129825-02. Principle Investigator.

## PUBLICATIONS

1. Henry, J.E., **Nelson, B.J.** & Jutilla, J.W. Pathology and development of grasshopper inclusion body virus in *Malonoplus sanguinipes*. J. Virol 3: 605, 1969.
2. Johnson, K.P. & **Nelson, B.J.** Multiple sclerosis: diagnostics usefulness of cerebrospinal fluid. Ann Neurol 2: 425, 1977.
3. Johnson, K.P., Arrigo, S.C., **Nelson, B.J.** & Ginsberg, A. Agarose electrophoresis of cerebrospinal fluid in multiple sclerosis. Neurology 27: 273, 1977.
4. Traviesa, D.C., Prytowsky, S.A.D., **Nelson, B.J.** & Johnson, K.P. Cerebrospinal fluid findings in asymptomatic patients with a reactive serum fluorescent treponal antibody absorption test. Ann Neurol 4: 524, 1978.
5. Johnson, K.P., Likowsky, W.H., **Nelson, B.J.** & Fine, G. Comprehensive viral immunology of multiple sclerosis. i. clinical, epidemiological and CSF studies. Arch. Neurol. 37: 537, 1980.
6. **Potts, B.J.**, Osburn, B.I. & Johnson, K.P. Border Disease: Experimental reproduction in sheep using a virus replicated in tissue culture. Am J. Vet Res 43: 1464, 1982.
7. **Potts, B.J.**, Osburn, B.I. & Johnson, K.P. Border Disease: tissue culture studies of the virus in sheep. Am J Vet Res 43: 1460, 1982.
8. King, B., **Potts, B.J.** & Brian, D.A. Bovine Coronavirus hemagglutinin protein. Virus Res 2: 53, 1985.
9. **Potts, B.J.**, Berry, L.J., Osburn, B.I., & Johnson, K.P. Viral persistence and abnormalities of the central nervous system after congenital infection of sheep with Border Disease virus. J. Infect Dis 151: 337, 1985.
10. **Potts, B.J.**, Sever, J.L., Tzan, N.R., Huddleston, D. & Elder, G.A. Possible role of Pestiviruses in microencephaly. Lancet 1: 972, 1987.
11. Elder, G.A., **Potts, B.J.** Multiple neural cell types are infected *in vitro* by Border Disease virus J. Neuropathol Exp Neurol 46: 653, 1987.
12. Elder, G.A., **Potts, B.J.**, Sawyer, M. Characterization of glial subpopulations in cultures of the ovine central nervous system GLIA 1: 317, 1988.
13. Willey, L., Bonifacino, S., **Potts, B.J.**, Martin, M.A. & Klausner, R.D. Biosynthesis, cleavage, and degradation of the human immunodeficiency virus 1 envelope glycoprotein gp 160. Proc Natl Acad Sci USA 85: 9584, 1988.
14. Maury, W.J., **Potts, B.J.**, & Rabson, A.B. HIV-1 infection of first trimester and full term placenta, a possible mode of maternal-fetal transmission. J Inf Dis 160: 583, 1989.
15. Maury, W.J., **Potts, B.J.**, & Rabson, A.B. Modern approaches to new vaccines including prevention of AIDS: infection of human placental tissue by HIV-1. In Vaccine 89: Modern Approaches to New Vaccines Including Prevention of AIDS, R.A. Learner, H. Ginsberg, R.M. Chanock & F. Brown, eds.,

Cold Spring Harbor Laboratory, Cold Spring Harbor, 1989.

16. **Potts, B.J.**, Sawyer, M., Shekarchi, I.C., Wismer, T. & Huddleston, D. Peroxidase-labeled primary antibody method for detection of pestivirus contamination in cell cultures. *J. Virol Methods* 26:1198, 1989.
17. **Potts, B.J.**, Maury, W. & Martin, M. Replication of HIV-1 in primary monocyte cultures. *Virology* 175: 465, 1990.
18. **Potts, B.J.**, Quantitative assays for virus detection: "Mini" reverse transcriptase assay. *Techniques in HIV Research*. Ed. A. Aldovini and B. Walker, 103, 1990.
19. Watkins, B.A., Doren, H.H.Y., Kelly, W.B., Armstrong, R.C., **Potts, B.J.**, Michaels, F., Dufta, C.V. & Dubois-Dulcq, M. Specific tropism of HIV-1 for microglial cells in primary human brain cultures. *Science* 249: 549, 1990.
20. Grimaila, R.J., Fuller, B.A., Rennert, P.D., Nelson, M.B., Hammerskjöld, M.D., **Potts, B.J.**, Murray, M., Putney, S.D., Gray, G. Mutations in the principal neutralization determinant of human immunodeficiency virus type 1 affect syncytium formation, virus infectivity, growth kinetics and neutralization. *J. Virol* 66:1875, 1992.
21. **Potts, B. J.**, Hoggan, M.D., Lamperth, L., Spivak, J. Replication of HIV-1 and HIV-2 in human bone marrow cultures. *Virology* 188:840, 1992.
22. Higgins, P.J., Paradis, T., **Potts, B.J.**, White-Scharf, M.E., Rusche, J.R., Scott, C.F. *In Vitro* inhibition of a variety of human immunodeficiency virus isolates by a broadly reactive, V3-directed heteroconjugate antibody. *J Inf Dis* 166, 198, 1992.
23. Moller, J.R., McLenighan, M., **Potts, B.J.**, Quarles, R.H. Effects of Congenital Infection of Sheep with Border Disease Virus on Myelin Proteins. *Journal of Neurochemistry* 61: 1808, 1993.
24. Spivak, J.L. & **Potts, B.J.** Human immunodeficiency and the bone marrow. In *Virus and Bone Marrow Basic Research and Clinical Practice*, Young NS ed., Marcel Dekker, Inc.. N.Y. 1993.
25. White-Scharf, M.E., **Potts, B.J.**, Smith, L.M., Sokolowski, K.A., Rusche, J.R., Silver, S. Broadly neutralizing monoclonal antibodies to the V3 region of HIV-1 can be elicited by peptide immunization. *Virology* 192:197, 1993.
26. **Potts, B.J.**, Field, K.G., Wu, Y., Posner, M., Cavacini, L., White-Scharf, M. Synergistic inhibition of HIV-1 by CD4 binding domain reagents and V3-directed monoclonal antibodies. *Virology* 197:415, 1993.
27. D'Souza, M.P., Geyer, S.J., Hanson, C.V., Hendry, R.M., Milman, G. and **collaborating investigators**. Evaluation of monoclonal antibodies to HIV-1 envelope by neutralization and binding assays: an international collaboration. *AIDS* 8:1-13, 1994.
28. Sawyer, L.S.W., Wrin, M.T., Crawford-Miksza, L., **Potts, B.J.**, Wu, Y., Weber, P.A., Alfonso, R.D., Hanson, C.V. Neutralization sensitivity of human immunodeficiency virus Type 1 is determined in part by the cell in which the virus is propagated. *J. Virol* 68:1342, 1994.

29. Robert-Guroff, M., Louie, A., Myagkikh, M., Michaels, F., Kieny, M.P., White-Scharf, M.E., **Potts, B.J.**, Grogg, D. & Reitz, M.S., Jr. Alteration of V3 loop context within the envelope of human immunodeficiency virus type 1 enhances neutralization. *J. Virol* 68 (6):3459, 1994.
30. O'Hagan, D.T., McGee, J.P., Wang, C.Y., **Potts, B.J.**, Koff, W.C. The UBI multicomponent HIV vaccine: The advantages of controlled release microparticles. *Huitième Colloque Des Cent Gardes*. 309-313, 1993.
31. McGee, J.P., Koff, W., Wang, C.Y., **Potts, B.J.**, Kennedy, R.C. & O'Hagan, D.T. Controlled release microparticles with an entrapped branched V3 peptide from HIV-1: Assessment of immunogenicity in baboons. *Proceed. Intern. Symp. Control. Rel. Bioact. Mater.* 21, 1994.
32. Richardson, J.L., McGee, J.P., Gumaer, D., **Potts, B.J.**, Wang, C.Y., Koff, W. & O'Hagan, D.T. Controlled release antigen delivery systems for mucosal immunization with an HIV-1 peptide in small animal models. *Proceed. Intern. Symp. Control. Rel. Bioact. Mater.* 21, 1994.
33. O'Hagan, D.T., McGee, J.P., Boyle, R., Gumaer, D., Li, X.-M., **Potts, B.J.**, Wang, C.Y., Koff, W.C. The preparation, characterization and pre-clinical evaluation of an orally administered HIV-1 vaccine, consisting of a branched peptide immunogen entrapped in controlled release microparticles. *Journal of Controlled Release* 36:75, 1995.
34. Stiehm, E.R., Mofenson, L., Zolla-Pazner, S., Jackson, B., Martin, N.L., Ammann, A.J., and the **Passive Antibody Workshop Participants**. Summary of the Workshop on Passive Immunotherapy in the Prevention and Treatment of HIV Infection. *Clinical Immunology and Immunopathology*, 175 (1):84, 1995.
35. Jelonek, M.T., Maskrey, J.L., Steimer, K.S., Cummins, L.J., **Potts, B.J.**, Higgins, K.W., Keller, M.A. Inhibition of the Offspring Anti -Recombinant gp120 Antibody Response to a Human Immunodeficiency Virus (HIV) Vaccine by Maternal Immunization in a Murine Model. *Infect Dis.* 172:539, 1995.
36. Jelonek, M.T., Maskrey, J.L., Stiemer, K.S., **Potts, B.J.**, Higgins, K.W., Keller, M.A. Maternal Monoclonal Antibody to the V3 Loop Alters Specificity of the Response to a Human Immunodeficiency Virus Vaccine. *Infect Dis.* 174; 866, 1996.
37. **Potts, B.J.**, Olson, D., Henn, M., Bankowski, M. Quality Control of Swine: The Critical Raw Material for Xenotransplantation. *Proc. American Ass. Swine Producers* 435, 2000.
38. Conn, C., Olson, D., Webb, CH., **Potts, B.J.**, Goyal, S., Theis, D., Struve, R. A Seroprevalence Study of Porcine Circovirus. *Proc. American Ass. Swine Producers* 245, 2000.
39. **Potts, B.J.**, Kivens, W., Detection and Removal of Porcine Viruses That May Contaminate Biopharmaceutical Raw Materials. *BioPharm* 26, 2000.
40. Eldering, J. A., Felten, C., Veilleux, C.A., **Potts, B.J.**, Development of a PCR Method for Mycoplasma Testing of Chinese Hamster Ovary Cell Cultures used in Biopharmaceutical Production. *Biologicals* 32; 183, 2004.
41. Fenaux, M., Opriessnig, T., Halbur, P.G., Xu, Y., **Potts, B.J.**, Meng, X.J. Detection and *In Vitro* and *In Vivo* Characterization of Porcine Circovirus from Porcine-Derived Commercial Pepsin Product. *Journal of General Virology* 85; 3377, 2004.

## PATENTS

1. 010329679  
WPI Acc No: 1995-231522/199530  
Hyperimmune globulin against two or more HIV-1 geographically diverse field isolates  
– used for treating or preventing HIV-1 infection by passive immunization  
Patent Assignee: UNITED BIOMEDICAL INC (UNBI-N)  
Inventor: KOFF W C; POTTS **B J**; WANG C Y
  
2. 009407143  
WPI Acc No: 1993-100653/199312  
Synnergistic compsn. for treating HIV-1 infection – comprises antibody to V3 loop of  
GP120 and antibody to CD4 binding site of GP120 or soluble CD4 polypeptide  
Patent Assignee: REPLIGEN CORP (REPK )  
Inventor: FIELD KG; HERLIHY WC; **POTTS B J**; WHITESHARP ME
  
3. 009288064  
WPI Acc No: 1992-415475/199250  
Hetero-conjugate antibodies for treating HIV infections – comprise an antibody specific  
for an effector cell surface antigen and an antibody to a V3 loop of GP-120 envelope  
protein of HIV  
Patent Assignee: REPLIGEN CORP (REPK )  
Inventor: HIGGINS P J; POTTS **B J**;