

Curriculum Vitae



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EXPERIENCE

Biologics Consulting Group, Inc., Senior Consultant
Cary, NC (August 2011 - present)

Talecris Biotherapeutics Sr. Director, Marketing and Training Intercontinental
Research Triangle Park, North Carolina (2008-2011)

- Establish long term strategies for EU and Intercontinental businesses (Asia Pacific, Eastern Europe, Middle East and Latin America), including launching existing products in new countries and pursuing partnerships designed to expand the company's current portfolio
- Establish and maintain compliant marketing strategies for entire product portfolio in 49 countries
- Develop and deliver science-based product training programs for distributors and sales forces worldwide
- Negotiate with regulatory authorities, pricing authorities, ministries of health and technical committees on behalf of Talecris
- Participate in company-wide product demand forecasting, sales forecasting, product allocation and pricing, as well as long range planning

Talecris Plasma Resources Head, Operational Excellence and Donor Experience
Research Triangle Park, North Carolina (2007-2008)

- Led a program to optimize operation efficiency in the Talecris plasma collection centers located throughout the United States, including establishing budgets and safety programs
- Developed operational tools, training programs, and check systems for all aspects of the centers;
- Rewrote standard operating procedures for the entire plasma collection process for better compliance/clarity/standardization across centers



Talecris Biotherapeutics (Bayer Biological Products) *Director/Senior Director of Virology and Transmissible Spongiform Encephalopathies (TSE) Department within Research and Development* Research Triangle Park, North Carolina (2001-2007)

- Responsible for the viral and TSE safety of plasma-derived and recombinant Biological Products manufactured by Talecris Biotherapeutics (previously Bayer).
 - This included developing pathogen reduction steps for manufacturing processes, validating pathogen reduction steps in a GLP-compliant manner, and providing risk assessments for emerging pathogens
- Prepared pathogen safety-related documents for regulatory submissions
- Interfaced with all regulatory agencies, world-wide, for issues relating to pathogen safety. Gave numerous presentations to regulatory agencies, opinion leaders, clinical investigators, distributors and at various scientific venues

U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) *Special Assistant to the Commander*
Frederick, Maryland (1996-2001)

- Provided both technical and regulatory expertise to the manufacturer as well as the management structure within the Department of Defense. Responsible for the coordination of four of these efforts within the Medical Research and Materiel Command (MRMC)
- Supervised the filing of a new IND to FDA for emergency use of the existing anthrax vaccine in conjunction with antibiotics for post exposure treatment
- Collaborated with the Centers for Disease Control to carry out a pivotal clinical trial to reduce the number of doses in the vaccination schedule for the current anthrax vaccine
- Provided regulatory oversight for the development of the next generation anthrax vaccine that is based on a recombinant expression product (PA)

U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) *Head, Department of Non-Clinical Studies, Office of Product Development and Regulatory Affairs*
Frederick, Maryland (1996-2000)

- Provided regulatory oversight and managed product development efforts for several viral, bacterial, and toxin vaccines and other biological products
- Prepared pre-IND packages for FDA, and participated in the preparation of INDs, protocols, and other documents required by regulatory agencies and/or the Department of Defense
- Oversaw manufacturing contracts for cGMP production of new vaccine candidates
- Coordinated GLP-compliant and other regulated non-clinical studies for viral vaccine (BSL-3 and BSL-4)
- Established an Institute –wide assay validation program

Hood College, Adjunct Professor

Frederick, MD (1998-2001)

- Taught a full semester graduate course: “A Practical Approach to GLPs”. This course served as one of the five core courses for a Master’s degree in Biomedical Sciences with emphasis in Regulatory Affairs as well as for a certificate in Regulatory Affairs. These degree programs are approved by Maryland Board of Higher Education

Frederick Research Center, Research Virologist/Supervisor, Viral Immunology and Flow Cytometry Laboratory, Frederick, MD (1993-1996)

- Provided administrative and scientific leadership to the Viral Immunology and Flow Cytometry laboratory and for implementing a GLP compliance program
- Served as Principal Investigator for three NIH contracts involved in the testing of HIV and SIV vaccines in nonhuman primates
- Provided oversight for several government and commercial task order contracts.
- Developed of animal models for testing of antiviral and vaccine therapies

Henri Beaufour Institute (IPSEN), Manager, Research and Development

Washington, D.C. (1992-1993)

- Prepared of IND applications to FDA and protocols
- Reviewed all pre-clinical and non-clinical data
- Prepared proposals, protocols, reports, and manuscripts relating to non-clinical data

National Cancer Institute (NCI), Group Leader, Flow Cytometry/Immunology, Laboratory of Cell and Molecular Structure, PRI/DynCorp (1989-1992)

- Provided administrative and scientific leadership to the Flow Cytometry / Immunology Laboratory that provides research support services to the FCRDC and the National Institute of Health scientific communities
- Provided oversight for several on-site and off-site projects related to the development of *in vivo* models for AIDS
- Developed of small animal models for Bovine Immunodeficiency-like virus (BIV) to be used in the testing of anti-lentivirus therapeutics and related immunological assays

USAMRIID, Research Microbiologist, Department of Epidemiology and Rapid Diagnosis, Disease Assessment Division, Fort Detrick, Frederick MD (1986-1989)

- Oversaw extramural contracts involving the development of rapid diagnostic assays and the characterization of live attenuated vaccine candidates of Argentine hemorrhagic fever virus
- Characterized animal models and developed new reagents and assays (ELISA, immunobeads, neutralization) for the diagnosis of infections caused by exotic RNA viruses (Bunyaviridae, Arenaviridae, Alphaviruses)

USAMRIID, *National Research Council Research Associate (Post-doctoral fellowship)*,
Division of Disease Assessment, Fort Detrick, Frederick MD (1985-1986)

- Developed and characterized monoclonal antibodies specific for Junin virus, the etiologic agent of Argentine hemorrhagic fever
- Conducted biochemical and antigenic characterization of virulent and non-virulent strains of Junin virus

EDUCATION

M.B.A., University of North Carolina, Chapel Hill (2008)

Ph.D. Microbiology, University of Maryland, School of Medicine, Department of Microbiology, Baltimore, MD (1985)

B.A. Biology, Goucher College, Towson, MD, (1979)

B.A. French Literature, Goucher College, Towson, MD, (1979)

Languages: Fluent in spoken and written English and French

Publications

1. Dichtelmuller H.O., L. Biesert, F. Fabbrizzi, R. Gajardo, A. Groner, I. Von Hoegen, J. I. Jorquera, C. Kempf, T. R. Kreil, D. Pifat, W. Osheroff, G. Poelsler. Robustness of solvent/detergent treatment of plasma derivatives: a data collection from Plasma Protein Therapeutics Association member companies. 2009. *Transfusion*, 49:1931-1943.
2. Li, H., D. Pifat, G. Klein, S. Petteway. Process Inspections and the OECD GLP Principles – Response to Letter to the Editor. 2007, *Quality Assurance Journal*, 11:108-110.
3. Mink, Mi., Hartwell, R. Bauman, P., Burdick, Mi. Kislán, M. Nelson, M. Oquendo, R. Pifat, D. Cai, K. Prion clearance capacity is improved by modification of a filtration step in the Gamunex (R) (IGIV) manufacturing process. 2007, *Blood*, 108 (11): 42B.
4. Li, H., D. Pifat, G. Klein, S. Petteway. Strengthening GLP Compliance Through Internal Audits. 2006, *Quality Assurance Journal*, 10(4):255-261.
5. Li, H., C. Pilkington, D. Pifat, S. Petteway. GLP-compliant Assay Validation Studies: Considerations for Implementation of Regulations and Audit of Studies. 2006, *The Quality Assurance Journal*, 10: 92-100.
6. Bauman, P.A., Lawrence, L.A., Biesert, L. Dichtelmuller, H., Fabbrizzi, F., Gajardo, R., Groner, A., Jorquera JI., Kempf, C., Kreil TR, Von Hoegen, I., Pifat, D., Petteway, S. Cai, K. Critical factors influencing prion inactivation by sodium hydroxide. 2006, *Vox Sanguinis*, 91 (1): 34-40.
7. Burdick, M.D. Pifat, D. Y., Petteway, S.R. Jr, Cai, K. Clearance of prions during plasma protein manufacture. *Transfusion Medicine Review*, 2006. 20(1):57-62.

8. Cai, K., Gierman, T., Hotta, J., Stenland, C.J., Lee, D., Pifat, D., and Petteway, S. Ensuring Biological Safety of Plasma Derived Therapeutic Proteins (invited review article), *Bio Drugs*, 2005, 19(2): 79-96.
9. Hartwell, R., Nelson, M., Kislán, M., Stenland, C., Miller, J., Pifat, D., Petteway, S., Cai, K. An improved Western blot assay to assess the clearance of prion protein from plasma-derived therapeutic proteins, *Journal of Virology Methods*, 2005, 125(2): 187-193.
10. Li, H, Hawlk, S, Renfrow , H, Hartwell, R, Chao, S-F, Sharp, G, Pilkington, C, Petteway, S, Remington, K, Pifat, D. Establishing a GLP compliance program for non-toxicology safety studies. 2004, *The Quality Assurance Journal*, 8: 94-101.
11. Remington, K., M. Trejo, J. Hotta, W. Lebing, C. Stenland, D. Pifat, and S. Petteway. IGIV-C, a novel immunoglobulin preparation, is manufactured with comprehensive pathogen safety by design. 2003. *Ann. Allergy Asthma, Immunol.* 90(1):67.
12. Korneyeva M, S. Rosenthal, P. Charles, S. Trejo, D. Pifat, S. Petteway. Important Parameters for Optimal Target Virus Clearance: Virus Spike Selection Issue. 2003. *American Pharmaceutical Review*.1-3.
13. Remington K.M., S. R. Trejo, G. Buczynski, H. Li, W. P. Osheroff, J.P. Brown, H. Renfrow, R. Reynolds, and D. Y. Pifat, "Inactivation of West Nile virus, vaccinia virus and viral surrogates for relevant and emergent viral pathogens in plasma-derived products". 2004. *Vox Sanguinis* 87:10-18.
14. Wang J, A. Mauser, S.F. Chao, K. Remington, R. Treckmann, K. Kaiser, D.Pifat and J. Hotta. Viral Inactivation and Protein Recovery in a novel ultraviolet C Reactor. 2004. *Vox Sanguinis*, 86:230-238.
15. Korneyeva, M., S. Rosenthal, S. Trukawinski, H. Li, J. Hotta, K. Remington, , L. Franks D. Pifat, S. Petteway and W. R. Alonso. Identification and Evaluation of Critical IGIV-SD Operating and Performance Parameters Affecting Virus Clearance. 2003. *Journal of Validation Technologies*. 9(2): 94-107.
16. Korneyeva, M., P.Charles, H. Li, S. McNaull, S.Smith, S.Petteway and D. Pifat. Factors influencing virus removal and product yield during nanofiltration on a highly purified plasma-derived protein with thrombolytic activity". *International Journal of Hematology* 2002; 76 (Suppl. 1):29.
17. Hotta, J., Klos, A., Petteway, S. Jr, and Pifat, D. Viral inactivation issues in aseptically processed parenterals in *Encyclopedia of Pharmaceutical Technology*, Eds. J. Swarbrick and J. C. Boylan, 2002, Marcel Dekker, Inc., NY, NY
18. Pittman, P.R., G. Kim-Ahn, D. Pifat, K. Coonan, P. Gibbs, S. Little, J. Pace-Templeton, R. Myers, G. Parker and A. Friedlander. Anthrax Vaccine: immunogenicity and safety of a dose-reduction, route change comparison study in humans. 2002. *Vaccine*, 2996:1-9.
19. Korneyeva, M., Hotta, J., Rosenthal, S., Lebing, W., Pifat, D., Petteway, S. Rapid and robust inactivation of enveloped viruses by caprylate in protein solutions (2000) *Blood*, 98 (11 PART II), pp. 96b.

20. Pifat, D.Y., W.H. Ennis, J.M. Ward, M.S. Oberste, and M.A. Gonda. Persistent Infection of Rabbits with Bovine Immunodeficiency-like virus. 1992. *Journal of Virology*. 66:4518-4524.
21. Latham, P.S., S.B. Sepelak, D.Y. Pifat, and J.F. Smith. Role of hepatocytes and Kupffer cells in age-dependent murine hepatitis caused by a phlebovirus, Punta Toro. 1991. *Journal of Medical Virology*, 33:10-18.
22. Gonda, M.A., M.S. Oberste, K.J. Garvey, L.A. Pallansch, J.K. Battles, D.Y. Pifat, J.W. Bess, Jr., and K. Nagashima. Development of the bovine immunodeficiency-like virus as a model of lentivirus disease. *In* *Developments in Biological Standardization*. S. Karger, Basel, Vol. 72, pp. 97-110, 1990.
23. Gonda, M.A., M.S. Oberste, K.J. Garvey, L.A. Pallansch, J.K. Battles, D.Y. Pifat, and K. Nagashima. Contemporary developments in the biology of the bovine immunodeficiency-like virus. *In* *Animal Models in AIDS*. Elsevier Science Publishers B.V./Biomedical Division, Amsterdam, pp. 233-255, 1990.
24. Sanchez, A., D.Y. Pifat, R. H. Kenyon, J. McCormick, M. Kiley, and C.J. Peters. Junin virus monoclonal antibodies: Characterization and cross-reactivity with other arenaviruses. *J.* 1989. *Journal of General Virology*. 70:1125-1132.
25. Canonico, P.G. and D.Y. Pifat. Highly pathogenic viruses of Africa and China. *In* *HIV and other highly pathogenic viruses*. Robert A. Smith, ed. Academic Press, Inc., pp. 63-80, 1988.
26. Sidwell, R.W., J.H. Hoffman, D.L. Barnard, and D.Y. Pifat. Effects of ribamidine, a 3-carboxamidine derivative of ribavirin, on experimentally induced phlebovirus infections. 1988. *Antiviral Research* 10:193-207.
27. Pifat, D.Y. and J.F. Smith. Antigenic analysis of Punta Toro virus and identification of protective determinants with monoclonal antibodies. 1988. *Virology* 167:442-450.
28. Sidwell, W.R., J.H. Hoffman, B.B. Barnett, and D.Y. Pifat. *In vitro* and *in vivo* phlebovirus inhibition by ribavirin. 1988. *Antimicrobial Agents and Chemotherapy* 32(3):331-336.
29. Pifat, D.Y. and J.F. Smith. Punta Toro virus infection of C57BL/6J mice: a model for phlebovirus-induced disease. 1987. *Microbial Pathogenesis* 3:409-422.
30. Pifat, D.Y. and J.F. Smith. Punta Toro virus infection of C57BL/6J mice: a model for phlebovirus-induced disease. 1987. *Microbial Pathogenesis* 3:409-422.
31. Pifat, D.Y. Resistance and immunity of Punta Toro virus infections. Dissertation, University of Maryland School of Medicine, 1985.
32. Smith, J.F. and D.Y. Pifat. Morphogenesis of Sandfly Fever viruses (Bunyaviridae family). 1982. *Virology* 121:61-81.