

## Curriculum Vitae



**Peter G. Probst**  
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Biologics Consulting Group, Inc.  
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### **EXPERIENCE**

**Biologics Consulting Group, Inc.**, *Vice President, Audits & Inspections.*  
Monrovia, MD (Oct. 1997 - present)

**FDA, Center for Biologics Research and Review**, Division of Establishment Licensing,  
*Reviewer/Inspector*  
Bethesda, MD  
(1993 to 1997)

- Chairperson of 50+ review committees for establishment submissions.
- Responsible for complete review of establishment applications and supplements associated with vaccines, monoclonal antibodies, allergenic extracts, in-vitro diagnostic test kits and plasma fractionation.
- Additional review experience as committee member for other establishment license applications and supplements as well cross-over member on product license applications and supplements.
- Review of Master Files.
- Lead inspector for prelicense and biennial CBER inspections. CBER inspector 1990-1997.
- Instructor for courses in product and process controls, and the changing role of inspections, as part of CBER's reviewer training program.
- Member of the CBER HVAC committee for the development and publication of guidelines to assist applicants in addressing establishment issues.
- Coordinated and conducted meetings with regulated industry and other sponsors of biologic products regarding issues pertaining to pending or prospective establishment applications. Provided guidance and interpretation of applicable regulations and guidelines.
- Consultant to product and application divisions regarding establishment issues.
- Advisor to CBER Office of Compliance regarding establishment issues as related to inspections.
- Member of the committee for development and publication of guidance for industry in the preparation of the CMC section of the proposed BLA for allergenic extracts.
- Member of the committee for development and publication of guidance for industry in the preparation of the ELA section of proposed BLAs for various products. \



- Comprehensive knowledge of established and evolving regulations, guidelines and policies involving facilities and cGMPs.

**FDA, Center for Biologics Research and Review**, Division of Bacterial Products (DBP), Laboratory of Allergy and Immunochemistry (LAI), *Research Biologist*  
Bethesda, MD  
(1985 to 1993)

- Responsible for development and certification of assays for selection, isolation and characterization of hybridoma cell lines for monoclonal antibody production
- Developed a standard CHO cell assay protocol for monitoring pertussis toxoids for toxins, and defined detection limits for preservatives and other cytotoxic agents.
- Trained U.S. and foreign scientists in the assay methodology.
- Inspection of CBER licensed facilities.
- Review of ELA supplements for allergenic extracts

**FDA, Center for Biologics Research and Review**, Division of Bacterial Products, Laboratory of Cellular Physiology, *Research Biologist*  
Bethesda, MD  
(1981 to 1985)

- Responsible for all aspects of production of hybridoma cell lines

**FDA, Bureau of Biologics**, Division of Pathology, *Research Biologist*  
Bethesda, MD  
(1972 to 1981)

- Development and characterization of unique cell lines for the detection, isolation and reproduction of selected viruses.
- Development of substrate and test systems with increased sensitivity for detection of bovine viruses.
- Investigation into mechanisms by which viral contamination of substrates could carry over to viral vaccines.
- Development of a rapid detection system for viral infection of cell cultures via immunofluorescence.
- Development of a system for elimination of bacteriophage from fetal bovine serum via affinity chromatography.

**NIH, Division of Biologics Standards**, Laboratory of Virology and Rickettsiology, *Research Biologist*  
Bethesda, MD  
(1964 to 1972)

#### **EDUCATION**

**B.S.** Catholic University, Washington, DC; Biology (1964)

#### **CONTINUING EDUCATION**

1998 Quality Assessment of GLP Contract Laboratories, PDA, Durham, NC



Peter G. Probst

- 1996 Cleaning Validation Strategies and CIP Integration: ISPE, Rockville, MD
- 1996 High Purity Water, Advanced: ISPE, Rockville, MD
- 1995 Principles of Validation: International Society for Pharmaceutical Engineering, Rockville, MD
- 1993-1994 CBER Reviewer Training for: Regulation of Biologics; IND Issues, PLA and ELA process; Postmarketing Regulations; Inspector Training, FDA/CBER
- 1993 Validation of Sterile Processes for the Pharmaceutical Industry: Institute for Applied Technology, San Francisco, CA
- 1989 Advanced Drug and Biologics Law: Staff College of the Center for Drug Evaluation and Research, Bethesda, MD
- 1989 Basic Drug and Biologics Law: Staff College of the Center for Drug Evaluation and Research, Bethesda, MD
- 1988 Biological Research HPLC: Waters Corporation, Milford, MA
- 1966 Immunogenetics: Graduate Program at NIH Foundation for Advanced Education in the Sciences, Bethesda, MD
- 1966 Virology: Graduate Program at NIH Foundation for Advanced Education in the Sciences, Bethesda, MD
- 1965 Immunology: Graduate Program at NIH Foundation for Advanced Education in the Sciences, Bethesda, MD

#### **HONORS AND AWARDS**

- 1994 FDA Group Recognition Award
- 1993 FDA Group Recognition Award
- 1990 FDA Commendable Service Award
- 1989 FDA Commissioners Medallion

#### **CERTIFICATIONS**

- Nov. 6, 1999 Regulatory Affairs Certified (RAC)
- May 24, 1993 FDA Certified Regulatory Inspector of Licensed Manufacturers of Biologic Products.
- 1993 FDA Regulatory Reviewer, Biologics Establishment & Product License applications.
- 1991 FDA Certified Regulatory Inspector of Licensed Manufacturers of Biologic Products.

#### **PROFESSIONAL SOCIETIES**

Regulatory Affairs Professional Society (RAPS)  
Parenteral Drug Association (PDA)

#### **REGULATORY PRESENTATIONS AND PUBLICATIONS**

1. Probst, PG, Orr, HC. (1970 Short-Term Storage at 4C of Trypsinized Tissues. Applied Microbiology 19 #2: 387-388.
2. Montes de Oca, H, Probst, PG, Grubbs, R. (1971) High Yield Method for Dispersing Simian Kidneys for Cell Cultures. Applied Microbiology 20 #1 90-94.

3. Probst, PG, Rogers, JL, Orr, HC. (1972) A Cradle for Support of Roller-Bottle Cell Cultures during Microscopic Examination. *Biotechnology & Bioengineering* XIV: 505-507.
4. Orr, HC, Harris, LE, Bader, AV, Kirschstein, RL, Probst, PG. (1972) Cultivation of Cells from a Fibroma in a Rattlesnake, *Crotalus horridus*. *J Nat Cancer Inst* 48: 259-264.
5. Orr, HC, Probst, PG, Rogers, JL, Davis, JP, Stocks, NP, Baker, J. (1973) Derivation and Biologic Properties of Cell Lines from Ophidian Tissues. *J Nat Cancer Inst* 51: 827-832.
6. Chu, FC, Johnson, JB, Orr, HC, Probst, PG, Petricianni, JC. (1973) Bacterial Virus Contamination of Fetal Bovine Sera. *In Vitro* 9: 31-34.
7. Orr, HC, Probst PG, Littlejohn, DC, Chu, FC, Petriccianni, JC. (1974) Persistence of Bacteriophages in Experimentally Infected Cell Cultures. *ASM* 27 #2: 1105-1107.
8. Orr, HC, Sabinovic, KH, Probst PG, Hochstein, DC, Littlejohn, DC. (1975) Bacteriological Activity in Unfiltered Calf Sera Collected for Tissue Culture Use. *In Vitro* 11 #4: 230-233.
9. Orr, HC, Weetall, HH, Probst, PG, Littlejohn, DC, Chu, FC, Johnson, JB, Petriccianni, JC. (1976) Elimination of Bacteriophages from Tissue Culture Serum By Affinity Chromatography. *ASM* 3 #4: 402-405.
10. Carter, PH, Orr, HC, McGrath, PP, Probst, PG. (1978) Virus Like Particles in WI-38 Cells Infected with Bovine Viral Diarrhea Virus. W Alton Jones Cell Science Center Symp. Lake Placid, NY. Oct 23-26. [Abstract].
11. Weetall, HH, Luderer, AA, Orr, HC, Probst, PG. (1979) Rapid Immunofluorescent Detection of Viral Infection In Tissue Culture. *Immunology Letters* 1: 11-13.
12. Kenimer, JG, Kim, KJ, Probst, PG, Manclark, CR, Burstyn, DG, Cowell, JL. (1989) Monoclonal Antibodies to Pertussis Toxin: Utilization as Probes of Toxin Function. *Hybridoma* 8: 37-51.
13. Chandler, DKF, Olson, LD, Kenimer, JG, Probst, PG, Rottem, S, Grabowski, MW, Barile, ME. (1989) Antibodies to *Mycoplasma pneumoniae* Membrane Glycolipids. *Infec and Immun.* 57:1131-1136.
14. Elizabeth Leininger, Peter G. Probst and James G. Kenimer (1990) Characterization of Monoclonal Antibodies Against the *Bordetella pertussis* Adhesin Filamentous Hemagglutinin. The 6th International Symposium on Pertussis. Bethesda, MD. Sept 26-28. [Abstract].
15. Rouse, DA, Morris, SL, Karpas, AB, Probst, PG, Chaparas, SD. (1990) Production, Characterization, and Species Specificity of Monoclonal Antibodies to *Mycobacterium avium* Complex Protein Antigens. *Infec and Immun.* 58: 1445-1449.

16. Olson, LD, Shane, SW, Karpas, AB, Cunningham, TW, Probst, PG, Barile, MF. (1991) Monoclonal Antibodies to Surface Antigens of a Pathogenic *Mycloplasma hominis* Strain. *Infec. and Immun.* 59: 1683-1689.
17. Rouse, DA, Morris, SL, Karpas, AB, Mackall, JC, Probst, PG, Chaparas, SD. (1991) Immunological Characterization of Recombinant Antigens Isolated from a *Mycobacterium avium* lambda gt11 Expression Library by Using Monoclonal Antibody Probes. *Infec and Immun* 59: 2595-2600.
18. Nancy A. Roscioli, Carolyn A. Renshaw, Alicia A. Gilbert, Cristina F. Kerry, and Peter G. Probst. (1996) Environmental Monitoring Considerations for Biological Manufacturing. *BioPharm* 8 No. 9: 32-40.