

Curriculum Vitae



Larry K. Winberry, Ph.D.
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Senior Consultant, Process Development
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Biologics Consulting Group, Inc.
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EXPERIENCE

Biologics Consulting Group, Inc., *Senior Consultant, Process Development and Manufacturing*
Rochester Hills, MI
(Sept. 2001 - present)

BioPort Corporation, *Vice President, Manufacturing Operations Group*
Lansing, MI
(May 1999 - Sept. 2001)

- Reported to the COO, with responsibility for day to day operations.
- Directed reports include the Vice Presidents of Vaccine Manufacture; Facility, Engineering, Maintenance, Validation and Metrology.
- BioPort Corporation is the only US manufacturer of Anthrax Vaccine Adsorbed™ and Rabies Vaccine Adsorbed™.
- The site employs approximately 200 staff with an annual operations budget in excess of \$20 million.

Hyland-Immuno, *Director of Quality Assurance, Quality Control*
Rochester, MI
(Oct. 1993 - May 1999)

- Reported to the Divisional Vice President of Quality
- Responsible for all on-site matters relating to quality systems and US FDA compliance activities at the Rochester, MI facility.
- Responsibilities included the following: Product release, Quality Assurance, Quality Control, Validation, FDA Inspections, 483 responses, Internal Compliance, Plasma Supplier Quality, Analytical Methods Development, Stability Program, Training, and Change Control.
- The facility fractionated 400k liters of human plasma annually into several therapeutic products including Human Albumin, AHF paste, Factors IX and VII, and ISG powder.



Larry K. Winberry, Ph.D.

Lederle-Praxis Biologics, *Director of Quality Assurance, Quality Control and Technical Services*

Sanford, NC Manufacturing Facility

(May 1991 - Oct. 1993)

- Reported to the Divisional Vice President of Quality
- Responsible for all on-site matters relating to quality systems and US FDA compliance activities at the Sanford, NC facility.
- Responsibilities included the following: Product release (HibTiter™ Vaccine), Quality Assurance, Quality Control, Validation, Calibration, FDA Inspections, 483 responses, Analytical Methods Development, Stability Program, Training, and Change Control.
- Key player on the Quality Team responsible for development, licensing, and launch of Tetramune™ Vaccine (Diphtheria Toxoid, Tetanus Toxoid, Pertussis Vaccine, and Hflub Conjugate Vaccine, Combined).
- Provided key quality support for the CPMP registration of HibTiter™ Vaccine in the UK and Germany.

Praxis Biologics, Inc., *Pilot Plant Manager, Scale-Up and Development*

Sanford, NC Manufacturing Facility

(Jan. 1989 - May 1991)

- Reported to the Director of Bacterial Vaccine Development
- Responsible for the day to day operations of the Pilot Plant.
- Responsibilities included the following: lab scale bacterial fermentation (10 to 150 liter) development, purification process development, and GMP clinical production of Phase I, II, and III materials.
- Process development experience with protein and saccharide purification, recombinant antigen production, and glyco-conjugate vaccine manufacture.
- Provided scientific, technical, and manufacturing support for newly licensed HibTiter™ Vaccine.
- Completed the characterization and subsequent FDA supplement approval for two new hyper-producing manufacturing strains.

Massachusetts Public Health Biologics Labs, *Head of Bacterial Vaccines Division*

Boston, MA

(April 1986 - Jan. 1989)

- Reported to the Program Director
- Responsible for the Vaccines Manufacturing Unit.
- The Biologics Lab manufactured DTP Vaccine for the State of Massachusetts.
- Responsible for manufacturing activities and the Vaccine Development Program.
- Responsible for the development of an acellular pertussis toxoid vaccine that was clinically investigated in a Phase I/II IND safety and immunogenicity trial.
- This technology was successfully transferred to the Swiss Serum Vaccine Institute who holds the European patent.

Larry K. Winberry, Ph.D.

Michigan Department of Public Health, Clinical Health Scientist
Lansing, MI
(May 1984 - April 1986)

Michigan State University, Research Associate, Department of Microbiology
Laboratory of Dr. Michele Fluck
(June 1982 - April 1984)

Case Western Reserve University, Department of Pharmacology
Laboratory of Dr. Alan Goodridge
(Jan. 1981 - June 1982)

University of California, Riverside, Department of Biochemistry
Laboratory of Dr. Darold Holten
1980

University of Toronto, C.H. Best Institute
Laboratory of Dr. Alex Marks
(Nov. 1976 - July 1978)

EDUCATION

B.S., Biochemistry, University of California, Riverside (1972)

Ph.D., Biochemistry, University of California, Riverside (1976)

PROFESSIONAL SOCIETIES

- Member, Working Group of the Chemical and Biological Arms Control Institute; The Development of a National Vaccine Strategy, (June 2nd, 2004)
- Member, Parenteral Drug Association (PDA)
- Member, International Society for Pharmaceutical Engineering (ISPE)
- Special Emphasis Panel, National Institute of Allergy and Infectious Diseases, Regional Biocontainment Laboratory Review (June 23-24, 2003).
- Member, Peer Review of Biodefense Vaccine Programs (USAMRIID), American Institute of Biological Sciences (August 18-20, 2003)
- Member Scientific Review Group, FY05 Medical Chemical And Biological Defense Program, Defense Threat Reduction Agency (May 13-14, 2004)

ABSTRACTS (PRESENTED AT SCIENTIFIC MEETINGS)

1. **Winberry, L.**, S. Hutchison, and D. Holten. 1976. Quantitation of 6-phosphogluconate dehydrogenase rates of synthesis and mRNA levels during dietary induction. Fed. Proc. 35, Abstract No. 1566.
2. **Winberry, L.**, and D. Holten. 1977. Dietary induction of glucose-6-P dehydrogenase synthesis in rat liver. Fed. Proc. 36, Abstract No. 647.

Larry K. Winberry, Ph.D.

3. Marks, A., L. **Winberry**, D. Cowdrey, and R. Baumal. 1977. Selective in vitro killing of IgG1-producing mouse myeloma cells with anti-gamma antiserum and complement. NCI Conference on Cell-mediated Immunity, Toronto.
4. **Winberry**, L., A. Marks, and R. Baumal. 1978. Characterization of immunoglobulin production and secretion by IgA producing MOPC 315 mouse myeloma cell mutants. Fed. Proc. 37, Abstract No. 2701.
5. Cowdrey, D., A. Marks, L. **Winberry**, and R. Baumal. 1978. Cytotoxic activity of rabbit sera for mouse myeloma cells. Proc. Can. Fed. **Bio1**. Soc. 21.
6. **Winberry**, L., A. Marks, D. Cowdrey, and R. Baumal. 1978. Characterization of light chain synthesis and secretion by IgA Producing MOPC 315 mouse myeloma cell mutants. Proc. Can. Fed. Bio1. Soc. 21.
7. Holten, D., S. Hutchison, R. Nakayama, J. Sun, N. Taylor, and L. **Winberry**. 1980. Mechanisms regulating the induction of lipogenic enzymes. Fed. Proc. 39. Abstract No. 1159.
8. **Winberry**, L., R. Nakayama, and D. Holten. 1980. Induction of glucose-6-P dehydrogenase in primary hepatocytes cultured in serum-free medium. Fed. Proc. 39. Abstract No. 1689.
9. Morris, S.M., Jr., L.K. **Winberry**, and A.G. Goodridge. 1983. Regulation of avian lipogenic enzyme gene expression. 12th Ann. UCLA **Symp.** Molec. Cell. Bio1. Abstract No. 472.
10. **Winberry**, L., C. Priehs, and M. Fluck. 1983. Expression of cellular oncogenes in normal and virally transformed (polyoma and SV40) rat fibroblasts. ASM Virology meeting, Michigan State University.
11. **Winberry**, L., C. Priehs, and M. Fluck. 1983. Expression of cellular oncogenes in normal and virally transformed (polyoma, SV40) rat fibroblasts. The Imperial Cancer Research Fund 1983 Tumor Virus Meeting, Cambridge, England.
12. **Winberry**, L., Walker, R., Cohen, N., Todd, C., Sentissi, A., Siber, G.: Evaluation of a new method for inactivating pertussis toxin with tetranitromethane. Abstracts, International workshop on Bordetella pertussis, Rocky Mountain Laboratories, Hamilton, Montana, August 18-20, 1988.
13. Siber, G., **Winberry**, L., Todd, C., Samore, M., Sentissi, A., Cohen, N.: Safety and immunogenicity in adults of pertussis toxoid inactivated with tetranitromethane. Abstracts, International Workshop on Bordetella pertussis, Rocky Mountain Laboratories, Hamilton, Montana, August 18-20, 1988.
14. Siber, G.R., Herzog, L., Marchant, C.D., Cohen, N, **Winberry**, L.K., and Todd, C.W., Pertussis Toxoid inactivated with tetranitromethane: Safety and immunogenicity in adults,

Larry K. Winberry, Ph.D.

children, and infants. Abstracts, Sixth International symposium on Pertussis, Bethesda, Maryland, September 26-28, 1990.

15. Cryz, S.J., Siber, G.R., Cohen, N., **Winberry**, L., Todd, C., Berger, R., and Just, M.: Safety and immunogenicity of a tetranitromethane pertussis toxoid in 14-18 month old Swiss Children. Abstracts, Sixth International Symposium on Pertussis, Bethesda, Maryland, September 26-28, 1990.

BIBLIOGRAPHY

1. **Winberry**, L.K., and J.B. Mudd. 1974. S-acyl gluathione thioesterase of plant tissue. *Plant Physiol.* 53:216-219.
2. Procsal, D., L. **Winberry**, and D. Holten. 1976. Dietary regulation of 6-phosphogluconate dehydrogenase synthesis. *J. Biol. Chem.* 251:3539-3544.
3. **Winberry**, L., and D. Holten. 1977. Rat liver glucose-6-P-dehydrogenase: Dietary regulation of the rate of synthesis. *J. Biol. Chem.* 252:7796-7801.
4. **Winberry**, L., R. Nakayama, R. Wolfe, and D. Holten. 1980. Regulation of glucose-6-P dehydrogenase activity in primary hepatocyte cultures. *Biochem. Biophys. Res. Commun.* 96:748-755.
5. **Winberry**, L., A. Marks, and R. Baumal. 1980. immunoglobulin production and secretion by variant clones of the MOPC 315 mouse myeloma cell line. *J. Immunol.* 124:1174-1182.
6. Hozumi, N., G. Wu, H. Murialdo, R. Baumal, T. Mossman, L. **Winberry**, and A. marks. 1982. Arrangement of lambda light chain genes in mutant clones of the MOPC 315 mouse myeloma cells. *J. Immunol.* 129:260-266.
7. Morris, S.M., Jr., J.H. Nilson, R.A. Jenik, L.K. **Winberry**, M.A. McDevitt, and A.G. Goodridge. 1982. Molecular cloning of gene sequences for avian fatty acid synthase and evidence for nutritional regulation of fatty acid synthase mRNA concentration. *J. Biol. Chem.* 257:3225-3229.
8. **Winberry**, L.K., S.M. Morris, Jr., J.E. Fisch, M.J. Glynias, R.A. Jenik, and A.G. Goodridge. 1982. Molecular cloning of gene sequences for avian malic enzyme. Nutritional and hormonal regulation of malic enzyme mRNA levels in avian lever cells in vivo and in culture. *J. Biol. Chem.* 258:1337-1342.
9. Hutchinson, J.S., L. **Winberry**, R. Nakayama, and D. Holten. 1984. Kinetics for changes in enzyme synthesis and mRNA content and hormones required for induction of 6-phosphogluconate dehydrogenase in hepatocytes. *Biochem. Biophys. Acta* 781:30-38.

Larry K. Winberry, Ph.D.

10. Goodridge, A.G., R.A. Jenik, M.A. McDevitt, S.M. Morris, Jr., and L.K. **Winberry**. 1984. Malic enzyme and fatty acid synthase in the uropygial gland and liver of embryonic and neonatal ducklings. Tissue-specific regulation of gene expression. *Arch. Biochem. Biophys.* 230:82-89.
11. Glynias, M.J., S.M. Morris, Jr., D.A. Fantozzi, L.K. **Winberry**, D.W. Back, J.E. Fisch, and A.G. Goodridge. 1984. A cloned cDNA for duck malic enzyme detects abnormally large malic enzyme mRNAs in a strain of mice (mod-1n) that does not express malic enzyme protein. *Biochemistry* 23:3454-3459.
12. Morris, S.M., Jr., L.K. **Winberry**, J.E. Fisch, D.W. Back, and A.G. Goodridge. 1984. Developmental and nutritional regulation of the messenger RNAs for fatty acid synthase, malic enzyme and albumin in the livers of embryonic and newly-hatched chicks. *Mol. Cell. Biochem.* 64:63-68.
13. **Winberry**, L.K., C.J. Stewart, B.S. Schaffhausen, and M. Fluck. 1985. Transformation by polyoma ts-a mutants: I. Characterization of the transformed phenotype. *Virology* 144:433-447.
14. **Winberry**, L., C. Priehs, K. Friderici, M. Thompson, and M. Fluck. 1985. Expression of cellular oncogenes in normal and papovavirus transformed or infected rat fibroblasts. *Virology* 147:154-168.
15. Priehs, C., K. Friderici, L. **Winberry**, and M. Fluck. 1986. Properties of cells transformed by the middle T-antigen coding region of polyoma virus. *J. Virology* 57:211-218.
16. Rosoff, P.M., R. Walker and L. **Winberry**, and M. Fluck. 1987. Pertussis toxin triggers rapid second messenger production in human T lymphocytes. *J. Immunol.* 139: 2419-2423.
17. Banga, H.S., R.K. Walker, L.K. **Winberry**, and S.E. Rittenhouse. 1987. Pertussis toxin can activate human platelets. *J. Biol. Chem.* 262:14871-14875.
18. Banga, H.S., R.K. Walker, L.K. **Winberry** and S.E. Rittenhouse, 1988. Platelet adenylate cyclase and phospholipase C are affected differentially by ADP-ribosylation. *Biochem J.* 252:297-300.

BOOK CHAPTERS

Granstron, M., M. Blennow, L. **Winberry**: Pertussis vaccine, in Cryz, S.J. (ed): Vaccines and Immunotherapy. Pergamon Press, Inc., 1991, pp. 20-35.

PATENTS

U.S. Patent Application, Serial No. 183,884: Pertussis Toxoid Vaccine.

European Patent Application, Serial No. 89107157.3: Pertussis Toxoid Vaccine.