



Leslie E. Walker, PhD

SUMMARY

Responsible, effective, innovative and dedicated Biotech Executive with extensive experience and success in planning, implementing, managing and completing drug development projects. Expertise in all aspects of cGMP Manufacturing, Project Management and Regulatory Submissions. Specialized strengths include department management, strategy development, innovative problem solving, project team unification, budget and timeline adherence.

PROFESSIONAL EXPERIENCE

L. E. WALKER CONSULTING

2009-Present

- IND preparation and review
- Preparation and review of technical documentation and data
- Design, preparation and review of manufacturing batch records and pre-clinical safety studies.

PHARMEXA INC. (Pharmexa-Epimmune Inc., IDM Pharma, Epimmune Inc.)

2000-2008 Director, Drug and Process Development

- Project Director, Universal Flu Vaccine – Responsible for coordinating and directing an international project team. All timelines were met, a drug candidate was chosen to move forward into development, animal protection models were developed and a project plan was in place through drug launch.
- Directed new vaccine product development including design of immunogenic protein antigens, cleavable multi-epitope peptides and plasmid DNA drug candidates.
- Responsible for all Manufacturing Activities of Drug Candidates (DNA, Peptide, Protein). Three plasmid DNA vaccine candidates, 10 peptide vaccine candidates and a protein vaccine candidate were successfully manufactured under cGMP on time and within budget.
- Responsible for formulation development for all drug products. Directed the development of drug product formulations for plasmid DNA, emulsion preparations containing up to 10 peptides, proteins adsorbed to aluminum. All formulations were stable for a minimum of 2 years.
- Responsible for outsourcing of Manufacturing, Preclinical Toxicology, Assay Development. Sourced, negotiated contracts and monitored outside activities. Designed and implemented preclinical safety studies for drug candidates.
- Responsible for regulatory and associated documentation (Manufacturing Batch Records, Quality, Regulatory, CMC). Wrote and assembled three IND packages (and pre-IND packages), respond to questions from FDA. Worked closely with DAIDS and DMID regulatory. All submissions were on time and all clinical trials started as planned.

CYTEL CORPORATION

1996-1999 Director, Drug and Process Development

1993-1996 Director, Molecular Biology and Biochemist

1990-1993 Assoc. Director, Molecular Biology and Biochemistry

- Supervised a diverse group of scientists including research molecular biologists and biochemists. Additionally supervised process development and manufacturing personnel.



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Directed group that produce 9 recombinant enzymes at large scale that were used for complex carbohydrate synthesis.

- Responsible for the development and scale up of enzymatic glycosylation cycles, enabling complex carbohydrate manufacturing technology. Developed technology allowed the cGMP production of carbohydrate drug candidate on the kilogram scale.
- Responsible for developing clinical formulations for carbohydrate, peptide and protein drug candidates. All drug products were stable for a minimum of 2 years.
- Supervised final formulation and filling operation of phase I, II and III drug product. Clinical drug supplies always produced on time.

SCRIPPS CLINIC AND RESEARCH FOUNDATION

1984-1990 Assistant Member, Department of Immunology

- Basic research on structure-function of class I and class II immune molecules. Multiple NIH funding as well as funding from industry.
- Developed and produced monoclonal antibody-drug conjugate tested in phase I clinical trial.

EDUCATION

- Postdoctoral studies, Scripps Clinic and Research Foundation
- Ph.D., Biochemistry, Oklahoma State University
- B.S., Biochemistry, Oklahoma State University

PUBLICATIONS

1. Ferrone, S., Naeim, F., Indiveri, F., Walker, L.E. and Reisfeld, R.A. Xenoantisera to human DR antigens. Serological and immunochemical characterization. *Immunogenetics* **7**:349, 1978.
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4. Allison, J.P., Ferrone, S., Walker, L.E., Pellegrino, M.A., Silver, J. and Reisfeld, R.A. Partial amino acid sequence of HLA-A9 antigen purified with a specific xenoantiserum. *Transplantation* **26**: 451-454, 1978.
5. Natali, P.G., Pellegrino, M.A., Walker, L.E., S. Ferrone, and R.A. Reisfeld. Antibody-coated protein A-bearing *Staphylococcus aureus*: A versatile and stable immune reagent. *J. of Immunol. Meth.* **25**:255, 1979.
6. Silver, J., Walker, L.E., Reisfeld, R.A., Pellegrino, M.A., and Ferrone, S. Structural studies of murine I-E and human DR antigens. *Molecular Immunol.* **16**:37-42, 1979.

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7. Walker, L.E., Allison, J.P., Silver, J., Pellegrino, M.A., Reisfeld, R.A., and Ferrone, S. Is serological polymorphism of human DR antigens determined by structural differences in the smaller (b) chain? *Cell Biological and Immunology of Leukocyte Function* **13**: 271-275, 1979.
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9. Callahan, G.N., Pellegrino, M.A. and Walker, L.E. Alterations in expression of glycoproteins by a murine fibrosarcoma detected with Staphylococcus aureus. *Transplant. Proc.* **12**:87, 1980.
10. Quaranta, V., Walker, L.E., Pellegrino, M.A., and Ferrone, S. Purification of immunologically functional subsets of human Ia-like antigens on a monoclonal antibody (Q5/13) immuno-adsorbent. *J. Immunol.* **125**:1421-1425, 1980.
11. Walker, L.E., Ferrone, S., Pellegrino, M.A., and Reisfeld, R.A. Structural polymorphism of the b chain of human HLA-DR antigen. *Molecular Immunology* **17**: 1443-1448, 1980.
12. Walker, L.E., Ferrone, S., Pellegrino, M.A., and Ralph A. Reisfeld. Structural analyses of HLA-DR antigens. In: *Current Trends in Histocompatibility* (R.A Reisfeld and S. Ferrone, eds.) Plenum Press, New York, p.511-529, 1981.
13. Callahan, G.N., Walker, L.E., and Martin, W.J. Biochemical comparison of mutant H-2Kkv1 (CeHfB/HeN) and parent H-2Kk (C3H/HeN) glycoproteins. *Transplantation Proc.* **13**:1787-1791, 1981.
14. Callahan, G.N., Walker, L.E., and Martin, W.J. Biochemical comparison of H-2K antigens isolated from C3HfB/HeN and C3H/HeN mice. *Immunogenetics* **12**:561-568, 1981.
15. Walker, L.E., Quaranta, V., Ferrone, S., and R. A. Reisfeld. Structural characterization of human Ia-like antigens by peptide mapping. In: *Immunobiology of the Major Histocompatibility Complex* (M.B. Zaleski, ed.) S. Karger, A.G. Basel, pp.147-154, 1981.
16. Quaranta, V., Walker, L.E., Ruberto, G., Pellegrino, M.A., and Ferrone, S. The free and the b2-microglobulin-associated heavy chains of HLA-A,B alloantigens share the antigenic determinants recognized by the monoclonal antibodies Q1/28. *Immunogenetics* **13**:285-295, 1981.
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19. Church, W.R., Walker, L.E., Houghten, R. A., and Reisfeld, R.A. Anti-HLA antibodies of predetermined specificity: A chemically synthesized peptide induces antibodies specific for HLA-A,B heavy chain. *Proc. Natl. Acad. Sci. USA* **80**:255-258, 1983.
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21. Niman, H., Houghten, R., Walker, L.E., Wilson, I., Hogel, J., and Lerner, R. Generation of protein reactive antibodies by short peptides is an event of high frequency: Implications for the structural basis of immune recognition. *Proc. Natl. Acad. Sci., USA* **80**:4949-4953, 1983.
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25. Varki, N.M., Reisfeld, R.A., and Walker, L.E. Effect of monoclonal antibody-drug conjugates on the in vivo growth of human tumors established in nude mice. In: *Monoclonal Antibodies and Cancer Therapy* (R. A. Reisfeld and S. Sell, eds.) Alan R. Liss, Inc. New York, p. 193-206, 1985.
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27. Fernsten, P.D., Pekny, K.W. and Walker, L.E. Antigens associated with human squamous cell lung carcinoma defined by murine monoclonal antibodies. *Cancer Research* **46**: 2970-2977, 1986.
28. Shani, J., Wolf, W., Chanachai, W., Mohd, S. and Walker, L.E. Labeling and comparative biodistribution of the monoclonal antibody KS1/4 in nude mice bearing human lung adenocarcinoma. *Nucl. Med. Biol.* **13**: 379-382, 1986.
29. Fantozzi, R., Bone, R., Fernsten, P., and Walker, L. Upper aerodigestive neoplasm perpetuated in the nude mouse. *Laryngoscope* **96**:621-624, 1986.
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