

Curriculum Vitae



Keith H. Wells, Ph.D.
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Massachusetts Office Head
Biologics Consulting Group, Inc.
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SUMMARY OF EXPERTISE

Broad based experience in biological process development and manufacturing, antiviral research, clinical diagnostics, and microbiology. Expertise in virology, tissue culture, cGMPs, process scale up, cell culture development, large scale chromatography, validation, and assay development. Experience in design, validation, and operation of biological manufacturing facilities. Additional experience in the preparation of regulatory submissions and manufacturing documents. A proven innovator adept in problem solving and adapting and implementing new technologies to existing problems.

EXPERIENCE

Biologics Consulting Group, Inc., *Massachusetts Office Head*

Franklin, MA (Oct. 2000 - present)

- Provide consulting services to the biopharmaceutical industry in areas of process development, process validation, facilities design and validation, manufacturing operations, and project management.
- Expertise in all biologicals unit operations from preparation of Master Cell Banks through Fill/Finish of commercial products.

Oravax, Inc., *Senior Director, Manufacturing and Process Development*

Cambridge, MA

(Jan. 2000 - Oct. 2000)

- Responsible for directing all aspects of the process development and manufacturing of entire Company vaccine and immune globulin product portfolio.
- Responsibilities include strategic planning, project scheduling and management, personnel management, and planning and management of operating budgets.
- Author of CMC sections of IND and BLA submissions for live virus vaccine, toxoid, and immune globulin products.



Keith H. Wells, Ph.D.

Oravax, Inc., Senior Director, Viral Vaccine Development

Cambridge, MA

(May 1999 - Dec. 1999)

- Project Manager for ChimeriVax™ program
- Responsible for directing all aspects of the development of the ChimeriVax™ product line through all agreed milestones, including Phase 1 clinical trials.
- Directed all activities of the viral vaccine process development group in support of ChimeriVax™ and other viral vaccine projects.
- Leading the design effort for a multiuse, biological safety level 3 cGMP pilot plant.

Oravax, Inc., Director, Vaccine Production

Cambridge, MA

(July 1998 - May 1999)

- Directed all aspects of the manufacture of viral vaccine clinical products, including the selection of contractors and negotiation of contracts.
- Responsible for directing all aspects of the process development for ChimeriVax™ live virus vaccine product line.
- Member of operating committee on ChimeriVax™ joint venture with Pasteur Merieux Connaught.

The Salk Institute Biological Development Center, Director, Vaccine Production and Product Development

Swiftwater, PA

(Sept. 1996 - July 1998)

- Responsible for directing all aspects of the process development and manufacturing of biological products according to cGMP guidelines in a multiuse, biological safety level 3 facility for government and private clients.
- Business development responsibilities included identification of appropriate clients and strategic partners, and negotiation of contracts.

Merck and Company, Biological Process Research and Development, Research Fellow

(Sept. 1994 - Sept. 1996)

- Performed process development research for human vaccine and gene therapy products.
- Responsibilities included process development and optimization, culture medium development, process scale-up, and demonstration of processes at manufacturing scale.
- Responsible for supervising the production of Master and Working Cell Banks and Virus Seeds.
- Responsible for development of immunologic and biochemical methods for monitoring of virus vaccine and gene therapy vector manufacturing processes.

Merck and Company, Biological Manufacturing, *Biological Process Specialist*
(Sept. 1992 - Sept. 1994)

- Led a staff of 3 that provided direct process support to manufacture of varicella, measles, mumps, rubella, and hepatitis A virus vaccine products.
- Responsibilities included trouble shooting, data analysis and trending, training of operators, and process optimization.
- Major contributions included the identification, development, and implementation of significant yield enhancements in key virus vaccine manufacturing areas.
- Process enhancements have been valued at a minimum of \$25 million.
- Gained expertise in mass culture of viruses in mammalian and avian cells in flasks and roller bottles (with and without robotic operations), Nunc Cell Factories™, CoStar Cubes™, and titanium disk reactors.
- Gained additional expertise in industrial scale purification of viruses.

Merck and Company, Biological Technical Services, *Senior Project Virologist*
(Feb. 1990 - Aug. 1992)

- Key contributor to development and technological improvement of live virus vaccine manufacturing processes.
- Instrumental in the development of the manufacturing processes for VARIVAX® and VAQTA®, and in the preparation of the PLA/ELA submissions for the products which culminated in their successful licensure.
- Significant contributions to the manufacturing of measles, mumps, and rubella live virus vaccines including process enhancements and identification of cost savings.

State University of New York Health Science Center at Syracuse, *Graduate Teaching Assistant/Doctoral Candidate*
(Sept. 1985 - Jan. 1990)

- Developed cellular and molecular based in vitro assays to screen large numbers of potential anti-retroviral compounds and to ascertain mechanisms of action.
- Conducted independent research into cellular and molecular mechanisms of action of anti-retroviral agents.

Syracuse University, *Technical Specialist*
(1983 - 1985)

- Developed immunoassays and monoclonal antibodies for metallothioneins.

Kallestad Laboratories, *Technical Associate*
Austin, TX
(1982 - 1983)

- Instrumental in the development of monoclonal antibody-based immunoassays for therapeutic drug monitoring, and immunoassay-based pregnancy test.

University of Texas at Austin, Department of Microbiology, *Technical Assistant*
Austin, TX
(1981 - 1982)

Keith H. Wells, Ph.D.



Helena Laboratories, *Technical Assistant - Biochemical Technical Services*
Beaumont, TX
(1979 - 1981)

EDUCATION

Ph.D. in Microbiology and Immunology, State University of New York Health Science Center at Syracuse (Jan. 1990)
Bachelor of Arts (cum laude) in Microbiology, University of Texas at Austin, (1981).

HONORS AND AWARDS

Special Emphasis Panel, National Institute of Allergy and Infectious Diseases, “National Biocontainment Laboratories” (2003).
Special Emphasis Panel, National Institute of Allergy and Infectious Diseases, “Cooperative Research for the Development of Vaccines, Adjuvants, Therapeutics, Immunotherapeutics, and Diagnostics for Biodefense” (2003).
Special Emphasis Panel, National Institute of Allergy and Infectious Diseases, “Regional Centers of Excellence in Biodefense and Emerging Diseases Research – East” (2003).
Special Emphasis Panel, National Institute of Allergy and Infectious Diseases, “Regional Centers of Excellence in Biodefense and Emerging Diseases Research – West” (2003).
Special Emphasis Panel, National Institute of Allergy and Infectious Diseases Scientific Review Group, National Institutes of Health, “Partnerships for Novel Therapeutics, Diagnostic and Vector Control Strategies in Infectious Diseases” (2002).
Source Selection Panel, National Institute of Allergy and Infectious Diseases, “HIV Vaccine Development Resources” (2002).
Special Emphasis Panel, National Institute of Allergy and Infectious Diseases, “HIV Vaccine Development Resources” (2001). (Chairman)
Source Evaluation Board, National Cancer Institute, “VRC Adenoviral Vector Production” (2001).
Special Emphasis Panel, National Institute of Allergy and Infectious Diseases, “Malaria Vaccine Production and Support Services” (2000). (Chairman)
Special Emphasis Panel, National Institute of Allergy and Infectious Diseases, “HIV Vaccine Production: Part A” (1999).

PROFESSIONAL SOCIETIES

Member, Editorial Board, *Biotechnology Letters*
Member, Editorial Board, *Biotechnology and Applied Biochemistry*

Member, American Society for Virology
Member, American Chemical Society
Member, Society for Industrial Microbiology
Member, American Society for Microbiology
Member, Parenteral Drug Association

BIBLIOGRAPHY

1. Wells K, Zamkoff K, Paolozzi F, Poiesz B, Meisner D, Graziano S (1986): Normal human serum contains a human monocyte/macrophage growth factor. *J. Leukocyte Biol.* 40:293A.
2. Limentani SA, Furie BC, Poiesz BJ, Montagna R, Wells K, Furie B (1987): Separation of human plasma factor IX from HTLV-I or HIV by immunoaffinity chromatography using conformation-specific antibodies. *Blood* 70:1312-1315.
3. Moskowitz BL and the HPA-23 Cooperative Study Group (1988): A clinical trial of tolerance of HPA-23 in patients with acquired immune deficiency syndrome (AIDS). *Antimicrobial Agents and Chemotherapy* 32:1300-1303.
4. Poiesz BJ, Ehrlich GD, Byrne BC, Wells KH, Kwok S, Sninsky J (1989): Use of polymerase chain reaction in the detection, quantification, and characterization of human retroviruses. *Current Communications in Molecular Biology, Polymerase Chain Reaction*, Cold Spring Harbor Laboratory Press, Cold Spring Harbor, NY, pp. 159-164.
5. Wells KH, Byrne BC, Poiesz BJ (1990): Detection, prevention and treatment of retroviral infections. *Seminars in Oncology* 17(3):295-320.
6. Wells KH, and Poiesz BJ (1990): Biology of retroviruses: Detection, molecular biology, and treatment of retroviral infection. *Obstetrics and Gynecology Clinics of North America* 17(3):489-521.
7. Wells KH, and Poiesz BJ (1990): Biology of retroviruses: Detection, molecular biology, and treatment of retroviral infection. *J American Academy of Dermatology* 22:1175-95.
8. Poiesz BJ, Ehrlich GD, Byrne BC, Wells KH, Kwok S, Sninsky J (1990): The use of the polymerase chain reaction in the detection, quantification, and characterization of human retroviruses, in *Medical Virology* 9, de la Maza LM and Peterson EM, eds. Plenum Press, NY pp. 47-75.
9. Wells KH, Byrne BC, Poiesz BJ (1991): Detection, prevention and treatment of retroviral infections. *Infectious Disease Digest* 2:20-21.
10. Wells KH, Latino J, Gavalchin J, Poiesz BJ (1991): Inactivation of human immunodeficiency virus type 1 by ozone in vitro. *Blood* 78:1882-1890.
11. Amin RM, Wells KH, Poiesz BJ (1991): Antiretroviral therapy, in *Kaleidoscope*, Rassu S, ed. Medical Systems, s.p.a., Genova, Italy. pp. 3-64.

12. Fan N, Gavalchin J, Paul B, Wells KH, Lane MJ, Poiesz BJ (1992): Infection of peripheral blood mononuclear cells and cell lines by cell free human T-cell lymphoma virus type 1 (HTLV-I). *J. Clinical Microbiology* 30:905-910.
13. Monath, Thomas P., Karen McCarthy, Philip Bedford, Casey T. Johnson, Richard Nichols, Sutee Yoksan, Ron Marchesani, Michael Knauber, Keith H. Wells, Juan Arroyo, Farshad Guirakhoo. 2002. Clinical Proof of Principle for Chimerivax (TM): Recombinant Live, Attenuated Vaccines Against Flavivirus Infection. *Vaccine* 20(7-8), 1004-1018.
14. Doctoral Dissertation: Effects of Agents on the Replication of Human Immunodeficiency Virus Type 1 In Vitro. (January 1990).