

Curriculum Vitae
Alex D. Kanarek, PhD BSc ARCS MCIM

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EDUCATION

1974 Member, (MBA equivalent), International Pharmaceutical Marketing
Royal Chartered Institute of Marketing, Cookham, UK.

1954 Ph.D., Virology
Molteno Institute & Fitzwilliam College, University of Cambridge, UK

1950 BSc. Special, ARCS, Botany, Zoology, Microbiology
Imperial College, University of London, UK

PROFESSIONAL EXPERIENCE

2006 – present Senior Consultant
BioProcess Technology Consultants, Inc., Acton, MA
Quality assurance and quality control consulting, focusing on compliance audits and related activities, GLP/GMP compliance, facility design and commissioning, and training.

Proprietor
AK Consulting, Rockwood, Ontario
This company is the successor to Bio Development Consulting

1993 – 2006 President & Managing Partner
BioDevelopment Consulting Services LLP, Uxbridge, Ontario
Founding partner, providing services to the biopharmaceutical industry, especially in the fields of GLP/GMP compliance, facility design and commissioning, staff training, and development project management.

1989 – 1993 Director of New Business Development
Pasteur Merieux Connaught, Toronto, Ontario
Established the Therapeutics Marketing Unit, to promote a new bladder cancer treatment, ImmuCyst™ and products for the immunosuppression of transplant recipients from Pasteur Merieux, France.

- 1986 – 1989 Director, Product Development
Connaught Laboratories Ltd., Toronto, Ontario
Directed the separation of Development responsibilities from Manufacturing and set up two GMP pilot plants for viral and bacterial vaccines. Co-author of the Connaught Project Management Manual.
- 1984 –1986 Director, Viral Vaccine Division
Connaught Laboratories Ltd., Toronto, Ontario
Responsible for the manufacture of a range of viral vaccines by a staff of 75. Supervised the complete reconstruction and re-validation of the main viral vaccine manufacturing plant, including the first 1,000 L microcarrier bioreactors for human diploid cells in North America.
- 1981– 1984 Assistant Director, International Operations
Connaught Laboratories, Ltd., Toronto, Ontario
Directed the projects which created two new GMP vaccine manufacturing laboratories, designed by me, for the National Institutes of Health, Islamabad, Pakistan.
- 1979 – 1981 Assistant Director, Marketing Planning & Research
Connaught Laboratories Ltd., Toronto, Ontario
Developed and introduced the concept of technology transfer for vaccine manufacture to developing countries.
- 1975 – 1979 European Regional Marketing Manager (based in the United Kingdom)
Connaught Laboratories Ltd., Toronto, Ontario
Represented Connaught on the Continent of Europe. Increased regional sales turnover by 300% in three years
- 1971 – 1975 International Product Manager for Biological Products
Wellcome Foundation Ltd. (Burroughs, Wellcome & Co.) London, UK
Controlled the overall marketing strategy for vaccines and insulin
- 1954 – 1971 Principal Scientist & Joint Head of Vaccine Manufacturing
Virus Vaccine Division, Wellcome Foundation Ltd. Beckenham, Kent UK
Responsible for the development and eventual manufacture of vaccines against polio (injectable and oral), measles, yellow fever, influenza and foot & mouth of cattle.

AWARDS AND HONORS

- 1950 Agricultural Research Council Research Scholarship to the Molteno Institute, Cambridge UK.

BOARD MEMBERSHIPS

Editorial Advisory Board, BioProcess International Magazine

PROFESSIONAL ASSOCIATIONS

Parenteral Drug Association
Canadian Association of Professionals in Regulatory Affairs (CAPRA)

SELECTED RECENT PRESENTATIONS

“GMP Compliance in Clinical Trials” Presented at Conference on Pharmaceutical Regulatory Compliance, Toronto, ON April, 2005.

“Effective Management of Regulatory Requirements” Presented at Conference on Contract Manufacture of Biopharmaceuticals, Toronto, May, 2005.

“Analytical Method Qualification versus Validation – A Clarification” presented at IBC’s Analytical Method Validation Conference, Boston, May 2005 and at Cambridge Healthtech Institute’s (CHI) Conference on GLP Bioanalytical Methods, Boston, October 2005.

“Ensuring Your Contractor’s GMP Compliance” A Barnett International’s Web Seminar, broadcast September 2005.

“An Introduction to the Common Technical Document and Electronic Submissions” Presented at Cambridge Healthtech Institute’s Conference on Regulatory Documentation, Boston, October 2005.

“Current Concerns in GLP Compliance” Presented at CHI’s Conference on GLP Compliance in Bioanalytical Testing, Philadelphia, October 2006.

“Similar Biological Products and Quality Issues” Presented at Canadian Association for Regulatory Professionals’ Annual Meeting, Toronto November 2006.

“Outsourcing Pre-clinical testing and Analytical Method Development.” Presented at Cambridge Healthtech’s Conference on GLP and Bioanalysis, Boston, August, 2007.

“Quality by Design in Biopharmaceuticals – Critical Points to Consider” Presented at FIP – Quality Conference, London UK, November, 2007.

SELECTED PUBLICATIONS

Books published by: Drug and Market Development Publications, Inc. Westborough, MA:

Guide to Good Laboratory Practice, October, 1999, Third edition, August, 2007.

Guide to Good Manufacturing Practice, January 2001, Third edition August, 2006.

Guide to Good Clinical Practice, May, 2001, Third edition, September, 2007.

Guide to Good Validation Practice, November 2001, Third edition, September, 2007

Guide to Good Design Practices for GxP Compliance, April, 2003.

Report on the Bioprocessing Industry, October 2000, Second edition January, 2003.

Article:

“The Launch of the Biosimilar Product,” *Biotechnology Focus*, June, 2006.