

## Curriculum Vitae



**Michael Gross, Ph.D., RAC**  
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Senior Consultant  
Biologics Consulting Group, Inc.  
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### **EXPERIENCE**

**Biologics Consulting Group, Inc., Senior Consultant**  
Philadelphia, PA (May 2009 - present)

**Chimera Consulting, Principal Consultant, Philadelphia, PA (2007 – May 2009)**

- Independent consultant specializing in quality, regulatory affairs and development strategy for drugs, biologics, devices and combination products

**Cardiome Pharma Corporation, Vice-President, Regulatory Affairs, Vancouver, BC (2005 – 2007)**

- Department head responsible for regulatory submissions, strategy and regulatory agency liaison with therapeutic focus on anti-arrhythmic and other cardiovascular drugs

**QLT Incorporated, Vice-President, Regulatory Affairs, Vancouver, BC (2004 – 2005)**

- Department head responsible for regulatory submissions, strategy and regulatory agency liaison with therapeutic focus on ophthalmologic, dermatologic, urologic and oncologic drugs

**Aventis Behring, Vice-President World-Wide Compliance, King of Prussia, PA. (2001- 2003)**

- Corporate Compliance department head responsible for regulatory agency liaison for quality systems compliance, internal audit, compliance enhancement and best practices for plasma collection and plasma derived biologics manufacture.

**Becton Dickinson & Company, Director Corporate Regulatory Affairs, Franklin Lakes, NJ (1995 -2001)**

- Pharmaceutical Systems Division regulatory affairs department head. responsible for, submissions strategy and regulatory agency liaison for business divisions developing and marketing pharmaceuticals, drug delivery systems and functional pharmaceutical packaging



**Becton Dickinson & Company**, *Director Regulatory Affairs and Quality Assurance*, Franklin Lakes, NJ (1992 -1995)

- Transdermal Systems Division regulatory affairs department head responsible for submissions, strategy and regulatory agency liaison and quality systems management for development and registration of drug-device combination products employing novel electrically assisted transdermal drug delivery (iontophoresis) technology

**Chiros International**, *Principal*, Buckingham, PA. (1990 -1992)

- Independent consultant specializing in regulatory requirements, submissions and drug development strategies for development and registration of chiral drugs for pharmaceutical clients ranging from large companies to small biotechnology companies.

**Schering-Plough Research Institute**, *Director Regulatory Affairs*, Kenilworth, NJ (1987 – 1990)

- Department head responsible for all submissions and regulatory liaison with FDA Divisions of cardio-renal, neuropharmacologic and generic drugs

**Triton Biosciences**, Shell Oil Company, *Director Regulatory Affairs/Government Affairs*, Alameda, CA (1983 – 1987)

- Department head responsible for regulatory submissions, strategy and FDA liaison for recombinant beta-interferon and project manager for development of fludarabine in collaboration with the National Cancer Institute

**U.S. Public Health Service**, Bethesda, MD (1970-1980)

*Chemist, Food and Drug Administration, Bureau of Biologics, Division of Blood and Blood Products, Plasma Derivatives Branch (1970-1980)*

- Reviewer and FDA Inspector for the regulation of plasma protein therapeutics.

*Research Chemist, Division of Bacterial Products, Allergenic Products Branch, (1974).*

- Research chemist and reviewer for allergenic extracts and atopic allergens,

*Research Chemist, National Institutes of Health, (1977 – 1980)*

*Health-Scientist Administrator, National Heart, Lung and Blood Institute, Division of Blood Diseases and Resources (1975 – 1977)*

- Extramural programs manager for basic and clinical research on blood diseases, hemostasis, clotting factors, plasma fractionation, blood products, blood substitutes and biomaterials.

*Grants Associate, Division of Research Grants (1974 - 1975)*

- One-year rotational internship in health-science administration, providing broad exposure to the structure, functions and programs of the NIH and sister agencies of the Public Health Service.



*Senior Staff Postdoctoral Fellow, National Institute of Dental Research (1970 – 1974)*

- Intramural scientist, engaged in basic research on fibrin cross-linking, protein chemistry, peptide synthesis, enzyme mechanism, substrate specificity and kinetics.

#### **OTHER RELATED EXPERIENCE**

- 2000-2004 Member, United States Pharmacopeia, Pharmaceutical Waters Expert Committee
- 1999-2000 Member, United States Pharmacopeia, Advisory Committee, Water & Parenterals Sub-committee
- 1998-present Leader, Parenteral Drug Association, Combination Products Interest Group
- 1984 Member, Advisory Committee on Biotechnology-California State Assembly
- 1982-1983 Consultant, United States General Services Administration
- 1977-1979 FDA Inspector, Security Clearance: Critical Sensitive
- 1976 PHS Grants Associates Program, Governing Board, Member

#### **EDUCATION**

Ph.D. *Organic Chemistry*, Temple University, Philadelphia, PA.

B.Sc. *Chemistry*, Philadelphia College of Pharmacy and Science, Philadelphia, PA.

#### **HONORS AND AWARDS**

- 1966 American Institute of Chemists Award, Philadelphia College of Pharmacy and Science

#### **PROFESSIONAL AND HONORARY SOCIETIES**

- 2006-2007 Chair, Regulatory Affairs Professionals Society, Southern BC Chapter
- 1991-1993 Member, Pennsylvania Biotechnology Association, Board of Directors
- 1989-1990 Member, Pharmaceutical Manufacturers Association, Committee on Racemic Mixtures
- 1983-1987 Founder and Member, Industrial Biotechnology Association, FDA Affairs Committee

#### **ADDITIONAL TRAINING**

- RAPS-RCAB, Regulatory Affairs Certified (RAC)