



Curriculum Vitae

Michael Trapani, M.S., M.B.A.
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Senior Consultant
Biologics Consulting Group, Inc.
Belle Mead, NJ

SUMMARY OF EXPERTISE

- Extensive experience in new drug/biologic registration, regulatory compliance and quality assurance.
- Strong management and leadership abilities.
- Experienced in establishing and developing regulatory affairs and quality assurance systems.
- In-depth knowledge of FDA regulations for GMP's, GCP's and GLP's.

EDUCATION

M.S. *Quality Assurance & Regulatory Affairs*, Temple University, Graduate School of Pharmacy, Ambler, PA.

M.B.A. Seton Hall University, Graduate School of Business, South Orange, NJ.

B.S. *Biology*, Brooklyn College, Brooklyn, NY.

EXPERIENCE

Biologics Consulting Group, Inc., *Senior Consultant*
Belle Mead, NJ (Jan. 2007 – present)

Ethicon, Inc. *Vice President, Worldwide Regulatory Affairs*
Somerville, NJ (2006)

- Led and directed worldwide regulatory affairs functions for new product registrations (devices and device combination products) and post-approval regulatory activities.
- Responsible for identifying and analyzing changes in worldwide regulatory requirements and developing strategies to address those changes relevant to the company's products.
- Responsible for regulatory review and approval of advertising/promotional materials and labeling.

Covance, Inc., *Vice President, Regulatory Policy & Quality Assurance*
Princeton, NJ (2001 – 2005)

- Responsible for all regulatory, quality assurance and compliance activities associated with Phase II-IV clinical research.



- Directed multifunctional regulatory projects for client companies including preparing, and submitting clinical trial and marketing approval applications and developing strategies for drug approval.
- Launched strategic regulatory consulting unit to assist small pharmaceuticals and biotech companies in developing and gaining approval of novel drugs and biologics.
- Developed a regulatory policy unit to assess and address changes to regulatory requirements for the development and approval of drugs and biologics.
- Globalized clinical quality assurance organization; harmonized processes and procedures to address worldwide clinical research requirements.

ImClone Systems, Inc. *Vice President, Regulatory Affairs & Quality Assurance*

Somerville, NJ (1999 – 2000)

- Developed regulatory strategies and directed regulatory and quality activities to gain FDA approval of therapeutic monoclonal antibodies and vaccines.
- Expanded and upgraded the quality assurance, validations and regulatory affairs departments to support multiple product development and pre-commercialization programs.
- Directed the regulatory activities for several important FDA meetings clearing the path for successful BLA filings.
- Established the framework for FDA to grant Fast Track Designation for the company's lead product. Secured Orphan Drug Designation for the same product.

Cytogen Corp. *Vice President, Regulatory Affairs & Quality Assurance*

Princeton, NJ (1996 – 1999)

- Developed and directed regulatory and quality assurance activities to secure approval of prescription drugs and biologics (Phases I-IV).
- Established advertising /labeling policies and quality assurance systems.
- Developed a corporate quality policy for regulatory, clinical and manufacturing activities
- Developed quality systems and procedures for the manufacture of multiple biologic products.

Pharmacia, Inc., *Senior Director, Regulatory Affairs*

Columbus, OH (1993 – 1996)

- Developed and implemented regulatory strategies for the approval of prescription drug products within the U.S.
- Successfully coordinated NDA submission activities of drug products for cancer, urology, rheumatoid arthritis, ulcerative colitis and smoking cessation.
- Centralized the regulatory affairs organization enabling the standardization of practices and procedures resulting in higher quality NDA submissions and faster drug approvals.
- Key regulatory affairs representative in merger transition team between Pharmacia and Upjohn

Pharmacia Laboratories (Kabi Pharmacia, Inc.) *Executive Director, Regulatory Affairs*

Piscataway, NJ (1981 – 1993)

- Directed US regulatory activities including new drug registration and compliance with FDA regulations and guidelines.
- Directed and coordinated the successful filing of several NDAs and NDA supplements.
- Spearheaded the company's US taskforce for expediting the global approval of new drugs.

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- Led FDA negotiations and directed the regulatory activities to address compliance issues facing the company.
- Developed and implemented a reorganization plan to centralize the regulatory affairs department.
- Liaison to FDA during plant inspections. Conducted internal GMP, GLP and GCP audits.

U.S. Food and Drug Administration

East Orange, NJ (1977 – 1981)

- Performed establishment inspections of drugs, medical devices and in-vitro diagnostics.
- Experienced with FDA regulations including GMP's, GCP's and GLP's.
- Received four letters of commendation for superior performance.

CERTIFICATIONS AND RELATED ACTIVITIES

- Regulatory Affairs Certified (RAC)
- Chair, Ethics & Clinical Practice Committee, Association of Clinical Research Organizations
- Chair, Ethics Committee, Regulatory Affairs Professional Society
- Editorial Board, FOCUS, Regulatory Affairs Professional Society
- Instructor, Regulatory and Legal Issues in Drug Development, Mercer County Community College