



Peter A. Patriarca, M.D.
Senior Clinical Consultant, Biologics Consulting Group, Inc.

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Dr. Patriarca received a BS from the University of Notre Dame in 1973; an MD from Tulane University School of Medicine in 1977; completed an internship and residency in Pediatrics at the University of Colorado in 1980; and subsequently completed Epidemic Intelligence Service (EIS) and Preventive Medicine residency training at the Centers for Disease Control and Prevention (CDC) in Atlanta. From 1980-1993, Dr. Patriarca was involved in epidemiologic research and public health programs and policy at the CDC, focusing primarily on vaccine-preventable diseases. From 1994-2001, he worked at the Center for Biologics Evaluation and Research (CBER), FDA. As Director of the Division of Viral Products, Office of Vaccines Research and Review (OVRR), Dr. Patriarca was responsible for all laboratory-based research programs as well as IND and BLA reviews and other regulatory activities. From 2001–2005, Dr. Patriarca served as Corporate Head and Vice President of Worldwide Regulatory Affairs and Pharmacovigilance at MedImmune, Inc., in Gaithersburg, Maryland, with strategic, operational and compliance responsibility for five licensed and 18 investigational products, including vaccines, monoclonal antibodies, plasma derivatives and small molecules. Dr. Patriarca is also an internationally renowned expert in influenza and poliomyelitis.

Dr. Patriarca has acquired diverse skills and competencies during his 25+ year professional career. While at CDC, he was an accomplished field and clinical investigator, with ~100 peer-reviewed journal publications, and was a major contributor to immunization programs and policy promulgated through the Advisory Committee on Immunization Practices (ACIP). While at CBER, he directed activities related to the research, regulatory and public health aspects of licensed and investigational viral vaccines and served as FDA liaison representative to the American Academy of Pediatrics' Committee on Infectious Diseases ("Redbook Committee"). As Division Director, Dr. Patriarca also ensured the quality and consistency of CMC and clinical reviews, actively participated in sponsor meetings, and was intimately involved with regulatory decisions and policy affecting the development and approval of numerous investigational products. While at MedImmune, Dr. Patriarca was responsible for regulatory strategy and compliance oversight for all infectious disease-, immunology- and oncology-related programs, and was a member of key strategic and commercial operations committees. He created a Regulatory Operations Division with publishing and electronic submissions capability, enhanced MedImmune's post-marketing drug safety surveillance capability, established risk management and regulatory intelligence functions, and served as regulatory lead for all mergers, acquisitions, in-licensing, and other due diligence activities. He maintained "hands on" skills by taking primary responsibility for writing and coordinating key submissions (e.g., MedImmune's first Investigational Medicinal Product Dossier and Common Technical Document) and by participating in all interactions with the FDA (e.g., sponsor and Advisory Committee meetings, teleconferences, and for pharmacovigilance, BIMO, and GMP inspections).

As a Senior Consultant with Biologics Consulting Group, Inc. Dr. Patriarca will utilize his clinical, research, regulatory, and public health expertise to assist clients in the following aspects of drug development and commercialization:

Technical

- Global development planning for drugs and biologics, including CMC and clinical aspects
- Strategic and operational input to streamline dossier development and maintenance throughout the product lifecycle
- Assistance in writing various sections of pre-IND, IND and BLA/NDA submissions
- Comprehensive “FDA style” reviews of IND, BLA and NDA draft submissions
- Assistance with the planning and conduct of clinical trials, including liaison, medical monitoring, and GCP oversight functions
- Development of risk management strategies to more effectively assess and monitor product profiles
- Preparation for FDA and Advisory Committee meetings

Managerial

- Project and product lifecycle management approaches
- Resource planning to meet the needs of cyclical submission activity
- Improving employee productivity, building cross-functional teams and aligning skills, competencies and responsibilities with corporate priorities and initiatives
- Assistance with due diligence activities, including potential mergers, acquisitions, in-licensing, and out-licensing

Marketing Initiatives

- Assistance with strategic and operational initiatives involving governmental or other agencies and/or advisory groups
- Advertising and promotional labeling