



Michael Gross, Ph.D. RAC
Senior Consultant

Biologics Consulting Group, Inc.
is pleased to make the following announcement:

Michael Gross, Ph.D., RAC has joined Biologics Consulting Group, Inc., as a Senior Consultant (Combination Products). He comes to BCG with over 25 years of experience in senior regulatory affairs, quality assurance and compliance roles in the pharmaceutical and medical device industries and the Food and Drug Administration. He holds a B.S. in Chemistry from the Philadelphia College of Pharmacy and Science, a Ph.D. degree in Organic Chemistry from Temple University and was a Staff Postdoctoral Fellow in biochemistry at the National Institutes of Health.

Michael is experienced in a variety of therapeutic areas including cardiovascular, neurological, pulmonary, urology, oncology, ophthalmology, dermatology, anti-infectives and blood products. He has personally written and/or managed the submission of investigational exemption applications [IND, IDE], marketing applications [NDA, 505(b)(2) NDA, sNDA, ANDA, BLA], device registrations [510(k), PMA] and other FDA regulatory filings [RFD, DMF, BMF, MAF].

Michael specializes in solving difficult technical, quality and regulatory challenges for drugs, biologics, medical devices and in particular combination products and enjoys assisting clients in navigating complex regulatory frameworks that result when different medical technologies are combined. As a Senior Consultant for Combination Products at the Biologics Consulting Group, Michael will utilize his broad technical, quality and regulatory expertise to assist clients in the following areas:

- Establishing short and long term development, regulatory and quality assurance strategies for drugs, biologics medical devices, combination products and other novel medical products with challenging regulatory issues;
- Establishing preclinical, clinical and CMC development pathways for drugs, biologics, medical devices and combination products;
- Technical, quality and regulatory strategy for the development of drug delivery devices and prefilled functional pharmaceutical packaging/drug delivery systems (e.g., injectors, nebulizers, MDIs, DPIs and transdermal patches).

- Interactions with regulatory agencies and the structuring, reviewing and preparation of applications and labeling for drugs, biologics, and medical devices and combination products;
- Establishing appropriate post-marketing compliance strategies for combination products strategies including the reporting of manufacturing changes and safety reports.
- Designing and implementing quality systems for combination products;
- Providing in-house training on technical, quality and regulatory issues and new policy developments concerning combination products.