



**Stuart Portnoy, M.D.**  
Senior Consultant - Medical Devices

Stuart Portnoy, MD joined Biologics Consulting Group, Inc., as a Senior Consultant for Medical Devices on August 6, 2007.

Dr. Portnoy received his Bachelor of Science in Chemical Engineering from Tufts University in 1985. After conducting life science research at the Weizmann Institute in Israel for one year, he attended George Washington University School of Medicine, receiving an MD in 1991 and completing an Internship in Internal Medicine in 1992. Concurrent with his medical studies, Dr. Portnoy also earned a Master of Science in Bioengineering in 1989 from the University of Pennsylvania.

From 1994-2000, Dr. Portnoy was a Medical Officer in the Division of Cardiovascular Devices (DCD), Center for Device Evaluation and Radiological Health (CDRH), FDA. In 2001, he was promoted to Branch Chief of the Interventional Cardiology Devices Branch, a position he held until leaving the agency in 2002. In 2001, Dr. Portnoy also served as an Acting Deputy Division Director of DCD.

As a Senior Clinical Reviewer at CDRH, Dr. Portnoy was responsible for the comprehensive review of safety and effectiveness results for a wide range of new cardiac medical technologies. This included working closely with device manufacturers to negotiate preclinical data requirements, clinical trial design, product labeling, and post-approval studies.

As Branch Chief and an Acting Deputy Division Director of DCD, Dr. Portnoy directly managed and supervised physicians and engineers with review responsibilities for numerous cardiac devices including conventional and drug-eluting stents. He reviewed or supervised review of hundreds of device applications along multiple pathways - IDEs, PMAs, and 510(k)s.

During his tenure, manufacturers submitted applications for the first drug-eluting stents. FDA had not previously evaluated a novel combination product raising so many new clinical and regulatory issues. Dr. Portnoy was a key agency leader in developing FDA's approach to reviewing drug-eluting stents and other drug/device combination products.

In 2002, Dr. Portnoy joined PharmaNet's Washington DC office and worked for 5 years as a Medical Device Consultant advising medical device manufacturer on regulatory strategy, clinical trial design, and technical issues to gain FDA market-approval for new products.

As a Senior Consultant at The Biologics Consulting Group, Dr. Portnoy will utilize his broad clinical, technical, and regulatory expertise to continue to assist clients in the following areas related to gaining FDA approval of medical devices:

High level regulatory strategy for medical technologies;

- Product development for drug/device and biologic/device combination products;
- Assisting clients with strategy and development of preclinical testing;
- Designing clinical protocols and drafting other documents that comply with FDA regulations and expectations;
- Representing clients in interactions with FDA;
- Assisting clients in preparing for FDA meetings;
- Guiding clients in writing Pre-IDE, IDE, 510(k) and PMA submissions;
- Providing clients with a comprehensive "FDA style" review of submissions.