

Miriam C. Provost, Ph.D.
Senior Consultant



Miriam C. Provost, Ph.D. joined Biologics Consulting Group, Inc., as a Senior Consultant (Medical Devices) in November 2008.

Miriam comes to BCG with over 13 years of experience with the Food and Drug Administration, Center for Devices and Radiological Health. Most recently, she was the Deputy Director for Science and Engineering Review in the Office of Device Evaluation. The Office of Device Evaluation is responsible for the review and approval of all medical devices in the U.S., with the exception of in vitro diagnostic devices. Miriam had oversight for policy development for all premarket applications and was the chief office signatory for guidance documents, 513(g)s and classification/reclassification actions. She played a leading role in combination product policy development for CDRH and was responsible for CDRH recommendations regarding jurisdictional decisions (RFDs).

Prior to her role as ODE deputy director, she served as deputy director and, for a period of time, acting director of the Division of General, Restorative and Neurological Devices in ODE. She had responsibility and oversight for premarket applications (including 510(k)s, IDEs, PMAs and HDEs) for general and plastic surgery devices, neurology devices and orthopedic and restorative devices. Miriam has also served as acting branch chief in the Division of Cardiovascular Devices and prior to that, she was a reviewer in the Division of Reproductive, Abdominal and Radiological Devices where she was an expert scientific reviewer in the area of dialysis and extracorporeal membrane devices.

She has received numerous awards at FDA, including the Commissioner's Special Citation, the FDA Engineer of the Year award and the FDA Scientific Achievement Award for Excellence in Review Science.

In 2007, Miriam joined M Squared Associates as a Senior Project Manager, advising medical device and combination product manufacturers on regulatory strategy, FDA submissions and product development issues.

She holds a B.S. in Chemical Engineering from the University of Dayton and M.S. and Ph.D. degrees in Chemical Engineering from the University of Pennsylvania.

As a Senior Consultant for Medical Devices Biologics Consulting Group, Inc. Miriam will utilize her broad technical and regulatory expertise to assist clients in the following areas:

- Short and long term regulatory strategy for medical device technologies and combination products;
- Assisting clients with strategy and development of preclinical testing and other product development issues;
- Representing clients in interactions with FDA;
- Assisting clients in preparing for FDA meetings and FDA Advisory Panel meetings;
- Preparing and assisting in the preparation of RFDs, Pre-IDEs, IDEs, 510(k)s and PMAs;
- Providing clients with a comprehensive "FDA style" review of submissions;
- Providing in-house training on FDA Regulatory issues and new policy developments