

Melanie T. Hartsough, Ph.D.
Senior Consultant



Melanie graduated magna cum laud with a B.S. degree in chemistry from Juniata College, Huntingdon, PA in 1991 and received her Ph.D. in Pharmacology from the Pennsylvania State University in 1997.

Immediately upon receiving her Ph.D., Melanie joined the National Cancer Institute, NIH, as a cancer research fellow. Her research focused on identifying protein-mediated signaling mechanisms associated with a metastasis-suppressor protein in breast cancer. During this time, she further developed her skills in various protein purification, biochemical and molecular biology techniques and received extensive opportunities for scientific review of grants and manuscripts.

In 2001, Melanie left the laboratory and joined the FDA's Center for Biologic Evaluation and Research (CBER), Division of Therapeutic Proteins as a full-time product reviewer. During this time, she performed chemistry, manufacturing and control (CMC) reviews of biologics/biotechnology products, including toxins, imaging agents, cytokines, growth factors, tumor vaccines, thrombolytic agents and enzymes, for all clinical indications. She served on and/or chaired BLA review committees for toxins, cytokines and several enzymes and participated in a pre-approval manufacturing facility inspection.

In 2004, Melanie transferred to the Division of Therapeutic Biological Oncology Products (now Division of Biologic Oncology Products), CDER as a pharmacology/toxicology reviewer. She

was responsible for reviewing the preclinical pharmacology and toxicology data submitted by sponsors to support the safety of clinical trials and, ultimately, the approval of new biological therapeutics. The types of products she reviewed included cytokines, growth factors, enzymes, toxins, thrombolytics and monoclonal antibodies. For approximately 1 ½ years, she reviewed biologic products for all clinical indications; however, the establishment of the Office of Oncology Products in October 2005 restricted review to oncology indications. During her time as a pharmacology/toxicology reviewer, Melanie co-authored several manuscripts, gave a number of presentations and was the chair, editor and major contributing author of "Guidance for Industry and Reviewers: Nonclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals" (Draft guidance completed August 2006, currently internal).

In October 2006, Melanie left the FDA and joined Aclairo, Pharmaceutical Development Group, Inc as a consultant. During her time at Aclairo, she aided drug sponsors with small molecule and biologic products with IND submissions (pharmacology/toxicology sections), provided product (CMC) review for biologic products and aided in the design and interpretation of toxicology studies.

As a Senior Consultant with Biologics Consulting Group, Inc. Melanie will utilize her expertise in the strategy and development of biotechnology-derived products to assist clients in the following aspects of drug development:

- IND and BLA submissions
- Design and interpretation of toxicology studies, including relevant species and immunogenicity issues and appropriate PK/TK studies
- Product review for biotechnology-derived products
- Planning and participating in FDA meetings
- Insights into the changes occurring with the review of nonclinical studies for biotechnology-derived products in CDER