



David T. Lin, Ph.D.
Senior Consultant

David Lin, Ph.D., MBA, has joined Biologics Consulting Group, LLC, as a Senior Consultant in January 2005.

Dr. Lin received a BA in Biochemistry from the University of Pennsylvania in 1984; a PhD in Organic Chemistry from the University of Maryland in 1989; and received a Masters Degree in Business Administration from the University of Maryland's RH Smith School of Business in 2002. From 1997-2001 he was a Chemistry Reviewer in the Division of Reproductive and Urologic Drug Products, Center for Drug Evaluation and Research (CDER), FDA, and in 2001 became the Team Leader in the same Division. He had been serving as the acting Deputy Division Director in the Division of New Drug Chemistry III (DNDCIII), Office of New Drug Chemistry since 2003, and was promoted in 2004 to the acting Division Director.

As a Chemistry Reviewer at CDER, Dr. Lin was responsible for the comprehensive review of Chemistry, Manufacturing and Controls (CM&C) data for drugs being investigated during Phase 1, 2, and 3 clinical studies. This included providing scientific and regulatory guidance during development of small molecular weight drugs and biotechnological/biological drugs across a wide variety of dosage forms for the therapeutic treatment of reproductive and urologic indications. As the acting Deputy Division Director and acting Division Director, he directly managed and supervised chemists with review responsibilities in 6 medical-reviewing divisions, anti-viral, dermatologic/dental, anti-inflammatory/analgesic/ophthalmologic, anti-infective, special pathogen/immunologic, and over-the-counter drug products. Dr. Lin reviewed CM&C data submitted to over 100 INDs and NDAs (original and supplemental) as a Chemistry Reviewer, contributed to decisions regarding the approval of drugs, made presentations before scientific and regulatory conferences, and participated in a variety of special FDA projects and committees, including serving as the Chair of the Stability Guidance Technical Committee.

As a Senior Consultant at The Biologics Consulting Group, Dr. Lin will utilize his drug quality (CM&C) scientific and regulatory expertise, along with business administration training, to assist clients in the following areas of drug development:

- Global CM&C development planning for drugs and biotechnological/biological drugs;
- Designing CM&C protocols and other documents which are compliant with FDA regulations and expectations;
- Assisting clients in the development of analytical methodology and design of stability testing protocols;
- Representing clients in interactions with FDA;
- Assisting clients in preparing for FDA meetings;
- Assisting clients in writing CM&C sections of pre-IND, IND and NDA submissions;
- Providing clients with a comprehensive “FDA style” review of IND and NDA CM&C submissions.