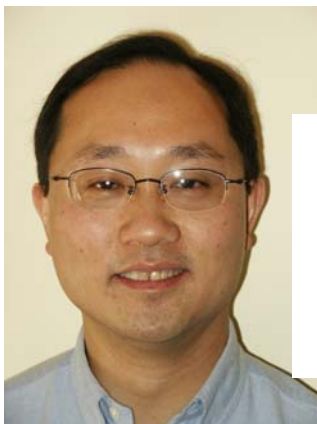


Curriculum Vitae



David T. Lin, Ph.D.
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Senior Consultant
Biologics Consulting Group, Inc.
Potomac, MD
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EXPERTISE

- 14+ years pharmaceutical regulatory experience.
 - 7+ years regulatory chemistry, manufacturing and controls (CMC) experience at CDER/FDA on small molecular-weight drugs, peptide drugs, protein drugs and botanical products formulated in a broad range of sterile and non-sterile dosage forms.
 - 3+ years research experience at CBER/FDA.
 - 4+ years experience as regulatory CMC consultant for drugs and biologics (small synthetic, peptide, protein, oligonucleotide, botanical, combination products)Regulatory guidance and strategy from pre-IND through NDA/BLA approval.
- Primary CMC review and assessment of drug product development
- Drug substance and drug product analytical method development and validation.
- Drug substance and drug product stability protocol development and stability data analysis.
- Gap analysis of drug development strategy.
- Due diligence audit of firm's product development data.
- Manufacturing contractor and vendor evaluation and selection.
- Management and technical oversight of contract manufacturing organizations (CMOs).
- Unique combination of biologic/biotechnological and small molecular-weight drug regulatory experience.
- Experienced in chemical synthesis, small-scale and pilot-scale fermentation, biologics/biotechnology, and protein chemistry.
- Experienced working in cross-functional teams (i.e., Pharmacology/toxicology, Clinical, Biostatistics, Biopharmaceutics, and Analytical).
- Ph.D. in Organic Chemistry; M.B.A. degree and training for managers.



EXPERIENCE

Biologics Consulting Group, Inc., Senior Consultant

Potomac, MD (Jan. 2005 to present)

- Evaluate client CMC scientific and regulatory strategies for a wide range of therapeutic drug products (biologic and non-biologic) formulated in a variety of dosage forms, at all stages of product development, from pre-IND through post-NDA approval.
- Provide regulatory strategies for combination products (drug/device, biologics/device).
- Review and provide advice on IND and NDA submissions for suitability relative to FDA expectations for CMC data.
- Perform gap analysis audits for deficiencies relative to FDA expectations.
- Conduct regulatory and scientific due diligence audits for business acquisitions and licensing partnerships. Provide assessment of strengths and deficiencies.
- Represent clients in interactions with FDA.
- Represent client as FDA regulatory expert in legal proceedings.
- Prepare and write submissions to FDA, with focus on CMC sections.
- Provide scientific and regulatory training and presentations at pharmaceutical/biopharmaceutical conferences.

FDA, CDER, Office of New Drug Chemistry, Division of New Drug Chemistry III,

Division Director (acting) March 2003 – December 2004

Deputy Division Director (acting) – July 2003 – March 2004

Rockville, MD.

- Supervised 34 employees in 9 therapeutic product classes, includes 6 Team Leaders, review chemists and administrative staff.
- Planned and set long-range plans and schedules for Division work. Directed and coordinated workload, and assured implementation of Division policies, goals and objectives.
- Made critical decisions and provided expert advice concerning regulatory and scientific approaches and options consistent with Office policies and objectives.
- Evaluated budget and fiscal controls to manage Division functions.
- Evaluated Team Leader and review chemist performance.
- Performed tertiary reviews of NDAs for new molecular entities.
- Represented FDA in dealing and negotiating with the regulated industry, and professional and industry organizations.
- Participated as invited speaker at regulatory and scientific conferences.
- Served as the Chair of the Stability Guidance Technical Committee, Co-chair of the Conjugated Estrogens Working Group and Co-chair of the Good Review Practices Working Group.



FDA, CDER, Division of Reproductive and Urologic Drug Products, *Lead Chemist (Team Leader)*

Rockville, MD (Oct. 2001 – July 2003)

- Managed a team of 4 review chemists in 2 therapeutic product classes.
- Responsible for secondary review, consistency of CMC reviews and adherence to FDA/ONDC policies and guidances.
- Coordinated reviewers' workload of IND and NDA submissions to ensure that reviews were conducted in timely manner.
- Extensive interactions with the regulated industry to provide regulatory direction during IND drug development and NDA post-approval activities.
- Active in the development of FDA guidances for industry and internal good review practices. Served as the Chair of the Stability Guidance Technical Committee, Co-chair of the Conjugated Estrogens Working Group and Co-chair of the Good Review Practices Working Group.

FDA, CDER, Division of Reproductive and Urologic Drug Products, *Chemistry Reviewer*

Rockville, MD (Apr. 1997 – Oct. 2001)

- Evaluated the quality of new drug products submitted to the FDA for approval.
- Integral part of a review team responsible for evaluating the quality and effectiveness of reproductive and urologic drug products being investigated in clinical studies.
- Major contributor to committees responsible for establishing drug product quality standards and publishing guidances for pharmaceutical companies.
- Provided regulatory guidance to pharmaceutical company representatives during drug product development through direct face-to-face meetings.
- Mentored new reviewers.
- Served as computer focal point to facilitate and troubleshoot computer issues.

FDA, CBER, Laboratory of Parasitic Biology and Biochemistry, *National Research Council Fellow*

Bethesda, MD (Feb. 1994 – Apr. 1997)

- Investigated the biological role of specific proteins in the sexual differentiation of the malaria parasite. Published three research papers in peer-reviewed journals.
- Presented research data at three separate scientific conferences.
- Supervised the research projects of college students.
- Responsible for the coordination of instrument repairs and the ordering of laboratory supplies.

General Electric Co. Corporate Research & Development, Biological Sciences Laboratory, *Staff Scientist*

Schenectady, NY (July 1989 – Jan. 1994)

- Developed recombinant biphenyl-metabolizing microorganisms capable of degrading environmental contaminants. Marketed this technology to the GE business units and government agencies responsible for environmental clean-up.



- Investigated the factors affecting aerobic biodegradation of indigenous PCBs in Hudson River sediment by various bacterial strains.
- Isolated and conducted mechanistic studies of the dioxygenase enzymes involved in biodegradation.
- Investigated the scientific and economic feasibility of biologically synthesizing aromatic monomers for use as a feedstock to produce biodegradable polymers.
- Supervised research projects of summer interns.
- Published research in peer-reviewed journals.
- Recruited at major East Coast universities. Interviewed and screened graduating science Ph.D. students for second round interviews at the Research Center.

University of Maryland, Dept. of Chemistry/Biochemistry, *Research Assistant*
College Park, MD (May 1985 – May 1989)

- Investigated mechanism of action of two bacterial enzymes, mandelate racemase and D-amino acid oxidase.
- Synthesized and tested novel halogenated aromatic hydroxy- and amino- acid analogs as potential irreversible inhibitors.
- Published research in peer-reviewed journals and co-authored one chapter in a biotechnology book. In addition, the research data was presented at two national scientific conferences.
- Served as the computer expert for the laboratory group.

EDUCATION

MBA, *Finance*, Robert H. Smith School of Business, University of Maryland, College Park, MD (2002)

Ph.D., *Organic Chemistry*, University of Maryland, College Park, MD (1989)

B.A., *Biochemistry*, University of Pennsylvania, Philadelphia, PA (1984)

TRAINING (SELECT LISTING)

Fall 2002 Facilitation Skills, CDER
Feb. 2002 Group Decision-Making Techniques, CDER
Spring 2002 Managing Written Communications for Team Leaders, CDER
Fall 1999 Organizational Behavior and Human Resources, University of Maryland

HONORS AND AWARDS (SELECT LISTING)

May 2004 FDA's Group Recognition Award
Nov 2002 CDER's Special Recognition Award
Nov 2002 CDER's Team Excellence Award

PRESENTATIONS (SELECT LISTING)

1. IVT Method Validation Conference, “Challenges in Understanding Impurities and Degradants for Biological/Biotechnological Products,” San Francisco, CA (Oct 2008).
2. IVT Method Validation Conference, “Strategies for Setting Biological Product Specifications,” San Francisco, CA (Oct 2008).
3. CBI 3rd Annual Stability Programs Conference, “Complex Stability Programs for Biologics,” Philadelphia, PA (Jun 2008).
4. IVT Lab Compliance Conference, “Stability Testing Fundamentals and Considerations in the Current Regulatory Environment,” Baltimore, MD (Apr 2008).
5. R&D Direction’s 5th Annual Drug Development Summit, “Looking Forward in 2008: Regulatory Priorities and Considerations,” Amelia Island, FL (Feb 2008).
6. 2007 AAPS Annual Meeting, “Critical Stability Evaluation of Biopharmaceuticals During Clinical Development Stages,” San Diego, CA (Nov 2007).
7. 2007 DIA Annual Meeting, “The Impact of FDA’s Quality by Design Initiative on Biologics Development,” Atlanta, GA (Jun 2007).
8. Institute for International Research: Formulation and Forced Degradation Strategies for Biomolecules, “Regulatory Requirements for Successful Product Development,” San Diego, CA (Mar 2007).
9. Cambridge Healthtech Institute’s PepTalk: Optimizing Protein and Antibody Therapeutics, “Regulatory Considerations for the Development of Protein Therapeutic Products,” San Diego, CA (Jan 2007).
10. Institute for International Research: Chemistry Manufacturing & Controls, “Clarifying and Understanding ICH Guidance to Help Meet International Requirements for Submissions,” Philadelphia, PA (July 2006).
11. CBI Stability Programs: New Approaches to Test, Analyze and Document Data for Improved Program Design and Global Compliance, "In Use Testing of Biotechnological and Biological Products," Princeton, NJ (June 2006).
12. IBC/TIDES: Oligonucleotide and Peptide Technology and Product Development, “Stability Considerations and Testing for Oligo- and Peptide-Based Therapeutics,” Carlsbad, CA (May 2006).
13. IBC Biopharm Manufacturing and Distribution Summit: Logistics for Biopharmaceuticals, “Stability Studies to Support the Chain of Custody of Biotechnology Products,” Reston, VA (Dec 2005).
14. 2005 AAPS Annual Meeting: AAPS Short Course on Degradation and Stability in Small Molecule Active Pharmaceutical Ingredients/Stability Testing for Global Filings, “Stability Requirements for Global Regulatory Filings,” Nashville, TN (Nov 2005).

15. Therapeutic Strategies Against Neurodegenerative Conditions, "The Regulatory Product Development Process," Burlington, MA (Oct 2005).
16. International Pharmaceutical Federation (FIP) Workshop: Harmonizing Clinical Trial GMP and Quality Requirements Across the EU and Beyond, "The US Investigational New Drug (IND) System," Noordwijk Zee, The Netherlands (Mar 2005).
17. AAPS Pharmaceutical Technologies 3rd Summer Conference: Optimizing the Global Clinical Trial Process, "IND Applications – FDA Perspective," Cherry Hill, NJ (Aug 2004).
18. PARCS Meeting, "Managing CMC Requirements during IND," Irvine, CA (Apr 2003).
19. DIA Meeting on Global Chemistry, Manufacturing and Controls: Pre IND/CTX and IND/CTX Development Challenges, "FDA Perspective on Stability Testing during IND Development," Philadelphia, PA (Feb 2003).

PUBLICATIONS (SELECT LISTING)

1. C. Syin, D. Parzy, F. Traincard, I. Boccaccio, M.G. Joshi, D.T. Lin, X.-M. Yang, K. Assemat, C. Doerig, and G. Langeley, "The H89 cAMP-dependent protein kinase inhibitor blocks *Plasmodium falciparum* development in infected erythrocytes," *Eur. J. Biochem.* 268, 4842 (2001).
2. J.P. McDaniel, C. Syin, D.T. Lin, M.B. Joshi, S. Li, and N.D. Goldman, "Expression and characterization of a *Plasmodium falciparum* protein containing domains homologous to sarcalumenin and a tyrosine kinase substrate, eps15," *Int. J. Parasitol.* 29, 723 (1999).
3. M.R. Harkness, M.L. Stephens, J.H. Lobos, W.P. Flanagan, K.M. Carroll, R.J. May, G.L. Warner, P.R. Wilson, A.A. Bracco, and D.T. Lin, "A comparison of aerobic PCB biodegradation in the laboratory and in the field," *Environ. Sci. Technol.* (1996).
4. D.T. Lin, V.M. Powers, L.J. Reynolds, C.P. Whitman, G.L. Kenyon and J.W. Kozarich, "Evidence for the generation of α -carboxy- β -hydroxy-*p*-xylylene from *p*-(bromomethyl)mandelate by mandelate racemase," *J. Am. Chem. Soc.* 110, 323 (1988).

BOOK CHAPTER

- N.R. Schmuff and D.T. Lin, "Contents of Module 3 for an Electronic Common Technical Document Investigational New Drug Application," in Preparation and Maintenance of the IND Application in eCTD Format, W.K. Sietsema (ed.), FDAnews, Falls Church, VA, 117-134 (2008).
- N.R. Schmuff and D.T. Lin, "Chemistry, Manufacturing and Controls (CMC)," in Wiley Encyclopedia of Clinical Trials, (2008).

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- J.A. Gerlt, G.L. Kenyon, J.W. Kozarich, D.T. Lin, D.C. Neidhart, G.A. Petsko, V.M. Powers, S.C. Ransom and A.Y. Tsou, "Structure-function relationships in mandelate racemase and muconate lactonizing enzyme," in Chemical Aspects of Enzyme Biotechnology, T.O. Baldwin, F.M. Raushel and A.I. Scott (eds.), Plenum, New York, NY, 9-21 (1990).