

Expertise

- 14 Plus years of regulatory experience with unique combinations in small molecules, peptides, botanical products, biological/biotechnological products and combinational products.
- 12 Plus years of regulatory chemistry, manufacturing and controls (CMC) experience at CDER/FDA in both small molecular-weight drugs, peptides, botanical products and biological/biotechnological products.
- Managed and supervised review activities of CMC teams of 45 reviewers in 6 CDER medical reviewing divisions including Endocrine/Metabolism, GI/Coagulation, Pulmonary/Allergy, Urologic/Reproductive, Critical Care/Abuse, and Imaging/Radiopharmaceuticals.
- Experienced in working with multi-disciplined drug review Teams in CDER (clinical, pharmacology, toxicology and GMP compliance) and product review teams in CBER for cross-center regulatory issues.
- Extensive knowledge in FDA and ICH guidances through active participation as a member of either ICH Expert Working groups or FDA internal working groups.

Professional Experience

PharmaNet, Inc., Princeton, NJ

Executive Director, Consulting Division

2005 – Present

Senior Director, Consulting Division

2004 – 2005

- Provide regulatory consultation and strategic planning for in-house clinical projects or stand-alone regulatory projects regarding CMC for chemical drugs, peptides, and biological/biotechnological products.
- Plan, prepare, and review CMC technical documents in support of clinical trials (INDs) or marketing applications (NDAs/BLAs) in compliance with FDA/ICH guidelines/regulations.
- Due diligence related to CMC issues and consultation on GMP audit issues.
- Prepare pre-IND, IND, End-of-Phase 2 and NDA submissions
- Plan, prepare, and review technical chemistry, manufacturing, and controls documents in support of clinical trials (INDs) or marketing applications (NDAs/BLAs) in compliance with FDA/ICH guidelines/regulations
- Plan, organize, and moderate meetings and other interactions with the FDA
- Provide regulatory consultation on BSE/TSE issues pertaining to animal-derived materials used in formulations and manufacturing processes

Food and Drug Administration, Rockville, Maryland

Deputy Director, Division of New Drug Chemistry II

Office of New Drug Chemistry, Center for Drug Evaluation and Research

2001 – 2004

- Planned, and managed general regulatory operations of the New Drug Chemistry Division II, with 45 Review Chemists co-located with six clinical divisions (Endocrine and Metabolism, GI and Coagulation, Pulmonary, Urologic and Reproductive, Critical Care and Abuse, Imaging and Radiopharmaceuticals).
- Participated in and coordinated review activities with multi-discipline review teams within clinical review division and with other FDA Centers.
- Coordinated activities pertaining CMC reviews and pre-approval and post-approval inspections between Division II and Office of Compliance.

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- Coordinated chemistry reviews and other scientific and regulatory issues for biotechnological products regulated by CDER.
- Participated in various CDER committees and working groups responsible for planning and drafting policies, regulations, and guidance related to biotechnological products.
- Served as a member of ICH Expert Working Groups for CTD-Q and Q5E (Comparability), a member of CDER Complex Drug Substance Coordinating Committee, Chairman of CDER Protein Products Technical Committee, and Vice Chairman of CDER BSE/TSE Committee.
- Served as chairman of CDER Follow-on Growth Hormone/Insulin Working Group, a member of FDA Follow-on Biologic Working Group and FDA Ad Hoc Reviewer for USP Biotechnology and Natural Therapeutics Expert Committee.

*Chemistry Team Leader, Co-located with Division of Metabolism and Endocrine Drug Products,
Division of New Drug Chemistry II*

Office of New Drug Chemistry, Center for Drug Evaluation and Research 1996 – 2001

- Planned and managed IND/NDA reviews conducted by the review chemists co-located with the Division of Metabolism and Endocrine Drug Products.
- Served as a focal point for consult reviews and provided expert advice to other chemistry review teams for regulatory and scientific issues related to biotechnological products and transmissible spongiform encephalopathies (TSE).
- Participated in and led many CDER/CBER joint committees and working groups responsible for drafting industry guidance, ICH documents, policies and regulations.
- Represented FDA/CDER as a member of ICH Expert Working Group for CTD-Q guidance.

Review Chemist, Division of Metabolism and Endocrine Drug Products

Center for Drug Evaluation and Research 1991 – 1996

- Evaluated the CMC sections of more than 250 INDs, NDAs, and Supplemental Applications covering both drugs and biological products.
- Performed primary reviews for more than 25 original commercial INDs and NDAs with extensive experience in recombinant DNA protein drugs.
- Assisted in the development of regulatory guidance and policies for drug of small molecules and biotechnological/biological products.
- Served as a member of CDER Biotechnology Technical Committee and various CDER/CBER working groups.

The Johns Hopkins University School of Medicine, Baltimore, Maryland

Post-Doctoral Fellow

Department of Molecular Biology and Genetics 1986 – 1991

- Performed original research in molecular biology, virology, protein chemistry and recombinant DNA technology aimed at understanding the mechanism of adenovirus DNA replication.

Education

University of Maryland School of Medicine, Baltimore, Maryland, 1986

PhD – Biochemistry and Molecular Biology

National Taiwan University, School of Medicine, Taiwan, 1979

MS – Biochemistry

China Medical College, Taiwan, 1975

BA – Pharmacy