Deputy Director

AREAS OF EXPERTISE

- **Help clients prepare Premarket Approval (PMA)**
- **Help clients prepare Investigational Device Exemptions (IDE)**
- **Help clients prepare Product Development Protocol (PDP)**
- **Help clients prepare *De Novo*, Section 513(g) and Request for Designation (RFD) submissions to FDA as well as helping management of company communications and interactions with FDA**
- **Conduct seminars for client research and development staff on device regulation, design and conduct of non-clinical and clinical research, and preparation of submissions to FDA for regulated products, as well as on national and global strategies**
- **Help clients prepare Premarket Notification [510(k)]**
- **Determining product classification(s) and optimizing regulatory options, from national and global perspectives, for medical devices and combination products (e.g., device / drug or device / biologic combinations); interacting with client management to optimize product development plans**
- **Develop or review of protocols, analyzing non-clinical and clinical study results, and developing presentations of results for regulatory submissions**
- **Interact with engineers, investigators, and medical consultants on issues of research, design, and interpretation of study results**

INTRODUCTION

Consultant has twenty-six years' experience in the U.S. Public Health Service, including eleven years senior Food and Drug Administration (FDA) management experience in regulation of medical devices. Subsequent to FDA, over twenty years' experience as a consultant expert in U.S. medical device law and regulation, medical device development and evaluation, regulatory strategy and policy formulation, and device / drug / biologic combination products. Prior to FDA, career focused on applying engineering and biomedical sciences in the field of public health, including risk assessment and management in the diverse fields of toxic chemicals, radiofrequency and microwave electromagnetic energy, and biohazards associated with biotechnology.

WORK EXPERIENCE

1994 – Present
Industry Consultant

1968 – 1994
U.S. Public Health Service
Commissioned Officer, Regular Corps

1983 – 1994
Food and Drug Administration (FDA), Rockville, MD
International Policy Analyst (1993 – 1994)
Duties:

- Participated in planning, directing and coordinating a comprehensive international policy program for FDA.
- As member of the staff, served as Agency focal point on international policy, including regulatory harmonization, trade negotiations, and international standards setting; facilitated communication and decision making within the Agency on international policy; and enhanced FDA representation with other Federal agencies, at international meetings, and before international groups.
- Areas of primary responsibility included medical devices, drugs, and biologics.

Deputy Director (1989 – 1993)
Duties:

- Participated with the Office Director in planning, managing, and directing the Office's programs to ensure the safety and effectiveness of all medical devices marketed throughout the U.S.
- The Office carried out the approval processes for clinical studies as required by the IDE regulations, for PMA applications for new medical devices, and for 510(k)s for new or modified devices before they are marketed.
- On behalf of the Director, exercised final review authority for FDA and signed all final decisions on IDEs and PMAs, and on precedent-setting, complex, or potentially controversial 510(k)s.
- Worked extensively on FDA's evaluation and regulation of combination products having attributes of both medical devices and drugs (or biologics)

Associate Director (1985 – 1989)
Duties:

- Provided overall direction, coordination, and advice to the Office Director for the enhancement, development, and operations of the Office's IDE, PMA, 510(k), and classification efforts supportive of the Medical Device Amendments of 1976; was responsible for assuring the quality and consistency of seven divisions of the Office; evaluated and addressed the changing needs of the IDE/PMA/510(k) management systems and was responsible for the supervision of the Program Operations Staff, and, on behalf of the Director, exercised final review authority for FDA and signed all final decisions on IDEs and PMAs, and on precedent-setting, complex, or potentially controversial 510(k)s.
- Worked extensively on FDA's evaluation and regulation of combination products having attributes of both medical devices and drugs (or biologics).

Associate Director for Device Evaluation (1983 – 1985)
Duties:

- Managed and coordinated Office support and participated in scientific reviews of medical device applications, voluntary consensus standards, compliance problems, Program Management Systems activity, and miscellaneous requests from outside the Office for assistance, opinions, and other scientific or technical contributions.

1978 – 1983
Center for Disease Control (CDC), Rockville, MD
Acting Associate Director for Standards Development (1982 – 1983)
Duties:

- As Acting Associate Director, participated with the Division Director in interpreting Division mission and program objectives, in addition to planning, developing, implementing, and coordinating Division projects

- Served as the Senior Division Official at the Rockville site.
- Concurrently served as Acting Chief, Priorities & Research Analysis Branch and managed the development and initiation of a system for recommending and justifying priorities for Institute epidemiologic and field studies, laboratory research, document development, and recommendations for occupational safety and health standards.

Assistant Chief / Acting Chief (1981 – 1982)

Duties:

- Developed and managed program of priority setting for Institute epidemiologic and field studies, laboratory research, document development, and recommendations for occupational health and safety standards; supervised the acquisition, review, and analysis of clinical and epidemiologic information and research data on emerging and ongoing issues and the preparation of critical evaluations and health risk assessments.
- Assisted and consulted with staff in providing scientific and technical support to NIOSH Director, Department of Labor, and other Federal agencies.

Environmental Engineer (1979 – 1971)

Duties:

- Served as the Branch specialist in engineering and environmental health sciences for the NIOSH Current Intelligence System.
- Developed projects concerned with gathering, evaluating, and supplementing information on occupational health hazards
- Wrote and coordinated the publication of NIOSH Current Intelligence Bulletins and other Institute documents.
- Provided expertise to NIOSH special projects and participated in policy development and program planning for the Institute.
- Addressed issues involving chemical, physical, and biological agents.
- Principal activities included health hazard assessments of ethylene oxide, radio frequency and microwave electromagnetic energy, and recombinant DNA and biotechnology.

Criteria Manager (1978 – 1979)

Duties:

- Served as assistant project officer and assumed NIOSH program responsibility for the development of contact documents concerned with recommending national standards (and the criteria for these standards) to prevent occupational illness and disease resulting from exposure to toxic chemicals and physical agents.
- Primary assignment was the criteria document for chlorinated benzenes.

1968 – 1978

National Institutes of Health (NIH)

Environmental Health Engineer (1974 – 1978)

Duties:

- Served as project officer to contract team engaged to provide technical assistance in laboratory operations, engineering design review and consultation, and safety and occupational health training to national cancer research community.
- Consulted on national and international scale with parties seeking assistance in the design and operation of biomedical research and healthcare facilities.
- Assessed and developed design criteria for biomedical research laboratories and equipment; directed ongoing, nationwide program of safety and environmental control surveys of cancer research

laboratories; and conducted applied research in contamination control, environmental health, and ventilation.

Engineer (1970 – 1974)
Duties:

- Supervised the development and design of prototype safety equipment for biomedical research facilities.
- Assessed and developed design criteria for biomedical research facilities.
- Conducted safety and environmental control surveys of cancer research laboratories.

Design Engineer (1968 – 1970)
Duties:

- Prepared engineering plans and specifications for utility and mechanical systems for biomedical research facilities.
- Work included all aspects of design development.

EDUCATION

1976
University of Minnesota, MN
Ph.D.: Environmental Health, Epidemiology

1973
School of Public Health, University of Minnesota, MN
Master of Public Health

1968
University of California, Santa Barbara, CA
Bachelor of Science: Mechanical Engineering

AWARDS AND HONORS

- 1990 Meritorious Service Medal
- 1989 Unit Commendation PHS Citation
- 1988 Nomination by Surgeon General's board to list of potentially eligible candidates for flag grade Outstanding Service Medal
- 1987 Exceptional Capability Promotion to Director grade (Capt., 06)
- 1985 Unit Commendation PHS Citation
- 1984 PHS Citation Commendation Medal
- 1983 Unit Commendation

PROFESSIONAL AFFILIATIONS

- Member, Regulatory Affairs Professionals Society (RAPS)
- Formerly a member of the American Academy of Industrial Hygiene, the American Conference of Governmental Industrial Hygienists, the American Public Health Association, and the American Society of Heating, Refrigerating, and Air-conditioning Engineers

CERTIFICATIONS

- Certified in Comprehensive Practice of Industrial Hygiene by American Board of Industrial Hygiene (1980, Certificate No. 1843); allowed to expire, 1986.

APPOINTMENTS / SPECIAL ACTIVITIES

- 2007-2011 NMT Medical, Inc., member Board of Directors
- 2003-2013 Advanced Medical Technology Association (AdvaMed), Moderator and/or faculty member at various Medical Technology Learning Institute (MTLI) programs (2003-2007 and 2011-2013)
- 2004-2007 Regulatory Affairs Professionals Society (RAPS), Program Chair, 2004, 2006, and 2007 PMA Webcast Series
- 2003-2005 Regulatory Affairs Professionals Society (RAPS), Member, Editorial Board, Fundamentals of US Regulatory Affairs and author of Chapter 20, Combination Products
- 2002Regulatory Affairs Professionals Society (RAPS), Program Chair, 2002 Medical Device Conference& Tabletop Exhibition
- 2001-2002 Center for Professional Advancement (CfPA), Course Director, Clinical Studies for Medical Devices
- 1999 Food Drug Law Institute (FDLI), Futurist Task Force on Medical Devices
- 1991-1993 FDA, Member, Combination Products Task Force
- 1990 Harvard University, John F. Kennedy School of Government, Participant, Program for Senior Managers in Government
- 1988-1990 CDRH, FDA, Member, IDE Steering Committee
- 1986-1993 CDRH, FDA, Member, Human Tissue Products Working Group
- 1984-1989 Tripartite (U.S., Canada, United Kingdom) Subcommittee on Medical Devices, Member, Toxicology Subgroup
- 1984-1985 CDRH, FDA, Member, PMA Criticisms Task Force
- 1983-1985 CDRH, FDA, Chairperson, Toxicology Committee
- 1982-1983 NIH, Recombinant DNA Advisory Committee, Member, Large-Scale Review Working Group
- 1981-1985 U.S. Public Health Service, Member, Engineer Professional Advisory Committee (formerly Engineer Career Development Committee)
- 1979-1981 Interagency Regulatory Liaison Group (IRLG), NIOSH representative, Radio Frequency and Microwave Task Force
- 1979 U.S. Environmental Protection Agency, Member, Review Committee for Health Effects Assessment Chapter of Consent Decree Water Quality Criteria Document for Chlorinated Benzenes
- 1978-1982 American Society of Heating, Refrigerating, and Air-conditioning Engineers, Inc. Acknowledged significant contributor to ASHRAE Handbook, 1978 and 1982 Applications Volume, Chapter on Laboratories
- 1977-1978 American Society of Heating, Refrigerating, and Air-Conditioning Engineers, Inc. Member, Technical Committee 9.2, Industrial Air-Conditioning
- 1976-1978 National Cancer Institute, Member, Viral Oncology Program Resources and Logistics Advisory Group

PRESENTATIONS

- U.S. District Court witness, testified as Government witness in litigation involving FDA and a medical device manufacturer. U.S. District Court, San Antonio, TX, June 24-25, 1993.
- Congressional hearing witness, addressed safety issues posed by contaminated syringe needles and other sharps; Subcommittee on Regulation, Business Opportunities and Energy; Committee on Small Business, U.S. House of Representatives, February 7, 1992.
- Congressional hearing witness, addressed a drug/device combination product under evaluation by FDA; Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, U.S. House of Representatives, February 6, 1992.
- Face to Face with FDA, Interview with Medical Devices and Diagnostic Industry Magazine, February 1992 issue.
- National print media interviews; various DHHS-cleared interviews by New York Times and Associated Press on subjects related to injectable collagen and silicone gel filled breast implants, August and September 1991.
- National cable television news interview; DHHS-cleared interview by *CNN* for news series "Medical Technology on Trial', broadcast various days of August 1990.
- Congressional hearing witness, addressed issues of premarket evaluation and post-approval surveillance of medical devices; hearing held in consideration of legislation, H.R. 3095, by Subcommittee on Health and the Environment, Committee on Energy and Commerce, U.S. House of Representatives, July 17, 1990. [The bill has been signed into law, the Safe Medical Device Act of 1990.]
- Presentations on the approach and data requirements for the clinical evaluation and regulation of diagnostic ultrasound devices indicated for fetal examinations; made to FDA's Obstetrics-Gynecology Devices Panel, January 1989 and June 1990.
- Presentation on preclinical and clinical data requirements for the evaluation of medical devices, as member of U.S. delegation to Tripartite Subcommittee on Medical Devices, Ottawa, June 5-6, 1989.
- Principal architect of the proposed decision framework for FDA's evaluation and regulation of products having attributes of both medical devices and drugs (*i.e.*, combination products); forwarded from Center for Devices and Radiological Health to
- Center for Drug Evaluation and Research, March 1989, and served as the basis for the formal 1991 intercenter agreement on combination products.
- Principal U.S. author of Tripartite Biocompatibility Guidance, Tripartite Subcommittee on Medical Devices, September 1986; officially recognized as policy pertaining to toxicity testing of medical devices by FDA's device approval program in April 1987.
- Presentation on preclinical and clinical data requirements for the evaluation of medical devices, as member of U.S. delegation to Tripartite (U.S., Canada, United Kingdom) Subcommittee on Medical Devices, London, October 6-8, 1985.