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Experience:

Merchant-Taylor International Inc. 1996-Present

Partner

MTI, Inc. was formed to assist clients who require a broad spectrum of services extending from facilities design, validation and operational activities through design and evaluation of clinical trials. Strategic planning for new product development and all aspects of product regulatory affairs support continue to be a major focus of activity. Special emphasis is provided in the area of emerging biological therapies.

Taylor Associates 1992-Present

President

Service to clients in all areas of drugs and biologics product development. This has included advisory and hands-on regulatory and broad product development support. Emphasis has largely been in the area of new products including classical small drug molecules as well as peptides and recombinant proteins. Efforts have included active preparation and/or support for more than 50 new INDs in addition to ongoing advice and support for many investigational and marketed drug and biological products.

ImmunoGen Inc., Cambridge, MA 1987-1992

Vice-President/Chief Regulatory Officer

Corporate Officer with primary responsibility for all local, state, federal and international regulatory matters as well as GMP Compliance, Quality Control, Quality Assurance and Health & Safety issues reporting to the Chairman/CEO. Provided cohesive influence and central communication function through establishment of group product planning, project teams and product development timelines. Served as chief liaison to major international licensees as well as primary vendors (monoclonal antibody, etc.), trade organizations (PhRMA, BIO and Massachusetts Biotech Council) and contract organizations for aseptic product fills, preclinical, QC and clinical testing.

Brought extensive drug development experience to start-up biotech company establishing pre-clinical toxicity and initiating clinical trials (Phase I/II) for new cancer therapeutics. Successfully initiated five U.S. and two Canadian INDs for monoclonal antibody immunotoxins without clinical hold. Processed INDs to Phase III pivotal trials during

time when company grew from <5 to >170 employees. Obtained Orphan Drug Designation for five U.S. INDs and received \$100,000 Orphan Drug Grant, one of only two commercial sponsors given such an award.

Carter-Wallace, Inc., Cranbury, NJ 1983-1987

Vice-President, Regulatory Affairs

Primary corporate regulatory position responsible for several Divisions including Wallace Labs (Ethical Pharmaceuticals), Wampole Labs (Devices and Diagnostics), Carter Products (Consumer Products) and Lambert-Kay (Veterinary Products). Maintained responsibility for 30-person Department to handle all regulatory aspects for investigational and marketed products as well as responsibility for Product Complaints and Clinical Packaging and Supplies..

Filed first new product NDAs (2) in several years (First NDA subsequently approved). Additional new product INDs processed to NDA stage (NDAs subsequently filed for all products). Several diagnostic products (monoclonal antibody-based) also filed as 510(k) submissions, approved and introduced for commercial sale.

Zeneca Pharmaceuticals ,Wilmington,DE 1979-1983

Director, Drug Regulatory Affairs 1980-1983

Primary North American drug regulatory position including responsible for GMP compliance and QA (GLP and GCP oversight). Several major INDs and NDAs processed including NDAs filed and approved for Tenormin and Tenoretic. Interaction with all FDA Drug Divisions. Extensive travel and international liaison with UK-based parent Corp.

Manager, New Drug Affairs 1979-1980

Primary responsibility for interaction with FDA and HPB (Canada) for all investigational products and new marketing applications.

Pfizer Central Research, Groton, CT 1967-1979

FDA Liaison Officer 1975-1979

Responsible for processing all Pfizer Research INDs and NDAs, including NDA filed for major NSAI commercial product, Feldene. Reported to Director.

Senior Research Scientist 1967-1975

Responsible for pharmacokinetic and metabolism studies with investigational drug products.

Argonne National Laboratories, Argonne,IL 1965-1967

Post-doctoral Fellow

Conducted research studies concerning toxicity and metabolism of radionuclides and effects of x-irradiation on thyroid glands of beagle dogs.

Education:

Ph.D. in Biochemistry, Purdue University	1966
M. S. in Biochemistry, Purdue University	1963
B. S. in Chemistry, Providence College	1960

Membership:

Alpha Chi Sigma (National Chemical Fraternity)
Sigma Xi (National Scientific Honor Society)
American Society of Pharmacology & Experimental Therapeutics
Drug Information Association
Regulatory Affairs Professional Society (Charter Member-1975)
American Society for Gene Therapy

Corporate Activities:

Board of Directors 1994-Present
Bio-Imaging Technologies, Inc., West Trenton, NJ

Presentations:

Drug Information Association 2001 Annual Meeting

Presentation: Regulatory Development in a Virtual Environment

IBC Monoclonal Antibody Conference

Presentation: Regulatory Considerations in Support of an Aggressive Product Development Strategy

FDA/NCI Gene Therapy Conference:

Presentation: Implementation of a Phase I Gene Therapy Program in a GLP/GMP Continuum

Regulatory Affairs Professional Society Meeting:

Presentation: Regulatory Interactions and Negotiation Skills

BIO Annual Meeting:

Presentation: Optimizing Regulatory Success for Accelerated Product Development

BioWest' 95

Presentation: Viral Safety Concerns with Xenotransplantation

BioEast'94:

CoChair: Creative Manufacturing Session

Presentation: Contract Manufacturing Session

Manufacturer's Perspective with a Regulatory Twist

BioWest'94

Session Chair: Regulatory Strategies for Manufacturing Changes

Presentation: Regulatory Strategies for Accelerated Approval

University of Connecticut H.G. Hewitt Symposium

Keynote Address: Introduction to Pharmaceutical Biotechnology: The Risks and Successes of Biotechnology Development

Society of Toxicology, Southern California Chapter

Toxicology of New Biotechnology-Based Pharmaceuticals

Presentation: Historical Perspectives on the Growth of the Biopharmaceutical Industry

Harvard/MIT Graduate Seminar:

Presentation: Regulatory Aspects of Biotechnology

FDA/NCI/NIAID Workshop: Preclinical Safety Testing Of Monoclonal Antibodies

Session Co-Chair with CBER Div. Director

Presentation: Antibody-Toxin Conjugates: Structural and Functional Profiles