Vice President and Chief Scientific Officer

AREAS OF EXPERTISE

- **Toxicology**
- **Chemistry**
- **Surgery**
- **Experimental Medicine**
- **Continuous Infusion**
- **Cardiovascular Assessment**
- **Business Development, Client Interactions**
- **Protocol Generation, Study Monitoring**
- **Data Interpretation, Reporting and Pricing**
- **Telemetry**
- **Safety Pharmacology**
- **Statistics**

INTRODUCTION

Consultant has training in Chemistry, Pharmacology and Toxicology, and ten years of experience in the Pharmaceutical Industry. Experience helping to grow a preclinical contract research organization that in 1990 employed only 85 people. Today, it has over 900 people in multiple locations and EBITIDA's consistently in the 26% range. Oversaw the growth of the Toxicology Department, pioneering expansion into new areas such as primatology, surgery and experimental medicine, continuous infusion, cardiovascular assessment, safety pharmacology and telemetry, such that it accounted for 45-50% of WRL revenue at the time of retirement. Led the company efforts on two key corporate acquisitions. Hass experience with working with a wide variety of clients and businesses; advising several clients on projects ranging from drug development to food additive registrations. Able to directly assist in the development of several marketed drugs (e.g., Lunesta, Namenda, and Provigil) as well as food ingredients (e.g., taurine, diacylglyceride based cooking oil, canola protein isolates), and HALON replacements. What these seemingly disparate projects had in common is that they all needed the application of sound scientific principles and attention to detail to address toxicological concerns. Worked on various projects involving stem cells, recombinant proteins and monoclonal antibodies.

WORK EXPERIENCE

2013 - Present
Industry Consultant
Duties:

- Independent consultant providing consultant providing scientific, regulatory and operational expertise. Examples of the types of projects for which I have been retained:
- Worked with two different oncology companies to design the toxicology study packages necessary to support their INDA, and then also worked with them in the preparation of the INDA's, which were successfully submitted.
- Currently working with an oncology company in the Pre-IND phase. Developed and oversaw the safety/toxicology strategy leading to compound nomination.
- In the first three months of 2017, performed due diligence in the review of four different molecules as potential in-license candidates.
- Advised three different CRO on operations and strategy development.

- Prepared a request for categorical exemption from completing an NDA Environmental Impact Statement.
- Performed a safety assessment review and prepared a whitepaper on the toxicity and risk associated with an unintended formulation additive in a drug delivery device.
- Performed a gap analysis on the necessary steps that would be required to import a new sun screen preparation in to the U.S.
- Prepared a GRAS notification that covered a new use for an established food additive.

09/1990 – 2013
WIL Research Co., Ashland, OH
Chief Scientific Officer, (10/2010 – 2/2013)
Duties:

- As Chief Scientific Officer of WIL Research Company, provide global scientific counseling as appropriate to the leaders of each operating subsidiary, the CEO and Chairman of WIL Research Company and to the Company's Executive Management Committee.
- Identify potential acquisition targets, prove appropriate due diligence support. Identify and pursue potential new service offerings for the Company.
- Develop seminar series for inter-company education of each other capabilities.
- Attend WRC Executive Committee meetings and follow up as appropriate on assignments; report periodically to the Committee regarding best scientific practices in the industry versus company practices.
- Develop and implement plans for a scientific advisory board. Set up systems (perhaps with the scientific advisor committee) that routinely review the methodologies used at the company's different locations. Assess for strengths and weakness. And provide for exchange of best practices as well as strategies for improvement, where needed.

Vice President and Chief Scientific Officer, (12/2008 – 10/2010)
Duties:

- As Vice President, worked with the Chief Operating Officer as appropriate to provide senior level leadership. Provided overall scientific and managerial leadership to the following departments: Analytical Chemistry/ADME, General Toxicology (including applicable juvenile toxicology and inhalation toxicology), Pathology, Safety Pharmacology, Study Analysis and Reporting, Surgery and Experimental Medicine, and Veterinary Services.
- Responsibilities included providing training and mentorship for direct reports, arranging for an appropriate departmental reporting structure that is not over complicated but also fosters growth while identifying backup.
- Fostered the development of systems that encourage efficiency while maintaining quality. Set-up systems and/or meeting schedules that fostered communication and coordination between departments, and provided for smooth resolution of interdepartmental disagreements. Chaired meetings as appropriate.
- Developed appropriate plans for assessing the market place and developing new service offerings. Delegated and tracked actual conduct of acquisition, validation and marketing of new services. Worked with the business development as appropriate.
- Reviewed reports, and provided scientific and technical advice as needed. Reviewed and approved PAR and CAR's as necessary.
- Promoted publication and professional society involvement.
- As Chief Scientific Officer of WIL Research, provided scientific counseling as appropriate to the Chief Operating Officer of WIL Research Holdings. Identified potential acquisition targets and provide appropriate due diligence support. Developed seminar series for intercompany education of each other capabilities.

- Attended WIL Research Holdings Executive Counsel meetings and followed up as appropriate on assignments. Developed and implemented plans for scientific advisory board.
- Set up systems (perhaps with the scientific advisor committee) that routinely reviewed the methodologies used at the company's different locations, assessed for strengths and weakness, and provided for exchange of best practices.

Director, Toxicology, (11/1997 – 12/2008)

Duties:

- The position had overall managerial and technical responsibilities for the operation of the General Toxicology, Inhalation Toxicology, and Safety Pharmacology Departments.
- Direct reports included Director, Inhalation Toxicology, Director, Safety Pharmacology and Cardiovascular Sciences, Head of the Surgery and Experimental Medicine, Associate Director, General Toxicology and Assistant Director (Head of Juvenile Toxicology).
- Kept abreast of changes in guidelines, regulations and/or technology that impacted the business climate in which the company operated.
- Reviewed and approved reports, protocols and SOPs.
- Responsible for the development and implementation of systems that are necessary for increases in efficiency and/or quality.

Senior Toxicologist, Toxicology, (12/1997 – 11/1997)

Duties:

- Served as study director on subchronic, chronic, carcinogenicity (both EPA and FDA guidelines) metabolism/PK and neuro-toxicology studies.
- This includes business development, client interactions, protocol generation, study monitoring, data interpretation, reporting and pricing. Took on special technical, management or marketing tasks as assigned.
- Reviewed reports, protocols and SOPs. Independent of study related activities, provided consultative services on drug development projects and problems concerning chemical toxicity.
- Assisted clients in developing the necessary study packages to support clinical testing, and/or product registration.

Associate Director, Toxicology, (09/1990 – 08/1995)

Duties:

- Responsible for technical and administrative management of the Toxicology and Metabolism Section, including project staffing, staff management, technical planning, training, budgeting and document preparation.
- Principal investigator on MRI's contract with the National Cancer Institute to conduct preclinical toxicology studies of candidate anticancer and anti-HIV agents.

07/1995 – 12/1995

Midwest Research Institute, Kansas City, MO

Section Manager

Duties:

- Responsible for technical and administrative management of the Toxicology and Metabolism Section, including project staffing, staff management, technical planning, training, budgeting and document preparation.
- Principal investigator on MRI's contract with the National Cancer Institute to conduct preclinical toxicology studies of candidate anticancer and anti-HIV agents.

1980 – 1990
Searle R & D, U.S. Product Safety, Skokie, IL
Group Leader, Toxicology, (1986 – 1990)
Manager, Experimental and Acute Toxicology, (1983 – 1986)
Research Investigator, (1980 – 1983)
Duties:

- Managed and/or coordinated the activities of the General Toxicology Group, (3 Group Leaders, 4 Supervisors and 13 technical level personnel).
- Specific responsibilities included reviewing protocols and procedures for technical appropriateness, designing special mechanistic studies, scheduling and budgeting responsibilities.
- Served as study director, as described by the Good Laboratory Practices Act, on assigned preclinical safety studies which included protocol generation, study scheduling and report preparation. Authored over 100 safety studies, including several pivotal chronic studies required to support INDs and NDAs.
- Chaired the R & D Health Effects Committee.
- Served as resource person and coordinator for toxicity issues relating to industrial health and/or worker safety. Included preparation of opinions and review of MSDS's.
- Initiated and oversaw the development or adoption of new testing protocols, particularly in the area of immunotoxicity, for supporting product applications and selection of drug candidates for development. Participated on both development and research project teams. This included designing and coordinating the toxicology study packages for product registration. Developed and chaired ad hoc committees charged with solving toxicological problems (heavy emphasis at Searle on matrix management or program management).
- Provided toxicological and scientific expertise in the following types of activities: preparation of toxicology summaries for consultants on company products, regulatory bodies, and scientific conferences concerning safety data.
- Reviewed (toxicology) data packages on compounds considered for possible in-license. Supervised literature searches and summaries.
- Managed the Experimental Toxicology Laboratory, a "special projects" unit designed to primarily investigate toxicological questions outside the scope of traditional safety studies.
- Designed and conducted experiments investigating mechanisms of toxicity involving the liver, thyroid, testes, kidney and heart.
- Organized and managed a small toxicology group discussion series, scheduled times and assigned topics to participants. These discussions serve as a continuing education forum and also kept the senior staff abreast of current topics of concern.
- In addition, organized and coordinated an in-house course on clinical chemistry and hematology.
- Served on the Institutional Animal Care and Use Committee.

ACADEMIC EXPERIENCE

1993 – 2002
Adjunct Faculty, Ashland University

1977 – 1980
Research Associate, Center in Environmental Toxicology
Vanderbilt University Medical School

1972 – 1977
PHS Doctoral Trainee
University of Illinois Medical Center
Department of Medical Pharmacology

1971 – 1972
Undergraduate Teaching Assistant
Allegheny College, Department of Chemistry

EDUCATION

1977
University of Illinois at the Medical Center, Chicago, IL
PhD: Pharmacology

1972
Allegheny College, Meadville, PA
Bachelors of Science: Chemistry

CERTIFICATIONS

- Diplomat, American Board of Toxicology, (1981; recertification in 1986, 1991, 1996, 2001, 2006, and 2011)

ADDITIONAL TRAINING

- ACT Continuing Education Course on Hematology and Immunotoxicity Assessment: Essential Principals and Emerging Modalities, 2017
- SOT Continuing Education Course on Read-Across: Case Studies, New Techniques, and Guidelines for Practical Application, 2017
- SOT Continuing Education Course on Technologies and Applications of Stem Cells for Use in Toxicology, 2017
- SOT Continuing Education Course on Molecular Imaging for Toxicologists, 2017
- SOT Continuing Education Course on Contribution of Mitochondria to Drug-Induced Organ Toxicities, 2016
- Sot Continuing Education Course on Approaches to Investigate and Assess Risks Associated with Drug-Induced Liver Injury (DILI), 2016
- ACT Continuing Education Course on Selection and Use of Non-Rodent Species for Nonclinical Safety Assessment - Benefits, Pitfalls and Caveats, 2015
- ACT Continuing Education Course on Fundamentals of Translational Neuroscience in Toxicological Pathology: Optimizing the Value of Animal Data for Human Risk Assessment, 2015
- SOT Continuing Education Course: Skeletal System Endocrinology and Toxicology, 2015
- SPS Continuing Education Course: Cardiac Electrophysiology: The Biophysics of Ion Channels for the Safety Pharmacologist, 2014
- ACT Continuing Education Course: Regulatory Toxicology –the FDA and Beyond, 2014
- ACT Continuing Education Course: Toxicology and Pathology of the Respiratory System, 2014

- SOT Continuing Education Course: Nonclinical Animal Models Enabling Biopharmaceutical Advances in Translational Medicine, 2014
- ACT Continuing Education Course: Inflammatory Biomarkers, 2013
- SOT Continuing Education Course: Tools and Technologies in Translational Toxicology, 2013
- ACT Continuing Education Course: Understanding Statistics in Toxicological Research & Drug Development, 2012.
- SPS Continuing Education Course: Improving Human Translation of Safety Pharmacology Models: Practical Applications of Advanced Tissue and Organ Engineering, 2012
- SPS Continuing Education Course: Safety Biomarkers – What Every Safety Pharmacologist Should Know, 2012
- SOT Continuing Education Course: Alternative In Vitro Toxicology Testing for the 21st Century, 2012
- SOT Continuing Education Course: Stem Cells in Toxicology, 2012
- SOT Continuing Education Course: MicroRNAs in Biology and Toxicology, 2012
- Cutting-Edge Imaging Technologies and Strategies in Preclinical Small Animal Research, 2012
- ACT Continuing Education Course: Introduction to Translational Imaging in Nonclinical Safety Assessment: A Technology and Applications Perspective, 2011
- Applied Pharmaceutical Toxicology Continuing Education Course: Dedicated to Reducing Safety-Related Attrition, South San Francisco, CA, 2011
- SOT Continuing Education Course: Immunology for Toxicologists, 2009
- SOT Continuing Education Course: Free Radicals for Toxicologists – From the Basics to Inflammation and Disease, 2009
- SOT Continuing Education Course: Technologies and Tools for Toxicity Testing in the 21st Century, 2009
- SOT Continuing Education Course: The Use of Transgenic Animal Technology in Toxicologic Research, 2008
- SOT Continuing Education Course: Nanotoxicology The Science of Developing a Safe Technology, 2008
- ACT Continuing Education Course: From Bench to Bedside: The Absolute Essentials of Preventative Vaccine Development, 2008
- ACT Continuing Education Course: Anti-Cancer Drug Development Overview: Advancing Our Understanding of Targeted Approaches to Anti-Cancer therapies, 2008
- SOT Continuing Education Course on Rodent Imaging for the Toxicologist, 2007
- ISSX Short Course P450-dependent Metabolism in Extrahepatic tissue: Implications for Drug Disposition and Toxicology, 2007
- ISSX Short Course Metabolism based Neurotoxicity by Xenobiotics: Mechanism and Biomakers, 2007
- Safety Pharmacology Society Continuing Education Course on Advanced Topics in Cardiovascular Assessment, 2006
- ACT Continuing Education Course on Photosafety: Basic Principles of Photosafety Testing and Regulatory Issues, 2006
- SOT Continuing Education Course on Clinical Pathology-The Grandaddy of Biomarkers, 2005
- SOT Continuing Education Course on International Harmonization of Technical Requirements for Conducting Non-clinical Safety Studies of Human Pharmaceuticals, 2005
- ACT Continuing Education Course on Assessment of Mitochondrial Function in Disease and Drug-Induced Toxicity, 2005
- SOT Continuing Education Course on Metabonomics Technology in Safety Assessment, 2004
- ACT Continuing Education Course on Genetic Toxicology Principles, Practices and Emerging Challenges, 2004

- SOT Continuing Education Course on Genomics and Proteomics Array Formats, 2003
- ACT Continuing Education Course on Toxicology Testing for Preventive Vaccine Development, 2003
- SOT Continuing Education Course of Strategies and Issues in non-Clinical Development of Intravenous Infusion Drug Products, 2002
- ACT Continuing Education Course on Biocompatibility and Regulatory Requirements for Medical Devices, 2002
- ACT Continuing Education Course on Metabolites in Safety Testing, 2002
- ACT Continuing Education Course on Practical Approaches to Applying Immunotoxicity Guidelines to Safety Assessment, 2001
- SOT Continuing Education Course on Toxicokinetics and Physiologically-Based Toxicokinetics in Toxicology and Risk Assessment, 2000
- SOT Continuing Education Course on Prediction of Human Toxicity and Metabolic Fate of Drugs using In Vitro systems, 2000
- SOT Continuing Education Course on Genomic Technologies and New Screening strategies for Toxicology, 1999
- ACT Continuing Education Course on Safety Assessment of Biotechnology Products, 1999
- ISSX Continuing Education Course on LC/MS and LC/NMR Techniques in Drug Metabolism, 1999
- SOT Continuing Education Course on Assessment of Cutaneous Toxicity, 1998
- ACT Continuing Education Course on Experimental design for Large Animal Toxicity, 1998
- ACT Continuing Education Course on Statistics and Carcinogenicity, 1997
- SOT Continuing Education Course on Safety and Risk of New Food Technologies, 1997
- SOT Continuing Education Course on Aptosis, 1996
- ISSX Continuing Education Course on Genetic Therapy, 1996
- ACT Continuing Education Course on Chronic Toxicity, 1996
- SOT Continuing Education Course on Cytokines, 1995
- MRC/SOT Short Course on Environmental Estrogens, 1995
- SOT Continuing Education Course on Genetic Toxicology, 1994
- SOT Continuing Education Course on Risk Assessment, 1993
- MRC/SOT Short Course on Immunotoxicology, 1993
- ACT Short Course on AIDs Models for Research, 1993
- SOT Continuing Education Course on Implementing PBPK, 1992
- SOT Continuing Education Course on Environmental Toxicology, 1991
- MRC/SOT Short Course on Gastrointestinal Pathology, 1991
- SOT Continuing Education Course on Advanced Hepatotoxicity, 1990
- SOT Continuing Education Course on Respiratory Tract Toxicity, 1990
- SOT Continuing Education Course on Advanced Renal Toxicology, 1989
- SOT Continuing Education Course on Concepts in Molecular Biology, 1989
- Reactive Metabolite Chemistry for Toxicologists, 1987
- SOT Continuing Education Course on Developmental Toxicology, 1986
- SOT Continuing Education Course on Environmental Toxicology, 1986
- IAPS Course - Toxicology of the Immune System, 1985
- SOT Refresher Course on Hepatotoxicity, 1984
- SOT Refresher Course on Carcinogenesis, 1984
- Mid America Toxicology Course, 1981
- SOT Refresher Course on Inhalation Toxicity, 1981
- Gordon Conference (Alcohol & Alcoholism), 1979

PROFESSIONAL AFFILIATIONS

- American Association for the Advancement of Science, associate member, 1974 - 1990
- American College of Toxicology, full member in 1986
- Organized and chaired symposium on animal models for the 1990 meeting
- Chaired the ad hoc Student Affairs Committee, 1990 - 1991
- Placement Service Coordinator, 1990
- Chaired Poster Sessions at Annual Meeting, 1991 - 1993
- Nominated and elected to Council, 1991 - 1994
- Chair of the Membership Committee, 1993 - 1994
- Member, Membership Committee, 1994 - 1995
- Elected Vice-President, 1995 - 1996
- President Elect, Chair of Program Committee, 1996 - 1997
- President, 1997 - 1998
- Past President, Chair of Nominating and Outreach Committees, 1998 - 1999
- American Society for Pharmacology and Experimental Therapeutics (A.S.P.E.T.), full member in 1987
- Member, Division of Drug Metabolism
- Member, Division of Toxicology
- Greater Chicago Chapter - ASPET, 1988 - 1990
- International Society for the Study of Xenobiotics, full member in 1986
- International Society for Immunopharmacology, 1988 - 1993
- Midwest Regional Chapter/Society of Toxicology, 1980
- Councilor and Chairman of the Membership Committee, 1985 - 1987
- President-elect and Chairman of the Program Committee, 1987 - 1988
- President, 1988 - 1989
- Councilor and Chairman of the Education Committee, 1989 - 1990
- Society of Toxicology, full member in 1985
- Member of several specialty sections
- Nominated to the Nominating Committee, 1987
- Chaired a platform session on biotransformation at national meeting, 1989
- Chaired a poster session on acute/ocular toxicity at national meeting, 1990
- Chaired a poster session on cardiotoxicity at national meeting, 2003
- Member of World Wide Web Committee, 2004 - 2006
- Japanese Society of Toxicology, Associate Member since 2000

AWARDS AND HONORS

- HHS National Research Service Fellowship, 1978 - 1980
- Selected to Strathmore's Who's Who, 2003
- Selected to Kiplings Whos' Who in Leading Business Professionals, 2008

PATENT

- Diol-metabolites of 7-phenyl-1,2,4-triazolo-(2,3-C)-pyrimidines-5-amines. Patent No. 4,866,063. September 12, 1989

OTHER PROFESSIONAL ACTIVITIES

- Member of the Industrial Biotechnology Association's subcommittee in charge of developing guidelines for the preclinical testing of novel products produced by biotechnology (1984 - 1986)
- Regular attendee (1980 - 1990) at the Drug Safety Subsection Meetings (Western Region) of the Pharmaceutical Manufacturing Association, the Toxicology Forum and the Toxicology Round Table (discussion leader in 1989)
- Representative on the Brominated Fire Retardants Industry Panel, 1990 - 1992
- Served on the ECETOC Expert Technical Committee for Developing a technical monograph on the assessment of solvent related cardiac sensitization (published in 2009)
- Peer reviewer for: Toxicology and Applied Pharmacology; Journal of Applied Toxicology; Research Communications in Chemical Pathology and Pharmacology; Food and Chemical Toxicology; Journal of Pharmacology and Experimental Therapeutics; J. American College of Toxicology; Molecular Pharmacology; In Vitro Toxicology
- Appointed to the Editorial Boards: Toxicology Methods and Mechanisms, 2000 - 2004; Fundamental and Applied Toxicology, 1990 – 1994; Journal of Applied Toxicology, 1998 - 2000

MANAGEMENT TRAINING

- Great Lakes Chemical Course on Leadership, 2003
- American Management Association course, "Improving Managerial Skills of the New or Prospective Manager," 1990
- Coates-Freeman seminars on collaboration in, and improving the quality of, decision making, 1989
- Performance Management System training; 1987.
- In-house course (Searle) on techniques for the Appropriate management of subordinates, and the setting and tracking of goals

PRESENTATIONS

- “Trends in FDA GLP Enforcement: Impact on Data Quality and Study Integrity.” American Association of Pharmaceutical Scientists, 2011