Stanley A. Roberts, Ph.D., D.A.B.T.

President, SAR Safety Assessment

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PROFESSIONAL OVERVIEW

- Pharmaceutical toxicologist with over 30 years of conducting and leading research in toxicology, drug metabolism and pharmacokinetics.
- Experienced executive in small biotech and large pharmaceutical companies with proven success for process improvement, innovative management and broad based integration of scientific disciplines to more efficiently identify the best new candidate compounds for further development.
- Demonstrated excellence in drug development across a broad range of therapeutic classes, targets and disease areas with scientific and regulatory experience in both small molecules and biotherapeutics (e.g., peptides, proteins and antibodies).
- Wide diversity of experience with animal models (rat, mouse and hamster) and non-rodents (dog, non-human primates, rabbits and swine). Duration of studies performed has encompassed single dose, sub-chronic and 2-year carcinogenicity. Administration routes for studies have included oral (gavage, capsule and dietary admixture) and parenteral (ocular, dermal, subcutaneous, aural, bolus intravenous (IV) and 24-hour continuous IV infusion).
- Extensive experience in scientific problem solving and integrating science with strategy across all preclinical scientific disciplines.
- Actively prepare and carry out preclinical development plans and plan/monitor/report all types of preclinical studies
- Direct and significant contributions to numerous registration packages including composing and editing position papers and submission packages.

EDUCATION

Post-Doctoral Fellowship in Molecular Toxicology **1981**
Medical University of South Carolina, Charleston SC
- Project: Structure-Toxicity Relationships of Acetaminophen: Correlation of Metabolism and Hepatotoxic Capability of Structural and Chemical Derivatives of Acetaminophen, Dr. David Jollow, Preceptor

Ph.D. in Pharmacology and Toxicology **1977**
Purdue University, West Lafayette, IN
- Thesis: Tolerance to Cadmium-Induced Inhibition of Drug Metabolism in the Male Rat: The In Vivo and In Vitro Role of Hepatic Metallothionein, Dr. R. C. Schnell, Advisor

M.S. in Pharmacology and Toxicology **1976**
Purdue University, West Lafayette, IN
- Thesis: Tolerance Development to Cadmium-Induced Potentiation of Drug Action in Male Rats: The Involvement of Hepatic Metallothionein, Dr. R. C. Schnell, Advisor

CERTIFICATION

Diplomate, American Board of Toxicology (1990)
- Re-certified in 1995, 2000, 2005 and 2010

WORK EXPERIENCE

SAR Safety Assessment – San Diego, CA **2010 – present**
President
- An independent consulting company specializing in toxicology, drug metabolism, pharmacokinetics and drug development.
- Services provided include creation of scientific and regulatory strategies for preclinical development of new (and existing) projects. Other services include; planning, monitoring, reporting and reviewing all types of preclinical development studies. Both small molecular weight (i.e., new chemical entities) and biotherapeutics (e.g., monoclonal antibodies, proteins, peptides etc.) are supported.

CovX Research, LLC – San Diego, CA **2006 – 2010**
Vice President – Preclinical Development
- Developed preclinical development strategy (i.e., toxicology and pharmacokinetics) for novel CovX monoclonal antibody based biotherapeutics (three successful IND filings in oncology and one in metabolic disease).
- Primary or co-author for all aspects of toxicology sections of all four successful IND filings. Primary or co-contributor with responsibility for all aspects of designing, monitoring and reporting of toxicology/pathology studies.
- Managed and supervised discovery focused vivarium.

Abbott Laboratories – Abbott Park, IL **1997 – 2005**
Global Director/Director/Manager – Preclinical Drug Metabolism and Pharmacokinetics
- Provided vision and managed ADME/PK research and personnel across the Abbott global organization.
- Led successful restructuring, reorientation and reorganization of all ADME/PK research to improve clinical success of new drug candidate molecules.
- Preclinical development lead for numerous potential in-licensing activities.

Section Head/Senior Research Investigator – Department of Toxicology **1990 – 1997**
- Supervised scientific staff in General Toxicology, Genetic and *In Vitro* Toxicology lab, drug safety representative to various drug development teams and Study Director for a variety of new candidate drugs in discovery/development.
- Significant contribution to the resolution for lack of human risk from rat Leydig cell tumors induced by Abbott proton pump inhibitor drug candidate

Sandoz Research Institute – East Hanover, NJ **1981 – 1990**
Section Head/Senior Research Investigator – Department of Toxicology
- Supervised scientific staff in General Toxicology, Toxicology Mechanism Laboratory, Acute and Ocular Toxicology labs.
- Drug safety representative to various drug development teams and Study Director for a variety of new candidate drugs in discovery/development.
- Led research and determined lack of human risk for rat Leydig cell tumors induced by Sandoz calcium channel blocker drug candidate. Also led research to determine mechanism and potential human relevance of cataracts in animals induced by a Sandoz HMG-CoA reductase inhibitor drug.

OTHER RELATED EXPERIENCE

EDUCATION

Lecturer — **1981 – Present**

- Provided over 50 lectures at various undergraduate, graduate and post-graduate organizations discussing various aspects of the pharmaceutical industry and the role of preclinical safety disciplines in drug development.

1995 - 1990

Committee Member

- Served on two Ph.D. research committees and three Ph.D. examining committees at the University of Connecticut and Rutgers University.

EXPERT WITNESS

Pharmaceutical Industry Researcher — **1987 - 1988**

- Provided expert testimony to governing committees in the New Jersey state Senate and House of Representatives on value of *in vivo* based pharmaceutical research to determine the efficacy and safety of new medications.

CORPORATE ADVISORY BOARDS

University of Washington – School of Pharmacy — **2003 – Present**

- Provided detailed evaluations and opinions related to funding, staffing and research activities.

BD Gentest Corporation — **2005**

- Provided vision of future research for toxicology and drug metabolism in the pharmaceutical industry.

CONTRACT AND GRANT REVIEWS

NIH/Neurotherapuetics Network

- Primary Reviewer on 2 contracts (March, 2011)

NIH/NIMH – National Cooperative Drug Discovery/Development Group for the Treatment of Mental Disorders and Drug or Alcohol Addiction

- Primary Reviewer on 4 grants (June, 2011)
- Primary Reviewer on 2 grants (November, 2011)
- Primary Reviewer on 2 grants (March, 2012)

COMMITTEES

BIO — **2007 – Present**

- Founding Chairperson of the Pharmacokinetics and Disposition – Expert Working Group.

- Member of BioSafe Leadership Committee (current status *ex officio*). — **2009 – Present**

PhRMA — **1987 - 2005**

- Served on various committees (*In Vitro* Toxicology, Drug Metabolism Technical Working Group, Drug Safety (liaison from Drug Metabolism), Biomarkers (liaison from Drug Metabolism).

1988 – 2002

COMMITTEES (cont.)

SOT **2008**

- Served as elected officer (President, President-Elect, Past President, Program Committee) for various regional SOT chapters.

ISSX

- Member of Organizing Committee for 2008 ISSX North American meeting.

PRESENTATIONS, BOOK CHAPTERS, PUBLICATIONS AND TECHNICAL REPORTS

Invited Presentations (25)

- Variety of topics including: the roles of toxicology, drug metabolism, pharmacokinetics and radiochemistry for improving the quality, success and efficiency in discovering/developing new drug candidates. Additional topics have also included how to improve the efficiency of identifying or determining the relevance of animal related effects to humans.

Book Chapters (3)

Publications (18) and Meeting Abstracts (27)

Webinars (3)

- Presented for Cambridge Healthtech Institute *What Types of Preclinical Studies are Required for an IND Submission*

Proprietary Internal Scientific Reports (427)

- Author or co-author on scientific and technical reports issued internally at CovX, Abbott and Sandoz.
- Primary focus for a majority was toxicological evaluation of new pharmaceutical compounds.

LANGUAGES

- English – native language

PROFESSIONAL SOCIETY MEMBERSHIPS

- Society of Toxicology (National and Southern California)
- International Society for the Study of Xenobiotics

Note: Details for all of the above activities can be provided upon request.