CURRICULUM VITAE

STANLEY ALLEN ROBERTS, Ph.D., DABT (Diplomate, American Board of Toxicology)

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EDUCATION:

1977-1981	Postdoctoral Fellow - Molecular Toxicology, Medical University of South Carolina, Charleston, South Carolina (Project: Structure-Toxicity Relationships of Acetaminophen: Correlation of Metabolism and Hepatotoxic Capability of Structural and Chemical Derivatives of Acetaminophen) Dr. David Jollow, Preceptor
1976-1977	Ph.D. - Pharmacology-Toxicology Purdue University, West Lafayette, Indiana (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
1973-1976	M.S. - Pharmacology-Toxicology Purdue University, West Lafayette, Indiana (Thesis: Tolerance Development to Cadmium-Induced Potentiation of Drug Action in Male Rats: The Involvement of Hepatic Metallothionein) Dr. R. C. Schnell, Advisor
1969-1973	B.S. - Animal Science Purdue University, West Lafayette, Indiana

EMPLOYMENT EXPERIENCE:

3/2010 – present	President, SAR Safety Assessment LLC (an independent consulting company)
1/2006 – 3/2010	Vice President, Preclinical Development, CovX Research LLC, San Diego CA 92121
6/2002 –12/2005	Global Director, Drug Metabolism and Preclinical Kinetics, Abbott Labs, Abbott Park, IL 60064-6114
9/1997 – 6/2002	Director/Manager Department of Drug Metabolism, Abbott Labs., Abbott Park, IL 60064
5/1993 – 9/1997	Section Head, Dept of Toxicology, Abbott Labs., Abbott Park, IL 60064
8/1990 – 5/1993	Senior Research Investigator, Dept. of Toxicology, Abbott Labs., Abbott Park, IL 60064
4/1981 – 7/1990	Senior Research Toxicologist (Fellow, Senior Scientific Staff), Department of Preclinical Safety Assessment, Sandoz, Inc., East Hanover, NJ
12/1977 – 4/1981	Postdoctoral Fellow, Department of Pharmacology, Medical University of South Carolina
8/1973 – 12/1977	Teaching and Research Assistant, Department of Pharmacology and Toxicology, Purdue University

ACADEMIC APPOINTMENTS:

1/1995 ~ 6/2004	Member of Adjunct Faculty, Department of Medicinal Chemistry and Molecular Pharmacology, Purdue University, West Lafayette, IN.
7/1987 ~ 12/1990	Adjunct Assistant Professor, Department of Clinical Laboratory Sciences, College of Medicine and Dentistry of New Jersey, Newark, NJ 07103
5/1984 ~ 12/ 1990	Associate Member of the Graduate Faculty Department of Pharmacology and Toxicology, College of Pharmacy Rutgers University, Piscataway, NJ 08854

CURRENT WORK RESPONSIBILITIES:

President, SAR Safety Assessment, San Diego CA

- Provide or review the scientific and regulatory strategies for toxicology, drug metabolism and pharmacokinetics for new (or existing) drug development projects. This can include gap analyses and project planning activities.
- Integrate scientific, management and regulatory strategies across all preclinical disciplines to insure successful project resolution in a team based environment including developing strategic, project and study specific plans.
- Compose/edit/review all types of documents including regulatory submissions (e.g., IND, NDA, BLA, PLA), position papers, white papers and study protocols.
- Full service – bidding, contracting, monitoring and reporting toxicology, drug metabolism and pharmacokinetic studies with appropriate partners (e.g., private research/marketing partners, CRO's, universities).
- Create, facilitate, assess and/or manage research plans to address mechanisms of toxicological/pathological findings in animals and their potential relevance to humans. This would include integration across all preclinical disciplines as well as with clinical researchers.
- Provide in- and out-licensing assessments, research strategy and data evaluations for companies and products.
- Actively participate in unique preclinical activities such as first-in-human dosage selection.
- Large molecular weight biotherapeutics (e.g., proteins, peptides and antibodies) as well as small molecular weight (NCE).

PREVIOUS WORK RESPONSIBILITIES (Selected Highlights):

A. Vice-President, Preclinical Development at CovX Research, LLC

- Responsible for strategy development plus the design, conduct and reporting of all preclinical safety assessment studies for novel CovX-body biotherapeutics. These studies include any related to the assessment of toxicological, pathological and safety pharmacology characteristics of new molecules. As necessary also assess ADME and pharmacokinetics characteristics of these new candidate drugs.
- Contribute to creation of company product portfolio. Evaluate and facilitate all aspects of discovery and development of company products.
- Supervise personnel responsible for conduct and reporting of preclinical toxicology, pathology and pharmacokinetic studies (one senior scientist)

COVX RESEARCH - PREVIOUS WORK RESPONSIBILITIES (cont.):

- Direct interaction with project teams to support world-wide regulatory submissions
- Budget – Responsible for annual budget of approximately $4 million dollars
- Timelines – Mentor leadership and membership of Clinical Development Team
- Supervision of company vivarium – Responsible for management and budgetary aspects of drug discovery program based vivarium. Insure regulatory and scientific compliance
- Serve on Institutional Animal Care and Use Committee
- Serve on Occupational Safety Committee
- Types of molecules – mono and bifunctional monoclonal antibody conjugates with peptidyl pharmacophores
- Disease targets – oncology (e.g., anti-angiogenic and anti-proliferatives) and metabolic disease

B. Abbott Laboratories Major Duties and Responsibilities:

Global Director – Metabolism and Preclinical Pharmacokinetics

1. Personnel Management Responsibilities
   a. Lake County, IL – United States
      Drug Metabolism (ADME)
      - 1 Director (Ph.D.)
      - 20 to 25 Junior Scientists (B.S./M.S.)
      - 14 Senior Investigators (Ph.D.)

      Radiochemistry
      - 1 Section Head (Ph.D.)
      - 4 Senior Investigators (primarily Ph.D.)
      - 1 Junior Scientist (B.S./M.S.)

      Preclinical Pharmacokinetics:
      - 1 Director (Ph.D.)
      - 1 Senior Investigator (Ph.D.)
      - 12 Junior Scientists (B.S./M.S.)

   b. Ludwigshafen, Germany (responsible for scientific management of site)
      Drug Metabolism (ADME) and Preclinical Pharmacokinetics (Drug Discovery support only)
      - 1 Director (Ph.D.)
      - 5 Senior Scientists (Ph.D.)
      - 10 Junior Scientists

2. Primary Job Responsibilities (across all world-wide corporate sites)
   a. Develop and harmonize common ADME and preclinical pharmacokinetic (PK): scientific research and philosophies, management strategies, scientific methods and practices.
   b. Evaluate global ADME efficiencies and monitor via performance metrics.
   c. Develop research and regulatory strategies with global Discovery Senior Management and Scientific Leaders regarding ADME, preclinical PK and Radiochemistry.
   d. Foster and encourage the development, evaluation and implementation of novel or emerging ADME/PK technologies to the efficiency or selection characteristics of new drugs for future human clinical trials.
   e. Ensure appropriate resources (personnel and equipment) are available to conduct necessary ADME and preclinical PK studies to support Discovery and Development activities.
   f. Ensure all documents/reports are reviewed and meet timelines for regulatory driven research.
   g. Facilitate integrated evaluation of all Preclinical Safety Divisional data including toxicology (e.g., Investigative and Regulatory), pathology, metabolism and pharmacokinetics (Non-Clinical and Clinical).

GLOBAL DIRECTOR ABBOTT - PREVIOUS WORK RESPONSIBILITIES (cont.):

h. Lead representative for preclinical development (i.e., toxicology, drug metabolism and pharmacokinetics) for numerous potential in-licensing activities
i. Facilitate successful achievement of appropriate career path for all employees via appropriate performance evaluation, mentoring and educational options.
j. Stay within appropriate budgetary constraints.
k. Budgetary Responsibilities (Lake County, USA)
   - Functional Budget – approx. $10,000,000
   - Capital Budget – approx. $1,500,000

Section Head, Department of Toxicology, Abbott Laboratories

1. Supervision of General Toxicology Staff:
   a. Direct supervision of five to seven Ph.D./M.S. level Study Directors
   b. Review reports and documents from Section
   c. Assist in Development of Departmental Goals and Philosophies

2. Supervision of Genetic and *In Vitro* Toxicology Laboratory
   a. Laboratory of one M.S. Senior Scientist and two B.S. Associate Scientists
   b. Assist in study design and supervision of GLP required studies and mechanistic studies regarding genotoxicity and safety issues of new drugs
   c. Review all projects, experiments and reports from laboratory

3. Project Management Liaison on Inter-disciplinary Drug Development Teams
   a. Assist in strategy development for new drugs and coordinate implementation of toxicology program
   b. Assist in creation of documents to support registration of new drugs to various regulatory authorities

4. Study Director
   a. Develop protocols, supervise conduct and compose final reports for non-GLP and GLP regulated toxicology studies for both in-house and contract laboratory studies.
   b. Direct supervision and monitoring of GLP toxicology studies.
   c. Supervision/guidance of technical staff conducting GLP toxicology studies.
   d. Preparation of final study reports for submission to the appropriate regulatory authorities

Senior Research Investigator, Department of Toxicology, Abbott Laboratories

1. Study Director for experimental studies to determine the mechanism of drug-induced toxicities
   a. Develop research strategies and conduct experiments designed to evaluate safety issues for new pharmaceutical compounds.
   b. Assist in projects to determine the mechanisms of drug-induced toxicities (and potential risk to humans) in the following areas:
      1. Leydig cell tumors
      2. Testicular degeneration, aspermatogenesis and prostatic atrophy
      3. Liver and kidney carcinogenicity

SECTION HEAD ABBOTT - PREVIOUS WORK RESPONSIBILITIES (cont.):

2. Study Director for IND and NDA Toxicology Studies:
   a. Prepare study protocols (GLP) including coordination with all relevant departments, contract laboratories and consultants.
      1. Both in-house and contract laboratory studies.
      2. Direct supervision and monitoring of GLP toxicology studies.
      3. Guidance of technical staff conducting GLP toxicology studies.

   b. Preparation of final study reports for submission to the appropriate regulatory authorities.
      1. Compose appropriate sections of report.
      2. Assist in correlation of toxicology, clinical pathology and histopathology data.

3. Types of Studies Conducted:
   a. Studies have been performed in rodents (rat, mouse) and non-rodents (dog and non-human primates).
   b. Duration of studies performed has encompassed single dose, sub-chronic and 2-year carcinogenicity.
   c. Administration routes of studies included oral (gavage, capsule and dietary admixture) and parenteral (subcutaneous and 24-hour continuous intravenous infusion).

4. Compounds/Products Evaluated:
   a. Synthetic chemistry-derived included: anti-hypertensives (renin inhibitors), anti-epileptics, various antibiotic classes, anti-ulcer (proton pump inhibitors), LHRH antagonists, 5-lipoxygenase inhibitors and attention deficit and anti-Alzheimer drugs
   b. Biotechnology-derived included: monoclonal antibodies (pharmacokinetic studies and program/strategy development and evaluation)

5. Project Management as Member of Inter-disciplinary Drug Development Teams
   a. Major responsibilities included: assist in development of toxicology program and coordinate toxicology studies
   b. Membership on following teams: angiotensin II receptor antagonists, peptide-based erythropoietin analogs, thrombolytics and cholinergic channel agonists

Sandoz Inc. Major Duties and Responsibilities:
Senior Research Toxicologist, Department of Preclinical Safety Assessment

1. Head of Toxicologic Mechanisms Laboratory:
   a. Manage design and renovation of laboratory (totaling approximately $200,000).
   b. Management of budget (approximately $250,000/year).
   c. Direct line supervision of 2 junior level scientists (B.S.).
   d. Design, evaluation and review of projects conducted within laboratory.
   e. Develop research strategies and conduct experiments designed to evaluate issues of safety of new pharmaceutical compounds.
   f. Projects to evaluate the mechanisms of drug-induced toxicities seen in laboratory animal toxicology studies and to determine the potential risk to humans in the following areas: Leydig cell tumors, testicular degeneration and aspermatogenesis, cataractogenesis, female reproductive tract tumors, thyroid dysfunction, mammary gland tumors, liver toxicity, induction of xenobiotic metabolizing enzymes, use of isolated hepatocytes in toxicology screens/pharmacokinetics/drug metabolism

SANDOZ SR. RESEARCH TOXICOLOGIST - PREVIOUS WORK RESPONSIBILITIES (cont.):

2. Management of Acute and Ocular Toxicology Testing:
   a. Direct line supervision of a Senior Scientist (M.S.) who was responsible for: protocol design, monitoring, interpretation and report composition for all acute toxicity testing as well as safety testing of all parenteral products.
   b. Protocol design, monitoring, interpretation and report composition for all eye irritation and special ocular toxicity studies.
   c. Performance of all in-house ocular (fundoscopic and slit-lamp) examinations.

3. Study Director/Responsible Toxicologist for IND and NDA Toxicity Studies:
   a. Preparations of Protocols (GLP) including coordination with all relevant departments, contract laboratories and consultants.
   b. Preparation of Final Reports for submission to the appropriate regulatory authorities including: composition of appropriate sections of reports, results correlated for toxicology and pathology reports.
   c. Directly supervised and monitored GLP toxicology studies.
   g. Interpreted and evaluated all toxicology and clinical pathology data and correlated with the histopathology data.
   h. Supervised technical staff that conducted GLP toxicology studies.

4. Types of Studies Conducted:
   a. Studies were performed in rodent (rat, mouse and hamster) and non-rodents (dog, rabbit and non-human primates).
   b. Duration of studies performed encompassed single dose to 2-year carcinogenicity (diet and gavage).
   c. Routes of studies included: in-dwelling intravenous catheter for 24-hour continuous infusion, acute and sub-chronic intravenous bolus, gavage, dietary admixture, subcutaneous and intraperitoneal.

5. Compounds/Products Evaluated:
   a. Synthetic chemistry-derived included: cardiovascular (calcium antagonists, angiotensin converting enzyme inhibitors and inotropic agents), major and minor tranquilizers, receptor agonists and antagonists for a variety of CNS & endocrinologic diseases, immunosuppressive agents (cyclosporin A), anti-diabetics, cholesterol lowering agents (HMGCoA reductase inhibitors), lipid altering agents, anti-platelet agents and anti-fungals.
   b. Biotechnology-derived included: peptide based cytokines and monoclonal antibodies.

6. Project Management as Member of Inter-disciplinary Drug Development Teams
   a. Develop toxicology program and schedule studies with management.
   b. Preparation of IND and NDA documents, summaries and etc.
   c. Preparation of official responses to regulatory agency questions.

7. Membership on various Drug Development/Discovery teams including: Cyclosporin A (ocular and dermal applications), HMGCoA Reductase Inhibitors (and other lipid altering agents), non-steroidal anti-inflammatories, anti-diabetics, neuroleptics and iontophoretic dermal delivery systems

RESEARCH INTERESTS:

New Drug Development, Regulatory Toxicology, Drug Metabolism and Molecular Toxicology

1. Strategy and program development for the successful submission of new drugs (small molecular weight and biotherapeutics) to regulatory authorities.
2. Strategy development, design and conduct preclinical toxicology and drug metabolism/pharmacokinetic studies for new drug development (small molecular weight and biotherapeutics)
2. Absorption, distribution, metabolism (detoxification and/or activation) and excretion of small molecular weight NCE's. Pharmacokinetic and disposition studies with large molecular weight biotherapeutics.
3. Development of *in vitro* and *in vivo* models for the detection of xenobiotic-induced toxicity.
4. Molecular mechanisms of target-organ toxicities in the liver, endocrine system and kidney.
5. Regulation of xenobiotic metabolizing enzymes by endocrine and dietary factors.

CURRENT PROFESSIONAL SOCIETY MEMBERSHIP:

1. Society of Toxicology
2. International Society for the Study of Xenobiotics
3. Regional Chapter of the Society of Toxicology (current-Southern California)

BOARD CERTIFICATION:

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

EDUCATIONAL ACTIVITIES (Lectures and Administrative):

Lectures

Three hours of lectures presented on: *The Design and Interpretation of Acute, Range-Finding and Subchronic Toxicity Studies and the Regulatory Requirements for the Duration of Pharmaceutical Toxicology Studies* in the "Pharmaceutical Toxicology Training Course" for the PhRMA Education and Research Institute on March 16-19, 1992 (Washington, DC) and on January 25-28, 1993 (Philadelphia, PA). November 14-17, 1993 (Georgetown, DC), October 31-November 3, 1994 (Wilmington, DE), March 27-30, 1995 (Georgetown, DC), October 30-November 2, 1995 (Chicago, IL), September 16-19 (Annapolis MD), September 15-18, 1997 (Arlington, VA), October 5-8, 1998 (Arlington, VA), October 4-7, 1999 (Arlington, VA), September 25-27, 2000 (Arlington, VA) and October 1-4, 2001 (Arlington, VA).

Course Co-director of "Pharmaceutical Toxicology Training Course" for the PhRMA Education and Research Institute from January 25-28, 1993 (Philadelphia, PA), November 14-17, 1993 (Georgetown, DC), March 27-30, 1995 (Georgetown, DC), October 30 - November 2, 1995 (Chicago, IL) and September 16-19 (Annapolis MD), September 15-18, 1997 (Arlington, VA), October 5-8, 1998 Arlington, VA), October 4-7, 1999 (Arlington, VA), September 25-27, 2000 (Arlington, VA) and October 1-4, 2001 (Arlington, VA).

Course Director of *Pharmaceutical Toxicology Training Course* for the PhRMA Educational Research and Education Institute given on November 14-17, 1993 (Georgetown, DC) and October 31-November 3, 1994 (Wilmington, DE).

One hour lecture presented on: *The Partnership of Safety Assessment and Drug Metabolism and Pharmacokinetics in Drug Discovery and Pre-clinical Development* in the "Drug Metabolism in Drug Development Course" for the PhRMA Education and Research Institute given on April 12, 2001 (Georgetown, DC)

EDUCATIONAL ACTIVITIES (continued):

One hour lectures presented on: *Drug Safety* in the *Basic Training Course on Drug Development* for the PhRMA Education and Research Institute given on September 29, 1992 (Arlington, VA), January 19, 1993 (Denver, CO) and May 24, 1993 (San Francisco, CA).

One hour lecture/discussion of *Applications of Toxicology and Pharmacology* in the *Beyond the Degree Career Expo in Life Sciences* and one hour panel discussion on *Let's Talk Business: Careers in the Biotech Industry* for University of California San Diego (UCSD) (April 19, 2007).

Two hour lecture/discussion Howard Hughes Medical Scholar Program. *An Evening with Scientists Careers in Toxicology, Pathology, Drug Metabolism and Pharmacokinetics* at the University of California San Diego (UCSD) (May 17, 2007).

Three hours of lecture *An Overview of PreClinical Development and the Role of Toxicology* for University of California San Diego (UCSD) Extension the Regulatory Affairs certification program (May 9 and 23, 2007; February 20, 2008; February 25, 2009 and February 22, 2010).

Presentation of approximately 20 lectures/seminars to undergraduate and graduate students on various subjects in toxicology at Purdue University, Rutgers University, University of Medicine and Dentistry of New Jersey and at the University of Connecticut.

Administrative

Served as member of two Ph.D. research committees (Dr. Joseph Brady, University of Connecticut and Dr. Anne Pilaro, Rutgers University).

Served as member of three Ph.D. examining committees (Dr. Joseph Brady, University of Connecticut and Drs. Lubow Jowa and Victoria Kindt, Rutgers University).

INVITED PRESENTATIONS

1 & 2 *Applied Toxicokinetics in New Drug Safety Assessmetnt* presented at the Pharmaceutical Manufacturers Association Meetings of DRUSAFE-WEST October 13, 1983 (Des Plaines, IL) and DRUSAFE-EAST November 9, 1983 (Cherry Hill, NJ).

3 & 4 *Correlation of Increased Gonadotropin Levels with Leydig Cell Tumors in the Sprague-Dawley Rat Induced by a Calcium Channel Blocker* at the Pharmaceutical Manufacturers Association Annual DRUSAFE Meeting, October 20, 1987 (San Antonio, TX) and Mid-Atlantic Society of Toxicology Fall Meeting, November 9, 1989 (Princeton, NJ).

5 *Ocular Toxicology: Current Issues* at the Pharmaceutical Manufacturers Association Meeting of DRUSAFE-EAST (Cherry Hill, NJ) May 2, 1989.

6 *Induction of Cataracts in Beagle Dogs Treated with an HMG-CoA Reductase Inhibitor* at the Pharmaceutical Manufacturers Association Meeting of DRUSAFE-EAST (Cherry Hill, NJ) November 30, 1989.

7 & 8 *Xenobiotic-Induced Increase in Leydig Cell Tumors in Rats: Disruption of the Hypothalamus-Pituitary-Gonad Axis* at the Fall Meeting of the Midwest Regional Society of Toxicology (Abbott Park, IL) on November 4, 1992 and to the Department of Pharmacology & Toxicology at Purdue University (W. Lafayette, IN) on April 7, 1993.

INVITED PRESENTATIONS (cont.)

9 *Preclinical Bottlenecks in Assessing the Toxicology and Metabolism of New Pharmaceuticals* at the IBC Conference on Drug Discovery (Boston, MA) in August 1999.

10 *What Are the Bottlenecks in Developing New Pharmaceuticals and How Can Radiochemists Help?* at the International Isotope Society Central United States-Meeting (Chicago, IL) in September 2000

11 *Strategies for Overcoming the Bottlenecks in Assessing the Metabolism and Toxicity of New Pharmaceuticals* at the IBC Conference on Drug Discovery (San Diego, CA) in November 2000.

12 *Using Old and New Techniques to Improve ADME Bottlenecks for Drug Discovery* at the IBC Conference on Drug Discovery (San Diego, CA) in November 2001.

13 *Examples of the Problem Solving Partnership between Drug Metabolism/Pharmacokinetics and Toxicology/Pathology* at the National Meeting of the American College of Toxicology (Hershey, PA) in November 2002.

14 & 15 Two hours of lectures on *The Role of Pharmacokinetics, Drug Metabolism and Toxicology in Identifying New Drugs* for the Purdue University Master's Degree Regulatory Affairs Certification Program via the Dept. of Industrial and Physical Pharmacy in the School of Pharmacy in February 2003, June 2003 and February 2004

16 & 17 One and one-half hour lectures on *The Discovery and Development of New Drugs: The Contributions of Pharmacokinetics, Drug Metabolism, Toxicology and Pathology at Abbott* for the Purdue University Master's Degree Regulatory Affairs Certification Program via the Dept. of Industrial and Physical Pharmacy in the School of Pharmacy in February 2004 and January 2005.

18 One and one-half hour lecture on *Regulatory Strategies and Documents* in Purdue University Master's Degree Regulatory Affairs Certification Program via the Dept. of Industrial and Physical Pharmacy in the School of Pharmacy in September 2005.

19 One and one-half hour lecture on *The Value of [^{3}H]-Radiolabels in the Discovery of New Pharmaceuticals* at the Fall meeting of the AAPS-Indiana Ohio Discussion Group in November, 2005

20 One-half hour lecture on *Industry Issues with the FDA Metabolites in Safety Testing Guidance* at the Fall joint meeting of PhRMA DruSafe – FDA in December 2005.

21 One-half hour lecture on *Using Preclinical Animal Studies to help select Phase 1 Clinical Trial Dosages for Unique Biologicals* at CHI Molecular Medicine Tri-Conference on Preclinical Development in February 2007

22 One-half hour lecture on *Selecting Dosages for First in Human Studies on Unique Biologicals* at BIO (Biotechnology Industry Organization) BioSafe General Membership meeting in October 2007

23 Twenty minute lecture on *Preclinical Development of a GLP-1 Agonist, CVX-096* at BIO (Biotechnology Industry Organization) BioSafe General Membership meeting in October 2008

24 Forty minute lecture on *The Role of Pharmacokinetics in the Design, Conduct and Interpretation of Toxicology Studies with Antibody-Based Biotherapeutics* at Cambridge Healthtech Institute PEGS (Protein Engineering Summit) in May 2010

INVITED PRESENTATIONS (cont.)

28 *CRO Study Conduct and Reporting* (30 minutes) at Covance Immunotoxicology Conference February 2012

INVITED WEBINARS

1, 2 & 3 Webinar (90 minutes) on *What Preclinical Studies should be Conducted to Enable an IND?* for Cambridge Healthtech Institute on October 2010, January 2011 and December 2011

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

1. PMA Drug-Safety Task Force on "*In Vitro* Toxicology" (1987 to 1993).

2. Councilor, Mid-Atlantic Society of Toxicology (1988 to 1990).

3. Program Committee, Midwest Region Society of Toxicology (1992 to 1994).

4. Midwest Region Society of Toxicology President-Elect (2000), President (2001), Past-President (2002)

5. PhRMA Drug Metabolism Technical Working Group (2001 through 2005)

6. PhRMA Drug Metabolism Technical Working Group (DMTWG) liaison to PhRMA Drug Safety Committee (DruSafe) (2004 through 2005)

7. PhRMA – DMTWG liaison to PhRMA Biomarkers Committee (2004 through 2005)

8. Biotechnology Information Association (BIO) Pharmacokinetics and Disposition Expert Working Group – Founding Chair (June 2007 to present)
   - Currently serving as voting member

9. International Society for the Study of Xenobiotics (ISSX) Meeting Organizing Committee for 2008 North American meeting in San Diego CA

10. BioSafe Toxicology Leadership Committee (November 2009 to present)
    - Currently serving as *ex officio* member

CORPORATE ADVISORY BOARDS

1. BD Gentest Corporation (January 2005)

2. University of Washington, School of Pharmacy (September 2003 to present)

EXPERT WITNESS

For New Jersey Research and Development Council before State Senate Natural Resources and Agricultural Committee, December, 1987 in opposition to legislation to prohibit the use of the Draize Test.

For New Jersey Health Products Council before State Assembly Health and Human Services Committee, September, 1988 in opposition to legislation to prohibit the use of the Draize test.

- In both instances the testimony centered on the current uses of the *in vivo* ocular toxicology testing (including the Draize Test) in safety assessment and the status of *in vitro* alternatives as supplements and/or replacements to the Draize Test.

BOOK CHAPTERS:

1. **Jollow, D.J., S.A. Roberts and V. Price**. *Biochemical Basis of Dose-Response Relationships in Reactive Intermediate Toxicity* in Second Biological Reactive Intermediates: Chemical Mechanisms and Biological Effects. p. 99-113, 1982. Plenum Press, New York, NY.

2. **Roberts, S.A., Woodnutt, G. and Bradshaw, C.W.** *Strategy Considerations for Developing the Preclinical Safety Testing Programs for Protein Scaffold Therapeutics* in Preclinical Safety Evaluation of Biopharmaceuticals. p. 633-648, 2008, Wiley and Sons, Hoboken NJ.

3 **Buckley, L.A., Garhyan, P., Ponce, R. and Roberts, S.A.** *Estimation of the Human Starting Dose for Phase 1 Clinical Programs* in Strategic, Technical and Regulatory Requirements for Investigational New Drug (IND) Applications. p. 423-464, 2010, Wiley and Sons, Hoboken NJ.

PUBLICATIONS:

1. **Roberts SA, Miya TS and Schnell RC**. Tolerance Development to Cadmium-Induced Alteration of Drug Action. Res. Commun. Chem. Pathol. Pharmacol. **14**:197-200 (1976).

2. **Schnell RC, Yuhas EM, Pence DH, Means JR, Roberts SA, Yau ET, Miya TS and Mennear JH**. Effect of Acute and Chronic Cadmium Treatment on Hepatic Drug Metabolism in Male Rats, Arch. Toxicol. **40**:269-277 (1978).

3. **Schnell RC, Means JR, Roberts SA and Pence DH**. Studies on Cadmium-Induced Inhibition of Hepatic Microsomal Drug Biotransformation in the Rat. Environ. Health Perspectives, **28**:273-279 (1979).

4. **Jollow, DJ, Roberts SA, Price VF, Longacre S and Smith C**. Pharmacokinetic Considerations in Toxicity Testing. Drug Metab. Rev. **13**:983-1008.

5. **Roberts SA and Schnell RC**. Cadmium Inhibition of *In Vitro* Hepatic Oxidative Drug Metabolism in the Rat. Comparison Between Ionic Cadmium and Cadmium-Thionein. Res. Commun. Chem. Pathol. Pharmacol. **35**:349-352 (1982).

PUBLICATIONS (cont.):

6. **Roberts SA and Schnell RC**. Cadmium-Induced Inhibition of Hepatic Drug Oxidation in the Rat. Time Dependency of Tolerance Development and Metallothionein Synthesis. Toxicol. Appl. Pharmacol. **64**:42-51 (1982).

7. **Robison RL, Visscher GE, Roberts SA, Engstrom RG, Hartman HA and Ballard FH**. Generalized Phospholipidosis Induced by an Amphiphilic Cationic Psychotropic Drug. Toxicol. Pathol. **13**:335-348 (1985).

8. **Roberts SA, Price v and Jollow DJ**. The Mechanisms of Cobalt Chloride-Induced Protection Against Acetaminophen Hepatotoxicity. Drug Metab. Disposition. **14**:25-33 (1985).

9. **Jollow DJ, Price VF, Roberts SA and Longacre S**. Chemical Modulation of Xenobiotic Metabolism *In Vivo* in Intermediary Xenobiotic Metabolism in Animals: Methodology, Mechanisms and Significance's, pp. 245-263, 1989. Taylor and Francis, New York.

10. **Roberts SA, Nett TM, Hartman HA, Adams TE and Stoll RE**. SDZ 200-110 Induces Leydig Cell Tumors by Increasing Gonadotropins in Rats. J. Am. Coll. Toxicol. **8**:487-505 (1989).

11. **Roberts SA, Price VF and Jollow DJ.** Acetaminophen Structure-Toxicity Studies: *In Vivo* Covalent Binding of a Non-Hepatotoxic Analog, 3-Hydroxyacetanilide. Toxicol. Appl. Pharmacol. **105**:195-208 (1990).

12. **Hockwin O, Evans M, Roberts SA and Stoll RE**. Post-Mortem Biochemistry of Beagle Dog Lenses After Treatment with Fluvastatin (Sandoz) for 2 Years at Different Dose Levels. Lens and Eye Toxicity Research **7**:563-575 (1990).

13. **Gillies SD, Young D, Lo K-M and Roberts SA**. Biological activity and *in vivo* clearance of Anti-tumor antibody/cytokine fusion proteins. Bioconjugate Chemistry 4:230-235 (1993).

14. **PMA/Drug Safety Subsection (Drusafe) *In Vitro* Toxicology Task Force**. A Collaborative Evaluation of an In Vitro Muscle Irritation Assay. Toxicol. Meth. 4:215-223(1994).

15. **Bjornsson, TD, Callaghan JT, Einolf HJ, Fischer V, Gan L, Grimm S, Kao J, King SP, Miwa G , Ni L, Kumar G, McLeod J, Obach RS, Roberts S, Roe A, Shah A, Snikeris F, SullivanJT , Tweedie D, Vega JM, Walsh J and Wrighton SA.** The Conduct of *In Vitro* and *In Vivo* Drug-Drug Interaction Studies: A Pharmaceutical Research and Manufacturers of America (PhRMA) Perspective. Drug Metab. Disp. 31:815-832, 2003.

16. **Kumar, GN, Jayanti VK, Johnson MK, Uchic J, Thomas S, Lee RD, Grabowski BA, Sham HL, Kempf DJ, Denissen JF, Marsh KC and Roberts SA**. Metabolism and Disposition of the HIV-1 Protease Inhibitor Lopinavir (ABT-578) given in Combination with Ritonavir in Rats, Dogs and Humans. Pharm Res 21:1622-1630, 2004.

17. **Ku WW, Bigger A, Brambilla G, Glatt H, Glocke E, Guzzie PJ, Hakura A, Honma M, Martus H-J, Obach RS and Roberts SA**. Strategy for Genotoxicity Testing-Metabolic Considerations. Mutation Res 627:59-77, 2007

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9 reports for Exploratory Dose Range-Finding Studies
4 reports for One-Month Subchronic Toxicity Studies (Rats)
5 reports for One and/or Three-Month Subchronic Toxicity Studies (Primates)
12 reports for Tissue Cross-Reactivity Binding Studies
1 report for Embryo Fetal Toxicity Study in Rats
1 report for Embryo Fetal Toxicity Study in Rabbits

Abbott Laboratories

2 reports for Exploratory Research Studies
1 report for Two-Week Subchronic Toxicity Study
3 reports for One-Month Subchronic Toxicity Studies
3 reports for Three-Month Subchronic Toxicity Studies
1 report for Six-Month Subchronic Toxicity Studies
1 report for One-Year Chronic Toxicity Study
3 reports for Rodent Carcinogenicity Studies
3 reports for Mechanistic Toxicology Studies

INTERNAL TECHNICAL REPORTS (Primary or Co-author):

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244 reports for Acute Toxicity Evaluation (Estimation of Lethality), Acute Tolerance and Parenteral Safety Evaluation Studies
37 reports for Range-Finding Toxicity Studies (2 to 13 weeks)
27 reports for One-Month Subchronic Toxicity Studies
7 reports for Three-Month Subchronic Toxicity Studies
19 reports for Six-Month Subchronic Toxicity Studies
2 reports for One-Year Chronic Toxicity Studies
9 reports for Rodent Carcinogenicity Studies
23 reports for Mechanistic Toxicology Studies