

ROBYN L. PHELPS, PHD



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SUMMARY

Nonclinical Drug Safety Evaluation Scientist and Director with over 25 years of industry, global pharmaceutical development, contract research, and academic experience in Toxicology, Safety Pharmacology, and Risk Assessment. In compliance with ICH global development practices, provides comprehensive, responsive, flexible, and innovative nonclinical scientific direction. Experienced in strategic drug development program planning/evaluation; CRO contract negotiations and placement; study design and management; preparation of regulatory documentation; and agency interactions as nonclinical representative. Knowledgeable of team based drug development practices, is an effective leader and team member who promotes cooperative input and innovation. Has specialized experience in the safety assessment of small molecules and botanically derived drug substances via parenteral and nonparenteral administration including dermal and ocular routes. Has additional expertise in the identification, development and utilization of unique administration routes and models for drug evaluation.

Specific areas of expertise include:

- Toxicology, Safety Pharmacology
- Nonclinical Drug Development Program Planning/Strategy
- Global Regulatory Interaction
- Preparation of Nonclinical Regulatory Documentation
- Pharmaceutical candidate assessment/due diligence for in-licensing
- ICH Compliant Study Design, Monitoring, Data interpretation, Report Preparation/Review
- CRO Liaison: Contracts, Technical Capability Assessment
- Nonclinical Model Design, Implementation, Data Acquisition/Evaluation
- Unique Administration Routes and Procedures
- Laboratory Management; Safety Pharmacology technology, training
- Technical Writing: position white papers, Manuscripts/Publications

EDUCATION

PhD (1991-1995)

Cardiovascular Physiology, Dept. of Zoology, University of British Columbia, Vancouver, BC, Canada

MSc (1989-1990)

Cardiovascular Dynamics, Dept. of Physiology, University of North Carolina, Greensboro, NC

BSc (1975-1979)

Mammalian Physiology, Departments of Physiology and Animal Husbandry, Michigan State University, East Lansing, MI

VPA (Licensed Veterinary Physician's Assistant) (1976), State of Michigan (Lapsed)

PROFESSIONAL EXPERIENCE

PHARMADVANCE CONSULTING, INC

President and Principal Advisor 2004-present

ALLERGAN, INC

Scientific Director, Safety Pharmacology,
Toxicology Division, Drug Safety Evaluation 2002-2006

Principal Scientist, Safety Pharmacology,
Toxicology Division, Drug Safety Evaluation 1999-2002

- Managed nonclinical toxicology and safety pharmacology evaluations/risk assessments (in-house and CRO) in accordance with global ICH regulations and within budget and timelines to meet project team milestones supporting compounds in development
- Multidisciplinary project team member and external nonclinical representative for safety pharmacology, toxicology, and drug safety evaluation
- Provided specific scientific expertise in dermal and ocular toxicology
- Recognized for scientific excellence in Safety Pharmacology and Toxicology through innovative approaches, introduction of new methodologies and direction of activities related to program-specific and basic research investigations

PROFESSIONAL EXPERIENCE (continued)

- Summarized data and authored nonclinical sections for IND/CTA, NDA, CTX and other national/international regulatory submissions
- Nonclinical representative to FDA and international regulatory agencies
- Performed due diligence for compound acquisitions and in-licensing
- Provided animal welfare guidance and compliance oversight as an AACUC Committee member

BATTELLE MEMORIAL INSTITUTE

Principal Investigator, Northwest Operations, Toxicology Dept. 1998-1999

Scientific Discipline Leader, Columbus Operations, Physiology Dept. 1996-1998

Principal Research Scientist, Northwest Operations,
Inhalation Toxicology Technical Group 1994-1996

- Principal Investigator and project administrator for pharmaceutical, chemical and industrial product toxicity testing
- Scientific client liaison officer for nonclinical drug investigations
- Safety Pharmacology leader responsible for coordination and integration of physiology support within multidisciplinary scientific services team and for new technology development/implementation
- Scientific discipline leader and technical Director of physiology for Battelle’s dual-campus pulmonary therapeutics/anti-neoplastic program
- Designed, conducted and interpreted toxicology and safety pharmacology studies of novel compounds and products per ICH regulations
- Prepared study protocols, authored reports, SOPs and manuscripts and provided GLP compliance oversight for physiologically based activities including preparation of CFR-compliant software and hardware validations
- Identified, developed and directed utilization of animal models and novel delivery devices for compound-specific toxicological/physiological evaluations
- Constructed and directed use of pulmonary sensory irritation rodent testing facility

PROFESSIONAL EXPERIENCE (continued)

**CANADIAN HEART AND STROKE FOUNDATION OF BRITISH COLUMBIA
AND THE YUKON**

Research Fellowship 1991-1994

- Designed animal model for murine hemodynamic evaluation to investigate species-dependent cardiovascular adaptations as they relate to the mechanisms of circulatory disease

R. J. REYNOLDS TOBACCO, CO.

Assoc. R&D Physiologist/Toxicologist, Director of Physiology Laboratory
Animal Biology Division 1987-1990

Assistant R&D Physiologist/Toxicologist
Animal Biology Division 1986-1987

THE BOWMAN GRAY SCHOOL OF MEDICINE

Research Surgical Specialist and Veterinary Medical Technician Supervisor
Department of Physiology and Pharmacology 1984-1986

Instructor in Microvascular Surgery
Department of Surgery 1982-1984

Assistant Research Scientist
Department of Physiology and Pharmacology 1981-1982

HONORS AND AWARDS

Excellence in Scientific Innovation, Robert Di Marco Award, RJ Reynolds, Inc., 1989

Excellence in Research, Canadian Heart and Stroke Foundation of British Columbia and the Yukon, 1994

Key Contributor, Business Results, Research and Development, Allergan, Inc., 2001

Key Contributor, Project/Program, Research and Development, Allergan, Inc., 2002

Key Contributor, Product Approval, Research and Development, Allergan, Inc., 2002

Authors and Inventors Recognition, Research and Development, Allergan, Inc., 2004

Award for Excellence, Bioassay Innovation, Drug Project Team, Allergan, Inc., 2004

Award for Excellence, Drug Safety Evaluation Business Innovation, Allergan, Inc., 2005

INVITED SPEAKER:

Arterial Hemodynamics of the Mouse: Modeling Human Disease. Annual Meeting of the British Columbia Heart and Stroke Foundation, Vancouver, BC, Canada, 1992

Radiotelemetry for Cardiovascular Evaluations in Laboratory Animals. Fourth Annual Biomedical Engineering and Biotechnology Forum, California State University, Long Beach, CA. 2000

Safety Pharmacology Study Design: Separately or Integrated into Toxicology Studies? Innovative Approaches to Safety Pharmacology Assessments Conference, Pharmaceutical Education Associates, 2004

Evaluation of Cardiac Drug Toxicity in Pharmaceutical Discovery and Development. Society of Toxicology 44th Annual Meeting, 2005

PROFESSIONAL MEMBERSHIPS

Society of Toxicology
Safety Pharmacology Society
American Physiological Society
Regulatory Affairs Professional Society
American Association for Laboratory Animal Science
Federation of American Societies for Experimental Biology
Sigma Xi, The Scientific Research Society

APPOINTMENTS:

Industry-Foundations Liaison Committee: Cardiovascular Section. The American Physiologic Society, 2005-2008
Scientific Advisor, Corporate Advisory Board, CorDynamics, Inc., 2006 - Present

CONTINUING EDUCATION

Cellular and Molecular Mechanisms of Apoptosis. Continuing Education Course. International Congress of Toxicology-VII Meeting, Seattle, WA, 1995
New Endpoints in Developmental and Reproductive Regulatory Studies: Methods for Success. Continuing Education Course. Society of Toxicology 34th Annual Meeting, Baltimore, MD, 1995
Aquatic Toxicology and Human Health Risk Assessments: Shared Metabolic Pathways, Shared Mechanisms of Action, Plus Data at the Bottom of the Dose Response Curve. Continuing Education Course. Society of Toxicology 35th Annual Meeting, Anaheim, CA, 1996
Unique Problems Associated with the Use of Animals in Inhalation Toxicology. Continuing Education Course. Society of Toxicology 36th Annual Meeting, Cincinnati, OH, 1997
In vitro and *in vivo* Assessment of Cutaneous Toxicity. Continuing Education Course. Society of Toxicology 37th Annual Meeting, Seattle, WA, 1998
Safety Pharmacology and Risk Assessment. Continuing Education Course PM. Society of Toxicology 39th Annual Meeting, Philadelphia, PA, 2000

CONTINUING EDUCATION (continued)

Molecular Approaches to a Comprehensive Understanding of Cardiotoxicity. Continuing Education Course. Society of Toxicology 39th Annual Meeting, Philadelphia, PA, 2000

Safety Pharmacology. Continuing Education Course. American College of Toxicology. 21st Annual Meeting, Washington DC, 2001

Cardiac Rhythms and Arrhythmia, Focus Group. 34th Congress of the International Union of Physiologic Sciences (IUPS), Christchurch, NZ, 2001

CNS Safety Evaluations: Current Issues and Future Directions. 2nd Annual Meeting of the Safety Pharmacology Society, Philadelphia, PA, 2002

Steps to Ensure Good Laboratory Practice in Compliance with 21 CFR Part 11. Innovative Approaches to Safety Pharmacology Assessments Conference, Philadelphia, PA, 2004

QT_c Assessment: Current Issues and Regulatory Expectations. 5th Annual Meeting of the Safety Pharmacology Society, Mannheim, Germany, 2005

Targeted Therapeutic Approach to Anti-Cancer Drug Development. Continuing Education Course. 45th Annual Meeting of the Society of Toxicology, San Diego, CA, 2006

Advanced Topics: Respiratory Safety Pharmacology. Continuing Education Course. 6th Annual Meeting of the Safety Pharmacology Society, San Diego, CA, 2006

Advanced Topics in Safety Pharmacology: Case Studies from Drug Selection to NDA. 8th Annual Meeting of the Safety Pharmacology Society, Madison, WI 2008

Novel Translational Safety Biomarkers and Safety First at the FDA. Informational Session. 48th Annual Meeting of the Society of Toxicology, Baltimore, MD 2009

PUBLICATIONS

deBethizy JD, Bates LE, Phelps, RL, and AT Mosberg. 1987. Demonstration of successful maintenance procedure for venous cannulae. R.J. Reynolds R & DM No. 181.

Mosberg AT, Coggins CRE, Burger GT, Hayes AW, Phelps RL, Reynolds SA, and PH Ayres. 1988. Ninety-day inhalation study in rats, comparing smoke from cigarettes which burned or only heated tobacco. 4. Minute Ventilation. *The Toxicologist*, 8:1009. (abstract)

PUBLICATIONS (continued)

Mosberg AT, Ayres PH, Phelps RL, and RA James. 1989. Estimation of the sensory irritation potential of sidestream smoke from cigarette prototypes in five categories. *R.J. Reynolds R & DM No. 95*.

Phelps RL, and RE Gatten, Jr. 1991. Thermal insensitivity of oxygen-pulse in spontaneously-active juvenile alligators. *Journal of Thermal Biology*, 16(5);303-307.

Mosberg AT, Phelps RL, deBethizy JD and KM Chang. 1991. "Effects of Continuous Infusion of Cotinine on Blood Pressure and Heart Rate in Rats". *The Biology of Nicotine*, eds. PM Lippiello, C Collins, JA Gray and JH Robinson. Raven Press, Ltd., New York. (Book Chapter)

Phelps RL, Gatten RE, Jr., and AT Mosberg. 1992. A new method for obtaining electrocardiograms in unrestrained crocodylian reptiles. *Laboratory Animal Science*, Feb. 42(1): 73-75.

Phelps RL, Jones DR, and AT Mosberg. 1995. Hemodynamics of rats and mice. 56. *Cardiovascular System. The International Toxicologist*, 7(1): 56-P-11 (abstract)

Phelps RL, Reynolds SA, Florek LJ, Ayres PH, Mosberg AT, Renne RA and GT Burger. 1995. Comparison of two cigarette designs by upper airways irritation assessment in the mouse. 20. *Respiratory Tract. The International Toxicologist*, 7(1): 20-P-15 (abstract)

Renne RA, Phelps RL, and AT Mosberg. 1997. Comparative subchronic inhalation study of mainstream smoke from a test cigarette and a reference cigarette in Syrian golden hamsters. 332. *Minute Ventilation. The Toxicologist*, Vol. 36, No. 1, Part 2:1687 (abstract)

Olajos EJ, Morgan EW, Renne RA, Salem H, McVeety B, Johnson R and RL Phelps. 1998. Acute inhalation toxicity of neutralized chemical agent identification sets (CAIS) containing agent in chloroform. *Journal of Applied Toxicology*, 18(5):363-372.

Minard KR, Wind RA and RL Phelps. 1998. A compact respiratory-triggering device for routine microimaging of laboratory mice. *Journal of Magnetic Resonance Imaging*, 8(6): 1343-1348.

Dill JA, Mellinger KH, Chou BJ, and RL Phelps. 1998. Disposition of inhaled gallium arsenide in the rat. NTP Internal Publication (abstract)

RA Renne¹, Phelps RL², Hayes JR³ and AT Mosberg³. 2000. A cigarette that primarily heats tobacco reduces toxicity of smoke in hamsters compared to a cigarette that burns tobacco. ¹Battelle, Richland, WA, USA; ²Allergan, Los Angeles, CA, USA; ³R. J. Reynolds Tobacco Co, Winston-Salem, NC, USA. *The Toxicologist* 36:332 (abstract)

PUBLICATIONS (continued)

Moore RJ¹, Phelps RL², Pierce JT¹, Baum SR¹, Dill JA¹, Johnson JD³, Graves SW³, Smith CS⁴, and AF Fuciarelli¹. 2000. Preliminary toxicokinetic studies of methyl-eugenol (meg) in female fischer 344/n rats and b6c3f₁ mice. ¹Battelle, Northwest Operations, Richland, WA; ²Allergan, Irvine, CA; ³Battelle, Columbus Operations, Columbus, OH; ⁴NIEHS/NTP, Research Triangle Park, Raleigh, NC. *The Toxicologist* 39:337 (abstract)

Renne RA, Phelps RL, Hayes JR, and AT Mosberg. 2001. A cigarette that primarily heats tobacco reduces toxicity of smoke in hamsters compared to a cigarette that burns tobacco. *The Toxicologist* 60:430 (abstract)

Woodward DF, Phelps RL, Krauss AH, Weber A, Short B, Chen J, Liang Y, Wheeler LA. 2004. Bimatoprost: a novel antiglaucoma agent. *Cardiovasc Drug Rev.* 2004; 22(2):103-20.

PRESENTATIONS

Phelps RL, Jones DR, and AT Mosberg, 1994. Hemodynamics of the Rat and Mouse. Presented at the Annual Meeting of the American Physiological Society, San Diego, CA

Phelps RL, Reynolds SA, Florek LJ, Ayres PH, Mosberg AT, Renne RA and GT Burger. 1995. Comparison of two cigarette designs by upper airways irritation assessment in the mouse. Presented at the International Congress of Toxicology – VII, Seattle, WA

Phelps RL, Jones DR, and AT Mosberg. 1995. Hemodynamics of rats and mice. Presented at the International Congress of Toxicology – VII, Seattle, WA

Minard KR, Wind RA and RL Phelps. 1997. A plethysmographic approach for routine respiratory gated MR imaging of live mice in a high-field, vertical bore magnet. Presented at the 5th Annual Meeting of the International Society for Magnetic Resonance in Medicine, Vancouver, B.C., Canada

Renne RA, Phelps RL, and AT Mosberg, 1997. Comparative subchronic inhalation study of mainstream smoke from a test cigarette and a reference cigarette in syrian golden hamsters. Presented at the 36th Annual Meeting of the Society of Toxicology, Cincinnati, OH

Phelps RL and DR Jones. 1997. A comparative study of allometric estimations and measured cardiovascular variables in small mammals. Presented at the Annual Meeting of the American Physiological Society, San Diego, CA

PRESENTATIONS (continued)

Fuciarelli AF¹, Moore RJ¹, Phelps RL², Pierce JT¹, Baum SR¹, Dill JA¹, Johnson JD³, Graves SW³, and CS Smith⁴. 2000. Toxicokinetic studies of isoeugenol (IEG) in female fischer 344/N rats and B6C3F₁ mice. ¹Battelle, Northwest Operations, Richland, WA; ²Allergan, Inc., Irvine, CA; ³Battelle Columbus Operations, Columbus, OH; ⁴NIEHS/NTP, Research Triangle Park, Raleigh, NC. Presented at the 39th Annual Meeting of the Society of Toxicology, Philadelphia, PA

Moore RJ¹, Phelps RL², Pierce JT¹, Baum SR¹, Dill JA¹, Johnson JD³, Graves SW³, Smith CS⁴, and AF Fuciarelli¹. 2000. Preliminary toxicokinetic studies of methyl-eugenol (meg) in female fischer 344/n rats and b6c3f₁ mice. ¹Battelle, Northwest Operations, Richland, WA; ²Allergan, Irvine, CA; ³Battelle, Columbus Operations, Columbus, OH; ⁴NIEHS/NTP, Research Triangle Park, Raleigh, NC. Presented at the 39th Annual Meeting of the Society of Toxicology, Philadelphia, PA

Reser D, Braun C, Lochner D, Clarke K, Oster M, Johnson L, Villasin M, Harner J, Chomicz S and RL Phelps. 2005. Imaging BOTOX[®] effects on muscle activity using thermal signature analysis. Toxins 2005 International Conference on Basic and Therapeutic Aspects of Botulinum and Tetanus Toxins. Denver, CO