Timothy W. Robison, Ph.D., DABT

SENIOR CONSULTANT, PHARMACEUTICALS

CONTACT INFORMATION

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PROFESSIONAL PROFILE

Dr. Timothy Robison is a Senior Consultant in ToxStrategies' Pharmaceuticals practice. He is a toxicologist with more than 39 years of experience in drug discovery and development, including close to 29 years at the U.S. Food and Drug Administration (FDA). He has nonclinical experience with biologic, biosimilar, and small-molecule products for a wide variety of pulmonary, allergy, autoimmune diseases, critical care, and transplant indications, as well as multiple routes of administration (e.g., inhalation, oral, intravenous, subcutaneous, intramuscular, intra-articular, and intranasal), in developing nonclinical sections (pharmacology, pharmacokinetics, toxicology) of regulatory documents (e.g., Interact, Pre-IND, IND, BLA/NDA), and regulatory agency interactions.

In the Center for Drug Evaluation and Research (CDER) at FDA, Dr. Robison served as a pharmacology/ toxicology supervisor/team leader and master reviewer in the Division of Pulmonary, Allergy, and Critical Care Products (DPACC) and Division of Rheumatology and Transplant Medicine (DRTM). As a supervisor, he was responsible for providing leadership and guidance to the Division's team of pharmacology/ toxicology reviewers with respect to evaluating nonclinical data submitted in Interact, Pre-Investigational New Drug Applications (INDs), INDs, and New Drug Applications (NDAs)/Biologics License Applications (BLAs). He ensured that the team's regulatory recommendations were scientifically sound and in line with applicable guidance documents. He also evaluated and presented recommendations on challenging scientific and regulatory issues to CDER senior management, including nonclinical hold deficiencies, complete responses to clinical holds, and other issues with the potential to influence clinical development.

Dr. Robison represented the Division's nonclinical expertise at internal, industry, and Advisory Committee (AC) meetings, and provided recommendations to the Executive Carcinogenicity Assessment Committee (ECAC) on dose selection for rodent carcinogenicity studies and carcinogenicity study outcomes. In addition, Dr. Robison participated in Pharmacology and Toxicology Coordinating Committee (PTCC) meetings and interacted with other CDER review divisions to address cross-division review issues.

As a reviewer, Dr. Robison was responsible for reviewing nonclinical data packages. He prepared comprehensive written reports of nonclinical data, including inhalation toxicology data, and provided regulatory conclusions and recommendations including recommendations for approved product labeling. Dr. Robison also worked on multidisciplinary teams, addressed cross-discipline review issues (e.g., excipients, impurities, genotoxic impurities, and leachables), and participated in meetings with industry representatives to provide regulatory advice and guidance on nonclinical drug development programs.

A member of the CDER PTCC Genetic Toxicity Subcommittee from 2001 to 2025, Dr. Robison co-chaired the subcommittee from 2006 to 2025. He also served on the Expert Working Group for the ICH S2 (R1) Guidance from 2008 to 2012, and as an FDA representative to the Product Quality Research Institute's initiative to develop thresholds for leachables in container closure devices used for parenteral drug products from 2013 to 2021. He was one of the organizers for two courses for manufacturing considerations and safety qualification of leachables (and extractables) from container closure devices used with parenteral drug products in 2015 and 2016. He was also one of the organizers of a working group in 2018 (and subsequently a subcommittee in 2019) for the safety qualification of extractables and leachables. This work culminated in a publication in 2021 on manufacturing considerations and safety qualification of leachables (and extractables) from container closure devices used with parenteral drug products.

Dr. Robison's previous academic experience includes appointments as a Research Assistant Professor of Molecular Pharmacology and Toxicology in the Pediatrics Division of Neonatology at the Children's Hospital of Los Angeles, and at the University of Southern California School of Pharmacy from 1986 to 1996.

EDUCATION AND DEGREES EARNED

1986 Ph.D., Pharmacology and Toxicology, University of California, Davis

1980 B.S., Biochemistry, University of California, Davis

LICENSES AND CERTIFICATIONS

2004 Diplomate of the American Board of Toxicology (DABT) *(recertified 2024, 2019, 2014, 2009)*

PROFESSIONAL HONORS/AWARDS

1997-2000	National Institutes of Health R01 Grant
1995-1996	National Institutes of Health Grant
1994-1995	American Lung Association of Los Angeles County Grant
1992-1996	National Institutes of Health First Award
1991-1992	Children's Hospital of Los Angeles Biomedical Research Support Grant
1990-1991	Children's Hospital of Los Angeles Biomedical Research Support Grant
1990-1991	American Lung Association of Los Angeles County Grant
1988-1989	California American Lung Association Postdoctoral Fellowship Award
1985-1986	University of California, Davis Jastro-Shields Graduate Research Award
1984-1985	University of California, Davis Graduate Student Research Award

PROFESSIONAL ASSOCIATIONS

1989–Present	Society of Toxicology (*Full member*)
2007–Present	American Society for Pharmacology and Experimental Therapeutics (ASPET)
1990-2006	American Physiological Society (APS)
1979–Present	American Association for the Advancement of Science
1997-Present	Society of Teratology
1999-Present	American College of Toxicology
2015-Present	Society of Toxicologic Pathology

SCIENTIFIC PANELS, COMMITTEES, AND WORKGROUPS

2018-2021	Lead, Product Quality Research Institute (PQRI) Extractables and Leachables Working Group/Subcommittee
2013-2021	Center for Drug Education and Research (CDER) Representative, PQRI, Regarding Extractables and Leachables in Parenteral Drug Products
2006-2025	Co-Chair, FDA/CDER Genetic Toxicology Committee (Member, 2001-2025)
2008-2012	Member, ICH Expert Working Group for ICH S2(R1) Genetic Toxicity Guidance,
2006-Present	Member, FDA/CDER Biologics Subcommittee
2002-2025	Member, FDA/CDER Pharmacokinetic/Toxicokinetic Subcommittee
2002-2010	Member, FDA/CDER Nonclinical Pharmacogenomics Subcommittee
2014-2018	Member, National Center for Toxicological Research (NCTR) Peer Review Promotions Committee
1998-2005	Member, FDA/CDER Inactive Ingredients Subcommittee

PEER-REVIEWED PUBLICATIONS

Faske JB, Gong B, LeBlanc DP, Funk J, Zhou G, Kehm S, White PA, **Robison T**, et al. 2026. Expansion of preexisting cancer driver mutant clones is induced by the genotoxic carcinogen benzo[b]fluoranthene in MutaMouse lung. Toxicol Sci 209(3):kfag030; doi: 10.1093/toxsci/kfag030.

Petibone DM, Shemansky JM, **Robison TW**, Atrakchi AH, Heflich RH. 2026. Assessing carcinogenic outcomes following short-term exposure to potentially DNA-reactive drugs: Are available data sufficient to inform risk assessment? Regul Toxicol Pharmacol 165(Feb):105993. doi: 10.1016/j.yrtph.2025.105993.

Xia L, Yan J, Chen Y, **Robison TW**, Chen T. 2025. Germline mutagenicity of molnupiravir and its active form, β-d-N4-hydroxycytidine, in Caenorhabditis elegans evaluated using whole-genome sequencing. Toxicol Lett 409(Jun):138-144; doi: 10.1016/j.toxlet.2025.05.007.

Dobrovolsky VN, Atiq OT, Heflich RH, Maisha M, McKinzie PB, Pearce MG, **Robison TW**. 2024. Erythrocyte PIG-A mutant frequencies in cancer patients receiving cisplatin. Cancer Med 13(3):e6895; doi: 10.1002/cam4.6895.

Wang Y, Le Y, Harris KL, Chen Y, Li X, Faske J, Wynne RA,..., **Robison TW**, et al. 2024. Repeat treatment of organotypic airway cultures with ethyl methanesulfonate causes accumulation of somatic cell mutations without expansion of bronchial-carcinoma-specific cancer driver mutations. Mutat Res Genet Toxicol Environ Mutagen 897(Jul):503786; doi: 10.1016/j.mrgentox.2024.503786.

Du H, Pan B, Alund AW, Yan J, Chen Y, **Robison TW**, Chen T. 2023. Evaluation of mutagenic susceptibility of different stages in germ cell development of Caenorhabditis elegans using whole genome sequencing. Arch Toxicol 97(8):2261-2272; doi: 10.1007/s00204-023-03526-z.

Pan B, Kaldhone PR, Alund AW, Du H, Guo X, Yan J, Chen Y,…, **Robison TW**, et al. 2021. Mutagenicity of silver nanoparticles evaluated using whole genome sequencing in mouse lymphoma cells. Nanotoxicol 15(3):418-432; doi: 10.1080/17435390.2021.1894614.

Revollo JR, McKinzie PB, **Robison TW**, Dobrovolsky VN. 2021. Mutational signatures in T-lymphocytes of rats treated with N-propyl-N-nitrosourea and procarbazine. Environ Mol Mutagen 62(6):350-363; doi: 10.1002/em.22448.

Robison TW, Heflich RH, Manjanatha MG, Elespuru R, Atrakchi A, Mei N, Ding W. 2021. Appropriate in vivo follow-up assays to an in vitro bacterial reverse mutation (Ames) test positive investigational drug candidate (active pharmaceutical ingredient), drug- related metabolite, or drug-related impurity. Mutat Res Gen Toxicol Environ Mutagen 868-869:503386; doi: 10.1016/j.mrgentox.2021.503386.

Wang Y, Mittelstaedt RA, Wynne R, Chen Y, Cao X, Muskhelishvili L, Davis K, **Robison TW**, et al. 2021. Genetic toxicity testing using human in vitro organotypic airway cultures: Assessing DNA damage with the CometChip and mutagenesis by duplex sequencing. Environ Mol Mutagen 62(5):306-318; doi: 10.1002/em22444.

Guo X, Seo JE, Petibone D, Tryndyak V, Lee UJ, Zhou T, **Robison TW**, Mei N. 2020. Performance of HepaRG and HepG2 cells in the high-throughput micronucleus assay for in vitro genotoxicity assessment. J Toxicol Environ Health A 83(21-22):702-717; doi: 10.1080/15287394.2020.1822972.

Revollo JR, Dad A, Pearce MG, Mittelstaedt RA, Casildo A, Lapidus RG, **Robison TW**, Dobrovolsky VN. 2020. CD59-deficient bone marrow erythroid cells from rats treated with procarbazine and propyl-nitrosourea have mutations in the Pig-a gene. Environ Mol Mutagen 61(8):797-806; doi: 10.1002/em.22402.

Seo JE, Wu Q, Bryant M, Ren L, Shi Q, **Robison TW**, Mei N, Manjanatha MG, Guo X. 2020. Performance of high-throughput CometChip assay using primary human hepatocytes: A comparison of DNA damage responses with in vitro human hepatoma cell lines. Arch Toxicol 94(6):2207-2244; doi: 10.1007/s00204-020-02736-z.

Revollo JR, Dad A, Pearce MG, Mittelstaedt RA, **Robison TW**, Dobrovolsky VN. 2019. Pig-a mutations in bone marrow erythroblasts of rats treated with 7,12-dimethyl-benz[a]anthracene. Mutat Res 848(Dec):503106; doi: 10.1016/j.mrgentox.2019.503106.

Seo JE, Tryndyak V, Wu Q, Dreval K, Pogribny I, Bryant M, Zhou T, **Robison TW**, et al. 2019. Quantitative comparison in vitro genotoxicity between metabolically competent HepaRG cells and HepG2 cells using the high-content Comet Chip assay. Arch Toxicol 93(5):1433-1448; doi: 10.1007/s00204-019-02406-9.

Revollo JR, Pearce MG, Dad A, Petibone DM, **Robison TW**, Roberts D, Dobrovolsky VN. 2018. Analysis of mutation in the rat Pig-a assay: I) Studies with bone marrow erythroid cells. Environ Mol Mutagen 59(8):722-732; doi: 10.1002/em.22211.

Dobrovolsky VN, Elespuru RK, Bigger CA, **Robison TW**, Heflich RH. 2011. Monitoring humans for somatic mutation in the endogenous PIG-a gene using red blood cells. Environ Mol Mutagen 52(9):784-94; doi: 10.1002/em.20667.

Robison TW. 2011. Dealing with positive in vitro mammalian cell genotoxicity assays. Inter Drug Discovery 6(5):40-43.

Goodsaid FM, Amur S, Aubrecht J, Burczynski ME, Catalano J, Carl K, Charlab C,…**Robison TW**, et al. 2010. Experience and impact of the US FDA and EMEA Voluntary Data Submissions (VXDS). Nat Rev Drug Discover 9:435-45; doi: 10.1038/nrd3116.

Elespuru RK, Agarwal R, Atrakchi A, Bigger CAH, Heflich RH, Jagannath D, Levy DD…**Robison TW**, et al. 2009. Current and future application of genetic toxicity assays: The role and value of in vitro mammalian assays. Toxicol Sci 109(2):172-179; doi: 10.1093/toxsci/kfp067.

Robison TW, Jacobs A. 2009. Metabolites in safety testing. Bioanalysis 1(7):1193-1200; doi: 10.4155/bio.09.98.

Leighton JK, Brown P, Ellis A, Harlow P, Harrouk W, Pine PS, **Robison T**, Rosario L, Thompson K. 2006. Workgroup Report: Review of genomic data based on experience with mock submissions: View of the CDER Pharmacology Toxicology Nonclinical Pharmacogenomics Subcommittee. Environ Health Perspect 114:573-578; doi: 10.1289/ehp.8318.

Zhou HF, Duncan RF, **Robison TW**, Forman HJ. 1997. Ca^{2+}-dependent p47phox translocation in hydroperoxide modulation of the alveolar macrophage respiratory burst. Amer J Physiol 273(5 Pt 1):L1042L1047; doi: 10.1152/ajplung.1997.273.5.L1042.

Liu RM, Hu H, **Robison TW**, Forman HJ. 1996. Differential regulation of γ- glutamyl transpeptidase and γ-glutamylcysteine synthetase by tert-butylhydroquinone in rat lung epithelial L2 cells. Amer J Resp Cell Mol Biol 14(2):186-191; doi: 10.1165/ajrcmb.14.2.8630269.

Liu RM, Hu H, **Robison TW**, Forman HJ. 1996. Increased γ-glutamylcysteine synthetase and γ-glutamyl transpeptidase activities enhance resistance of rat lung epithelial L2 cells to quinone toxicity. Amer J Resp Cell Mol Biol14(2):192-197; doi: 10.1165/ajrcmb.14.2.8630270.

Robison TW, Kim KJ. 1996. Enhancement of airway epithelial Na^+,K^+-ATPase activity by nitrogen dioxide and the protective role of nordihydroguaiaretic acid. Amer J Phys 270(2 Pt 1):L266-L272; doi: 10.1152/ajplung.1996.270.2.L266.

Robison TW, Zhou HF, Kim KJ. 1996. Generation of glycolaldehyde from airway epithelial monolayers exposed to NO_2 and its effects on sodium pump activity. Environ Health Perspect 104(8):850-854; doi: 10.1289/ehp.96104852.

Forman HJ, Shi MM, Iwamato T, Liu RM, **Robison TW**. 1995. Measurement of γ-glutamyltranspeptidase and γ-glutamylcysteine synthetase activities in cells. Methods Enzymol 252:66-71; doi: 10.1016/0076-6879(95)52009-0.

Mathias NR, Kim KJ, **Robison TW**, Lee VHL. 1995. Development and characterization of rabbit tracheal epithelial cell monolayer models for drug transport studies. Pharm Res 12(10):1499-1505; doi: 10.1023/a:1016291522345.

Robison TW, Forman HJ, Thomas MJ. 1995. Release of aldehydes from rat alveolar macrophages exposed in vitro to low concentrations of nitrogen dioxide. Biochim Biophys Acta 1256(3):334-340; doi: 10.1016/0005-2760(95)00041-a.

Robison TW, Kim KJ. 1995. Dual effect of nitrogen dioxide on barrier properties of guinea pig tracheobronchial epithelial monolayers cultured in an air-interface. J Toxicol Environ Health 44(1):57-71; doi: 10.1080/15287399509531943.

Robison TW, Zhou HF, Forman HJ. 1995. Modulation of ADP-stimulated inositol phosphate metabolism in rat alveolar macrophages by oxidative stress. Arch Biochem Biophys 318(1):215-220; doi: 10.1006/abbi.1995.1223.

Thomas MJ, **Robison TW**, Samuel M, Forman HJ. 1995. Detecting and identifying volatile aldehydes as dinitrophenylhydrazones using gas chromatography mass spectrometry. Free Rad Biol Med 18(3):553-557; doi: 10.1016/0891-5849(94)e0121-x.

Robison TW, Kim KJ. 1994. Air-interface cultures of guinea pig airway epithelial cells: Effect of active sodium and chloride transport inhibitors on bioelectric properties. Exp Lung Res 20(2):101-117; doi: 10.3109/01902149409064376.

Robison TW, Dorio RJ, Kim KJ. 1993. Formation of tight monolayers of guinea pig airway epithelial cells cultured in an air-interface: Bioelectric properties. BioTechniques 15(3):468-473. PMID: 8217160.

Robison TW, Forman HJ. 1993. Dual effect of nitrogen dioxide upon rat alveolar macrophage arachidonate metabolism. Exp Lung Res 19(1):21-36; doi: 10.3109/01902149309071078.

Robison TW, Murphy JK, Beyer LL, Richters A, Forman HJ. 1993. Depression of stimulated arachidonate metabolism and superoxide production in rat alveolar macrophages following *in vivo* exposure to 0.5 ppm NO_2. J Toxicol Environ Health 38(3):273-292; doi: 10.1080/1528739930953171.

Rajpert-De Meyts E, Shi M, Chang M, **Robison TW**, Groffen J, Heisterkamp N, Forman HJ. 1992. Transfection with gamma-glutamyl transpeptidase enhances recovery form glutathione depletion using extracellular glutathione. Toxicol Appl Pharmacol 114(1):56-62; doi: 10.1016/0041-008x(92)90096-b.

Dalessandri KM, Giri SN, **Robison TW**, Hayashi HH, Talken L. 1991. No change in $alpha_1$ adrenoreceptors in canine femoral arteries after lumbar sympathectomy. J Invest Surg 4(2):137-140; doi: 10.3109/08941939109140773.

Robison TW, Duncan DP, Coates TD, Forman HJ. 1990. Inhibition of production of LTB_4 and chemotactic agent from rat alveolar macrophages treated with t- butyl hydroperoxide is independent of ATP depletion. Biochim Biophys Acta 1045(1):9-16; doi: 10.1016/0005-2760(90)90197-6.

Robison TW, Duncan DP, Forman HJ. 1990. Chemoattractant and leukotriene B_4 production from rat alveolar macrophages exposed to nitrogen dioxide. Amer J Resp Cell Molecular Biol 3(1):21-26; doi: 10.1165/ajrcmb/3.1.21.

Robison TW, Forman HJ. 1990. t-Butyl hydroperoxide stimulates alveolar macrophage biosynthesis of cyclooxygenase products. Prostaglandins 40(1):13-28; doi: 10.1016/0090-6980(90)90053-x.

Robison TW, Sevanian A, Forman HJ. 1990. Inhibition of arachidonic acid release by nordihydroguaiaretic acid and its antioxidant action in rat alveolar macrophages and Chinese hamster lung fibroblasts. Toxicol Appl Pharmacol 105(1):113-122; doi: 10.1016/0041-008x(90)90363-y.

Robison TW, Giri SN, Wilson DW. 1989. Effects of chronic administration of doxorubicin on myocardial creatine phosphokinase and antioxidant defenses and levels of lipid peroxidation in tissues and plasma of rats. J Biochem Toxicol 4(2):87-94; doi: 10.1002/jbt.2570040204.

Robison TW, Duncan DP, Forman HJ. 1988. Kinetics of uptake and distribution of arachidonic acid by rat alveolar macrophages. Prostaglandins 36(4):443-461; doi: 10.1016/0090-6980(88)90042-1.

Giri SN, Sanford DA, **Robison TW**, Tyler NK. 1987. Impairment in coupled beta-adrenergic receptor and adenylate cyclase system during bleomycin-induced lung fibrosis in hamsters. Exp Lung Res 13(4):401-416; doi: 10.3109/01902148709069601.

Robison TW, Giri SN. 1987. Effects of chronic administration of doxorubicin on heart phospholipase A_2 activity and *in vitro* synthesis and degradation of prostaglandins in rats. Prostaglandins Leukot Med 26(1):59-74; doi: 10.1016/0262-1746(87)90152-1.

Robison TW, Giri SN. 1987. Effects of chronic administration of doxorubicin on myocardial alpha-adrenergic receptors, histamine, cyclic nucleotides, calcium, norepinephrine, calmodulin, and guanylate cyclase activity, and plasma catecholamines in rats. Virchows Archiv B 54(3):182-189; doi: 10.1007/BF02899210.

Robison TW, Giri SN. 1987. Effects of chronic administration of doxorubicin on plasma levels of prostaglandins, TxB_2 and fatty acid in rats. Cancer Chemother Pharmacol 19(3):213-220; doi: 10.1007/BF00252975.

Robison TW, Giri SN. 1986. Effects of chronic administration of doxorubicin on heart adenylate cyclase activity in mice. Biochem Biophys Res Commun 136(2):745-752; 10.1016/0006-291x(86)90502-4.

Robison TW, Giri SN. 1986. Effects of chronic administration of doxorubicin on myocardial beta-adrenergic receptors. Life Sci 39(8):731-736; doi: 10.1016/0024-3205(86)90021-4.

Robison TW, Giri SN, Parker HR, Curry DL, Ishizaki G, Schiedt M. 1985. Effects of intravenous infusion of doxorubicin on blood chemistry, blood pressure, and heart rate in rabbits. J Appl Toxicol 5(6):382-387; doi: 10.1002/jat.2550050609.

Robison TW, Giri SN. 1984. Effects of ibuprofen on doxorubicin toxicity in mice. Pharmacol Res Commun 16(4):409-418; doi: 10.1016/s0031-6989(84)80008-9.

NON-PEER-REVIEWED PUBLICATIONS/REPORTS/BOOK CHAPTERS

Robison TW (Chair) and Extractables and Leachables Subcommittee. 2021. Safety Thresholds and Best Demonstrated Practices for Extractables and Leachables in Parenteral Drug Products (Intravenous, Subcutaneous, and Intramuscular) PQRI Document. October 28, 2021.

Thomas MJ, **Robison TW**, Forman HJ. 2000. Assessment of tissue injury from reactive oxygen metabolites. In: Chronic Lung Disease in Early Infancy. R.D. Bland and J.J. Coalson, eds. Marcel Dekker, Inc., New York. pp. 779-792.

Robison TW. 1993. Inositol phosphates and calcium signaling. In: Free Radical Biology & Medicine, Vol. 26: Advances in Second Messenger and Phosphoprotein Research. James W. Putney, Jr., volume ed; Paul Greengard and G. Alan Robison, series eds.

Forman HJ, **Robison TW**, Skelton DC, Duncan DP. 1992. Perturbation of arachidonic metabolism and membrane function by oxidants. In: The Molecular Basis of Oxidative Damage by Leukocytes. CRC Press, Inc.

Forman HJ, **Robison TW**. 1991. Arachidonic acid metabolites and phagocytic cells as mediators of tissue injury. In: In Vitro Toxicology: Mechanisms and New Technology. A.M. Goldberg, ed. Mary Ann Liebert, Inc., New York. pp. 3-17.

PRESENTATIONS

Internal FDA Workshops, Panels, Courses, Guidance, and Presentations

Organizer, workshop to discuss how many doses of an Ames- positive (DNA-reactive) investigational drug can be safely administered to healthy subjects. Workshop included a panel with expertise in genotoxicity and carcinogenicity to discuss the health risks associated with exposure to an Ames-positive compound. 2019.

Co-lead and Presenter, FDA Extractables and Leachables course. This course went into significantly more detail about designs of extractables and leachables studies with the container closure system (adequacy of design and toxicological evaluation of leachables to assess patient safety). Identified speakers, subject matter to cover, and presented. Over 200 reviewers attended. November 2016.

Presenter, FDA Genetic Toxicity course. Presented on the *in vivo* micronucleus test (with use of manual cell counting as well as flow cytometry for cellular analysis). 2016.

Presenter, FDA Genetic Toxicity course. Presented on the *in vitro* bacterial reverse mutation assay. 2016.

Co-lead and Presenter, FDA Extractables and Leachables course. This course provided a background into what extractables and leachables are, and the safety risks that they can pose to subjects using the products. Identified speakers and subject matter to cover, and presented. Over 400 reviewers attended. May 2015.

Author, Good Reviewer Practice TeachTool module, *in vivo* micronucleus test. 2015.

Organizer and Presenter, FDA course presenting changes introduced with the adoption of the ICH S2 (R1) Guidance "Guidance for Industry S2(R1) Genotoxicity Testing and Data Interpretation for Pharmaceuticals Intended for Human Use." Presented on changes introduced by the Guidance. 2011.

Author, Good Reviewer Practice TeachTool module for the *in vitro* bacterial reverse mutation assay (Ames test). The TeachTool provides supports for the GRP template by illustrating good review practice principles, and has a potential CDER-wide impact. For new reviewers, it offers specific and helpful training. For experienced reviewers, it serves as a reference source or refresher for studies. Updated 2011 and 2006; original version authored 2001.

Presenter, Appropriate safety margin for immune complex-mediated vascular injury associated with a monoclonal antibody. Silver Spring, MD, September 3, 2008.

Presenter, Point: Counterpoint - Discussion of the Revised ICH S2(R1) Genetic Toxicity Guidance. Silver Spring, MD, September 3, 2008.

Presenter, Human metabolite case study: Metabolite Ro-205-2349. Gaithersburg, MD, March 2, 2005.

Presenter, Carcinogenicity testing of pantoprazole. FDA/CDER, September 1999.

Invited Presentations

Robison TW. A regulatory perspective. Symposium S03-3 in Symposium S03: Beyond the Vessel Wall: Translational Insights into Vascular Information, American College of Toxicology (ACT) 47th Annual Meeting, San Antonio, TX, November 2026.

Robison TW. How many doses of an Ames-positive/mutagenic (DNA reactive) drug can be safely administered to Healthy Subjects? Genetic Toxicology Association, 2021.

Robison TW. Regulatory evaluation of leachables that are potential sensitizers. Symposium: Harnessing Current Knowledge on Sensitization Thresholds and Applying It to Extractable and Leachable Impurities in Drug-Device Combination Products, American College of Toxicology Annual Meeting, 2020.

Robison TW. Extractables and leachables: Application of thresholds and expectations: Regulatory perspectives. USP/PQRI/FDA Annual Meeting, 2018.

Robison TW. Extractables and leachables: Outline of current regulatory framework – Challenges and uncertainties. Webinar presentation to Turkish Regulatory Authority and Pharmaceutical Association, December 2018.

Robison TW. Use of thresholds for the safety qualification of leachables in parenteral drug products from a regulatory perspective. Smithers Rapra Extractables and Leachables USA Annual Meeting, 2018.

Robison TW. Dealing with extractables & leachables from a regulatory perspective: 1. Design of extractables & leachables studies; and 2. Safety assessment of leachables. American Association for Pharmaceutical Sciences, 2017.

Robison TW. Dealing with extractables & leachables from a regulatory perspective: 1. Design of extractables & leachables studies; and 2. Safety assessment of leachables. Smithers Rapra Extractables and Leachables USA Annual Meeting, 2017.

Robison TW. Dealing with extractables & leachables from a regulatory perspective: 1. Design of extractables & leachables studies; and 2. Safety assessment of leachables. USP/PQRI/FDA Annual Meeting, 2017.

Robison TW. Extractables & leachables: 1. Design of extractables & leachables studies; and 2. Safety assessment of leachables. Smithers Rapra Extractables and Leachables USA Annual Meeting, 2016.

Robison TW. Safety assessment of extractables and leachables from a regulatory perspective. American College of Toxicology Annual Meeting, 2015.

Robison TW. Safety assessment of extractables and leachables from a regulatory perspective. Smithers Rapra Extractables and Leachables USA Annual Meeting, 2015.

Barat S, **Robison TW**. Information and report formats to facilitate safety qualifications. USP/PQRI/FDA Annual Meeting, 2014/2013.

Robison TW, Barat SA. Information and report formats to facilitate safety qualifications suitability and compatibility for packaging and delivery systems. Workshop Co- sponsored by USP and PQRI, USP Meetings Center, Rockville, Maryland, April 28, 2014.

Robison TW. Regulatory review of XELJANZ® (Tofacitinib) from the nonclinical perspective. American College of Toxicology Annual Meeting, 2013.

Robison TW. Toxicology in the nonclinical development of drugs and biologics. Pharmaceutical Education and Research Institute, Genetic Toxicology, Arlington, VA, October 2011.

Robison TW. Assessing genotoxic impurities. DIA Meeting (Early drug development: Navigating the treacherous rapids). Bethesda, MD, October 2010.

Robison TW. Dealing with genotoxic impurities from a regulatory perspective. IQPC Genotoxicity and Carcinogenicity Testing 2010 Conference, London, UK, October 2010.

Robison TW. Dealing with positive *in vitro* mammalian cell genotoxicity assays. IQPC Genotoxicity and Carcinogenicity Testing 2010 Conference, London, UK, October 2010.

Robison TW. Genotoxic impurity guidance – Current experiences, FDA perspective. USP Annual Meeting, New Orleans, LA, December 2010.

Robison TW. Toxicology in the nonclinical development of drugs and biologics. Pharmaceutical Education and Research Institute, Genetic Toxicology, Arlington, VA, September 2009.

Robison TW. Case examples of qualification of extractables and leachables in therapeutic biologic products: A toxicological perspective. WCBP CMC Strategy Forum--Extractables and Leachables: Challenges and Strategies in Biopharmaceutical Development (Sponsored by CASSS and the United States Food and Drug Administration), Washington, DC, January 2008.

Robison TW. Dealing with metabolites from an FDA perspective. Ninth Annual Land O'Lakes Bioanalytical Conference: Sponsored by the University of Wisconsin-Madison, Devil's Head Resort, Merrimac, WI, July 2008.

Robison TW. Toxicology in the nonclinical development of drugs and biologics. Pharmaceutical Education and Research Institute, Genetic Toxicology, Arlington, VA, September 2008.

Robison TW. Toxicology in the nonclinical development of drugs and biologics. Pharmaceutical Education and Research Institute, Genetic Toxicology, Arlington, VA, September 2007.

Robison TW. Toxicology in the nonclinical development of drugs and biologics. Pharmaceutical Education and Research Institute, Genetic Toxicology, Arlington, VA, September 2006.

Robison TW. Generation of lipid peroxidation products from alveolar macrophages exposed to nitrogen dioxide and their effects on cellular function. Invited presentation, California Air Resources Board, Riverside, CA, 1992.

Robison TW, Kim KJ. Guinea pig airway epithelial cells cultured in an air-interface actively transport Na^+ and Cl^-. Invited speaker for paper presentation, Federation of American Societies for Experimental Biology, 1992.

Robison TW, Sevanian A, Forman HJ. Inhibition of arachidonic acid release by nordihydroguaiaretic acid and its antioxidant action in rat alveolar macrophages and Chinese hamster lung fibroblasts. Invited Speaker for paper presentation, Federation of American Societies for Experimental Biology, 1990.

Other Conference/Meeting Presentations

Robison TW, Kim KJ. Enhancement of airway epithelial Na^+,K^+-ATPase activity in response to nitrogen dioxide exposure involves inhibition of protein phosphatase. Abstract A504, Society of Toxicology 35th Annual Meeting, Anaheim, CA, March 1996.

Zhou H, Duncan R, **Robison TW**, Forman HJ. Effect of oxidative stress on P47phox phosphorylation during the respiratory burst of alveolar macrophages. Biological Oxidants and Antioxidants, Santa Barbara, CA, 1996.

Liu RM, Hu HP, **Robison TW**, Forman HJ. Differential regulation of γ-glutamyl transpeptidase (γGT) and γ-glutamylcysteine synthetase (γGCS) expression by t- butylhydroquinone (TBHQ) in rat lung epithelial L2 cells. Oxygen Club of California, Pasadena, CA, 1995.

Robison TW, Kim KJ. Effect of NO_2 on airway epithelial Na^+,K^+-ATPase activity and the role of toxic lipid peroxidation products. Oxygen Club of California, Pasadena, CA, 1995.

Robison TW, Kim KJ. Enhancement of sodium pump activity in airway epithelial cells exposed to nitrogen dioxide. Oxygen Society International Meeting, Pasadena, CA, 1995.

Robison TW, Kim KJ. Generation of glycoladehyde from airway epithelial monolayers exposed to NO_2 and its effect on barrier and active ion transport properties. American Thoracic Society Annual Meeting, Seattle, WA, 1995.

Zhou H, Duncan R, **Robison TW**, Forman HJ. Effect of protein phosphatase inhibitors on the respiratory burst of the rat alveolar macrophage. Oxygen Society International Meeting, Pasadena, CA, 1995.

Robison TW, Kim KJ. Nitrogen dioxide decreases paracellular resistance and increases short-circuit current of guinea pig tracheobronchial epithelial monolayers cultured in an air-interface. American Thoracic Society Annual Meeting, Boston, MA, 1994.

Robison TW, Zhou H, Forman HJ. Oxidant stress inhibits ADP-stimulated increases of inositol phosphates in rat alveolar macrophages. American Thoracic Society Annual Meeting, Boston, MA, 1994.

Robison TW, Freeman L. Nitrogen dioxide-induced formation of arachidonate metabolites from guinea pig tracheobronchial epithelium cultured in an air-interface. American Thoracic Society Annual Meeting, San Francisco, CA, 1993.

Robison TW, Thomas MJ, Samuel M, Forman HJ. Generation of toxic aldehydes from rat alveolar macrophages exposed in vitro to low concentrations of nitrogen dioxide. American Thoracic Society Annual Meeting, San Francisco, CA, 1993.

Robison TW, Kim KJ. Tight monolayers of guinea pig airway epithelial cells: Bioelectric properties and active ion transport. American Thoracic Society Annual Meeting, Miami Beach, FL, 1992.

Robison TW, Forman HJ. Changes in pulmonary alveolar macrophage arachidonate metabolism in response to *in vitro* and *in vivo* exposure to nitrogen dioxide. American Thoracic Society Annual Meeting, Anaheim, CA, 1991.

Robison TW, Thomas MJ, Samuel M, Forman HJ. Generation of aldehydes from rat alveolar macrophages exposed to nitrogen dioxide. International Society for Free Radical Research 5th Annual Meeting, Pasadena, CA, 1990.

Robison TW, Forman HJ. Alterations of eicosanoid biosynthesis by alveolar macrophages exposed to nitrogen dioxide. Society of Toxicology 28th Annual Meeting, Atlanta, GA, 1989.

Robison TW, Forman HJ. Production of aldehydes from alveolar macrophages under oxidant stress. American Society of Cell Biology Annual Meeting, Houston, TX, 1989.

Robison TW, Forman HJ. Alterations of eicosanoid synthesis by alveolar macrophages exposed to t-butyl hydroperoxide. Federation of American Societies for Experimental Biology Annual Meeting, Las Vegas, NV, 1988.

Robison TW, Forman HJ. Alterations of prostaglandin synthesis by alveolar macrophages exposed to nitrogen dioxide. Federation of American Societies for Experimental Biology Annual Meeting, Washington DC, 1987.

Robison TW, Giri SN. Effect of chronic administration of doxorubicin on myocardial antioxidant defenses and levels of lipid peroxidation in tissues and plasma. Federation of American Societies for Experimental Biology Annual Meeting, St. Louis, MO, 1986.

Robison TW, Giri SN. Effect of chronic administration of doxorubicin on plasma levels of prostaglandins, and TxB_2 in male Sprague Dawley rats. Federation of American Societies for Experimental Biology Annual Meeting, Anaheim, CA, 1985.

Robison TW, Giri SN, Parker HR, Curry DL, Ishizaki G, Schiedt M. Effects of intravenous infusion of doxorubicin on blood chemistry, blood pressure, and heart rate in rabbits. Federation of American Societies for Experimental Biology Annual Meeting, St. Louis, MO, 1984.