

TIMOTHY J. MCGOVERN, Ph.D.
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WORK EXPERIENCE

White Oak Regulatory Tox, LLC
Co-Founder, Principal Consultant

April 2025 – present

Responsibilities:

- Provides regulatory and scientific consulting services to the healthcare product industry. Specializes in developing nonclinical testing strategies and evaluating data for small molecule pharmaceuticals, biologics, biosimilars, and medical devices.
- Develops scientific-based strategies to facilitate drug development.
- Participates on Expert Toxicology Panels to provide advice on drug development programs.
- Assists in preparing regulatory submissions and represented drug sponsors in meetings with regulators.
- Recognized for nonclinical regulatory and scientific expertise in developing drug products with an emphasis on inhalation and intranasal products, evaluation of genotoxic and carcinogenic potential, products indicated to treat pain and addiction, and for resolving issues related to the safety qualification of genotoxic impurities, including nitrosamines, metabolites, and product-related leachables.

United States Food and Drug Administration
Center for Drug Evaluation and Research
Office of New Drugs (OND), Immediate Office
Associate Director for Pharmacology/Toxicology

November 2013 – April 2025

Responsibilities:

- Provide high level input on complex pharmacology and toxicology scientific issues for drug products under agency review as a member of the OND Senior Pharm/Tox Team. Evaluate complex scientific and regulatory issues that impact review of products across multiple review divisions and results in development of new FDA guidance.
- Provide expert pharmacology and toxicology support for urgent and emerging public health needs associated with human pharmaceuticals and addressing external queries to the agency.
- Represent OND on Agency and Center level Task Forces evaluating public safety concerns with nitrosamine impurities in drug products and electronic nicotine products.
- Evaluate carcinogenicity protocols, final study reports, and weight-of-evidence submissions under ICH S1B as a standing member of the OND Executive Carcinogenicity Assessment Committee.

- Develop new guidances and policies on nonclinical development of human pharmaceuticals including guidances related to DNA-reactive impurities (ICH M7; Expert), assessment of carcinogenicity of human drug products (ICH S1B, Rapporteur), residual solvents (ICH Q3C; Rapporteur and Topic Lead), and elemental impurities (ICH Q3D; Rapporteur), and policies related to nonclinical programs to support programs focused on severely debilitating and lethal indications and COVID-related development programs.
- Interact with industry stakeholders to understand current drug development issues and facilitate the resolution of such issues including IQ Pharma and BioSafe as well as interactions via International Council for Harmonisation Working Groups. Serve as an Agency representative to external US Pharmacopeia, OECD, and Health and Environmental Sciences Institute groups related to biocompatibility, carcinogenicity evaluation, nitrosamines, and genetic toxicology issues.
- Facilitate implementation of new guidances across the pharmacology and toxicology discipline by developing and providing training.
- Provide leadership on internal pharmacology and toxicology committees as well as inter-office committees tasked with development of training for review staff, evaluation of issues related to nitrosamine impurities, genetic toxicology assessment and computational toxicology, nonclinical programs in support of pediatric drug development, and evaluation of excipients, leachables, and extractables.
- Participate in agency and external groups related to developing and assessing new technologies and alternative approaches in pharmacology and toxicology including the Tissue Chip Consortium organized by NIH/National Center for Advancing Translational Sciences.
- Support efforts at developing and implementing the use of electronic nonclinical data as part of the OND Division Data Standard Leads Subcommittee, provide training for review staff, and address internal and external questions on data standards.

SciLucent, LLC

Nonclinical/Regulatory Managing Consultant

August 2008 – November 2013

Responsibilities:

- Provided regulatory and scientific consulting services to the healthcare product industry. Specialized in developing nonclinical testing strategies and evaluating data for small molecule pharmaceuticals, biologics, biosimilars, and medical devices.
- Recognized for nonclinical regulatory and scientific expertise in developing drug products with an emphasis on inhalation and intranasal products, products indicated to treat pain and addiction, and for resolving issues related to the safety qualification of genotoxic impurities, metabolites, and product-related leachables.
- Developed scientific-based strategies to facilitate drug development.
- Participated on Expert Toxicology Panels to provide advice on drug development programs.
- Assisted in preparing regulatory submissions and represented drug sponsors in meetings with regulators.

- Presented at numerous scientific meetings on regulatory and scientific issues related to drug development and participated on expert working groups to develop scientific consensus on controversial nonclinical safety issues including interpretation of the adverse nature of pulmonary inflammatory responses.
- Participated on US Pharmacopeia Expert Toxicology Committee.

**United States Food and Drug Administration
Center for Drug Evaluation and Research
Division of Pulmonary and Allergy Products and Division of Anesthetic, Critical Care, and
Addiction Products**

Supervisory Pharmacologist

March 2001 – August 2008

Responsibilities:

- Acted as group supervisor in the area of pharmacology and toxicology. Assigned and reviewed work of subordinates, provided advice, counseled and provided instruction to staff and appraised employee performance. Planned, coordinated and evaluated the programs and activities of the Division.
- Served on committees, including CDER's Pharmacology/Toxicology Coordinating Committee, dealing with policy development in the fields of Pharmacology and Toxicology. Applied knowledge of FDA regulations, policies and guidances, and other guidances (e.g., ICH, OECD) to regulatory issues.
- Served as co-chair of CDER's Pharmacology/Toxicology Coordinating Committee Subcommittee on Genetic Toxicology.
- Consulted and negotiated with sponsors to improve study designs and other details of regulatory submissions.
- Contributed to formulation of regulatory guidances and policy decisions especially regarding inhalation drug development, genotoxic impurities, safety evaluation of metabolites.

**United States Food and Drug Administration
Center for Drug Evaluation and Research
Division of Pulmonary and Allergy Drug Products**

Toxicologist: Primary Reviewer

August 1997 - March 2001

Responsibilities:

- Evaluated and prepared comprehensive written reviews of nonclinical pharmacology and toxicology data in IND and NDA submissions in pulmonary therapeutic area (β -agonists, anticholinergics, antihistamines, glucocorticoids, phosphodiesterase inhibitors).
- Evaluated data from studies of efficacy models, safety pharmacology, pharmacokinetics, systemic toxicology, genetic toxicology, reproductive toxicology, and carcinogenicity protocols.
- Recommended safe human clinical doses and regulatory actions based on evaluations of preclinical data.
- Presented scientific issues and regulatory positions at internal and industry meetings.

- Consulted and negotiated with sponsors to improve study designs and other details of regulatory submissions.
- Contributed to formulation of regulatory guidances and policy decisions.

ICF KAISER, INC.

Toxicology Consultant

February 1997 – May 1997

- Acted as a consultant on various projects according to client's needs. This work included development of Acute Reference Exposures (AREs), Inhalation Reference Concentrations (RfCs), and risk analysis methodology in remediation of hazardous waste sites.

EDUCATION

1996 Ph.D., Environmental Toxicology, New York University, New York, NY

1993 M.S., Environmental Toxicology, New York University, New York, NY

1988 B.S., Biology, Fairfield University, Fairfield, CT

PROFESSIONAL ACTIVITIES

American College of Toxicology (ACT): President (2021), Secretary (2015-2018); Councilor (2011 – 2014)

Society of Toxicology (SOT); Inhalation and Regulatory and Safety Evaluation Specialty Sections (RSESS): Councilor for RSESS (2025-2028)

Association of Inhalation Toxicologists (AIT)

Member of USP Expert Toxicology Committee (2011-2014)

PUBLICATIONS (SELECTED)

Heflich, RH, McGovern, TJ, et al. Optimizing the detection of *N*-nitrosamine mutagenicity in the Ames test. 2024. Reg Tox and Pharmacol. 153.

Kruhlak, NL, McGovern TJ et al. Determining recommended acceptable intake limits for *N*-nitrosamine impurities in pharmaceuticals: Development and application of the Carcinogenic Potency Categorization Approach (CPCA). 2024. Reg Tox and Pharmacol. 150.

Bourcier, T, McGovern, T et al. ICH S1 prospective evaluation study: weigh of evidence approach to predict outcome and value of 2-year rat carcinogenicity studies. A report from the regulatory authorities subgroup. 2024. *Front Toxicol.* 6

Bourcier, T, McGovern, T, Stavitskaya, L, Kruhlak, N, Jacobson-Kram, D. Improving prediction of carcinogenicity while aiming to reduce, refine, and replace their use of experimental animals. 2015. *J Am Assoc for Laboratory Anim Sci.* 54(2): 163-169.

Forbes, B, O'Lone R, Allen, PP, Cahn, A, Clarke, C, Collinge, M, Dailey, LA, Donnelly, LE, Dybowski, J, Hassall, D, Hildebrand, D, Jones, R, Kilgour, J, Klapwijk, J, Maier, CC, McGovern, T, Nikula, K, Parry, JD, Reed, MD, Robinson, I, Tomlinson, L, and Wolfreys, A. 2014. Challenges for inhaled drug discovery and development: Induced alveolar macrophage responses. *Advanced Drug Delivery Reviews.* 71: 15-33.

Nikula, KJ, McCartney JE, McGovern, T, Miller GK, Odin, M, Pino MV, Reed, MD. 2014. STP Position Paper: Interpreting the significance of increased alveolar macrophages in rodents following inhalation of pharmaceutical materials. *Toxicol Pathol.* 42(3): 472-86

McGovern, T. 2012. Use of Safety Thresholds in the Pharmaceutical Development Process for OINDP: USA Regulatory Perspectives. In Ball, D.J. and Norwood, D. (eds.) *Development of Safety Qualification Thresholds and their Use in the Evaluation of Orally Inhaled and Nasal Drug Products.* Hoboken, NJ: John Wiley & Sons, Inc.

Osterberg, RE, Demerlis, CC, Hobson, DW, McGovern, TJ. 2011. Trends in excipient safety evaluation. *Int J Toxicol.* Volume 30(6): 600-610.

Forbes, B, Asgharian, B, Dailey, LA, Ferguson, D, Gerde, P, Gumbleton, M, Gustavsson, L, Hardy, C, Jones, R, Lock, R, Maas, J, McGovern, T, Pitcairn, GR, Somers, G, Wolff, RK. 2011. Challenges in inhaled product development and opportunities for open innovation. *Advanced Drug Delivery Reviews.* Volume 63(1-2): 69-87.

Bercu, JP, Dobo, KL, Gocke, E, McGovern, TJ. 2009. Overview of Genotoxic Impurities in Pharmaceutical Development. *International Journal of Toxicology,* Volume 28 (6): 468-478.

Ball D, Blanchard J, Jacobson-Kram D, McClellan RO, McGovern T, Norwood DL, Vogel W, Wolff R, Nagao L. 2007. Development of safety qualification thresholds and their use in orally inhaled and nasal drug product evaluation. *Toxicological Sciences,* Volume 97(2):226-36.

McGovern, T and Jacobson-Kram, D. 2006. Regulation of genotoxic and carcinogenic impurities in drug substances and products. *Trends in Analytical Chemistry,* Volume 25(8):790-5.

Kinney PL, Nilsen DM, Lippmann M, Brescia M, Gordon T, McGovern T, El-Fawal H, Devlin RB, Rom WN. 1996. Biomarkers of lung inflammation in recreational joggers exposed to ozone. *Am J Respir Crit Care Med.* 154(5):1430-5.

McGovern TJ, el-Fawal HA, Chen LC, Schlesinger RB. 1996. Ozone-induced alteration in betaadrenergic pharmacological modulation of pulmonary macrophages. Toxicol Appl Pharmacol. 137(1):51-6.

INVITED PRESENTATIONS (SELECTED)

ICH S1B(R1): US Regulatory Perspectives on the New Weight of Evidence Approach. American College of Toxicology Webinar, December 2024.

US Regulatory Perspectives on Impurity Qualification in Drug Substances/Drug Products. American College of Toxicology Annual Meeting, November 2024.

ICH S1: Re-evaluating Traditional Carcinogenicity Testing. American College of Toxicology Annual Meeting, November 2019.

Evaluating Carcinogenicity: A Reviewer's Perspective. Society of Toxicology Annual Meeting, March 2017.

Regulatory Perspectives on the Role of Juvenile Animal Studies. Society of Toxicology Annual Meeting, March 2016.

Toxicology Considerations in Drug Development for Asthma and COPD, Pharmaceutical Education & Research Institute Course (PERI) – Asthma and COPD: Clinical Drug Development, March 2013

Interpretation of inflammatory responses in the lung and impact on pulmonary drug development. American College of Toxicology Annual Meeting, November 2012.

Genotoxic Impurities – US and EU Regulatory Perspectives, American College of Toxicology Annual Meeting, November 2008

Increased Sponsor Interest in CROs in China: Perspectives from the US FDA, American College of Toxicology Annual Meeting, November 2007

Regulatory Aspects of Nonclinical Testing for Inhalation Drug Development, Association of Inhalation Toxicologists, October 2007