

Todd Bourcier, Ph.D.

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Professional Experience

White Oak Regulatory Tox, LLC

Co-Founder, Principal Consultant

March 2025 – Present

Responsibilities:

- Provide expert consulting services to the pharmaceutical industry, specializing in developing nonclinical testing strategies and evaluating data for small molecule pharmaceuticals and biologics.
- Recognized for regulatory and scientific expertise in design, evaluation, and application of nonclinical development programs with an emphasis on products for cardiovascular, endocrinology, and non-malignant hematology indications.
- Specialized experience in development of carcinogenicity assessment strategies and navigating complex, problematic programs.

US Food and Drug Administration

Office of New Drugs, Center for Drug Evaluation and Research

Office of Cardiology, Hematology, Endocrinology, and Nephrology

Director, Division of Pharmacology & Toxicology (DPT)

March 2020 - March 2025

Responsibilities:

- Provided leadership to the Division of 45 scientists across 5 review teams comprised of primary reviewers, team leaders, supervisors, and a Deputy Director.
- Developed policies and practices to facilitate consistency of scientific review and regulatory actions recommended by primary and senior review staff.
- Developed drug class and indication-specific profiles to refine efficiencies in testing strategies for nonclinical development programs.
- Ensured that nonclinical programs are developed and applied to most effectively support clinical development and to protect clinical trial participants.
- Provided tertiary review of nonclinical assessments in marketing applications and served as decisionary authority on regulatory matters stemming from nonclinical programs.
- Contributed to setting policies, developing regional and international guidances, and guiding scientific direction of the OND pharm/tox discipline as a member of the Senior Leadership Team.

- Guided sponsors in development and application of nonclinical testing programs that satisfy regulatory requirements under US regulation and that meet contemporary international and domestic guidances.
- Interacted with industry stakeholders to address challenges in contemporary drug development issues including IQ Pharma and BioSafe as well as interactions via International Council for Harmonisation Working Groups. Served as an FDA representative to external Health and Environmental Sciences Institute groups related to carcinogenicity evaluation, safety pharmacology, and cardiac safety issues.
- Served on the ICH Expert Working Group on the conception, development, and implementation of ICH S1BR1 addendum that introduced a weight of evidence approach as an option for assessment of carcinogenicity risk of small molecule pharmaceuticals.

US Food and Drug Administration
Office of New Drugs, Center for Drug Evaluation and Research
Division of Metabolic and Endocrine Products
Supervisory Pharmacologist

Aug 2006 – March 2020

Responsibilities:

- Directed and provided oversight of the review, evaluation, and preparation of comprehensive summaries of scientific submissions focusing on nonclinical toxicology data in support of clinical development programs and marketing applications including Investigational New Drugs (INDs), New Drug Application (NDAs), Biologics License Application (BLAs), and associated amendments and supplements.
- Planned and assigned work to be performed by a team of primary pharmacologists and toxicologists in the Division. Set and adjusted both short-term and long-term priorities for the nonclinical review team in the Division. Provided secondary review of work performed by direct reports for scientific and regulatory content.
- Oversaw meetings and interactions with industry representatives on the exchange of information and the provision of advice and guidance regarding nonclinical programs submitted in support of clinical development programs and marketing applications.
- Conducted performance evaluation of direct reports and provided advice, counsel, and instruction to employees on both work and administrative matters.
- Interviewed candidates for pharmacologist/toxicologist positions in the Division and recommended the appointment, promotion, or reassignment to such positions.

- Participated as a member of the Pharmacology Toxicology Coordinating Committee on matters of policy and practice within the Office of New Drugs.

US Food and Drug Administration
Office of New Drugs, Center for Drug Evaluation and Research
Division of Metabolic and Endocrine Products
Pharmacologist: Primary Reviewer

Sept 2004 – July 2006

Responsibilities

- Reviewed, evaluated, and prepared comprehensive summaries of scientific submissions focusing on nonclinical toxicology data in support of clinical development programs and marketing applications including Investigational New Drugs (INDs), New Drug Application (NDAs), Biologics License Application (BLAs), and associated amendments and supplements.
- Reviewed proposed drug labels pertinent to verifying sponsor's claims of safety on carcinogenesis and reproductive toxicity.
- Interacted with industry representatives to provide advice and guidance on nonclinical requirements for drug development programs.
- Made substantive recommendations from review of applicant's submissions on nonclinical drug development programs to supervisory pharmacologists/toxicologists for consideration.

Brigham & Women's Hospital/Harvard Medical School
Department of Anesthesiology, Perioperative and Pain Medicine
Department of Cardiovascular Medicine
Instructor

Sept 1999 – June 2004

Responsibilities

- Conducted and lead research efforts into immune mechanisms of cardiac and vascular injury. Supervised and mentored post-doctoral fellows and laboratory personnel.
- Secured grant support for research efforts, a Scientist Development Grant of the American Heart Association (PI, 2000-2004), and an RO1 Regular Research Grant of the NHLBI (PI, 2002-2004).
- Presented findings at numerous national and international scientific conferences
- Published findings in competitive peer-reviewed scientific journals

Brigham & Women's Hospital/Harvard Medical School
Department of Medicine
Vascular Medicine and Atherosclerosis Unit
Post-Doctoral Fellow

Aug 1995- Sept 1999

Responsibilities

- Conducted investigative studies into mechanisms of vascular inflammation and atherosclerosis using animal and human materials (Laboratory of Dr. Peter Libby)
- Mentored several rotating physicians in investigative laboratory techniques
- Presented findings at numerous national and international scientific conferences
- Published findings in competitive peer-reviewed scientific journals
- Secured the competitive Individual National Research Service Award of the NHLBI (1996-1999) to fund post-doctoral compensation.

Education

1995 Ph.D. Pharmacology, New York Medical College, Valhalla, NY
1993-1995, Visiting Graduate Student, University of Tennessee, Memphis
1991 M.S. Pharmacology, New York Medical College, Valhalla, NY
1989 B.A. Marine Biology, Roger Williams University, Bristol, RI

Selected Activities and Awards at US FDA

International Conference on Harmonization, S1B Guidance Expert Working Group
FDA topic lead to EWG in reassessing carcinogenicity testing requirements for small molecule pharmaceuticals.

Recipient of Regulatory Science Research Grant, Office of New Drugs
Project lead with Dr. Barbara Parsons of the National Center for Toxicological Research on investigating epigenetic and genetic mechanisms of lorcaserin-induced carcinogenesis

Rotating Member of the Executive Carcinogenicity Assessment Committee
Committee responsible for oversight of carcinogenicity assessments in animals

Member, Pharmacology and Toxicology Coordinating Committee
A consultative and policy-making group on pharmacology/toxicology issues at the FDA

Division Transition Lead for Pharm/Tox, OCHEN
Served as 'DTL' for the New Drug modernization efforts in OND, Feb 2019-2020

OND Associate Director Detail, Pharm/Tox IO
Served as the Pharm/Tox AD in a detail from Oct-Nov 2014 and participated in leadership transition tasks during the 2014/15 timeframe.

Speaker/Discipline Team Leader, Endocrine & Metabolism Drug Advisory Committees

Presented / authored background material for various EMDAC meetings in cases with pertinent pharm/tox issues

Recipient of CDER's Frances O. Kelsey Drug Safety Excellence Award (2020)

'For addressing thromboembolic risk from methionine aminopeptidase inhibitors in drug development for metabolic disorders'

Recipient of CDER's Honor Award for Team Excellence (2021)

'For exceptional effort to identify a risk of cancer associated with Belviiq and promptly removing the product from the US market'

Selected Publications

1. Bourcier T, McGovern T, Cavaliero T, Ebere G, Nishikawa A, Nishimura J, Ogawa K, Pasanen M, Vespa A, Van der Laan JW. ICH S1 prospective evaluation study: weight of evidence approach to predict outcome and value of 2-year rat carcinogenicity studies. A report from the regulatory authorities subgroup. **Front Toxicol**. 2024 Apr 11;6:1353783. doi: 10.3389/ftox.2024.1353783. PMID: 38665214; PMCID: PMC11043531.
2. Faske JB, Myers MB, Bryant M, He X, McLellen F, Bourcier T, Parsons BL. CarcSeq detection of lorcaserin-induced clonal expansion of Pik3ca H1047R mutants in rat mammary tissue. **Toxicol Sci**. 2024 Sep 1;201(1):129-144. doi: 10.1093/toxsci/kfae070. PMID: 38851877; PMCID: PMC11347771.
3. Ackley D, Birkebak J, Blumel J, Bourcier T, deZafra C, Goodwin A, Halpern W, Herzyk D, Kronenberg S, Mauthe R, Shenton J, Shuey D, Wange RL. FDA and industry collaboration: Identifying opportunities to further reduce reliance on nonhuman primates for nonclinical safety evaluations. **Regul Toxicol Pharmacol** 2023; 138:105327.
4. Avila A, Bebenek I, Bonzo JA, Bourcier T, et al. An FDA/CDER perspective on nonclinical testing strategies: classical toxicology approaches and new approach methodologies (NAMs). **Regul Toxicol Pharmacol** 2020; 114:104662.
5. Egan AG, Blind E, Dunder K, de Graeff PA, Hummer BT, Bourcier T, Rosebraugh C. Pancreatic safety of incretin-based drug: FDA and EMA assessment. **N Engl J Med** 2014; 370(9): 794-797.
6. Bourcier T, McGovern T, Stavitskaya L, Kruhlak N, Jacobson-Kram D. Improving prediction of carcinogenicity while aiming to reduce, refine, and replace the use of experimental animals. **JAALAS** 2015; 54(2):163-169
7. Morton D, Bourcier T, Alden CL. Improving carcinogenicity assessment. **Toxicol Pathol** 2013; 41(2):263-270.
8. Massaro M, Habib A, Lubrano L, Del Turco S, Lazzerini G, Bourcier T, Weksler BB, De Caterina, R. The omega-3 fatty acid docosahexaenoate attenuates endothelial cyclooxygenase-2 induction through both NADPH oxidase and PKC epsilon inhibition. **Proc Natl Acad Sci** 2006;103(41):15184-9.
9. Walsh MC, Bourcier T, Takahashi K, Shi L, Busche MN, Rother RP, Solomon SD, Ezekowitz RA, Stahl GL. Mannose binding lectin is a regulator of inflammation that accompanies myocardial ischemia and reperfusion injury. **J Immunol**. 2005: 175(1):541-6.

10. Oyama J, Blais C, Liu, XL, Pu M, Kelly RA, *Bourcier T. Reduced myocardial ischemia-reperfusion injury in TLR4-deficient mice. **Circulation**. 2004; 109(6):784-789. (*Corresponding Author)
11. Frantz S, Kelly RA, *Bourcier T. Role of TLR2 in the activation of nuclear factor-kappa B by oxidative stress in cardiac myocytes. **J Biol Chem**. 2001; 276(7); 5197-5203. (*Corresponding Author)
12. Bourcier T and Libby P. HMG CoA reductase inhibitors reduce plasminogen activator inhibitor-I expression by human vascular smooth muscle and endothelial cells. **Arterioscler Thromb Vasc Biol**. 2000; 20,556-562.
13. Mach F, Schonbeck U, Sukhova GK, Bourcier T, Bonnefoy JY, Pober JS, Libby P. Functional CD40 ligand is expressed on human vascular endothelial cells, smooth muscle cells, and macrophages: implications for CD40-CD40L signaling in atherosclerosis. **Proc Natl Acad Sci** 1997; 94(5): 1931-6.

Federal Register Notifications

Food and Drug Administration, HHS. International conference on harmonization; proposed change to rodent carcinogenicity testing of pharmaceuticals: request for comments. Notice; request for comments. Fed Regist. 2013 Mar 18; 78(52); 1668-4.

Selected Book Chapters

Bourcier, T., Roy, D. (2015). Addressing Positive Findings in Carcinogenicity Studies. In: Graziano, M., Jacobson-Kram, D. (eds) Genotoxicity and Carcinogenicity Testing of Pharmaceuticals. Springer, Cham. https://doi.org/10.1007/978-3-319-22084-0_9

Frantz S, Kelly Ralph A, Bourcier T. (2004) Toll-like receptors and the cardiovascular system. GZ Feuerstein, P Libby, DL Mann, Eds. Inflammation and Cardiac Diseases. Birkhauser Verlag AG.