



toXcel/LLC
7140 Heritage Village Plaza
Gainesville, VA 20155-3061
USA
Tel: +1 (703) 754-0248
Fax: +1 (703) 310-6950

toXcel/International Ltd
P.O. Box 93
Ledbury
HR8 9JE
United Kingdom
Tel: +44 (0) 1531 638999

www.toxcel.com

US and International Clientele

toXcel is an expert consultancy team dedicated to providing clients with the reliable scientific, technical, and regulatory support needed for compliance with US and international regulation of pharmaceutical, cosmetic and chemical products and devices. We are experienced in obtaining registrations of plant protection chemicals and biocides as well as for approvals of pharmaceutical active substances, inert ingredients, adjuvants, and excipients. Our experience also includes comprehensive preparation of scientific position papers, dossiers, food and chemical safety assessments, and toxicological support for nonclinical pharmaceutical testing programs.

Extensive Experience

toXcel's highly experienced and multidisciplinary staff includes former senior government scientific and regulatory review managers, as well as regulatory affairs and R&D directors from industry. These leading consultants focus their collective professional talents to assist chemical manufacturers, formulators, pharmaceutical companies, personal care/consumer product manufacturers and suppliers, trade associations, law firms, and the food industry.

Full Range of Services

toXcel provides a full range of services to support obtaining marketing approvals by governmental agencies, with emphasis on developing regulatory strategies and managing all aspects of the preparation of applications and dossiers. This includes the performance of toxicological data evaluations, exposure and risk assessments, safety and toxicological evaluations, and the design and management of GLP analytical chemistry, residue, efficacy, environmental fate, mammalian toxicity, metabolism/pharmacokinetics (ADME), and ecotoxicity studies. Our staff also advises companies about compliance with REACH, the EU Cosmetics and Biocidal Products Regulations, and Classification, Labeling and Packaging (CLP) as well as other EU regulations and guidelines.

Litigation and Enforcement

toXcel professionals provide expertise and support to law firms representing clients in litigation involving product liability and toxic torts and enforcement actions. Our senior staff consultants are experienced in due diligence procedures associated with mergers, acquisitions, and registration transfers. They also provide expert opinions in data compensation negotiations and serve as expert witnesses in scientific, technical, and regulatory matters.

toXcel Personnel

- **Alan C. Katz, M.S., DABT - President** - Alan is a board-certified toxicologist with over 40 years of experience in the pharmaceutical, chemical, food ingredients and supplements, cosmetic, and agrochemical fields. He is broadly experienced in the public and private sectors, including management of toxicology, product chemistry, risk assessment, and regulatory affairs programs in industry, government, and consulting. Following an extensive career in industrial research in chemistry, toxicology, and pharmacology, he served as a senior toxicologist with the US EPA Office of Pesticide Programs and has since spent over 20 years as a consultant in scientific and regulatory affairs. Alan is past-president of the Society of Comparative Ophthalmology and currently serves a dual role on the editorial staff of the *Journal of Applied Toxicology* as a member of the Editorial Advisory Board and Editor of the *Toxicology Updates* feature. Alan serves as an elected member of the Awards Committee of the American College of Toxicology and is an active participant in the Society of Toxicology, where he is a member of the national Society and the Mid-Atlantic Chapter, as well as the Drug Discovery, Regulatory and Safety Evaluation, Neurotoxicology, Ocular Toxicology, and Risk Assessment Specialty Sections. He also holds membership in the American Chemical Society where he has contributed to a number of research presentations over the years.
- **Chris McAlinden, DABT, UK and European Registered Toxicologist, Assoc. Director** - Christine is a board-certified toxicologist with over 20 years experience within the industry. She began her career with a UK CRO as a Study Director in general toxicology where she gained a solid practical understanding of toxicological studies and data evaluation. In 2001 Chris first joined toXcel International Ltd as a consultant toxicologist, gaining added experience in the regulatory environment and providing advice and support to clients on the safety assessment of animal food additives (EFSA and FDA), agrochemicals and pharmaceuticals (MHRA and EU). Between 2007 and 2011 she continued with consultancy work and also gave toxicological support to an Indian CRO, including training and protocol/report reviewing. She has been actively involved with REACH, providing only-representative services, consortium representation, dossier and CSR compilation and dossier submission. Chris has served on the education committee of the British Toxicology Society and is currently a Panel member for the UK Register of Toxicologists. In early 2011, Chris re-joined toXcel to establish our new European office in Ledbury, England and to further develop our comprehensive REACH services. In her role as Associate Director, Chris provides leadership in business and scientific affairs on behalf of our European operations, registered in England and Wales.
- **J. Michael Kelley, Ph.D., Vice President** - Mike is a Ph.D. microbiologist with over 35 years of diversified experience in research, the chemical industry, and regulatory affairs associated with obtaining required domestic and international approvals for chemical products. He routinely reviews regulatory options for clients and works closely with them to develop and implement resultant regulatory strategies. His industry experience includes serving as Global Director of Regulatory Affairs for a large international specialty chemical manufacturer of coatings, flame retardants, and agricultural and water treatment pesticide products. During his time in industry, he chaired various industry panels including the ACC Biocides Panel. Mike has obtained, and worked to maintain, chemical product approvals under FIFRA, TSCA, and the EU's Biocidal Products Directive. His training in microbiology, chemistry, and toxicology, together with his years of experience in industry, facilitate communications and development of innovative problem solving. He is a member of the Society of Toxicology.
- **Gary K. Whitmyre, MA, DABT, Senior Director of Exposure and Risk Assessment** - Gary is a board-certified toxicologist with over thirty years of technical experience focused on residential, occupational, and consumer exposure analysis, risk assessment, and toxicology of environmental chemicals. As Principal of risksciences, LLC, since 1997 and Whitmyre Research since 1999 and his previous experience on the staff of other scientific consulting firms, he has been actively engaged in a wide variety of risk assessment projects. His experience includes probabilistic modeling of human exposure to chemicals in indoor and outdoor environments, development of expert opinions for litigation cases, regulatory compliance through product-specific exposure assessments under California Proposition 65, preparation of human health risk assessments for inclusion in applications for US federal and state marketing approvals, and international dossiers supporting pesticides and antimicrobial products and other chemical registrations.
- **Robert M. Sielaty, J.D., Executive Director of Product Registration and General Counsel** – Bob is an accomplished Washington, D.C. consultant with over 40 years experience in regulatory positions in the federal government, national trade associations, private law practice, and consulting firms. With a background of studies in science and law, he assists chemical companies and the health care industry with government approval processes, legislative issues, and compliance programs for the marketing of pharmaceutical, agricultural, biochemical, and antimicrobial products. He advises companies on complex issues involving

toxic substances and compliance. He is well-known by industry and government representatives as a reliable and knowledgeable regulatory expert, and has made numerous presentations at industry and government forums on topics involving the regulatory process. As General Counsel, he provides advice and guidance on the company's legal and business affairs.

- **Jane C. Eickhoff, M.S., Director of Strategic Services** – Jane has over 30 years experience in the environmental field, providing advice and assistance to the food industry and chemical manufacturers concerning compliance with environmental and agrochemical regulations and registration requirements. She evaluates potential exposure and health risks of chemical contaminants, crop residues and additives in foods by conducting refined dietary and aggregate risk analyses using non-proprietary models including CARES, DEEM, and LifeLine[®] software. Her experience also includes obtaining tolerance and exemption from tolerance petition approvals, effective interaction with European, Canadian, and US regulatory authorities, ensuring compliance with regulations, evaluating data compensation issues, serving as facilitator for an industry task force, and coordination of trade association working committees for crop protection and agricultural research.
- **Michele L. Loftus, Ph.D., Senior Consulting Chemist** – A chemist with over twenty years experience providing expert advice on the regulation and new product approval of pesticide, antimicrobial, pharmaceutical, biotechnology, and industrial chemical products, Michele has an extensive background in designing and monitoring product chemistry, animal and plant metabolism, residue chemistry studies, residue food surveys, and environmental fate studies in compliance with Good Laboratory Practice (GLP) standards and federal regulatory guidelines. A former US EPA reviewer in the Residue Chemistry Branch of the Office of Pesticide Programs, Michele specializes in placing and monitoring studies at contract laboratories as well as preparing study protocols and reports, position documents, product labels, Confidential Statements of Formula, and other documents for submission to U.S. and international regulatory authorities. She provides representation to regulatory authorities, develops regulatory strategy for product registration and defense under FIFRA, FQPA, and Federal Food, Drug, and Cosmetic Act (FFDCA). Among Michele's areas of expertise are designing and overseeing magnitude of the residue studies for the post-harvest fumigation of crops and processed foods.
- **Nicola D. Cowen, M.S., Senior Associate Scientist** – Niki coordinates and manages efforts between Directors and project support teams. She evaluates and summarizes toxicology studies required to support regulatory actions on agricultural chemicals, antimicrobials, and inert ingredients. She also leads efforts to prepare FIFRA and state submissions in support of pesticide products and interacts directly with EPA and clients to resolve labeling issues. She is trained in performing and interpreting FOCUS models for EU aquatic exposure risk assessments. Niki closely monitors the US Environmental Protection Agency's global harmonization efforts. In addition to maintaining the company's database of international CRO study capabilities and costs, she places and monitors studies. Niki is proficient in both conducting NPIRS searches and interpreting the findings to confirm data compensation requirements for specific products and to provide clients with valuable competitive intelligence. She holds current memberships in the American College of Toxicology (ACT) and the Society of Environmental Toxicology and Chemistry (SETAC).
- **Jennifer L. Wagar, B.S., Senior Associate Scientist** – Jennifer is experienced with preparing dossiers, including IUCLID documentation, required for the registration of products for Annex I listing under the European Union's Biocidal Products Directive (BPD; 98/9/EC) as well as the Plant Protection Products Directive (91/414/EEC). Jennifer is also knowledgeable with the Canadian registration processes through Health Canada's Pest Management Regulatory Agency (PMRA) and has played an integral role in a number of international registration efforts of pesticides. She has experience preparing the scientific data packages required for state registration applications, including those for submission to California, New York, and Florida. She is proficient in conducting literature searches, scientific research, data evaluation, and preparing data summaries. Jennifer plays a key role in all aspects of preparation of regulatory submissions to the EPA regarding pesticide active ingredients and products and interacts directly with EPA on behalf of clients to resolve issues. Jennifer is trained in the use of the National Pesticide Information Retrieval System (NPIRS) and is toXcel's primary contact for the Accepted Labels State Tracking and Repository (ALSTAR). She holds current membership in the Regulatory Affairs Professional Society (RAPS).
- **Nicole F. Perkinson, B.S., RAC, Associate Scientist** – Nicole is experienced in the preparation of a wide variety of FIFRA applications, including reduced-risk pesticide applications and compiling associated data waiver arguments. She has demonstrated proficiency for data compilation, evaluation, and technical writing as well as in-depth label reviews for regulatory compliance. She has practical experience in risk assessment methods and risk management policies. Nicole has experience registering both new and existing active ingredient pesticide products in all 50 states and maintains state product registrations on a routine basis. She also maintains regular contact with state regulatory authorities and is trained in the use of

the National Pesticide Information Retrieval System (NPIRS). She is also experienced in the preparation of applications for submission to Canada's Pest Management Regulatory Agency (PMRA). Nicole has experience with the FDA regulatory process, including OTC drug establishment registration and product listing. She is currently a member of the Regulatory Affairs Professional Society (RAPS) and is Regulatory Affairs Certified.

- **Christopher J. Burnside, B.S., Associate Scientist** - Chris first began his work with toXcel as an intern during college. Rejoining the toXcel team immediately after graduation, he applies practical experience as an analytical and environmental chemist to the evaluation and development of environmental fate and product chemistry studies. Chris integrates a working knowledge of the chemical realm into the detailed preparation of scientific and regulatory documents required for federal and state registrations of pesticide products (insect repellents, agrochemicals, and antimicrobials) under FIFRA and Pre-manufacture Notices (PMNs) under TSCA for EPA acceptance of new chemical substances.
- **Crystal A. Turner, Office Administrator** – Crystal is an experienced administrative associate and a member of the International Association of Administrative Professionals and the Society for Human Resource Management. In addition to her function as the office manager, she handles accounting matters and maintains financial records, conducts NPIRS and other on-line data searches, and consistently resolves complex document production issues in a timely and efficient manner. Crystal has valuable experience with the formatting of regulatory submissions and oversees document quality assurance with great attention to detail.

PRODUCT SUPPORT FOR:

- **Pharmaceuticals**
- **Medical Devices**
- **Personal Care Products**
- **Insect Repellents**
- **Agricultural Pesticide Products**
- **Antimicrobial Pesticide Products**
- **Biological and Biochemical Pesticide Products**
- **Biocides under EU's BPD/BPR**
- **Inerts, Adjuvants and Excipients**
- **Veterinary Drugs**
- **Industrial Use Chemicals**

CLIENTELE:

- **Health Care/Consumer Product Manufacturers**
- **Pharmaceutical Companies**
- **Agricultural and Antimicrobial Pesticide Producers**
- **Biological and Biochemical Product Producers**
- **Bulk Chemical Manufacturers**
- **Formulators**
- **Trade Associations**
- **Investors**
- **Law Firms**
- **Food Industry**

SERVICES:

- **Registration and Amendment Applications**
- **Dossiers**
- **Technical Position Documents**
- **Exposure Analysis and Risk Assessments**
- **Product Safety Evaluations**
- **RfDs, ADIs & PADs**
- **New Data Development – Nonclinical Study Placement and Management**
- **Technical Representation and Negotiations**
- **Data Analysis and Interpretation**
- **Technical Support in Data Compensation Negotiations**
- **Due Diligence**