Amy M. Sheppard

SUPERVISING SCIENTIST

CONTACT INFORMATION

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PROFESSIONAL PROFILE

Ms. Amy Sheppard is a Supervising Scientist in ToxStrategies' Food and Consumer Products practice. She brings 30 years of experience to the firm, having supported the safe marketing of consumer- and professional-level products, including cosmetics, over-the-counter drugs, cleaning products, biocides, and pest control products. Her experience includes the use of data-driven risk assessments to ensure compliance with regulatory guidelines and requirements.

Ms. Sheppard's broad experience in the consumer products industry encompasses a summer internship, scientist positions in product safety, and middle and senior management roles in toxicology, raw material assessment, pesticide safety, and human, environmental, and product safety. She has worked for multiple global consumer product manufacturers.

In addition to her scientific endeavors, Ms. Sheppard is a certified Emergency Medical Technician and is also certified in Hazardous Materials Operations. She serves as an EMT for the Union Grove–Yorkville (Wisconsin) Fire Department (since 2009), and is also a CPR Instructor, providing training in Heartsaver and Healthcare Provider CPR/AED courses, as well as general first aid.

DEGREES AND CERTIFICATIONS

1991 Bachelor of Science, Biology
1992 Bachelor of Science, Chemistry
University of Wisconsin–Parkside, Kenosha, Wisconsin

2009 EMT Basic Certification
2011 EMT Advanced/IV Tech Certification
2011 Hazmat Ops Certification
Gateway Technical College, Burlington, Wisconsin

SELECTED PROFESSIONAL EXPERIENCE

Toxicology
Ingredient and Raw Material Assessment
Human, Environmental, and Product Safety

Conducted toxicological data reviews and subsequent risk assessments in support of a variety of globally marketed consumer and industrial/institutional products, within guidelines established by local regulations. Transitioned to mentoring and leading teams to complete similar tasks, managing priorities as needed. Specific aspects of the assessments include:

- Managed the human health and environmental toxicology team in the preparation of risk assessments for the global portfolio of pest control products, in accordance with global and/or local regulatory requirements
- Supported global toxicology team for other businesses, as requested
- Led an ingredient and raw material assessment team to collect required raw material compositional, regulatory/compliance, and toxicological information
- Managed resources to support cross-functional business requirements
- Collaborated with cross-functional teams to develop best practices for identifying alternative suppliers without compromising data integrity
- Completed product safety human health risk assessments for global portfolio of cleaning products used in consumer and industrial markets, using Globally Harmonized System (GHS) and local regulations, as required
- Participated on external trade association teams and working groups involving the safety of industry-used chemicals as needed, including the Household and Commercial Products Association (HCPA) and the Personal Care Products Council (PCPC)
- Mentored and trained new and junior members of the human toxicology team in risk assessments, documentation, and corporate processes
- Communicated with internal and external customers to address safety inquiries, including food contact safety assessments in the industrial and institutional market

- Participated on cross-functional teams by providing toxicological assessments and recommendations for quality and/or defect items, including guidance on potential recall issues
- Researched data and prepared safety reviews for cosmetics, including baby care products, skin-care supplements, sun-care products, and fragrances, and conducted risk assessments as required.
- Provided recommendations for claims or precautionary label text based on the toxicological assessment of the formula
- Represented the toxicology team on new venture research projects, providing direction to the research teams during development

Safety Studies and Claims Support

Conducted *in vivo, in vitro*, and clinical safety studies used for general product support, registration submission, and claims substantiation. In addition to contracting the studies, collaborated with colleagues and laboratories to continue the drive to replace animal testing with alternative methods.

- Participated in internal validation efforts for alternatives to animal testing, and external consortia to enhance the use and influence regulatory acceptance of non-animal alternatives
- Led the partnership with Legal and Regulatory functional teams to provide label statements and safety-related claims support, ensuring a robust scientific approach
- Advised cross-functional teams regarding toxicological requirements during new product development and/or innovation projects
- Coordinated applicable *in vitro* and *in vivo* studies for toxicological support, as supported by global regulatory requirements
- Managed a product safety clinical testing program by serving as the primary contact for all contracted studies, maintaining appropriate documentation for compliance, and conducting regular audits of the testing facilities
- Conducted in-house *in vitro* SPF and clinical cumulative irritation patch testing, including protocol development, data collection and analysis, and issuance of final reports
- Completed GLP training annually
- Worked with third-party test laboratories to develop protocols specific to claims or product types, in consideration of exposure and foreseeable misuse

Product Safety Process Support

Participated in the development and enhancement of standard procedures to ensure that consistent, yet defensible, processes are followed in supporting the safety of numerous products across multiple companies and professional roles.

- Led project with external consultants to identify efficiencies and implement improvements for raw material and formula review processes
- Chaired an internal Clinical Advisory Board, reviewing clinical protocols for scientific soundness, safety, and regulatory compliance, and leading meetings to establish guidelines and procedures for contracting clinical studies

- Led the process for child-resistant package testing and trained colleagues to successfully transition the project
- Developed internal procedures and work instructions, as necessary, to support safe product marketing, when used according to directions and under foreseeable misuse conditions
- Participated on cross-functional process improvement projects, representing the safety and regulatory teams and delivering recommendations to upper management
- Managed air-care projects within corporate global safety and regulatory affairs team
- Served as liaison between Global Safety and Regulatory Affairs and RD&E to prioritize projects and ensure timely completion of safety and regulatory/registration assessments for air-care projects
- Researched, developed, and managed the internal review processes for specific chemicals, including fragrances, preservatives, and colorants
- Maintained corporate Material Safety Data Sheet (MSDS) system
- Conducted training globally on corporate internal Product Safety Clearance System

ABSTRACTS

Sheppard A, Baker E, Bermudez D, Blattner J, Boyd K, O'Neal S, Rahim T, Whittle E. Use of alternative methods to assess skin irritation of chemical mixtures. World Congress for Alternatives to Animal Testing, Seattle, WA, 2017.

Sheppard A, Baker E, Bermudez D, Blattner J, Boyd K, O'Neal S, Rahim T, Whittle E. Implementing an alternate testing strategy for assessing skin irritation. Society of Toxicology, Abstract #2734, Baltimore, MD, 2017.

Willems SS, **Sheppard AM**, Treichel JL, Raabe H, Curren R. An evaluation of the reconstructed human epidermis (RhE) method for predicting skin corrosivity of chemical products with extreme acid pH. World Congress, Canada, 2011.

Burrows-Sheppard AM, Willems SS, Heitfeld FA, Treichel JL, Raabe H, Curren R. An evaluation of the EpiDerm Corrosivity and Corrositex Assays for predicting skin corrosivity of chemical products with extreme alkaline pH. Society of Toxicology, Abstract #489, Salt Lake City, UT, 2010.

PATENT

U.S. Provisional Patent Application No. 61/430,323. Non-corrosive stripping compositions and methods of making and using same. Savaglio C, **Sheppard A**, Ludtke N, applicants.

ADDITIONAL TRAINING

EPA & OECD Good Laboratory Practices, Quality Associates (12/15, with updates 2016, 2017, 2018, 2019, 2021)

OPEX Champion Bootcamp, SC Johnson OPEX team (11/2020)

Child Resistant Packaging Today, Perritt Laboratories, Inc (5/2019)

EU Hazardous Materials Regulation, ChemAdvisor, Inc (1/04)

Toxicology: Principles and Applications, American Chemical Society (5/02)

Practical Methods in In Vitro Toxicology, Institute for In Vitro Sciences (6/99)

Auditing Techniques for Clinical Research Professionals, Barnet International (5/99)

Toxicology for Chemists, American Chemical Society (11/94)