



Exponent®

Engineering & Scientific Consulting

Stephanie Stephens

Principal Scientist | Chemical Regulation and Food Safety

Washington DC

+1-435-647-6209 | sstephens@exponent.com

Professional Profile

Ms. Stephens has more than 26 years of experience with EPA, FDA and USDA regulatory projects.

Ms. Stephens' experience includes pesticide (FIFRA) regulatory projects through her work in industry, consulting, and the Federal government. Her US work includes strategic planning, agency liaison activities, data development planning and management, submission and follow-on support for new food and non-food use active ingredient and product registrations for conventional chemicals, microbial and biopesticide registrations, inert ingredient approvals, import tolerances. In addition, she manages responses for Agency reviews of existing pesticides the pesticide reevaluation (registration review) process for existing chemicals under review. Ms. Stephens has significant experience planning global registration strategies with multi-disciplinary teams and has key contacts to support global registration efforts partnering with Exponent.

In addition to pesticide expertise, she has experience with FDA-regulated animal drug approvals, including assessing data requirements for New Animal Drug approvals (NADs) and obtaining and managing Investigational New Animal Drug approvals (INADs) for these types of products.

Ms. Stephens has also managed USDA APHIS program projects as a Federal employee and written, managed, and reviewed compliance projects under the National Environmental Policy Act (NEPA) both as a Federal employee and as a consultant. Ms. Stephens has expertise in permitting for non-genetically modified and genetically modified organisms regulated by USDA APHIS.

Academic Credentials & Professional Honors

M.S., Environmental Management, University of Maryland, College Park, 2005

B.A., Biology, Colorado College, 1987

Phi Kappa Phi academic honor society

Publications

Kurl RN, Holmes SC, Verney E, Sidransky H. Nuclear envelope glycoprotein with poly(a)polymerase activity of rat liver: isolation, characterization, and immunohistochemical localization. *Biochemistry* 1988; 27 (25):8974-8980.

Kurl RN, Holmes SC, Verney E, Sidransky H. Tryptophan binding to nuclei of rat liver and hepatoma. *The Journal of Nutritional Biochemistry* (Impact Factor: 4.55) 1995; 6(2):73-79.

Project Experience

Prepared and conducted multiple FIFRA training seminars for Federal (USDA) employees, industry and clients.

Led multiple large-scale, multi-year data development projects for new pesticide registrations on behalf of clients and industry. Projects included preparing registration strategic plans, negotiating with regulatory agencies, placing and monitoring studies at contract laboratories, reviewing study reports, assembling and submitting data packages, managing agency review process, managing multi-disciplinary scientist teams, and managing project costs and timing.

Led multiple multi-year EPA pesticide reevaluation projects, including preparing responses to EPA, negotiating with EPA staff on technical and administrative regulatory issues, and advising clients on strategies and approaches for responding to EPA.

Led due diligence and data compensation projects, including managing multi-disciplinary scientist teams, managing project costs and timing, assisting clients in preparing for testimony (data compensation cases) and preparing findings reports to clients.

Negotiated and managed jurisdictional consideration process for chemicals with potential multi-agency jurisdiction, including assisting with establishing lead jurisdiction agency on behalf of Federal and industry clients.

Led registration projects with multi-agency jurisdiction (EPA/USDA/FDA), including acting as primary communication between agencies, advising clients on strategies and approaches for achieving timely approvals/registrations.

Prepared, submitted and managed review process for numerous import tolerance petitions for pesticides to Canada, the US and other countries.

Conducted numerous facility-wide pesticide regulatory compliance audits (both on- and off-site) and presented findings and action items to clients.

Conducted program-wide pesticide regulatory compliance audits for Federal agency (USDA and associated Services), presented findings to staff and senior leaders, and implemented program-wide actions based on findings.

Authored multiple National Environmental Policy Act documents including Environmental Assessments, Environmental Impact Statements, and technical support documents for Federal and industry clients.

Managed regulatory compliance issues for animal drugs with FDA on behalf of USDA's Wildlife Services.

Managed compliance program for USDA's Wildlife Services Vertebrate Control Program. Provided technical and regulatory advice and project management for multiple USDA APHIS program projects including VS feral swine program, BRS permitting program, and PPQ commodity inspection activities.

Advisory Appointments

Regulatory Advisor, USDA National Institute of Food and Agriculture, Emergency Citrus Disease Research and Extension Program: Advanced testing and commercialization of novel defensin peptides and therapies for HLB control