

## Smithers Viscient Pharmaceutical Consulting

Smithers Viscient is a global Contract Research Organization (CRO) providing environmental testing services and regulatory consultancy to the Pharmaceutical and Animal Health industry.

### Product Stewardship

Our team has the real-world knowledge to evaluate your existing aqueous waste programs to reduce risk, identify improvements and opportunities, and save money. Smithers Viscient specializes in environmental manufacturing risk/hazard assessment strategies designed to increase revenue and productivity while reducing environmental impact and costs.

Our goal is to offer flexible solutions designed to strengthen your organization today, while building a foundation for *sustainable growth in the future*.

### Risk and Opportunity Assessment Strategy

Adhering to regulatory requirements, as well as to company policy, is vital for strategic growth with minimal risk. FDA and EMA require *Environmental Assessments/Environmental Risk Assessments* (EA/ERA) for all human and veterinary pharmaceuticals. Smithers Viscient develops risk assessments based on due diligence product reviews, robust testing strategies, and study management to accommodate your timelines.

Our team continually cultivates relationships with industry leaders and key regulators to better comprehend current and evolving global regulatory requirements. With this acumen, we assist you in developing the appropriate near- and long-term solutions for your organization.

Smithers Viscient offers contract research and regulatory services for the crop protection, pharmaceutical, industrial chemical, and consumer and household product industries. We offer testing in the following areas: analytical, toxicology and environmental, including product and residue chemistry, aquatic and terrestrial ecotoxicology, avian toxicology, environmental fate, metabolism, and *in vitro* and *in vivo* toxicology for endocrine disruptor testing. Additionally we offer computational and mathematical modeling services for use in designing and predicting properties of chemical substance testing.



### Smithers Viscient core competencies

- Scientific approaches and methodologies for design of testing programs that *reduce costs and increase productivity*
- Comprehensive understanding of existing and developing *guidance documents*
- Global regulatory knowledge and experience with practical applications
- Coordinating and monitoring *environmental fate and effect* studies
- A reputable and highly qualified team that understands clients' expectations
- Flexible and dedicated staff able to work to short deadlines

### Services offered that will improve your organization's success

*Environmental Registrations — Centre for Veterinary Medicine (CVM), Centre for Drug Evaluation and Research (CDER), European Medicines Agency (EMA)*

- Indication of New Drug (IND), New Drug Application (NDA), and Marketing Authorization Application (MAA) submissions
- Prepare Categorical Exclusion for a NDA submittal
- Manufacturing Risk/Hazard Assessment — site and local impact analysis
- Dossier review
- Interpretation of regulatory responses
- Support supplemental filings on New Therapeutic Indications

*Product Stewardship/Life Cycle Assessment — reducing the environmental impacts of products*

- Hazard Determination
- Manufacturing Risk/Hazard Assessment
- Environmental exposures scenarios
- Study development and management
- Pharmaceuticals in the Environment (PiE)
- Regulatory or toxic compounds — Product formulations and mixtures
- Green Chemistry — Environmental fate and effects-based chemical ranking
- Mathematical, computational and structure-based modeling



**Web:** [www.smithersviscient.com](http://www.smithersviscient.com)  
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