



EPA'S ENDOCRINE DISRUPTOR SCREENING PROGRAM (EDSP)

Consulting Support for EDSP Tier 1 Test Orders

Regulatory Strategy

Regulatory support to product registrants impacted by U.S. Environmental Protection Agency (EPA) test orders under the Endocrine Disruptor Screening Program (EDSP). Review test orders and advise registrants regarding regulatory options to evaluate potential endocrine disrupting effects in human health (toxicology) and environmental assessments (ecotoxicology). Agency liaison to define regulatory & technical approach.

New Data Generation

Scientific support for EDSP Tier 1 test battery following EPA's **Option 1** for complying with the test order. Identify contract research organizations (CROs). Place and monitor studies according to EDSP Tier 1 protocols. Review and interpret study results. Assure compliance with Good Laboratory Practice (GLP) standards. Format and submit required test result documents.

Existing Data Review & Evaluation

Review existing data under EPA's **Option 2** for complying with the test order. Advise registrant on potential EPA acceptability of previous studies. Determine approach for defending submitted or cited data in lieu of new data generation. Data gap analysis and recommendations. Prepare "Initial Response" to EPA re: existing data position and address Weight of Evidence (WoE) for submitting or citing such studies.

Task Force Representation / Administration

Provide client representation on industry trade association consortia under EPA's **Option 3** for complying with the test order. Senior CSI staff have experience serving in administrative and/or lead technical roles on numerous chemical task forces.

Advice on Other Regulatory Options

Guidance to registrants for EPA's non-testing Options such as: not subject to order claims, voluntary cancellation of pesticide registrations, product reformulation to exclude subject chemical, formulators' exemption claims, and other options as detailed in the test order.

Tier 2 Testing Insight

Advice to registrant on potential Tier 2 requirements under subsequent EPA order for additional testing based on review and evaluation of Tier 1 screening results.

Regulatory & Scientific Specialists



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