Study Design, Placement & Monitoring

Award-Winning Consultancy Providing Innovative Solutions to Meet Regulatory and Environmental Challenges

Appropriate Study Conduct Maximizes Regulatory Compliance

CSI places great importance on the design and conduct of studies that are conducted to support product registration. Data must be generated according to standardized guidelines and must address data needs appropriate to the product. Our technically experienced consultants guide registrants through the matrix of studies required for registration of agrochemicals, home and garden products, biopesticides, consumer and industrial chemicals and biocidal / antimicrobial products. We begin by conducting a data gap analysis to identify the necessary and appropriate data to be generated. During the process of generating the data, we function as agency liaison when novel product questions arise. We oversee protocols, data and reports for compliance with U.S. EPA, OECD, FDA and other international regulatory testing guidelines.

Protocol Development and Study Design

Our study monitors participate in protocol development to assure the best study design, and that the protocol satisfies regulatory guidelines. One pitfall of study design is to utilize an acceptable protocol, but yet produce poor quality data and false negative effects as a result of rarely detected, but preventable, deleterious animal behaviors or subtle, unintentional, technical mistakes associated with inadequate protocol detail. Such false negatives often result in falsely low NOECs and LOECs, or complete failure to define these critical study endpoints. Our highly experienced consultants can provide detailed protocol language that will guide the testing facility around these problems, maximize data quality, and minimize type II errors (false negative findings) in the final data analyses.

Study Placement, Monitoring, and Reporting

CSI communicates regularly with contract research laboratories (CROs) to ascertain study pricing and capabilities. We discuss the fine details of study design with potential CROs to identify the most competent CRO for a specific study type. Once a study is placed with a CRO, our study monitors engage in routine progress update communications throughout the course of the study until the report is finalized. When deemed necessary, we will visit the CRO during a study, to assure all procedures are consistently carried out and data are appropriately recorded, verified and analyzed. Finally, we review key data sets, statistical analyses, and draft and final reports in coordination with the Study Sponsor to assure a high quality, compliant, final report is generated.

Consultant Expertise

CSI staff has extensive experience in regulatory study requirements for a variety of chemical products. We can place and monitor studies at CROs in the following areas:

- Ecological Effects (including tier I, II and III polinator and avian laboratory and field studies)
- Product Chemistry
- Product Performance / Efficacy
- Toxicology
- Human Exposure
- Environmental Fate
- Analytical Chemistry
- Residue Studies (including pollen and nectar residue studies)
- Biocidal / Antimicrobial Product Efficacy
- Endocrine Disruptor Evaluations
- Exposure and Effects Modeling

Good Laboratory Practices (GLP)

CSI's Quality Assurance (QA) professionals evaluate the quality assurance program and process of CROs prior to placing a regulatory study. Our consultants review QA audits conducted during the study to assure compliance with the Good Laboratory Practice (GLP) guidelines, CRO Standard Operating Procedures (SOPs), and the study protocol. CSI can provide full GLP support to the testing facility on behalf of the Study Sponsor if requested.

Global Regulatory and Environmental Strategies since 1988

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