Good Laboratory Practice (GLP) Quality Assurance Consulting

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

Third Party Quality Assurance (QA) Support

CSI's qualified Quality Assurance (QA) professionals provide GLP expertise to comply with International Organization for Economic Cooperation and Development (OECD), U.S. Environmental Protection Agency (EPA), and U.S. Food and Drug Administration (FDA) GLP regulations and principles.

Contract Research Organization (CRO) Supplementary Support

CSI can deploy QA professionals to supplement QA personnel at contract research organizations (CROs) challenged with workload or personnel transition. Our QA staff are experienced with all aspects of Good Laboratory Practices and can audit any phase or entirety of a study. We can also provide QA support for small or start-up companies, GLP training assistance, and off-site (field) support.

Data and Report Audits

CSI will review GLP study raw data and reports in regard to quality and integrity of information submitted to regulatory agencies. Data and reports are assessed for accuracy, completeness, and compliance with study protocols and GLP regulations.

Standard Operating Procedures (SOPs)

We provide on-site or remote support to scientific staff for evaluation of the organization and efficiency of Standard Operating Procedures (SOPs) to ensure that appropriate and understandable study procedures are in place as defined by GLP regulations.

CRO Inspections and Audits

We provide on-site inspections and audits at CROs on behalf of study sponsors. Auditable phases include:

- In-process study inspections
- Facility audits
- Evaluation of internal systems and procedures
- Mock regulatory inspections to identify compliance deficiencies, and recommended improvements.

CSI Regulatory and Scientific Expertise

CSI's QA professionals bring a wealth of experience to GLP QA consulting. Our consultants have worked in CRO, government, and/or industry positions with regulatory science expertise in human health toxicology, environmental toxicology, and product chemistry.

Global Regulatory and Environmental Strategies since 1988

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