WHITE-SALTERSCONSULTING, LLC

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Quality Assurance • Auditing • GxP Training

White-Salters Consulting specializes in providing experienced, professional auditors who will partner with your company to identify areas of non-compliance to regulatory requirements and industry standards. Allow us to join your team and provide the following audit services to ensure global regulatory compliance:

PRE-APPROVAL INSPECTION (PAI) READINESS -

ensures that your facility is in compliance with FDA regulations.

- Evaluate the preparedness of manufacturing facilities for regulatory inspections
- Assess readiness of site personnel for FDA Pre-approval inspections
- Compare Chemistry, Manufacturing and Control (CMC) submissions against supportive documentation
- Review submitted method validation

GOOD CLINICAL PRACTICES (GCP) -

ensures that the rights of trial subjects are respected (as per the Declaration of Helsinki) and that the integrity of the trial data can be assured.

- Process audits (clinical monitoring, drug safety, clinical supplies)
- Document audits (protocol, clinical study report, IB, marketing application)
- Investigator site audits
- Trial Master File audits
- Vendor audits (e.g., CRO, IRB)
- Review of standard operating procedures (SOP)

GOOD LABORATORY PRACTICES (GLP) -

ensure the uniformity, consistency, reliability, reproducibility, quality, and integrity of chemical (including pharmaceuticals) non-clinical safety tests; from physio-chemical properties through acute to chronic toxicity tests.

- Audits of facilities, studies and reports
- Assessment of laboratories for compliance with GLP regulations
- Audits of bioanalytical laboratory facilities to GLP
- Training of staff in the requirements of GLP

GOOD VIGILANCE PRACTICE (GVP) -

ensures that a sponsor's drug safety and pharmacovigilance operations comply with applicable laws, regulations and guidances worldwide, and compare to best practices for organizations.

- Review of case processing to safety reports
- Assessment of quality management systems, the safety database, staff training and back-up procedures
- Validation of Computer Systems, Security, Back-up and Disaster Recovery
- Literature Screening
- Signal Detection and Management
- Risk Management/Pharmacovigilance Planning

GOOD MANUFACTURING PRACTICES (GMP) -

ensures products are consistently produced and controlled to the quality standards appropriate for their intended use and conform to the regulatory requirements stipulated by health authorities.

- Perform routine and qualification audits of contract facilities used for manufacturing, packaging and labeling, and distribution for compliance with global GMP regulations
- Assess qualification and training of personnel
- Review organization structure and SOP content
- Assess analytical laboratories and sub-contracted testing facilities

Call White-Salters Consulting at 978.772.7423 to learn how easy and cost effective it is to partner with us to service your GxP auditing needs.

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