GCP and GMP Training Services

LANDRICH GROUP

Why Do You Need Us?

At Landrich Group, we provide comprehensive support to help you navigate the complex regulatory landscape of clinical research and product development. Our integrated GxP services, with focus on Good Clinical Practices (GCP), and Good Manufacturing Practices (GMP)that are designed to ensure the highest standards of quality, compliance, and patient safety across every phase of your product lifecycle. Whether you're preparing for a clinical trial or manufacturing investigational products, we deliver pragmatic and effective solutions that align with global regulatory expectations, mitigate risk, and ensure data and product integrity from start to finish.

Good Clinical Practice (GCP) Services

Compliance Training (Available Upon Request)

GCP Training

Customized training programs based on ICH Harmonized GCP Guidelines, ISO Standards, FDA regulations and Guidance Documents to ensure all stakeholders understand their responsibilities and maintain compliance throughout the Clinical Trial process.

HIPAA Training

Guidance on privacy and data protection standards for handling Protected Health Information (PHI) in clinical research.

IRB Support

Guidance on IRB submission strategies, documentation, and compliance, including drafting and reviewing IRB applications, Informed Consent Forms (ICFs), and responses to IRB queries.

Study-Specific Documentation

Development and review of protocols, ICFs, Instructions for Use (IFUs), Monitoring Plans, Investigational Plans, and other key study documents.

Trial Master File (TMF) Management

Support in setting up, organizing, and maintaining a compliant TMF or electronic TMF (eTMF) throughout the clinical trial lifecycle.

Informed Consent Process

Structured guidance to ensure ethical and regulatory-compliant execution and documentation of the informed consent process.

Good Manufacturing Practice (GMP) Services

Documentation & Records

Establishment of accurate and complete documentation systems, including Batch Records, SOPs, and Analytical and Clinical Plans, Protocols and Reports.

Design Control and Risk Management

Expert guidance completing GAP assessments and implementing U.S. FDA Quality System Regulation (QSR), ISO Standard 13485 and ISO Standard 9001 compliant processes.

Equipment, Facility and Process Validation

Validation and maintenance of appropriate manufacturing equipment, facilities, and processes to ensuring inspection readiness and regulatory compliance.

Packaging & Labeling Compliance

Use of suitable and sustainable materials and processes to protect product integrity and meet regulatory standards.

Quality Assurance Audits

Independent QA oversight, including routine audits and compliance checks to monitor GMP adherence and ensure FDA and other regulatory inspection readiness.

Landrich Group's GCP and GMP services are built to ensure that the highest standards of regulatory compliance, operational rigor, and quality assurance support your clinical programs and investigational products. By combining ethical clinical practices with robust manufacturing processes, we help you build confidence in your data, your product, and your path to market.

Contact us for a free consultation at admin@landrichgroup.com