MWA CONSULTING, INC. | QUALITY WITH VISION

CLINICAL SERVICES

CONSULTING EXPERTISE IN GOOD CLINICAL PRACTICES AND PHARMACOVIGILANCE

MWA provides exceptional compliance consulting expertise from development through commercialization for the pharmaceutical, biotechnology, and medical device industries. Since 1995, **MWA** has successfully partnered with our clients to meet and exceed regulatory compliance requirements and guidelines. Quality with Vision: providing our clients with tactical and strategic solutions for compliance today and tomorrow. That's what we deliver!

MWA is a trusted and reliable choice for your GCP, GLP, and GMP compliance consulting projects. With more than 350 experienced associates located in the US, Canada, India, Europe, and South America, we are geographically positioned to provide expert resources in the most cost-effective manner.

MWA's Clinical Services team possesses a remarkable depth and breadth of experience, allowing us to provide precisely-targeted clinical trial auditing expertise and a wide range of support for our clients in the development and implementation of their Clinical Quality Assurance (CQA) programs and compliance infrastructure.

MWA's compliance associates seamlessly integrate with client project teams, policies, and standard operating procedures. Our globally available services include: audits; clinical trial design, development, and implementation; mock regulatory inspections and training; pharmacovigilance support; virtual clinical QA services; clinical project management; and GCP training. Every client project benefits from our extensive knowledge of US FDA, Health Canada, European regulatory body regulations, and ICH guidelines.

CONTACT US TODAY

Discover the power of partnership with
MWA CONSULTING, INC.
and reach your compliance goals
with our expertise in consulting.
We look forward to hearing from you.

CALL

(toll-free) 866-497-7787
Email: info@gxpsrus.com
For more information:
Visit www.gxpsrus.com

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CLINICAL SERVICES

AUDITS & ASSESSMENTS: BIOLOGICS, DIAGNOSTICS, DRUGS, AND MEDICAL DEVICES

Clinical Investigator Audits

- For-Cause
- GCP Milestone and In-Process
- Pre-FDA Inspection

Regulatory Inspections

- FDA-483 and/or Warning Letter Response and Remediation
- Gap Analyses
- Inspection Support and Facilitation
- Investigator Site Training and Preparedness
- Mock GCP Regulatory Inspections
- Routine, For-Cause, and Follow-up Audits
- Sponsor/CRO Training and Preparedness

Sponsor Audits and Services

- Clinical Database and Data Management Audits
- Clinical Protocols and Clinical Study Reports (CSR)
- Clinical Trial Audits
- Investigator Brochures (IB)
- Regulatory Submission Document Review and Audits
- Trial Master Files (TMF) Audits

SPECIALIZED CONSULTING

- Biostatistics
- Clinical Operations
- Medical Writing: INDs, NDAs, CTD/eCTDs, BLAs, IBs, CSRs, Protocols, ICFs, CRFs/eCRFs design
- Process Assessments (Process Mapping)
- Safety Surveillance/Pharmacovigilance

VENDORS / CONTRACT SERVICE PROVIDER AUDITS

- 21CFR11 Compliance: IVRS, IWRS, EDC, eDiary, CTMS, EDMS
- Bioanalytical & Toxicology Laboratories (GLP)
- Central Laboratories (GCP)
- Contract Research Organizations (CROs)
- eSystem Service Providers: Datacenters, ECG Core Laboratory Data Centers, eDiary
- In-Vitro Diagnostic and Medical Device Sites
- IRBs/IECs
- Manufacturing, Storage, and Distribution Sites
- Pharmacovigilance and Complaint Handling Sites
- Phase I-IV Investigator Sites

DOCUMENT DEVELOPMENT

- Corrective Action and Preventive Action (CAPA)
- Design CRFs and eCRFs
  Prepare clinical documents:
  INDs, NDAs, CTD/eCTDs, BLAs,
  IBs, CSRs, Protocols, ICFs
- Protocol and Report Writing/Editing
- Review Monitoring Plans, Communication Plans, Data Management Plans, Data Validation Plans, and Statistical Analysis Plans
- SOPs/Policies/Forms and Quality System Development

TRAINING (Customized and Standardized)

- Clinical Monitoring Techniques
- Good Clinical Practices
- Oversight of Clinical Service Providers
- Pre-Approval Inspection (PAI) Readiness
- Standard Operating Procedures (SOPs)

MWA's expertise includes: drugs, biologics (vaccines), biopharmaceuticals, blood products, cellular immunotherapy, gene therapy, medical devices, and solid organ/bone marrow transplantation. Therapeutic areas include, but are not limited to:

- Musculoskeletal Disorders
- Nephrology
- Neurology
- Obstetrics and Gynecology
- Oncology
- Ophthalmology
- Orthopedics
- Pulmonary/Respiratory
- Rheumatology
- Trauma
- Urology
- Anti-inflammatory
- Auto-Immune
- Cardiology/Vascular Disease
- Category A, B, and C Biodefense trials
- Dental
- Dermatology
- Endocrinology
- Gastroenterology
- Hematology
- Immunology
- Infectious Diseases

MWA shares in your commitment to quality and understands how critically important regulatory compliance is to the success of your business. Our solutions provide you with value-added options in addressing your strategic and tactical resource needs.

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For more information:

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