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GLOBAL PRESENCE

WHO ARE WE

FULL SERVICE CRO

A comprehensive global healthcare solutions company specializing in end to end of Materiovigilance, Pharmacovigilance, Medical Information Call Center, Database Hosting, Regulatory Affairs, Medical Affairs, CDM and Staff Augmentation

CERTIFICATIONS

- ISO 9001:2015
- ISO 27001:2022

SYSTEMS

- Cost-efficient, turnkey solutions
- Pre-validated ready to deploy systems
- AI ML NLP tools for Triage and Reportability Assessment

4C PHARMA SOLUTIONS

Presenting

QARA SERVICES

WWW.4CPHARMA.COM

THERAPEUTIC AREAS

MEDICAL DEVICE VIGILANCE

Cardiology, Orthopedics, Neurology
Oncology, Ophthalmology, Dermatology
Endocrinology, Gastroenterology &
Respiratory Care.

IVD

- Infectious Disease Diagnostics
- Oncology & Companion Diagnostics
- Chronic Disease & Metabolic Disorders
- Hematology & Immunology
- Neurology & Neurodegenerative Disorders
- Women's & Reproductive Health
- Genetic & Molecular Diagnostics
- Gastrointestinal Diagnostics

OUR SERVICES

Quality Affairs

Regulatory Affairs

"YOUR RESPONSIBILITY OUR PASSION."

HOLISTIC SOLUTIONS

4C PHARMA SOLUTIONS

COMPLAINTS HANDLING

- Vigilance Reporting
- Good Faith Efforts
- Periodic Reports
- Follow-Ups
- Investigation
- Closure

RISK MANAGEMENT

- Support in creating & updating Risk Management File Per ISO 14971
- Hazard Analysis
- DFMEA, PFMEA & UFMEA
- Risk Benefit Analysis
- Risk Management Procedure, Plan & Report

POST MARKET SURVEILLANCE

- PMS Planning & Documentation
- Complaints Handling
- Adverse Event Reporting
- CAPA Management
- PSUR, PMSP and Summary of Safety and Clinical Performance (SSCP)
- Post Marketing Clinical Follow-up (PMCF)

REGULATORY & QUALITY

- Support for FDA, MDR, IVDR compliance, & dossier preparation
- CER, CEP and SOTA
- Performance Evaluation Plan (PEP)
- Performance Evaluation Report (PER)
- Scientific Validity Report (SVR)
- Summary of Safety and Performance (SSP)

"Each project is executed with expert precision and decades of experience, embedding regulatory, quality, and clinical excellence at every step."

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