



Safety at Fulcrum Pharma

Fulcrum Pharma is a professional service company providing clients with expert solutions for the development of therapeutic products.

An accurate and comprehensive pharmacovigilance system throughout the clinical and post-marketing phases is essential for the protection of patients and public health.

New directives and regulations have been implemented to enhance patient safety monitoring that can require significant additional resource, time and expertise. Fulcrum provides customised pharmacovigilance and risk management solutions required to ensure products comply with these increasingly stringent safety requirements.

Whether you are a multi-product organisation or a single product biotech company we can use our track record in auditing to help you become inspection ready. With our experience in working in both clinical and post-marketing environments, we have developed systems and processes that allow us to offer a phase appropriate and cost effective solution to your pharmacovigilance needs.



Safety Matters

We have a dedicated team of safety professionals with expertise across the following areas:

- Processing of AE & SAE reports from Clinical Trials or Post-Marketing
- European Qualified Persons for Pharmacovigilance
- Medical Monitoring
- Expedited reporting of single cases to Competent Authorities, EMEA, FDA, Ethics Committees, Institutional Review Boards & Investigators
- Electronic expedited reporting
- Monthly line listings and Annual Safety Reports
- Post-Marketing safety reporting to Competent Authorities, EMEA and FDA
- Periodic Safety Update Reports (PSUSs)
- Summary Bridging Reports
- Addendum Reports (or Addendum PSURs)
- Global weekly literature searches, including review
- Client access to their information on safety database
- Writing of clinical safety narratives
- European Qualified Person for Pharmacovigilance and local Qualified Person for Pharmacovigilance
- Safety Data Exchange Agreements
- Responsible person for Eudravigilance and all aspects of Eudravigilance set up and management
- Drug Safety Advisory Boards
- Risk Management Plans
- Medical safety reviews
- Training of Pharmacovigilance and non-Pharmacovigilance staff
- Preparation for PV audits and inspection readiness
- Conducting safety audits
- Writing and maintenance of client specific SOPs and Process Guidelines

Our drug safety service offering is enhanced by our close collaboration with **Quantum Solutions, India. Together we deliver compliant safety solutions for clients using:**

- A cost leadership model
- Excellence in execution
- A proven track record in quality & compliance
- Experienced, reliable & dependable staff
- Validated market-leading global safety database
- Real time local support through offices in Europe, North America, Japan & India
- Full service team support working together with Fulcrum's Regulatory, Clinical, Development and Consultancy teams

For more information on our Safety expertise please contact us at:
BD@fulcrumpharma.com

Consulting

Development

Regulatory

Safety