



Pharmacovigilance services

KleemKara is a specialized Pharmacovigilance services provider that assists and enables small, medium and large Pharma and Biotech organizations to satisfy worldwide regulatory requirements. The KleemKara team consists of highly qualified and skilled experts who are committed to helping companies meet and exceed the challenging demands of the R&D lifecycle.

we are able to support pharmaceutical companies within specific functions. Our Pharmacovigilance service is particularly useful for Pharma and Bio tech companies without a dedicated Pharmacovigilance department that are looking for specific, cost- effective solutions for Pharmacovigilance tasks.



ICSR Case Processing

- Triage
- Data entry
- Med DRA Coding
- Narrative writing
- Medical review
- Quality Control
- Medical review
- Submission



Aggregate Safety Reports

- Periodic safety updated Reports (PSUR)
- Periodic benefit risk evaluation report (PBRER)
- Development safety update report (DSUR)
- Periodic Adverse Drug Experience Report (PADER)
- Annual Reports



Risk Management Plan

- Sahl Pharma provides strategic advice and analysis; develops US for risk evaluation and mitigation strategies (REMS)
- REMS update reports
- Risk management plans (RMPs) for Europe



Signal Detection

- identified and potential signals
- Analysis of ongoing signal evaluation
- Label update analysis



Medical Call Center

- 24*7 support
- Tracking for Product Quality Compliant
- Product Inquires and comments

Literature Servillance

Literature for reports of odverse events for all types of products, using standard terms, triage analysis, and relevant processing for expedited or periodic reporting

Our Capabilities

- Rapid implementation time and timely delivery of Projects
- 247 Support and do Support and domain expertise
- Date Migration, setup and maintain Pharmacovigilance activities in compliance in house of Sponsor's SOPs Meeting regulatory requirements
- Flexible to work on any type of Business models (Off shore/ On shore)

Other Service Clinical Management

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