



Overview

To streamline our processes we have set up a Knowledge Process Outsourcing (KPO) unit which ensures flexibility and scalability of our services to meet the operational scale of our clients.

Our KPO offers integrated solutions to support data management, medical writing, drug safety during clinical trials and post-marketing safety surveillance. We provide support to companies ranging from small to medium size CROs, pharmaceutical, biotechnology or medical device companies to Global companies.

We provide flexible, result driven and scalable solutions tailored towards our client needs which enable them to focus on their business and benefit from the competence of a trustful provider.

Management

Our People

MedHimalayas has integrated expertise with the latest technologies to meet the client needs. Our professionals have the competence and regulatory knowledge to meet the needs of our customers keeping up with the compliance standards in the areas of Pharmacovigilance, Data Management and Medical writing.

We have a pool of talented professionals to facilitate with uninterrupted and smooth running of ongoing projects.

The pharmacovigilance unit consists of experienced Medical writers, Data Associates, Pharmacovigilance officers, Drug safety physicians, Pharmacovigilance project leads and Pharmacovigilance manager.

The team is supported and monitored by the best international industry Pharmacovigilance and regulatory consultants all of whom have many years experience of European and FDA operational structure.

Our Working

Our pharmacovigilance and drug safety unit work closely with our clinical research, data management, regulatory and medical writing team. Pharmacovigilance forms the core of our working system.

MedHimalayas use a fully validated, industry-standard 21 CFR Part 11 compliant database for SAE management, reporting and regulatory reporting (including E2B). The system is web-based and allows us for maximum flexibility and scalability according to the operational scale of our clients.



Pharmacovigilance

With the regulations in pharmacovigilance becoming more stringent, the pharmaceutical industry is facing an increased demand for patient welfare and safety. Companies need to collate all the vital safety information about their products to meet these regulations.

Good Pharmacovigilance Practices (GPvP) have to be ensured by the companies and are absolutely necessary for the safety of patients and for marketing authorization.

Our pharmacovigilance outsourcing services are aimed at providing our clients with cost effective, knowledge based solutions to their needs.

MedHimalayas offer integrated Drug safety solutions and consulting services.

- ✓ European Qualified Person for Pharmacovigilance (QPPV) services
- ✓ Strategic planning
- ✓ AE and SAE logging, data entry, tracking, using tracking databases
- ✓ Adverse Events and Serious Adverse Events case processing
- ✓ MedDRA and WHODRL coding
- ✓ Serious Adverse Events narrative writing
- ✓ Safety medical assessments by the physician
- ✓ Generation of forms - CIOMS/Medwatch
- ✓ Expedited reporting according to regulatory requirements
- ✓ E2B electronic reporting format generation
- ✓ Literature search and reviews
- ✓ Management of follow-up cases
- ✓ Notification of Suspected Unexpected Serious Adverse Reaction (SUSARs)
- ✓ Periodic Safety Update Reports (PSUR) and Annual Safety Update Reports (ASUR) preparation
- ✓ Signal detection and Benefit-risk assessment
- ✓ Training in pharmacovigilance to the staff
- ✓ Compliance monitoring and QC checks
- ✓ Archiving
- ✓ Full Data back up support
- ✓ Medical Information services

Medical Writing



MedHimalayas provide a wide range of Medical writing services to meet the client's needs. Our highly qualified team of physicians and scientists has a thorough understanding of ICH, EMEA and FDA guidelines and are skilled in writing a wide range of scientific documents.

Our Medical Writers work in close association with our Project Managers, Clinical Research Physicians, Statisticians and Pharmacovigilance consultants.

We can assist with the following services:

- ✓ Clinical Research Reports
- ✓ Clinical Trial protocols
- ✓ Investigator Brochures
- ✓ Designing Case Report forms (CRFs)
- ✓ Subject Recruitment documents
- ✓ Statistical Report Preparation
- ✓ Case Narrative Company Assessment
- ✓ Summary of Product Characteristics
- ✓ Risk Benefit Assessments
- ✓ Periodic Safety Update Report (PSUR) & Periodic ADE Report (PADER) assessments
- ✓ Reference Safety Information (RSI) Review

Data Management

MedHimalayas offers a full array of data management services according to client's specifications and expectations.

We use standard data management tools along with effective communication for the accurate collection, organization, validation and analysis of client's data.

Our data management team comprises of highly experienced professionals that are up-to-date with the required regulations delivering accurate, fast and quality work. Our data management services include but are not limited to:

- ✓ Data Management Plan (DMP) Development
- ✓ Case Report Form Design, Printing, Distribution, Collection, and Analysis
- ✓ Data Validation Specifications
- ✓ Database Design , programming and management
- ✓ Data entry, data monitoring, data tracking and data cleaning Randomization
- ✓ SAS programming of tables, listings & graphs
- ✓ Data Validation and Quality checks
- ✓ Statistical analysis & reporting



Why Choose Us



Qualified and Skilled Professionals

Time and Cost Effectiveness

Fully Validated 21 CFR Part 11 Compliant Database

Quality Management System

Data Confidentiality

Regulatory Compliance At Every Step

Flexible and Focused Approach

Quality Deliverables

Quick and Efficient Processes