Medical writing

Overview

Global pharmaceutical industry is under pressure due to the changing dynamics, expiring patents and depleting product pipelines. It is exploring new ways to leverage outsourcing of non-core activities to address challenges of increasing cost and shorter drug-development cycle times.

Medical writing is integral to the product development lifecycle. In recent years, regulatory agencies have adopted critical review measures to ensure product efficacy and safety requiring the submission of an ever growing amount of documentation during the drug development process. At the same time, the timely dissemination of the scientific and clinical data on a product to healthcare professionals is important for its commercial success. This has led to an increase in the volume of medical writing for pharmaceutical companies. The pharmaceutical industry can meet this demand by outsourcing medical writing activities to a partner and leave its internal resources to focus on its core competencies. HCL offers professional medical writing services across a spectrum of domains to global biopharmaceutical industry.

Service Offerings (Medical Writing)

Regulatory Writing Offerings

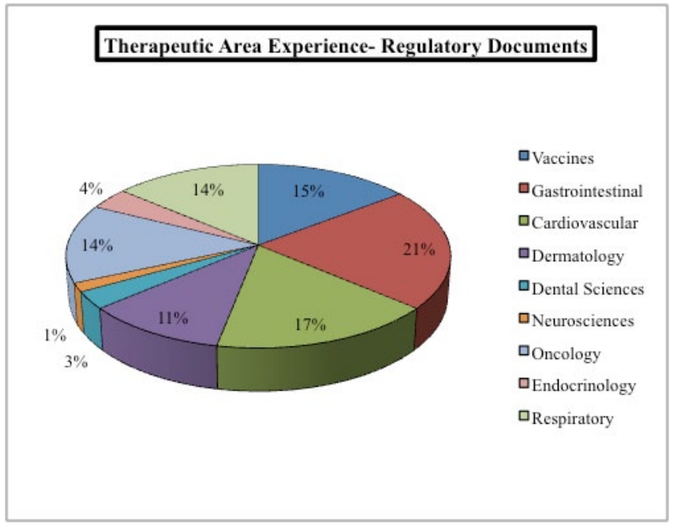
HCL has a comprehensive understanding of various regulatory guidelines such as ICH-GCP, FDA, EMEA and CD-SCO-DCGI guidelines. We understand the clients' challenges in developing material for drug life cycle process. Our writing team will dedicatedly work with you to develop the documentation needed and ensure that the documentation is up-to-date and in accordance with relevant guidelines.

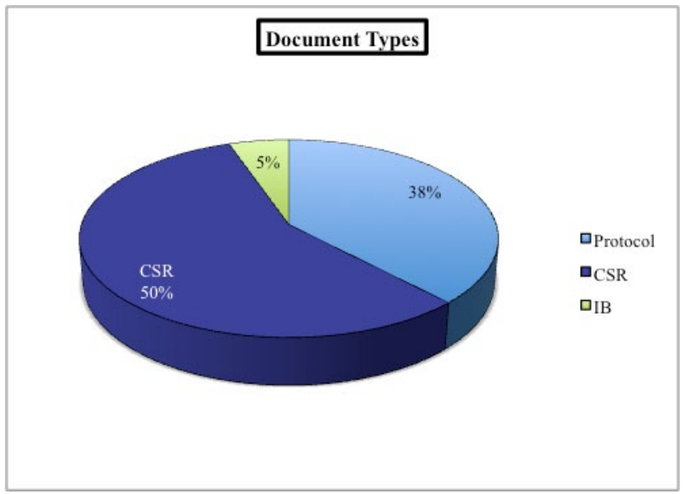
- Protocol & Informed consent documents
- Investigator brochures
- Patient safety narratives

- Clinical study reports
- Clinical Summary and Clinical overview documents for e-CTD submissions
- Non-clinical Summary and Non-clinical overview documents for e-CTD submissions
- New drug application (NDA) and Investigative new drug application (INDA)
- Development safety update reports & Periodic safety update reports (DSUR, PSUR)

Regulatory Writing Experience

HCL has regulatory writing expertise in diverse therapeutic areas such as Oncology, Neuro-sciences, Cardiovascular, Diabetes, Endocrinology, Antiviral, Anti-infective, Biological, Gastroen-terology, Dermatology, Dental, Respiratory and Orthopedics. We align our medical writing team based on therapeutic area expertise. Team has expertise in diverse documents types ranging from Protocol, Investigator's brochure to Clinical study reports.





Scientific Writing

The scientific writing group at HCL is well versed with ICMJE guidelines, GPP, CONSORT statement, E2C (PSUR) and E2F (DSUR) and routinely apply them in the preparation of the scientific documents. We prepare documents as per the specific journal/conference guidelines or as per the client requirements. Our writers understand your research goals and ensure that your scientific results and ideas are conveyed accurately to maximize the impact of written documents. HCL scientific publication services offered include:

- Manuscripts
- Publication planning
- Publications
- Literature Reviews
- Journal articles
- Review articles
- Abstracts
- Synopses

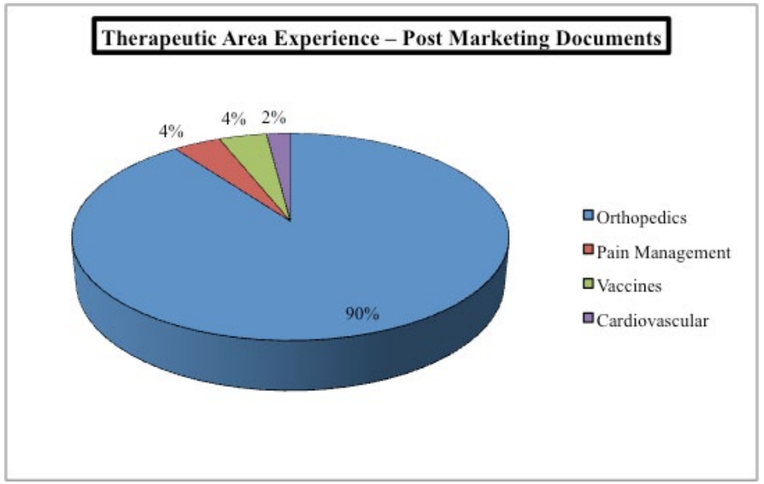
Commercial Writing

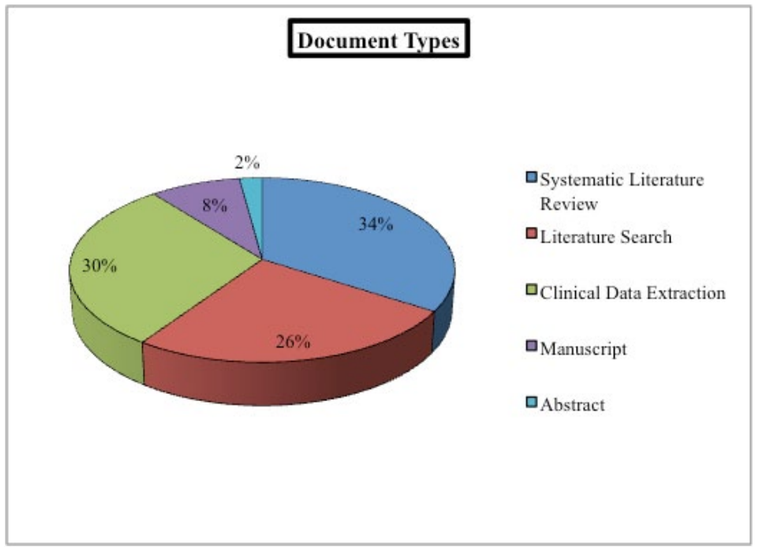
HCL has experience in medico-marketing communication writing involving development of marketing material

- Posters
- Newsletters
- Training slide decks
- Training manuals
- Slide Presentations
- Physician information booklets
- Patient education materials

Scientific and Commercial Writing Experience

HCL has diverse scientific and commercial documents authoring experience. Our medical writ-ing is well versed with systematic literature search, clinical data extract, manuscript and abstract writing services.

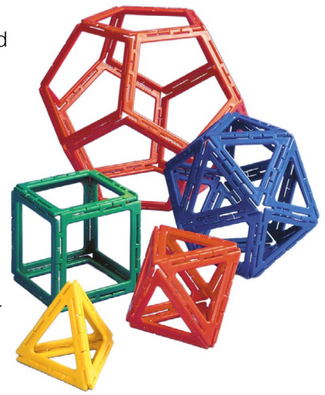




Frameworks/Description

Medical writing team at HCL is a blend of subject matter experts with qualifications (MBBS, PhD, Masters in Pharmacy and Masters in Public Health) hailing from academics, bio-medical research, medical and pharmaceutical industry. We are experienced in writing a spectrum of documents like regulatory, scientific and medico-marketing domains with understanding of drug development processes and regulatory requirements for different geographies. Our writers have the necessary skills and ability to grasp, inquisitiveness to explore, meticulousness and adaptable to change. In addition to solid writing skills our writers possess the ability to see relationships between ideas and organize complex information.

HCL has a dedicated Center of Excellence for medical writing services and provides services in the areas of regulatory, medico-marketing/commercial and scientific writing across all phases of product life cycle from pre-clinical to post-marketing literature. HCL provides end to end medical writing services to clients in pharmaceutical and medical device industries. We understand that clear, concise and well written documents play a critical role in the timely review and quick approval of products. We ensure that the documents are of superior quality, clear, concise, and also comply with regulatory, journal, or other guidelines in terms of content, format and structure. We understand the criticality in confidentiality of information & data security in medical writing for our clients. Hence our IT security systems and procedures are benchmarked with best practices across the globe.



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Key Differentiators

Flexibility

- Flexible and core team to deal with ongoing and new projects efficiently
- Ability to quick ramp up and steady state services helps to deal with small and large projects at the same time
- Flexible pricing models to suit the budget of the prospective customer
- Successful in breaching out the language barrier in analyzing the information

Resources

- Qualified and experienced people with relevant domain knowledge
- Therapeutic area wise aligned teams to speed up the process with high quality data

Processes

- Robust processes to ensure quality deliverables
- Timeline compliance
- Data confidentiality

Business Value to our Customers

Advantages

- **Onsite SMEs with direct client interactions**
- **Labour intensive process at offshore with training, oversight and QA of final deliverables by onsite SMEs**
- **Low cost and trained Healthcare professional availability**
- **Transactional based pricing**
- **Use of tools and accelerators**
- **Clear visibility of operational and business metrics**

Benefits

- **Round the clock seamless communication across the geographies**
- **High quality data generation through highly trained resources**
- **Reduced operational costs**
- **Increased operational efficiency through complete visibility of metrics**