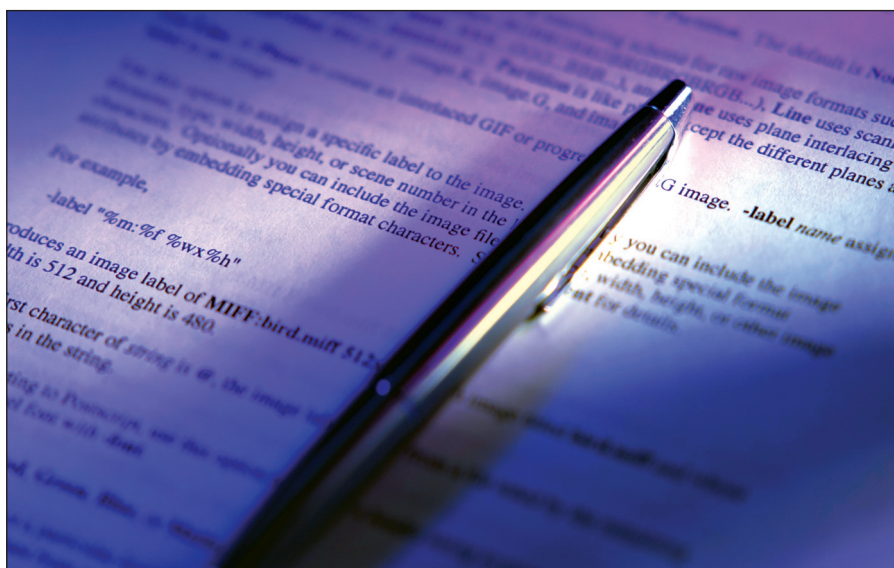


Outsourcing knowledge-based skills

Medical writing on the radar

Medical writing primarily involves writing on topics for the medical fraternity as well the common man. As the healthcare market is growing, demand for healthcare information is also increasing. Outsourcing is on a growing curve, since India has a pool of qualified and experienced professionals. A look at the fast-growing discipline.



Escalating cost of drug development, exhausting pipeline of effective molecules, expiry of patents, fierce competition from generics and the economic recession have put a lot of pressure on the global pharma industry for cost containment and maintaining profitability. The recent German legislation to control healthcare costs that proposes linking the prices of drugs with their efficacy may further add to worry of pharmaceutical companies and

force them to strictly control the R&D costs. To manage these challenges many companies are trying to reduce their overhead costs by focussing on their core R&D strengths and entering into strategic partnerships with Contract Research Organisations (CROs) for the non-core functional areas to utilise the CRO's expertise.

For long term gains, companies are shifting their focus from individual project outsourcing models to the strategic Full Time Equivalent (FTE)/Functional Service Provider (FSP) partnership models, as these partnerships offer flexible models to handle diverse trials.

Models adopted

FTE/FSP models provide a win-win situation for the sponsors as well as vendors. In collaborative FTE/FSP models, companies get access to a trained and qualified resource pool of the service

provider, without adding additional overhead costs. Also, having the same set of resources working across multiple projects over a period of time helps to bring in efficiency by implementing learning from the previous projects and thus translates into direct cost savings for the pharma company. Besides the operational efficiencies in strategic partnership models, companies also save significant time spent in contract negotiations for each independent project. Vendors prefer this model as it assures revenue continuity for them and avoids the need of entering into a new contract for every study and it also provides them with better visibility.

The outsourcing of knowledge-based services like Clinical Data Management (CDM), biostatistics and medical writing from large biopharma companies to the Asia Pacific region is continuously on the rise. Medical writing is a niche domain that has gained huge momentum in the outsourcing industry since the last decade as companies are looking for faster ways to bring safe and effective medicines to the market and maximise their benefits. According to a Centerwatch report, the medical writing market has grown by 15 per cent year-on-year and it has almost doubled from \$345 million in 2003 to approximately \$694 million in 2008.

Preview: Medical writing

Medical writing is about communicating scientific and clinical information about drugs, biologicals and devices to a varied audience including regulators, clinicians, patients, as well as the scientific community in a clear, unbiased and accurate manner.



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Medical writing can be categorised into Preclinical and Clinical writing.

Preclinical writing: Preclinical writing primarily involves the writing of documents for the drug discovery phase, eg, preclinical study reports, toxicological reports, preclinical summaries and overviews, preclinical publications, etc.

Clinical writing: Clinical writing involves documents related to drug development and the post-marketing phase. It can be categorised as follows:

Regulatory medical writing: Regulatory medical writing covers the major share of the medical writing market and this involves preparing different documents required as per law by regulatory agencies. For example:

- Clinical study protocols
- Patient information sheet and informed consent forms and assent forms
- Investigators brochures
- Clinical study reports
- Annual Safety Reports (ASRs) and Periodic Safety Update Reports (PSURs)
- Periodic Adverse Drug Experience Reports (PADERS) and safety narratives
- Clinical overviews and summaries
- Integrated summaries of safety and efficacy
- Package inserts (prescribing information for physicians)
- Clinical trial registry summaries and PhRMA web synopsis

Publication writing: Publication writing, a more niche segment, primarily involves the writing of manuscripts, review articles, case reports, letters to editors for publication in scientific and medical journals and the preparation of posters and presentations for various scientific conferences. The huge increase in the number of scientific and biomedical journals since the last decade, including online journals shows the necessity and growing importance of publications in the healthcare industry.

Medico-Marketing: This involves the preparation of promotional product literature, product handouts, training material for medical sales representatives, etc.

Medical education material: This includes the preparation of articles, slide decks, e-learning modules for nurses, physicians and pharmacists for Continued Medical Education (CME). Textbooks and chapters and patient education materials are also included.

The audience for medical writers may be regulators, academicians, research scientists, physicians, medical sales representatives and patients. There are distinct requirements for different types of documents depending on the purpose, phase of the trial and the audience for the document. In addition, within a particular kind of document, depending on the therapeutic area, study methodology and results, there may be huge variations in presentation and writing style and as it is important to communicate correct information in a precise and succinct manner, it is said that medical writing is a combination of art and science.

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High on Art

Clinical Research

Getting into it

Earlier in developed countries, a degree in English held higher priority and these professionals were provided clinical training. However, now the trend has changed. Medical writers need to possess a portfolio of skills, including a background in medical sciences, life sciences or pharmaceutical sciences, along with a good command over English and a flair for writing, a sound understanding of research methodology, biostatistics and basic Microsoft Office skills. Many companies do hire copy editors to support scientific writers.

Since the last decade, India is seen as a key destination for the outsourcing of medical writing, leading to a huge demand for well trained and experienced medical writers in the industry. Though India has a huge English speaking, scientific and medical community, there is scarcity of an employable talent pool because of a lack of formal education and industry experience in medical writing and the shortage of professional medical writing training programmes. The scarcity of the trained talent pool in the industry results in attrition and the need to attract and retain talent ultimately leads to spiralling wages and adding to costs. This talent crunch of professionally trained medical writers in the Indian healthcare industry may strangulate India's growth story, and hence it is very important for the industry to self-regulate and manage its needs. Various companies are trying to manage the scarcity of resources in

their own ways such as enhancing the industry and academia partnership to have a supply of employable talent pool, conducting education and professional training programmes, internships and cross functional trainings of the resources in other domains. Recently, SIRO Clinpharm, launched the 'Centre of Excellence for Medical Writing' which offers basic and advanced certificate courses in medical writing, based on an industry aligned curriculum.

Due to the spurt in the demand of medical writers in the industry, a lot of young people working in other allied domains like pharmacovigilance, medical affairs, CDM or medical transcription streams in CROs, Business Process Outsourcing (BPOs), Knowledge Process Outsourcing (KPOs) or pharma companies are seeking out training programmes in medical writing, to build a career in this niche domain. Adequate availability of skilled and trained resources helps the industry to a great extent in keeping a reasonable resource cost control over a period of time and also helps to quickly ramp up the teams if required.

While hiring medical writers, it is critical to evaluate and identify people with the right skill sets, and attitude. Apart from a command over English, soft skills like analytical and logical thinking, an eye for details, a passion for reading and writing, multitasking and organisational capabilities are also important. Adequate time should be invested in onboarding and providing

functional training. Effective and thorough training on International Conference on Harmonisation (ICH) guidelines, regulatory requirements for USFDA & European Medical Agency, Consolidated Standards for Reporting of trials (CONSORT), International Committee of Medical Journal Editors (ICMJE), Writing style (eg, AMA style manual), key therapeutic areas and biostatistics go a long way in ensuring quality. Use of tools such as standard templates, checklists, document management and tracking systems, project management tools and innovative tools like macros help writers to make the process leaner.

Collaborate to grow...

The skilled resources for knowledge-based services like CDM, biostatistics and medical writing are available in emerging markets at significantly lower costs. While cost is one of the key factors for strategic outsourcing, for the selection of long term strategic CRO partners, companies do focus primarily on the competencies of the resources, their domain expertise, and thus their ability to deliver the defined quality as per service level agreements per timelines. It is imperative for service providers to foster a culture of innovation at work and to focus on process improvements and efficiencies to remain competitive in the business.

To summarise, biopharma companies will continue to establish strategic partnerships for knowledge-based business critical services like medical writing to keep R&D costs under control. Hiring people with right sets of skills and attitude and investing adequate time in proper training on regulations, guidelines and technical aspects, culture of innovation and smart thinking helps drive strategic partnerships. Long term strategic collaborations will help the pharma industry to bring cost-effective medicines at affordable prices in the market. **MPH**

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Classification

