

Key factors a pharmaceutical company should consider while outsourcing medical writing services

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Abstract

Medical writing teams are crucial in the pharmaceutical industry at every stage of drug development. With growing regulatory pressure and shrinking profit margins, outsourcing these activities is considered a viable option that provides multiple advantages such as high-quality documents produced in a shorter time and at a lower cost. Correct identification of an outsourcing partner is critical for success. We propose the following eight key criteria that a sponsor company should consider when choosing a medical writing service provider: types of services offered, organisational structure of the provider, resources, quality of services, communication, client relationship, contract, and cost-effectiveness.

Keywords: Medical writing, Outsourcing, Selection, Pharmaceutical company, Clinical research organisation, Medical writing agency

With a rapid decline in research and development productivity, increasing pricing pressure, shrinking profit margins, heavy competition, and stricter regulatory requirements, the pharmaceutical industry faces a constant challenge to achieve and maintain profitable growth.¹ A viable option in this scenario for any company is to cut down on the costs and efforts required to bring a drug into the market by outsourcing clinical trials and related activities that constitute the major part of costs during the drug development process.² It is in this pursuit of acquiring valuable, trained, and experienced resources, as and when needed, that the outsourcing market for drug development research (clinical trials) reached \$36.6 billion in 2011 and is projected to grow to \$60.8 billion by 2016.³ Clinical trial operations such as medical and clinical monitoring, product safety, and project management, together with data processing, have been the predominant outsourcing areas,

but a similar upsurge in recent years has also been witnessed for other functions including biostatistics, pharmacovigilance, and, in particular, medical writing and communications.

The medical writing field encompasses a vast range of activities (Figure 1) and involves clear, unbiased, accurate, and effective communication of scientific and clinical information to address needs of different sets of audiences, which include regulators, clinicians, patients, and the scientific community.⁴ Preparing a number of high-quality medical documents for a quick regulatory submission and marketing authorisation within the time, resource, and budget constraints is a challenge to pharmaceutical companies, and it is probably the reason why medical writing has become the fourth most frequently outsourced service. According to one analysis, the market for medical writing reached about \$700 million in 2008, of which the maximum contribution was from outsourcing.⁵

Emergence of medical writing agencies and clinical research organisations

Sparked by the expansion in the amount of work to be outsourced, the number of clinical research organisations and medical writing agencies has increased exponentially in recent years. As the identification and selection of the correct partner is a key to success, an important question that has received little attention is how to choose the right one from a wide choice of service providers. Clearly what works for one service (e.g. clinical trial operations) may not necessarily work for another (e.g. medical writing), as the benchmarks for selection would be entirely different. Avoiding the prevailing tendencies of 'the bigger the better', 'always used', and 'going by the name', sponsor companies should consider other



Figure 1: Medical writing services overview.

factors while selecting an outsourcing partner for their services.

In this article, we discuss eight critical elements for selection of an outsourcing partner, which may assure best results in the long run and build a collaboration based on mutual respect, trust, transparency, and flexibility from both sides (Table 1). The following section discusses each criterion from the point of view of a sponsor.

Services

Types of services offered by an agency are an important consideration for a sponsor company; however, outsourcing needs may differ from one company to another. While some companies may seek complete assistance for development of scientific documents (regulatory or communications) at every level of drug development, others may be interested in consultancy or partial assistance for the same documents. Choosing a niche agency could be a better option for specialised services like publication planning, product branding, messaging, conceptualisation, quality control, or training. Whereas when looking to outsource entire clinical operations as well as specialised services, an agency with significant and diverse experience in handling all these activities could be the better option.

Organisation

Even if there are a number of organisations that offer the same service(s) you need, partnership with one

that shares a similar corporate vision, mission, and values can be beneficial. The outsourcing partner in this case is more likely to honour your goals, more willing to harness the intellectual capital at your disposal, and less likely to work at cross purposes. Size, turnover, and years in business are indicators of the staying power of a company, consistency of service, reliability of response times, and problem-solving capabilities. Assessing leadership of a company is essential as it directly reflects vision, decision making, and ability to plan. A service provider with a large customer base that has similar needs indicates that the provider will have the required breadth and depth of relevant experience and can provide more creative solutions. Also, a service provider with a record of delivering high-quality documents and expertise in overall study management is likely to deliver successful results with or without relevant therapeutic area experience. A service provider engaged in a continuous endeavour to ‘up its game’ by means of various initiatives like white papers, webinars, and presence at various conferences would be able to efficiently leverage its knowledge assets.

Resources

Sponsor companies may understandably expect to be provided with a team of highly trained medical writers who are experienced in a broad variety of therapeutic areas and document types and are sufficiently trained and skilled in preparing clear, well-

Table 1: Essential elements for successful outsourcing partner selection.

Element	Specific attributes	Writing and reviewing	Training and mentoring	Branding, planning, and strategy building	Competitive intelligence and market analysis	Audit compliance
Organisation	Size, reputation, values, vision, leadership	X	X	X	X	X
	Years in industry	X		X	X	
	Record of long-term client relationships	X		X	X	
	Experience across therapeutic areas	X	X	X	X	
	Metrics for similar projects	X		X	X	
	Initiatives: webinars, white papers, workshops, news items, infographics	X	X	X	X	
	Professional networking	X	X	X	X	
Resources	Manager/lead: qualifications, experience	X	X	X	X	
	Associates: number, qualifications, experience	X		X	X	
	Stability-attrition rate	X		X	X	
	Awards, recognition	X	X	X	X	
	Information technology, electronic tracking, infrastructure	X	X	X	X	
	Process:	X		X	X	X
	<ul style="list-style-type: none"> ● Clear and audit compliant ● Process flow ● Updated SOPs, templates, style guides, training modules 					
Quality	Outcome of previous audits	X				X
	Turnaround time of documents	X				X
	Client feedback on quality, timeline adherence, and overall satisfaction	X	X	X	X	X
	Issue log maintenance	X	X	X	X	X
	Strict adherence to applicable processes, policies, regulations, and guidelines	X		X	X	X
	Communication	Written and verbal skills	X	X	X	X
Assertiveness and passion		X	X	X	X	
Follow meeting etiquette		X	X	X	X	X
Customer focused		X	X	X	X	X
Regular follow-up		X		X	X	
Communication channels compatible with geographical barriers		X	X	X	X	
Relationship	Positive, transparent	X	X	X	X	X
	Flexible	X	X	X	X	X
	Discuss expectations	X	X	X	X	X
	Integrity and honesty	X	X	X	X	X
	Respect of cultural diversity	X	X	X	X	X
Contract	Clear, unambiguous	X	X	X	X	
	Good faith	X	X	X	X	
	Legally compliant	X	X	X	X	
	Streamlined invoicing	X	X	X	X	
Cost	Justifiable	X	X	X	X	X
	Hidden costs	X	X	X	X	X
	Cost versus time	X	X	X	X	X

structured documents that meet regulatory requirements and journal standards. However, it is better to look at the track record of the study manager and the team assigned to your study, their hands-on experience, the timelines and quality of previous documents, training, and skill sets. It is also likely that the employees initially suggested may not be included in the team that eventually conducts the project. The leaders and coordinators must set up and achieve the desirable goals, and they must have adequate staff and material resources at their disposal. A well-defined team structure with independent writers, quality controllers, and reviewers ensures quality and accuracy of deliverables.

Quality

The sponsor company should ensure that an appropriate quality assurance program is established and effectively executed by the partnering agency. All documents should go through an internal review and quality control cycle to ensure the highest quality, accuracy, and compliance with all applicable regulatory guidelines. To ensure that good practices are followed, the service provider should be able to demonstrate updated standard operating procedures, training modules, process flows, and guidance documents. The service provider should also provide relevant documents on the outcomes of previous audits and client feedback on quality, timeline adherence, and overall satisfaction.

Communication

Communication is the key for outsourcing companies to benefit fully from an outsourcing partner. An agency that is willing to discuss expectations, clarify any areas of confusion, and set realistic goals is more likely to provide focused and reliable results. Emphasis should be placed on the content and style of the communications in the business plan, partnership agreement, monitoring, and evaluation systems. Communications should be precise and provide all the information relevant for the partners. Promptness, inviting feedback, and regular follow-up will demonstrate that the outsourcing partner is eager to take up and complete the job. Efforts to establish good communication channels across linguistic, cultural, and geographical boundaries should be acknowledged.

Relationship

To achieve a sustainable competitive advantage, the relationship between the sponsor and outsourcing partner should be of equals and collaborative in nature. Outsourcing to a company is beneficial if the outsourcing partner is flexible and adapts well

to change so that they can deal effectively with the complex issues of a dynamic global economy. Another point to bear in mind is the outsourcing partner's corporate culture, which can be critical in determining whether a relationship succeeds or fails. Positivity, transparency, integrity, and honesty are imperative when it comes to establishing trust and building long-term relationships.

Cost

An agency is less likely to cause numerous changes that surpass the budget if it is realistic about the costing and provides sample cost estimates in the proposal. Going with an agency offering the lowest bid may not necessarily be the best option because it could mean that the providers did not understand the full specifications or resources needed for the project or that there may be hidden costs that will be added at a later date. Preferred agencies are experienced and provide accurate and comprehensive estimates and have additional processes for quality oversight that include the tracking of time and events against the money spent.

Contract

Preparing a contract that is unambiguous and provides a clear understanding of the expectations and commitments should be given preference. An accurate, detailed, legally compiled, and comprehensive proposal provided with a fair and accurate cost assessment aids in the decision-making process.

Conclusions

Outsourcing medical writing services to a team of competent and dedicated medical writers with relevant expertise to work on the clinical and regulatory documents has become a popular business strategy in pharmaceutical companies in recent years. Several types of services may be outsourced and used only when the workflow demands. Outsourcing decisions have traditionally been driven by cost factors, but factors other than cost also require frequent and urgent consideration. If due diligence is applied, the eight criteria outlined in the present article will aid in choosing the right service provider for an effective and long-term partnership.

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