ENSURING QUALITY IN A STRATEGIC MEDICAL WRITING PARTNERSHIP

We are talking about two things here – quality, and medical writing – so first let's examine both of these terms. Quality really means different things to different people – some consider it to be a degree of excellence, while others may see it as 'being fit for purpose'. While perfection would be desired, it is always important to balance effort against output. Hence, rather than targeting perfection, it is important to focus on what matters: those critical data points that will make all the difference.

Medical writing involves the authoring of scientific content and could encompass a range of documents specific to different stages of the product life cycle, resulting in classifications for regulatory writing, safety writing, publications, medico-marketing, and so on. Even within each class of writing, there is a diverse collection of documents that can vary in terms of complexity, intended audience, authoring processes, and end objectives. In addition, the documents authored and the processes followed are quite different when authoring documents for drugs and when authoring documents for medical devices, respectively.

While there cannot be one blanket strategy for ensuring quality in medical writing, a survey conducted with a few key stakeholders across the drug and device industries indicates some common standard approaches for doing so. These include:

· Ongoing functional trainings on SOPs, style guides, document types, and therapeutic areas
· Ongoing training on regulations
· Ongoing functional trainings on data interpretation and presentation
· Recurring trainings on style guides
· The use of standardized document templates
· The use of QC checklists
· The use of automation to ensure consistency
· Others quality control checks for document compliance, template, sections, content and format

Robust SOPs, standardized document templates, and thorough training are essential pillars of quality. It is not about providing training at the beginning and getting done with it. Refresher trainings and trainings on new regulations are essential. In addition, it is important to establish a competency framework and to ensure that resources are signed off after being assessed so that they move from one competency level to the next. Documents should be assigned based on the competency level of the writer. When it comes to writing, its important to remember that just because a writer has worked for many years on certain document types or therapeutic areas, they may not necessarily succeed, without suitable training, when working on new document types or other therapeutic areas. Even within the same organization, different therapeutic area leads have different expectations, and it takes time for writers to adapt to new document formats and expectations. Especially when working with freelancers, sponsors need to ensure that that writer has the relevant experience and invest in setting clear expectations.

Medical writers do not work in silos. They need to partner with multiple stakeholders, and having a clear RACI (Responsible Accountable Consulted Informed) matrix is essential to prevent conflicting messages from being generated within the document. Quality checklists need to be tailored to the document type being authored, and an independent reviewer needs to review the document. QC reviewers need to be properly trained, and they need to document their findings as well. This review needs to be followed by a QC verification process to ensure that all findings have been addressed in the new version before the QC process can be completed. As QC is usually the last step in the process, there is significant pressure on the quality reviewers owing to a time crunch. It is very important to provide those reviewers with enough time to thoroughly review the document. This also involves providing the quality reviewer all the source documents well in advance. Thus, planning for a timely and effective quality review requires a lot of effort.

It is also recommended that QC should be integral to the entire medical writing process, and should have been performed prior to the review of the first draft, so as to ensure that all data is accurate and that it has been presented and interpreted appropriately. While certain documents can be pretty large, it is not advisable to have multiple reviewers review different pieces of the document independently, as there needs to be internal consistency of information in the document; this may not be addressed when multiple quality reviewers are working on the same document. Quality is not only about the accuracy of data, formatting, grammar, and style – it is also about the consistency of messaging throughout a document and across multiple documents. Version control is critically important in medical writing, and without it there can be many inconsistencies in the final outcome.

Poor quality resulting in rework is the Cost of Poor Quality (CPQ). Therefore, driving quality at the grassroots level is important. Investing enough time in designing the right document templates, and drafting and reviewing SOPs thoroughly, would significantly enhance quality. The Quality Team is always under pressure, not only from a time perspective, but also from a cost perspective, as the additional pair of eyes is often perceived as an additional cost. While integrating quality at the design level is highly recommended, it is equally essential to ensure that the final quality check is in place.

Automation can add significant value. Programmed content creation, resulting in the auto-population of content while generating documents such as clinical study reports and narratives, not only enhances efficiencies, but also reduces the likelihood of manual errors. Nevertheless, a final review to ensure that information has not been distorted is important. This also allows the writer to focus on adding scientific value while eliminating some of the mechanical tasks. One should keep in mind the stage at which data was pulled and whether it was clean or not, as this may significantly impact the final interpretation. This is something that may be neglected while working with automated systems.

It is also important to distinguish between QC and peer review. Both contribute to the quality of the document in independent ways, with QC focusing more upon data accuracy, formatting, grammar and style, while peer review weighing in more upon data interpretation and messaging. The skill sets, the experience levels and the training required for these roles are also different. Strategizing, well in advance, on key messages, helps reduce the number of iterations required and ensures a high-quality deliverable.

From a medico-marketing perspective, when developing high quality promotional material, a critical piece to keep in mind is the communication of 'balanced information'. It is the role of the Promotional Review Committee (PRC) or the Medical Legal Review (MLR) Committee to maintain a fine balance between meeting business objectives and compliance with legal and regulatory requirements. The medical reviewer plays a key role in claims substantiation, and should be experienced and trained to perform this task effectively. In addition to compliance, high-quality advertisements need to be adapted to local culture, and content must be localized in such a way that it will be contextually meaningful.

When creating health materials for patients, it is important that the language used aligns to the health literacy levels of the patient, and that the content is 'speaking to', rather 'talking down' to the patients. Even though the EU Clinical Trial Results Regulation EU CTR 536/2014 mandates that lay summaries of trial results should be shared with trial participants within a year of the last patient visit, less than 2% of completed or terminated clinical trials have provided lay summaries to the participants in the past three years. In many cases, where information is available, it may not be fit for purpose. In fact, ICH guidelines recommend a 'fit for purpose' approach to quality, focusing efforts on what counts.

When medical writing is outsourced, it is not uncommon for medical writers to co-author documents. It is important that the reviewer assesses the flow and the readability of the document and ensure that it does not convey pieces of information in in a disjointed manner. Thus, a quality strategy for medical writing should incorporate a continuous improvement program for the team in order to reduce variance in writing styles and ensure consistency in messaging. If significant issues are noted on an ongoing basis, a jointly agreed upon Corrective and Preventive Action (CAPA) Plan needs to be implemented. Ongoing sponsor audits and internal audits also contribute to building a quality-focused organization.

While organizations can implement multiple measures to ensure quality when establishing a strategic medical writing partnership, there are still several challenges that one encounters along the way. Some of these include:

· Lack of recognition for a learning curve when working on new systems and SOPs; lack of gradual scaling up in quality metrics
· Inconsistent training at the vendor's end
· Lack of alignment on quality metrics
· Inadequate efforts spent on initial training from the sponsor
· Resources being moved too quickly across document types or therapeutic areas
· High attrition at the vendor's end, resulting in knowledge loss over time
· Inadequate efforts spent on expectation setting between the sponsor and the vendor
· Lack of transparency and trust in the partnership, preventing the open sharing of issues and the ability to work together to resolve them
· Lack of auditing for systems and processes from both sides
· Inability of the team to reorient themselves to the audience they are writing for
· Lack of a governance process for evaluating performance on an ongoing basis
· Lack of appreciation for high-performing resources
· Too much pressure for rush jobs from the sponsor's side and the lack of ability to decline from the vendor's side
· Lack of a sign-off process for ensuring that the resources are ready to work on live documents

Interestingly, the outcome of a survey conducted on key decision makers across pharma, medical device, and vendor groups indicated that the highest-ranked challenge for all was 'Inadequate efforts spent on expectation setting between the sponsor and the vendor'. A leading global pharma highlighted the importance of regular (monthly) meetings between sponsor and vendor managers to discuss worklists, expectations, what is working well, and gaps to address. It also highlighted the challenges posed to vendors resulting from their ever-changing portfolio and timelines, which had a direct impact on quality.

Interestingly, 'Inadequate efforts spent on initial training from the sponsor', was a point rated as second priority by another pharma.

While quality is subjective, even quality needs to be measured. Different organizations have different ways of measuring quality. Some of the key quality metrics highlighted from a pharma perspective include subjective quality assessments for outsourced deliverables, and the amount of rework required, as well as the number of drafts that need to be reviewed. From a QC perspective, this may include metrics such as the number of major QC comments per page, the overall number of QC comments, and the number of data errors. The need to define quality gates and monitor a vendor's progress are a core part of the quality strategy.

Some of the key metrics shared by the senior leadership at a large global medical device company include:

· KPIs pertaining to a harmonized document put together by different authors to have continuity for Clinical Evaluation reports etc., required by EU regulators for Medical Devices
· Internal review of contents before sending to customers to reduce rework
· The level of interaction required with the customer team – needs to be kept to the minimum
· The assessment of quality of clinical justifications from all the data/information sources provided

One interesting input from a senior regulatory strategist is that is it very important to know your work: to know what you know and what you do not know, and to keep up-to-date on any changes in the source. She also emphasizes that it is also important to quickly and carefully assess the sponsor's team, identify any weak links or interpersonal issues, and determine how these can be fixed. All of these measures will help enhance quality and drive efficiency.

Quality in medical writing can be viewed in many ways:

· Being 'fit for purpose'
· Ensuring consistency in messaging
· Driving clarity of thought
· Integrating harmony and flow within the document
· Having high readability
· Aligned to the target audience
· Having contextually relevant and localized content

To conclude, you don't get a second chance to make a first impression! When working to ensure that you get it right the first time, quality can never be compromised.

Acknowledgments: A note of appreciation to all who completed the survey and shared their expert inputs.

CSOFT HEALTH SCIENCES

CSOFT Health Sciences provides end-to-end medical translation services for all phases of the product lifecycle, from pre-clinical to post-launch. We also specialize in market access consulting, medical writing, and CTD/eCTD submissions with the FDA, EMA, and NMPA. Our operations are compliant with ISO 17100 and certified in ISO 9001:2015 and ISO 13485:2016, ensuring our customized solutions meet the rigorous regulatory requirements of global submissions.

CSOFT INTERNATIONAL

CSOFT International is a leading provider of cross-border communications for enterprises seeking growth in global markets. Our expertise in translation and localization, documentation, and branding encompasses a full range of end-to-end content and consulting services that we deliver in over 250 languages. With a focus in health sciences and smart technology, we work closely with our clients to deliver precision solutions to the challenges of engaging markets, consumers, and regulatory environments worldwide.

CSOFT's operations are segmented in two core service areas dedicated to our clients' distinct requirements: CSOFT Health Sciences, and CSOFT Communications.