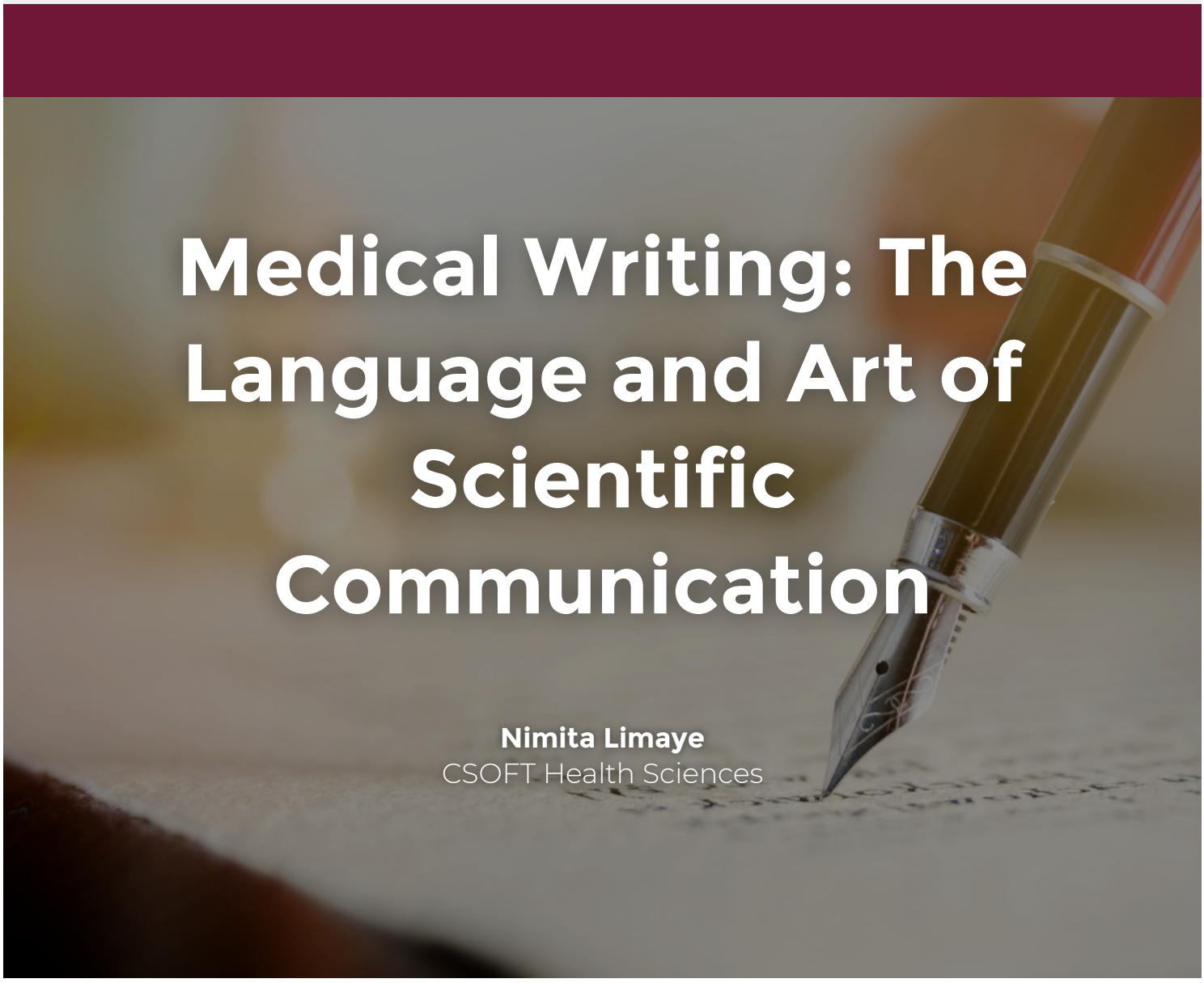

Medical Writing: The Language and Art of Scientific Communication

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Medical writing is a scientific skill that writers deploy to author a multitude of documents addressing the needs of diverse and demanding stakeholders. This requires not only a deep understanding of therapeutic areas, regulations, and document types, but also soft skills such as strong negotiation skills and project management skills. The ability to present data and communicate the desired message is just one of those skills. This article describes different types of writers who author documents aimed at different objectives, including regulatory submissions, publications, safety, and medico-marketing.

Medical writers (MWs) are professionals from diverse backgrounds who address different business needs. Writers hone their skills over the years and master the art of digesting voluminous and complex information and presenting it in a succinct and objective manner. The diversity of the target audience, and thus the distinct differences in the objectives of scientific communication, poses a significant challenge. Balance this with the need to ensure regulatory compliance, prioritize patient safety, and manage the diverse views of multiple stakeholders from diverse therapeutic areas, and the challenge becomes even more daunting. Finally, the writer also needs to have expertise in evolving tools and technologies, deal with different style guides and increasingly complex and diverse document types, and ultimately deliver a strategically thought-out high-quality document on time.

To quote Helle Gawrylewski, Principal at Hawkwood Consulting, LLC, "Writing should support understanding. Being acutely aware of what the audience needs to know is extremely important. Writing for understanding requires clarity, brevity, and good organization. As they say, words matter, and they do!"

Competency Framework

It is important for organizations to develop a competency framework defining the specific skills required for each type of writer. The DIA Medical Writing Special Interest Area Community (SIAC) **developed a competency framework in 2009** that categorized functional and technical competencies associated with regulatory and publication writers. It also outlined the associated behavioral skills.

Regulatory Medical Writers (RMWs)

An RMW has a clinical background, logical scientific thinking, exceptional communication skills, and the ability to adapt to evolving regulations. An experienced writer recognizes the reasons why information, on occasion, needs to be presented differently in different sections of a document (such as in-text tables used to illustrate a point), and against detailed tables that may be included as appendices at the end. Well-established peer review processes are essential to ensure that the clinical significance of the information is being appropriately communicated and is not lost somewhere in a flood of data. Documents such as the study protocol and the Investigator's Brochure are authored before the start of the clinical trial. For authoring of clinical study reports (CSRs), writers are involved at different stages, beginning with the drafting of the shell report using mock "tables, figures and listings" (TFLs) once the statistical analysis plan (SAP) has been drafted. Prior to database lock, the writer reviews the blinded listings and, once the database is locked, the writer uses the final TFLs to draft the final CSR. The three "Ps" – **"Planning, Persuasiveness, and Patience"** – are all required to drive this process effectively.

Publication Writers (PWs)

PWs must be well-versed in the relevant guidelines, such as those outlined by the International Committee of Medical Journal Editors (ICMJE), the Consolidated Standards of Reporting Trials (CONSORT) guidelines, and Good Publication Practices (GPP). The ability to understand the specific requirements of your target audience and to develop and present information oriented to its needs reflects the maturity and the experience of the PW. It also requires the understanding of concepts such as authorship, plagiarism, ghost-writing, and publication bias. Documents authored by a PW include reviews, manuscripts, abstracts, posters, etc. "A key difference in writing manuscripts versus study reports is the ability to address comments from multiple stakeholders (both *internal*, such as sponsor company authors, and *external*, such as non-sponsor authors, journal editors, peer reviewers, and key opinion leaders)," says Susan Glasser, Director of Medical Writing, Regulatory Management Operations, Daiichi Sankyo, Inc. "A *good* PW understands that the success of their manuscript depends on their success in creating effective relationships with these stakeholders. A *great* PW plans and anticipates the comments and queries from the relevant stakeholders and addresses these proactively."

Just like regulatory writing, publication writing can also involve a lot of effort and elaborate strategic planning, as is the case with **systematic literature reviews that constitute an invaluable tool in an**

evidence-based medicine world, in publication planning, journal selection, manuscript submission, and addressing reviewer's comments. While the required expertise and skills required of PWs and RMWs are rather different, there are certain commonalities, such as the ability to review large volumes of data and interpret and present them objectively.

Pharmacovigilance (PV) Medical Writers

PV medical writers must have an understanding of Good Pharmacovigilance Practices (GPP), strong therapeutic area expertise, and a thorough understanding of regulatory requirements and different document types. While aggregate reports such as DSURs, PSURs, PADERs, and PBRERs require the ability to analyze and represent the applicant's understanding of the drug's risk-benefit profile, the risk management plan (RMP) requires the writer to also outline both identified and potential risks, present risk minimization strategies, respond to comments from regulators, maintain oversight of multiple versions of RMPs that may have been created for parallel submissions, and ensure consistency in content and messaging across all submission documents. Drafting FDA REMS (Risk Evaluation and Mitigation Strategies) documents is a challenging task, as no two REMS programs are the same; extensive stakeholder engagement and strategic foresight is required. Authoring narratives, on the other hand, requires a skilled writer to be able to identify the right data sources and the type of narrative to be authored, to narrate a flow of events, and to take them to conclusion, while assessing medical plausibility, evaluating drug-drug interactions, and identifying underlying factors that triggered the adverse event.

Supplemental Resources

Strategic Medical Writing: Why Settle for Less?

Authoring a Periodic Adverse Drug Experience Report…Here's What You Need to Know!

Medical Writing Competency Model – Section 1: Functions, Tasks, and Activities.

Medical Writing Competency Model – Section 2: Knowledge, Skills, Abilities, and Behaviors.

Medico-marketing requires a combination of push-and-pull strategy to engage customers and drive prescribing/buying decisions. It requires creative writing skills to deliver high-quality content, without compromising on ethics. Documents such as product monographs, training materials, patient information leaflets (PILs), and leave-behind leaflets (LBLs) require the development and presentation of material that is both engaging and impactful. Sensitivity to cultural and local needs and the specific needs of the community are essential to facilitate the desired outreach.

This is equally important in the case of Lay Summaries, where the ability to communicate the summary of trial results in straightforward "lay" language is no easy task. Adapting the language of these documents to ensure that it is clear to the target audiences requires appropriate linguistic expertise.

A Strategic Negotiation

Data speak for themselves to a certain extent and are surely the scientific basis for the documents that are produced. The MW works on the data, pokes them, prods them, "chews" on them, and gradually teases out a narrative that walks the reader through a sequence of events and effectively synthesizes the desired message in the reader's mind. Medical writing is not just tactical or simply about putting pen to paper (or, these days, fingers to a keyboard); it's a strategic task in which the writer ensures that the desired data-driven messaging is achieved.