

## THE QUICK AND THE DIRTY: BEST PRACTICES FOR WRITING AND EDITING UNDER TIGHT TIMELINES

### Speakers

**J. Kelly Byram, MS, MBA, ELS**, *Immediate Past President and Director-at-Large for New Mexico, AMWA Southwest Chapter, Freelance Editor and Writer, Owner of Duke City Consulting, LLC, Albuquerque, NM*

**Theresa E. Singleton, PhD**, *2021 AMWA Fellow, Freelance Scientific Writer, Owner of Singleton Science, LLC, Beverly, MA*

**Damiana Chiavolini, MS, PhD**, *President-Elect of AMWA Southwest Chapter, Academic Writer, Editor, and Instructor, Richardson, TX*

### By Stephany Panlilio, MS

In medical writing, the scope and timeline for documents varies, depending on the type of document and the client for which the document is being prepared. However, these 2 aspects determine a medical writer's ability to take on a new project. This article summarizes the experiences of Ms Byram and Dr Singleton as freelance medical writers and editors, and Dr Chiavolini as a medical writer and editor in academia, and their best practices for writing and editing under tight timelines.

### Tight Timelines Versus Short Notice

It is important to first differentiate between a tight timeline and short notice. In some cases, a client can reach out requesting help with a project, but the expectation is the project starts right away. This is short notice. On the other hand, a client may reach out ahead of time, but provide only a short amount of time to prepare a document, hence, a tight timeline. In either instance, the first step would be to identify the scope of the project and define expectations of the medical writer/editor and the client.

For freelance medical writers/editors, other considerations may include if this is a new client or an established client and the time needed to educate on the process. Taking on a rush project from a new client is riskier because the client may be new to the process in general or may not have worked on a given document type. Dr Singleton emphasized, "As a freelance medical writer, the best asset I have to offer is my word," and taking on a project that could potentially compromise quality could impact a writer's reputation. There is a lot of value added in taking the time to educate a new client on how the process might look, setting expectations, and establishing a schedule. If the timeline does not account for this, the client may not be a good fit.

In academia, there is more flexibility in timelines for many documents, with the exception of grant proposals.

However, it is still important to set expectations and educate stakeholders on the process and typical turnaround times.

### Advice for New Writers and Editors

The first piece of advice given by Ms Byram, Dr Singleton, and Dr Chiavolini to new writers when working on a document with a tight timeline was to ask questions. Asking questions may slow down the process, but it is imperative to get as much information as needed upfront from the client and to fully understand the agreements being made and to clarify deliverables.

Another critical piece of advice is to set boundaries. Freelance writers are typically hired to solve problems that a client may not have the experience or expertise to solve. Establishing boundaries (eg, typical turnaround times and exceptions) and expectations from both the writer and the client early in the process is important. Boundaries are not meant to create barriers and hinder progress, instead they strengthen collaboration between the writer and client, keeping the project focused and on target.

### Strategies Used When a Project Is Not on Schedule

When working on a tight timeline, every minute matters. If a risk arises that could potentially cause a project timeline to not be met, the best strategy is communication. Reaching out to the project team as soon as possible is critical. It also provides the opportunity to ask questions. Is the scope of the work negotiable? Is it possible to focus on the key messages of the document rather than the language? If the project team is not providing the information needed to author pertinent sections of the document, reach out to the principal investigator for assistance; for example, ask whether there is a possibility for timeline extension.

Proactively setting expectations and maintaining clear communication throughout a project can help to keep the project on schedule.

### Tools

A variety of tools are available to assist with authoring, editing, and composing documents of all types, and ensuring timelines are met. Examples of tools utilized by Ms Byram, Dr Singleton, and Dr Chiavolini for different documents are provided below.

- CONSORT (Consolidated Standards of Reporting Trials) guidelines and extensions for writing manuscripts
- Plain language guidelines (eg, Multi-Regional Clinical Trials Center's Clinical Research Glossary, released in June 2021)
- Client-specific style guide cheat sheets

- Second (or even third) computer monitor
- Printouts of grant request for proposals and request for applications
- Templates for writers
- Glossaries from cancer centers or other stakeholders
- Digitally curating information
- Time tracking/management tools
- Optimizing software already in use
- Checklists and detailed project notetaking

A medical writer's ability to take on new projects depends on the scope and timeline for a given document. Clear communication, educating the client, and setting expectations and boundaries upfront are needed to ensure the project is completed according to the timeline, without compromising quality. In their presentation, Ms Byram, Dr Singleton, and Dr Chiavolini provided several strategies for assessing the ability to take on a project with a tight timeline, as well as several tools for creating high-quality documents within that timeline.

*Stephany Panlilio is a Senior Associate in Medical Writing at Gilead Sciences, Inc. (Foster City, CA)*

**Author declaration and disclosures:** *The authors note no commercial associations that may pose a conflict of interest in relation to this article.*

**Author contact:** *stephany.panlilio@gilead.com*

\*\*\*

## TIME TO CLOCK IN: APPLYING MANUFACTURING BEST PRACTICES TO CONSISTENTLY AND EFFICIENTLY PRODUCE HIGH-QUALITY DOCUMENTS

### Speaker

**Jenni Pickett, PhD**, *Whitsell Innovations, Inc., Chapel Hill, NC*

**Mary Ellis Bogden, BA**, *Whitsell Innovations, Inc., Chapel Hill, NC*

### By Stephany Panlilio, MS

Regulatory writing and manufacturing have many commonalities. As with manufactured products, regulatory documents should be produced at a reasonable cost, completed per an agreed upon timeline, be fit for intended purpose, and should meet a set of corporate, legal, and customer standards. What can regulatory writers learn from advances in manufacturing processes?

## Manufacturing Best Practice Philosophies

Many modern manufacturing processes and principles came from the car manufacturer, Toyota. The Toyota Way operates under 4 driving principles.<sup>1</sup> These principles can also be applied to medical writing, as described below.

- **Long-term Philosophy – Forward Thinking.**  
Focusing on the processes used to create products or documents can help improve efficiency over time.
- **Add Value to the Organization by Developing Your People and Partners.**  
In manufacturing and regulatory writing, ensuring that team members have the right skills is essential.
- **The Right Process Will Produce the Right Results.**  
A robust process will ensure a high-quality product.
- **Continuously Solving Root Problems Drives Organizational Learning.**  
Manufacturers and regulatory writers should develop and maintain a system to identify root causes and quickly address issues.

## Good Regulatory Writing Practice

Manufacturers of pharmaceutical products must adhere to Good Manufacturing Practice (GMP) to mitigate risk. A robust GMP quality system includes training people; controlling starting materials and equipment; clearly defining manufacturing, packaging, and storage processes; testing for quality; and documenting each step.

To produce high-quality documents, the following are necessary: trained people, correct source materials that are up-to-date and easy to use, defined processes for the writing and review cycles, a quality control review process, and documenting each step (Figure). So, what would a theoretical good regulatory writing practice include?

- Developing the team by ensuring team members have the proper education, relevant experience, and knowledge of regulations and company policies can help to reduce the risk of human error. Specific risks to your team can be evaluated by a gap analysis of critical skills. Cultivating a growth mindset culture in which employees feel comfortable being noisy in their ignorance helps identify critical training needs.
- Creating a Quality Document Profile, similar to the Quality Target Product Profile used in GMP, verifies the correct template, sources, interpretation, and team expectations are used for the document. Using a storage management system prevents errors due to use of incorrect templates, outdated data, or irrelevant sources.