

- 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.

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## 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*

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### 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.

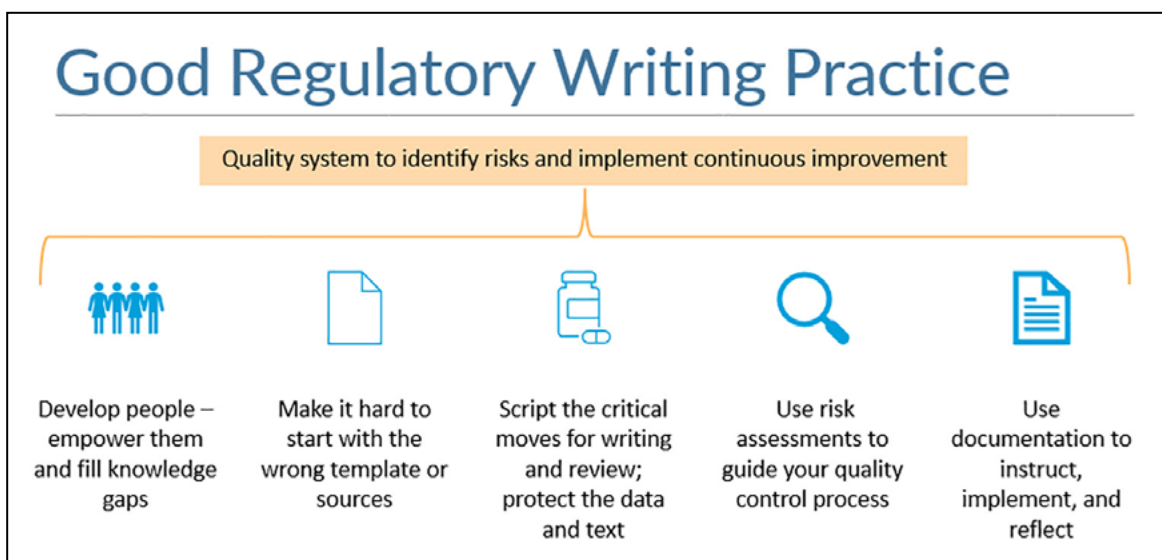


Figure. Elements of a theoretical good regulatory writing practice.

- Protecting the data and text by using good data hygiene and limiting review cycles prevents transcription errors, incorrect data interpretation, and inconsistent text or messages within the document. Reviewer fatigue and consistency errors can be reduced by waiting until the last review to write certain sections, such as the executive summary, synopsis, list of abbreviations, and summary of changes.
- Using risk-based quality control techniques can improve efficiency and ensure the most important areas in the document are correct. In GMP, Critical Quality Attributes (CQAs) are factors which would impact the overall quality of the product. Identifying CQAs in your document (ie, new data in an investigator brochure) can help your reviewer prioritize where to start.
- Recording the document development process in a tracker allows you to confirm you have followed all the key steps above and also see where improvements can be made.
- Reviewing your document development process periodically will allow you to address new risks as you discover them and improve efficiency and quality over

time. GMP uses Corrective Action Preventative Action, a system in which root causes are identified, and solutions are proposed, verified, and implemented.

Identifying risks throughout regulatory document processes and finding ways to proactively mitigate them are imperative steps to creating high-quality documents. As regulations evolve and processes increase in complexity, implementing elements of a good regulatory writing practice provides a framework to focus on long-term investments in efficiency and quality of your documents by continually improving your people and processes.

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1. Liker, JK. *The Toyota Way: 14 Management Principles from the World's Greatest Manufacturer*. McGraw-Hill; 2004.