

TOPICAL FEATURE

The Key to Better Regulatory Writing: Tell Your Device's Story

Scott Dill, PhD / NAMSA, Minneapolis, MN

ABSTRACT

Medical device development requires regulatory documentation, but what constitutes good writing in those documents has no well-established pedagogy. Senior regulatory experts often use the language of storytelling when asked what makes for good regulatory writing. Twelve such senior experts interviewed for this article responded with some version of, "It all depends on how you tell your device's story." But what does this claim really mean? Regulatory documents are long and technical; they are not usually considered in literary terms. This article explains how storytelling can help hone your regulatory writing. It uses the literary components of setting, plot, and character to show how selecting contextual details, tightening causal connections, and keeping the focus improve document quality. Furthermore, it employs real life examples taken from the FDA and notified body submissions to illustrate exactly where and how those details, connections, and focuses contribute to good storytelling. Key transitional phrases, syntactical constructions, and relevant contextual data make all the difference.

Successful medical device development involves truckloads of documentation, from design control records to clinical literature to post-market surveillance. Yet none of these documents are accompanied by as much handwringing as the device's regulatory submissions. Years and years of work hang suspended by the thread of a single submission packet. Will the FDA approve it? Will it be CE marked?

Curiously, little training is associated with the specific writing skills that such vital regulatory documentation demands. The early twentieth-century boom in engineering birthed an entire profession of technical writers. Medical writers can attend specialized graduate programs at a number of universities. Yet outside a smattering of individualized courses or certificate programs, the regulatory field has no commensurate area of professionalized *writing* expertise, even though degrees in medical device regulation abound.

Is document quality inconsequential to regulatory agencies? In 2014, *Medical Writing* devoted 2 different issues to

argue the contrary.^{1,2} More recently, survey results published by the *AMWA Journal* in 2021 demonstrate the value of good regulatory writing: 87% of the regulatory reviewers surveyed claimed that poor writing impedes their assessment.³

This lack of a distinct professionally adjacent writing field may be due to the strict stipulations regulatory agencies provide. Major medical device manufacturers have company templates for what to write. Technical understanding of the product and its relationship to the clinical field and current state of the art is likely more important than the quality of a submission's prose. Yet the AMWA's 2021 survey demurs. Moreover, when you talk to longtime regulatory insiders who have worked for the FDA or notified bodies, they tend to stress the writing. In my experience, when you ask these experts what makes for successful regulatory submissions, they answer with some version of, "It all depends on how you tell your device's story."

Regulatory experts frequently stress the importance of storytelling, which I soon realized as I collaborated with them. (A benefit of working at a clinical research organization is the exposure you get—not only to multiple devices but high levels of expertise.) The first time I heard it was from a senior colleague who had worked at the FDA for decades. I was helping to draft part of a pre-submission letter to the FDA. "Remember," I was counseled, "it's all about the story we're telling." A few days later, it popped up from another ex-FDA employee in a similar circumstance.

Then, in the middle of a large meeting, I heard a consultant who used to work with a notified body insist, "We must help our clients to tell their device's story well—that is crucial!" Medical device regulation is a highly technical field—it demands familiarity with the precise terminologies used in medicine, engineering, and law. Why were these technically proficient industry insiders talking about stories?

It struck me as strange. Story is, after all, a catchall type of term. It's amorphous, applying as much to a novel as a painting, as much to an advertisement as a lie. Storytelling belongs in the dusty corners of coffee shops, not brightly lit biomedical engineering labs. Yet it was near ubiquitous advice: tell your device's story, they said, over and over again.

Many universities offer courses in “medical humanities,” a field that harnesses the power of narrative to explore how humans experience medicine. Story is essential for how that field understands medical practice and can overlap with the concerns of technical communicators.⁴ Yet these regulatory experts didn’t mean anything close to the medical humanities. They meant story as an organizing principle, not an encounter with the humanities.

I began interviewing 12 senior regulatory experts to understand what they meant by storytelling, asking them pointed questions to draw it out as exactly as possible. What follows in this article uses their terminology’s literary sensibility, only amplified with particulars extrapolated from their generalities. Setting, plot, and character encompass the practices necessary for good medical device storytelling.

ESTABLISH THE CONTEXT: SETTING

You’ll often hear novelists say they long to provide a distinct sense of place. Near the beginning of her essay “Place in Fiction,” Eudora Welty claims that a novel’s sense of place determines its quality.⁵ Beyond a lofty goal, however, she notes that fiction is structurally “all bound up in the local.” Place, or the setting of a story, is crucial to how it works. The setting gives a story its feel, its sense of completion. Setting makes a story *believable*.

Good storytelling means providing the appropriate amount of context. This was usually the first thing a person said when I asked them how to tell a device’s story: “Provide enough context—but not too much!” Too many details overwhelm; strive for the right ones. Although the reviewers who read regulatory submissions often have impressive technical backgrounds, they will likely know little about your device. They won’t know how your device was developed or how it fits into a specific medical field. Prejudices from previous experiences might incline them to make unhelpful assumptions about your device. It’s your job to preempt such misunderstandings. Your ability to put the device in the appropriate setting makes your submission believable.

A couple of practices can help make this happen. First, do not make the mistake of assuming executive summaries and conclusions are unimportant textual padding. Make use of these sections. If you’re using boilerplate language instead of crafting these key passages to convey the appropriate context, you’ve thrown away a vital chance to communicate with your reviewer.

Second, pay attention to phrasing. Adding helpful contextual details to frame your claims and data will create the right setting. Below is a paragraph taken from a pre-submission letter to the FDA (altered, with data and references removed). It is meant to provide an example of how attention to phrasing establishes helpful context. The underlined

phrases below provide background to situate the data in the device manufacturer’s deliberately selected setting. In brief, the goal was to clarify how an off-label procedure (in the US) was safe and had clinical data, although from elsewhere.

Other US surgeons are employing off-label procedures to address the need for a more unified approach to heavily calcified disease extending into the aorta. In a special issue for *Endovascular Now*, the New York-based vascular surgeon John Smith explains his preference for “advanced treatment of lengthy aortic disease with a covered endovascular reconstruction of the aortic bifurcation (CERAB) technique for complex aortic disease.” Dr Smith’s preference is rooted in data now familiar to vascular surgeons. Published studies comparing standard endovascular treatment, CERAB, and open surgery found higher 30-day mortality rates, but better medium-term patency with open surgery compared to the endovascular techniques [*hard data here*.] Due to its recent development, long-term data is not yet available for CERAB techniques.

Note how the writer contextualizes the opening sentence with what came before—we can infer that the previous paragraph discussed the views of US surgeons. Beginning with “Other US surgeons” establishes the critical context for the paragraph: we’re still talking about the US and its surgeons. That’s what’s often called a “signal term.” The surgeon quoted in the second sentence is placed in a US city. Does the city in which this doctor practices matter? Not really. But US practices and the US population matter for the FDA, and we want to remind the readers that this comes from US-based surgeons’ opinions. This provides a meaningful context to interpret the safety and performance data that closes the paragraph.

Finally, note the last underlined phrase. “Due to its recent development” puts the finishing touch on the setting. Setting is about place; yes, certainly. It’s also about time. We want to know *when* something took place. The timing matters, too. The data are put into a chronological history of medical developments. Taken together, these small additions create an interpretive framework for the reviewer.

KEEP THE THREAD: PLOT

The British novelist E. M. Forster once said, “‘The king died and then the queen died’ is a story. ‘The king died and then the queen died of grief’ is a plot.”⁶ Plot, in Forster’s famous formulation, provides the causal relationship between events in a story. The king’s death and the queen’s death are simple events. We can tell the story of when, where, and how they happened. But for that story to have a plot

we must answer *why*. The king's death causes the queen's death—she died “of grief.” See how the event now takes on a causal relationship? Something made her death happen: the queen died *of grief*. That's what we want in a plot—we want clear causal connections.

Regulatory documentation keeps its plot thread by drawing out causal connections. Almost everyone I interviewed emphasized keeping a sense of connection at various levels: between claims and data, between arguments, and between sections. This even applies to long documents, such as the Clinical Evaluation Reports required as part of marketing submission to the European Union.

If explicit connections are missing and the reviewer struggles to follow your case, you've opened the door to doubt. An auditor or reviewer could give up in frustration and write you off as unprepared. Or they might begin to wonder—how does this relate to such and such? Soon they will start to wonder what you're not saying. Are you overlooking something or—worse—hiding something? A lack of clear causal connections can erode your authority and invite counterarguments that might never have arisen with tight transitions between points.

One straightforward way to think of this is, don't skip the rationales! Robust rationales are critical to communicating the logic behind design changes to the concerned regulatory agency. The basic principle of providing robust rationales—explaining *why* something changed instead of simply glossing over *how* it changed—can be broadly applied to all the claims you make in your documentation.

Other strategies can help you keep your causal connections clear. First, signal the beginning, middle, and end with signal terms such as first, second; after, before; etc. This provides a sense of order. Second, use transition words that make the causal relationship between sentences clear. Keep the plot going with words like another, yet, while, furthermore, etc. Third, remind the reader of the overall arc of the document and how this particular point relates to the overall point. For example, the State of the Art section in a Clinical Evaluation Report, which often feels forced and out of place, should be linked back to the rest of the document. That section places your device in the context of relevant treatments. Do so!

Fourth, we were all taught to use topic sentences, but how consciously do we do so when using a template for regulatory documents? Yet those topic sentences provide the logical connections between your main points. They provide roadmaps to what is coming and how that point connects to what came before. Topic sentences keep the reader engaged—on the writer's terms.

Additionally, the logical connections in your prose should go even deeper than topic sentences and transition

terms. The way each sentence links up with the following sentence is a simple way to keep your logical connections tight. Think in terms of the grammatical logic of subjects and predicates. Usually, the predicate presents the information that needs to be communicated about the sentence's subject. If you consider your sentences as proceeding from a familiar subject to a new predicate, your prose will keep its logical connections rooted in its grammar.

The example below is from a clinical literature review on a device used during high-risk percutaneous interventions. This short paragraph explains how the indication of high risk has a unique history that matters for understanding how the device in question works. Although this paragraph does not reference the device, it connects each sentence to the following through the logic of its grammar. The paragraph opens with a historical claim and ends with a justification for the increased vulnerability of the relevant population. As you read through it, note how the subject in bold font links back to the underlined predicate preceding it.

Percutaneous coronary interventions (PCIs) now carry less risk than they did nearly half a century ago, when the procedure was first introduced. All PCI patients who were considered “**high risk**” (HR) **patients** early in the procedure's development. Back then, **procedural success** was <60% and a cardiothoracic surgeon was required to be in the operating room. **Procedural success is now nearly 100%** and the definition of HR-PCI has now focused on a specific subset population. Specifically, **patients who are HR-PCI typically present** with unprotected left main coronary artery, multivessel, and bifurcation lesions, as well as those with chronic total occlusions. **Such conditions** are indeed “high risk.”

English usually begins sentences with the subject of the sentence and then introduces some new information about that subject in the predicate, the second part of the sentence, which is often a verb or verb phrase. Regulatory documents should be written in what is called Plain English (or sometimes, Global English), whether they're for a notified body or the FDA. Plain English is simplified and strives to be nonidiomatic. Thinking about the basic subject-predicate structure of your sentences can help produce the clarity associated with this style. More to the point, it will help you keep the plot by tightening your writing's causal connections.

MAINTAIN FOCUS: CHARACTER

Another way to tell your story well is to develop key characters. Who's at the center of your story? How will you keep the reader's focus on that main character? In the data dump of technical specifications and clinical findings, it can be easy

to lose focus. The true protagonist in every regulatory document is the patient. Remember, each piece of data you pull into your writing represents an actual human being. Real people hide behind your statistics. The point behind developing new medical devices is, after all, to help people! The reviewers at regulatory agencies are there because they want to help people—both by keeping them safe and enabling new developments. Don't become careless in your tone or terminology such that your writing loses that human focus.

Other types of character inhabit regulatory documents. The device in question may be your focus, but related alternative treatments are key to how readers perceive its value. Take the following review of the current state of the art for stenting. Example #3 below is taken from the State of the Art section of a Clinical Evaluation Report on a guidewire device. Stenting, not any specific stent, is the character being developed here. As you read through it, note that we are told *why* stents are employed over other procedures and *why* new stents have developed over time. A meaningful pattern has been presented here: a pattern that creates the story of stenting. Note how the information is being interpreted for us so that we keep the focus on the stenting.

Finally, notice how the underlined text explains the value of the nearby claim (in bold text). Sometimes the claim in bold text comes first, as in the first sentence, and sometimes it follows the explanation. But the sentences are built to focus on stenting while developing and enlarging what that entails.

Stenting: Today, two main types of bare-metal stents are available: self-expanding stents and balloon-expandable stents. **Because of the technical limitations of self-expanding stents, and their tendency to provoke greater neointimal hyperplasia, balloon-expandable stents are now used for nearly all coronary stent procedures.** Covered stents are most frequently used to treat emergent coronary perforations. **As restenosis is a significant problem with bare-metal stents, drug-eluting stents were designed with immunosuppressant or cytotoxic drugs to inhibit neointimal hyperplasia. The risk of very late events associated with the implantation of permanent metallic stents (eg, stent thrombosis and restenosis, fracture) led to the development of fully bioresorbable stents, more commonly known as bioresorbable scaffolds.**

This is only an example, one way of thinking about how to keep your focus. Nevertheless, it demonstrates the value of explaining your claims and how this simple rhetorical practice helps clarify the paragraph's focus. Paying attention to sentence construction, as this writer has done, gives the reader a clear sense of how stenting has developed.

CONCLUSION

The goal of this article has been to distill insights gleaned from a group of experienced regulatory experts on why they value good storytelling so highly. Although they often used literary terminology, it was unclear what that meant for them in practice. However, if you establish the context or setting for the device, keep the causal connections clear, and maintain focus on key characters, you'll be off to a good start.

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

Author contact: *scottdill@gmail.com*

References

1. Morley G. Regulatory writing basics. *Med Writ*. 2014;23(2):81-82. doi:10.1179/2047480614Z.000000000191
2. Chamberlain-James L. Post-approval regulatory writing. *Med Writ*. 2014;23(4):257. doi:10.1179/2047480614Z.000000000256
3. Cooper J, Chamberlain James L, Affleck J, Bass B, Forjanic Klapproth J, Harris D. Value of medical writing: the regulator's perspective. *AMWA*. 2021;36(4):145-151. doi:10.55752/amwa.2021.83
4. Angeli EL, Johnson-Sheehan R. Introduction to the special issue: medical humanities and/or the rhetoric of health and medicine. *Tech Commun Q*. 2018;27(1):1-6. doi:10.1080/10572252.2018.1399746
5. Welty E. Place in fiction. In: *Stories, Essays, and Memoir*. Library of America, 1998.
6. Forster EM. *Aspects of the Novel*. Harcourt Brace & Co., 1927.