

## **The Impact of Ineffective Writing on Drug Development**

By Pamela E. Hurley, PhD

Most everyone in the drug-development industry knows about the delays that often plague clinical trials, and they're probably familiar with the cost of these delays. A 2003 article in *Applied Clinical Trials* suggests "the average daily cost of drug development runs about \$30,000 per day and rises by 10 per cent to 12 per cent per year. Development cycle times range from three to 12 years."<sup>1</sup> Further, "For a drug destined to make half a billion dollars in annual sales, a one-day delay costs about \$1.3 million."<sup>2</sup>

The delays in drug development can certainly be blamed in part on the U.S. Food and Drug Administration (FDA), which, although it has "reduced its review time for new drugs by 30 per cent,"<sup>3</sup> still drags its feet: some estimates suggest that it takes "12 years to get from initial research through FDA approval."<sup>4</sup> And Lasagna's Law, which states that sites chronically overestimate the number of subjects they can enrol for any given study, certainly should share some of the responsibility for the lag.

But beyond the FDA and Lasagna's Law, a more insidious, yet treatable, problem may be costing biotech and life science firms money, and wasting valuable time and energy. This culprit is poor communication — specifically, the written documents generated in this industry to help readers determine events, read data and, ultimately, determine what actions to take.

### **Poor Communication: Its Impact on Drug Development**

Unlike in many other industries, the writing done in drug development is complex: the documents often have multiple audiences, and are so varied that writers must be equipped with a large arsenal of writing tools at their disposal.

In addition to the complexity and number of the documents, other forces are at play that often determine how and why the documents are written. One, the industry is literally swimming in documents, both regulatory and other varieties; two, these documents serve different functions both within and outside the organization that generates them; and three — and perhaps one of the most troubling aspects — biotech and other scientific companies involved in drug development often don't train their staffs to write. Often, the assumption is that highly educated people have been trained in their academic careers to write and to write well. However, the major complaint from the business world upon hiring science and engineering students is that they have deficient writing skills.<sup>5</sup>

While certainly many in this industry can — and do — write very well, too often, the variety and complexity of the documents can create problems for writers, primarily because they haven't been trained to properly analyse writing tasks to be able to tackle them competently. Part of this problem is the fault of academia. In many colleges, students are required to take only two writing classes (and those typically in their first year), and professional writing classes aren't offered in many nursing and science programs.<sup>6</sup> And even when such classes are offered, writing isn't necessarily emphasized

in the other classes the student takes, resulting in a gap between what the student learns in the writing class and the application of those concepts to other writing tasks.

The goal in this industry is to produce documents that are clear, coherent and comprehensible. Beyond these obvious things, however, writers have to create documents that are usable by readers *and* that meet readers' needs. Usable documents are those in which readers can quickly and easily find information, and in which the purpose of the document — what action the reader is to take — is evident.

For writers to be prepared to create such documents means that they have to understand the role of critical thinking in writing; that is, to complete the varied and multiple writing tasks demanded by this industry, writers must be able to “think outside the box.” They must be able to analyse their audience and construct the document so that it meets reader needs, whatever those needs may be. Writers must also understand that good, effective documents require the reader to take some “action” — be it filing the document, making a decision about information in the document, or throwing the document away — and that that action must be clear to the reader.

### **Ramifications of Unusable Writing**

Interestingly, even though many of the documents composed in this industry are rigorously edited and revised (sometimes by multiple editors), comprehension problems still exist. A recent CenterWatch (Boston, MA) survey reveals that in informed consents, “30 per cent of participants did not understand that their study could carry additional risks and discomforts, and 70 per cent didn't know what questions to ask at the outset of the informed consent process.”<sup>7</sup>

While research studies on the documents generated in this industry are scarce, stories about miscommunication are not. One of the more relevant to this article focuses on brochures provided to patients and their families in palliative care units. “Only 64 per cent of the leaflets could be understood by only an estimated 40 per cent of the British population.”<sup>8</sup> Many of the leaflets did not meet basic legibility and readability guidelines.

While writers in this industry don't necessarily write pamphlets, this example illustrates a common misconception: that following the “rules” of writing (taught from Grade 7 onward, and reinforced in many professional and technical writing textbooks) will help writers create effective documents. In this case, over 76 per cent of the brochures contained no medical jargon; only 18.14 per cent were written in passive voice; the paragraphs were short (only 1.7 sentences on average), as were the sentences (averaging 16.9 words).

Since the writers adhered to the rules — no jargon, little use of passive voice, and short paragraphs and sentences — then the failure may be attributable to a lack of critical thinking. It seems the writers simply failed to analyse their audience: the information the audience needed; how the document was to be used; why the audience read the brochures; and the choices available to deliver the information so that it was readable and useful. The writers, for instance, were unaware that larger font (12-point or above) would

have been preferable to the 11-point used, and that a more personal style of writing can engage readers more effectively. In this example, adherence to writing rules and a failure to think critically about the audience and its needs generated unusable brochures.

### **What is Critical Thinking?**

Critical thinking is roughly defined as the ability to “think outside the box.” In the case of the writers in this industry, it means asking them to abandon the rules (temporarily) in favour of thinking more globally about the document. Why should writers be encouraged to use their critical thinking skills? Because doing so allows them to problem-solve and create a document that meets audience needs.

One critical aspect of writing that is often overlooked in this industry is that writers are encouraged to think and write a certain way. While this is common in most industries, this kind of organizational mandate (even though it’s often very subtle) may disempower writers to think critically about their documents and how they should be organized, what words or phrases should be used, or the construction of sentences and paragraphs — in essence, the choices available to the writer to create a usable, comprehensible document that serves its intended purpose.

While certainly most organizations would argue that they want employees who can think for themselves, the use of templates, for example, is one way that organizations constrain critical thinking. In the example of the leaflets, the writers may have overlooked the fact that their audience was probably unfamiliar with palliative care, and needed to have information that was easy to understand and read, and, more importantly, that allowed readers to understand the options available to them.

Critical thinking, then, encourages writers to think globally about the document: its audience and purpose, certainly, but also about the choices inherent in any writing task: organization, words, phrases, and sentence and paragraph structure (always keeping in mind, of course, FDA regulations) that allow the writer to get the point across easily and simply. Too often, the documents written in this industry are cookie-cutter style: writers tend to use the same organization of the document, the same phrases, the same terms, the same sentence and paragraph structure, even when the audiences and purposes vary. Not only does such an approach constrain the writer, but may also negatively affect the reader and cause the reader to overlook vital information.

Writers must be provided with critical thinking tools: for instance, information on how readers read and digest information; on sentence and paragraph construction and its effect on readers; and about how to emphasize vital information. Many writers aren’t aware that certain words and phrases carry connotations or may have a negative effect on readers, or that placement of information determines how seriously a reader considers it. This is the essence of critical thinking: teaching writers about available choices, and then allowing them to consider the choices to generate a truly usable, understandable document.

### **Encouraging Critical Thinking**

Most writers are already critical thinkers; they may just be unaware of it. Critical thinking is about making decisions, and certainly people make decisions every day. The trick is helping writers understand how vital critical thinking is to their writing and how they can employ it.

First, writers should see writing as problem-solving, but on paper. That is, when they are ready to generate a document, they should consider audience needs and the document's purpose (both what they wish to achieve with the document and why the audience is reading it). Beyond this, they should be encouraged to consider the choices they have when writing, and how best to employ these choices to create a usable document: constructing sentences so that they make sense and get the point across; organizing documents to emphasize appropriate information; using visual cues to allow readers to quickly and easily find information.

Beyond writing the documents, writers need to work in an environment where new ideas, especially those related to written documents, are listened to and welcomed. Editorial comments should be such that they encourage critical thinking by asking questions rather than providing all the answers, and editors and writers should be encouraged to discuss their writing with each other.

While such actions may take more time in the short run, over the long-term they will help develop writers who are better able to compose a variety of documents. Such writers are better prepared to think critically about their audience, the document's purpose, and if the document is useful and meets readers' needs.

One comment concerning these ideas may be that writers in this industry are working under time constraints. But if writers take the time to engage fully in the writing process, to fully explore their options in writing, and to think more critically about the documents they're generating, they will become more proficient, which will, in time, allow them to complete writing tasks with greater efficiency and less frustration.

In addition (and perhaps most important), increased efficiency, with less rewriting and revising, will ultimately result in more documents being generated that are more usable, more coherent, and that better meet audience needs, which can certainly help decrease the time involved and the money wasted in drug development.

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