Training Nonwriters to Write

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It is no secret to anyone in this industry that writing, and writing well, is important to ensure that a study progresses as it should. Writing allows personnel to stay informed and helps everyone involved in the study understand what is going on.

What may be less obvious is that many of those working in biopharmaceutical, drug development, and contract research organizations lack the necessary writing skills to write well. I label such workers "nonwriters" because they are expected to write, to write often, and sometimes write prolific amounts. The term is not meant to be derogatory, but rather to label a group of people who have not been previously trained to understand what it means to write well, especially in the biopharmaceutical industry. Put another way, they often lack the necessary tools to be competent, efficient, and effective writers. These "nonwriters," while very often extremely intelligent people, simply do not write well because they have not been trained to do so.

Training these nonwriters is often a battle for several reasons: 1) they sometimes feel that poor writing is due to a lack of knowledge of grammar, a discipline many of them have little or no time to relearn); 2) many biopharmaceutical, drug development, and contract research organizations lament the lack of strong writing skills, but fail to implement any kind of writing training; 3) well-meaning but poorly trained managers and supervisors attempt to edit the work of nonwriters by focusing on grammar and style, which are the only factors managers often consider necessary for good writing; and 4) companies often use poorly written models to illustrate how a document is to be written.

Point One: While grammar is important in a well-written document, it is not of primary importance because it is the easiest part of any document to remedy. Research has shown that too much of a focus on grammar actually inhibits writers, as they become overly concerned with sentence and paragraph structure rather than concentrating on what they wish to say and how they wish to say it. Grammar, believe it or not, also changes depending on the organization and its belief in how something should be articulated in writing.

Point Two: The lack of writing training in these organizations illustrates two things. The first goes back to the axiom, "If it ain't broke, don't fix it." Many of these firms believe that if the documents themselves are getting the job done, as they seem to be, why bother to spend money on writing programs? However, what often goes unrealized is the wasted time and effort spent by project managers, supervisors, and the nonwriters who must edit and revise these documents. In contract research organizations at least, CRAs complain about sites routinely failing to complete the requested actions, resulting in additional

correspondence and increased frustration. Queries are an excellent example of a document that may literally be sent back and forth dozens of times in an effort to elicit a correct response. In many drug development companies, clients may also complain because they are unable to understand what the company has done and how the information is to be used by and impacts the client.

Point Three: Frequently in these organizations, the editing is left up to project managers and supervisors, many who have not been adequately trained to write and/or edit. For instance, I've had project managers tell me that they don't allow their personnel to use the gerund form ("ing") of a verb or to use the word "that" in any of their written documents. This reliance on antiquated and often senseless rules often results in editing that frustrates part of the nonwriter. This person either does not understand the changes being suggested, or resists making the changes since that means giving up ownership of the document. A person in this situation may delay writing so that the project manager has less time to edit, which creates less work because less editing will be required. This well-intended but misdirected kind of editing often destroys the motivation and morale of nonwriters. Such treatment often causes nonwriters to do one or both of the following: put little time or planning into their writing since they feel that it will be rewritten anyway; and/or put off their writing tasks so that when the documents are written they are barely readable. Further, the product of this constant editing and re-editing are documents that shift and that lack consistency.

Point Four: The use of models in these companies is rampant, and for good reason: they save nonwriters time. They can also be used to "teach" nonwriters quickly and easily not only the components of a particular document but also, inadvertently perhaps, teach the language that the document is supposed to contain. The problem with many of these models is that they frequently are ill conceived. For reasons to be mentioned later, the language used may undermine both the credibility of both the writer and the writer's company.

What Can Be Done?

Biopharmaceutical, drug development, and contract research organizations would be well served to rethink the writing component of their businesses and how they train nonwriters to write. Devising a writing training program is in such a company's best interest because it would result in clearer, more effective documents. These groups are in greater need of a writing program than others because they employ such a large number of nonwriters, and because so much of their business depends on written communication. Further, a well-planned writing training program that emphasizes language and choice over grammar would make their nonwriters more efficient and effective. The result would be less editing, increased writing competence, and enhanced communication between the company and the world outside.

Rhetorical and/or critical thinking has to be one of the primary components of such a program, as both help lay the foundation for teaching nonwriters about choice. This does not necessarily imply that content should be chosen. As we all are painfully aware, dictates from the FDA and various sponsors determine

content. Instead, writers should understand that choices could refer to language, to how a message is relayed, to organization, and to a document's accessibility. For instance, instead of asking writers to follow mindlessly the often poorly conceived and poorly written models written by others within the organization, nonwriters may be better served to analyze several things:

- The audience for the writing
- The purpose of the writing
- The constraints inherent in the message itself

When writers understand these elements and the choices inherent in considering them, they give themselves more freedom to compose documents that ultimately serve the writer and the company. A thorough analysis of one's audience, the reason for the document, and the message's constraints can provide the nonwriter with a better understanding of the choices available.

The Audience

Most writers in this industry may be unfamiliar with thinking about audience. In fact, many of them may never have heard that their audience should be one of their primary concerns. For others, audience refers to an assumption that everyone reads in exactly the same way, and is looking for exactly the same information organized exactly the same way in every document.   Logic tells us, however, that organization has to change from document to document because situations change, not only for us but also for the audience as well.

Readers can vary in several ways. For example, one reader may have little tolerance for the message, and possibly for the writer. Another may be hostile, while another may have certain expectations for the message and for how it is relayed. Readers and their attitudes can also change from message to message and be extremely inconsistent. However, nonwriters can fashion appropriate and effective documents if they understand an important principle: the more knowledge they have of their audience the better, and understanding audience variations may help them fashion an effective message the first time. That message will likely require less editing and revision later.

Writers may also examine audience characteristics that go beyond tolerance, hostility, and expectations. For instance, it may be helpful for writers to anticipate an audience's reaction to a message, or to consider how an audience's knowledge or ignorance about the workings of a study may color their reaction to a message. How busy is the physician at the site? Who will be the person responsible for reading and acting upon the document? Will the reader and actor be different people? Helping nonwriters answer these questions can enable them to profile an audience and to then make choices about organization and language, for instance, that help them compose a document that is well-received and quickly acted upon.

The Purpose

When writers are asked about their goals in writing a phone contact report, for example, they will often indicate that their purpose is to "document the phone call." They would be mostly correct in understanding that they are required to fashion a text that documents a phone call. However, such a response overlooks

the nonwriter's and the company's goal in documenting the call. The belief that documentation is the only goal ignores other possibilities and essentially enslaves the writer to one-dimensional thinking.

Instead, the nonwriter should be encouraged to consider the multiple purposes inherent in any written document. They include making the nonwriter and the company appear professional, knowledgeable and acutely aware of what the audience wants and expects from the document, and encouraging reading and action by the reader. The purpose of any written document, then, goes beyond a goal set by the organization of having a written document in place. Consider this: phone contact reports vary in their readability, yet they all supposedly serve to document a phone call. In many organizations, it doesn't seem to matter if the reader can figure out by the written document what is going on. What matters is that a document has been written and can be placed in the file. If the goal, then, is only to write a document of questionable readability, then essentially any mishmash of words will suffice. If, however, the goal of the company and the nonwriter is to produce a readable document that promotes the integrity of the company and of the nonwriter, then the nonwriter must consider the document outside the goals set by the company. The goal to simply have a document in place fails the company and the nonwriter in many ways. It de-emphasizes the company's ability to perform its job, while denigrating the company's professionalism as well as the nonwriter's ability to problem-solve. Using the phone contact report as an example, the writer has two options. She can report the information verbatim and allow the readers to figure it out for themselves, or she can write it in a way that demonstrates her ability to analyze and interpret information. Choosing the latter option would illustrate her intelligence and her knowledge of the topic. The audience is incorporated if our writer considers that her audience needs to know only the important information from the phone call. She can determine this by analyzing her audience and understanding how they will use the information. If she knows that her project manager is the primary reader and has a low tolerance for superfluous information, for example, she might consider relaying the information in a bulleted list. If the project manager wants a "top-down" approach, she can analyze the information and organize it in order of priority.

Message Constraints

The third consideration a writer should be aware of is message constraints. This refers to the elements and manner of the message, and how the reader will respond to it. If a thorough audience analysis is conducted, a good idea of reader response should be clear.

The typical follow-up letter provides a good example of this. Many such letters begin by informing the reader of the visit and who was present. They then go on to advise the site of the number of enrollees in the study. The organization of the letter then typically follows a chronological order. Whatever happens next is relayed, often with little thought given to what should be included in what paragraph. This is demonstrated when the topic sentence fails to provide a true indication of the information the message contains).

When this kind of letter contains purely mundane information of which the reader is already aware, using chronology may not impede the reader's understanding. However, when it includes information about deviations and the actions required by the site to correct them, a chronological rendering may fail to indicate importance of events and thereby fail to incite the reader to act. Readers need to be able to quickly and easily find the deviations and, more important, understand what needs to be done to correct them.

Therefore, nonwriters need to be able to organize information in such a way that it makes sense to the reader and meets reader expectations. Conducting a careful audience analysis, understanding and delineating the purpose, and knowing the message constraints can enable the nonwriter to figure out he or she needs to plan, organize, and compose the message. Finally, when considering message constraints and organizational patterns, an understanding of visual cues such as bold type, headings and subheadings can aid in relaying the message appropriately. Such cues can soften a harsh message, render a message neutral, and enhance positive messages. These kinds of cues also work within a document to hasten the reader's ability to access information, to understand the nonwriter's organization, and to help in creating the appropriate action by the reader.

Conclusion

A university-level writing program that emphasizes critical thinking over grammar can help nonwriters in biopharmaceutical, drug development, and contract research organizations to understand the choices they have in writing. It can also help them to become more efficient and produce more quality work. This can only result in increased efficiency, and ultimately greater savings of both time and money. Some nonwriters will even begin to enjoy the writing process as they gain a fuller understanding of what writing means.

Selecting consulting companies to do this type of training can be tricky, as there are many such firms out there. My advice is to take your time in choosing, and be sure that the company you select has the proper credentials. Those qualities include a track record of teaching writing in the industry for at least five years; a full understanding of the types of documents written in this industry; and an understanding of how the writing in this industry is different from "technical" or "medical" writing. Another important quality is an emphasis on critical thinking or rhetorical theory that emphasizes choice over rules. Also, be aware that teaching nonwriters to write involves a commitment of more than a one- or two-day workshop. Because writing is a process, nonwriters should be involved in a series of classes that help them understand the wonderful choices they have when writing.

Finally, the company itself must commit the time and the energy to make such a program fruitful. This may require that extra time be provided to those interested in attending the program to write and rewrite documents, to take the course, and to meet with the instructor. It could also require new books that encourage writing for the library. Incentives could be provided to those participants who attend a certain number of classes. A full commitment would be needed by project managers and supervisors, who themselves would be required

to attend the sessions. These activities may prove to be frustrating and time-consuming in the short term, but in the long run employees will benefit as they become more competent, confident and effective writers. The company will realize savings of time and money through more efficient writing and editing by employees. One of the greatest benefits to companies, however, is the image projected by their written documents that illustrates their professionalism, competence, and quality.

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