When writing is central to the job of assuring health, safety, and quality, can you afford to be loose with language prone to misunderstanding? Why take a chance? Don't assume someone in your own scientific profession understands your use of jargon. Be a tireless editor of your own and other's writing. Here are a few strategies to edit for quality control.

Language as Quality Control; or, Sonicate Until the Cockroaches Disappear

--Steven P. Schultz, Ph.D.

Advice on writing is plentiful—whether for writing short stories or scientific articles: "Avoid vague statements, jargon and laboratory slang" (1); scientific writing must be "be precise and unambiguous" (2); "the writer should so write that his reader not only may, but must, understand" (3); and "read closely and revise your own manuscript at least three times before submission" (4).

But where do you start when editing your own or someone else's work? What do you look for? In *How to Fail an FDA Quality Audit*, Mort Levin states that based on "sampling statistics, if 1% of [written] procedures have problems, the probability of finding one or more in a group of 100 is 63%." (5) In other words, if you find one cockroach, dozens more surely lurk in the dark. So my advice for a first editing step is to examine the language and **look for the cockroaches**. They thrive in vague wording, jargon, and ambiguity.

Non-specific language

When introducing a unit on language in writing seminars, I often start with an excerpt from a pharmaceutical standard operating procedure I once edited: "Inspect the vials periodically for microbial growth." Is the directive *periodically* up to quality standards? Many defend it. Since this vague word is found in so much documentation, some believe there must be a successful strategy behind it. I have heard explanations, such as *you don't want to be too clear because if the FDA comes in and you're inspecting the vials on the eighth day when it should be done on the seventh, you're in trouble*. Would the FDA really be fooled? Use *periodic* and you may very well have sent the invitation for a visit. So, how to edit this? Ask the chemist or microbiologist to explain the purpose of inspecting the vials and the best time to make the inspection to assure the intended outcome. Revision: Inspect the vials for microbial growth every 7 days after incubation.

This is not an isolated example of unclear scientific writing. Examine every batch of writing intended to provide specific direction and quality assurance, and you will find more:

All exposed jewelry must be removed if in close proximity of operating equipment.
How close is close proximity? (And *close proximity* itself is redundant.)

Select 10 biohazard autoclavable hazardous material bags (or equivalent).
Would someone new to this method know what's autoclavable, as well as its equivalent?

Objective: To detect any obvious high and low filled vials.

What's obvious? Could the high and how range be measured?

Some solvents can damage the appearance and function of the instrument.

Which solvents? How will the reader know?

Unless otherwise directed, non-company personnel are required to wear safety glasses.

Directed by whom or what? And who are non-company personnel?

This uncalibrated capper count appears to be more accurate than the average tray count.

Is the uncalibrated count more accurate or not? What's the basis of this appearance?

When necessary, identify isolates using an appropriate microbial identification system.

When would this be necessary, and what system would be appropriate?

Minimize reaching over open containers, syringe baskets, etc. on the tables and the number of people moving at one time in the rooms during operations in the class 100 areas.

Is reaching over sterile components acceptable at all? How many times and how many people moving at one time jeopardize product quality? What other types of items could *etc.* refer to?

Not all of these examples might jeopardize quality or safety or prevent a scientist from reproducing another's results. But why take a chance?

When editing for clarity, ask yourself, is this specific enough, will this produce consistent results, could two people interpret it in more than one way? If it's fine as is, move on. If there is a probability for misunderstanding, then rewrite so readers *must* versus *may* understand. Vague language shifts the burden or responsibility to the reader, who will either find out what's *necessary, appropriate, obvious*, or guess and make a decision based on subjective, loosely chosen language. Why take a chance?

Jargon—the bottom line, if you will, of synergistic scenarios.

Jargon is so pervasive in English that it's often hard to recognize or see what's wrong with it and why writing guides decry it. We use jargon, as we do slang, in everyday conversation, not realizing it—I'm going to *scoot to* the store, *pick up* groceries, and *whip up* something for dinner. In science, the jargon might sound more technical, but it's just as potentially vague, imprecise, and troublesome. Here are some examples:

The new study has been performed for ***optimization*** purposes.

Sounds great; who isn't for optimization? The study's objective, however, buried pages later in the study, was to increase a product's shelf life by 6 months.

Products in question will be formulated and held at their required storage ***parameters*** per their respective master records by the Formulation Department.

Who doesn't love a parameter . . . and its melodious sound on the tongue, sprinkled with a little *per* and *respective*? But the writer could have stated the point directly and simply—the products will be formulated and *stored* as their master records require.

The biggest cockroach in the jargon family is *utilize* and its fellow hatchlings *utilizing* and *utilization*.

> Laboratory documentation was reviewed to determine the number of samples that were ***utilized*** in the testing performed.

Possible revision: *We reviewed the documentation to determine the number of samples tested.*

> Biologically, perchlorate interferes with the ***utilization*** of iodine and disrupts hormone production by the thyroid gland.

What's the actual causation described here? What is utilizing the iodine and the relation between iodine and the thyroid? When writers make a commitment to avoiding the jargon (in this case, not using *utilization*), they choose more descriptive verbs and concise phrasing: *Perchlorate interferes [or inhibits] the thyroid's intake of iodine needed to produce hormones.*

Again, because jargon and imprecise language are so pervasive, it would seem the scientific professions condone it, even though all scientific style guides—whether from the American Chemistry Society or the Council of Biology Editors—devote chapters that discourage it. Why, when so well documented in these sources, is jargon hard to exterminate? Possibly because it sounds (to the writer) intelligent, sophisticated, in the know, and part of the profession. Using jargon may make the writer feel good. It's also easy to use.

Nonetheless, jargon makes the job of reading more complicated, abstract, and longer than necessary. Is there a compromise? For an editor, I'd say no. Scientific, peer reviewers, however, may be more tolerant, focusing on accuracy, precision, or reducing the probability for failure. If the jargon creates inflated, sluggish prose that is difficult to read, fine (but still try to improve it). But if the language is potentially ambiguous, not technical and accurate enough, as illustrated in this article's examples, simpler, specific language is a must.

It's always been done this way . . . and they should know this.

The most difficult obstacle to overcome as a writer and editor might be a resistance to change based on an unfounded belief that because a practice is so common, it must have been proven scientifically infallible. When it comes to writing, it can be difficult to prove a case for applying best practices because the metrics are often subjective. Even though an editor can demonstrate jargon's shortcomings or how to delete wordiness, it's difficult to overcome statements like, *that's just our style*, *this is the standard language we always use*, and *if they are working in this field, they should know this*.

Two common examples I've found yield some metrics and support for avoiding jargon and using plain yet specific language. One is based on research; the other, on interviews with QA personnel in R&D and manufacturing and their on-the-job experiences.

For External Use Only. A study of prescription drug warnings at Northwestern University has centered on how to improve the warnings—the *standard* warnings now in use—to assure patient comprehension and reduce the risk of errors (6).

The research compared adult patients' responses to current standard drug warning labels with responses to drug warnings that were rewritten in more plain language with less text. These are three of the nine labels and revisions the study used:

Standard Warning Label	Revised Simplified Warning
FOR EXTERNAL USE ONLY	Use only on your skin
IT IS VERY IMPORTANT THAT YOU TAKE OR USE THIS EXACTLY AS DIRECTED. DO NOT SKIP DOSES OR DISCONTINUE UNLESS DIRECTED BY YOUR DOCTOR.	Do not stop taking unless directed by your doctor.
OBTAIN MEDICAL ADVICE BEFORE TAKING NON-PRESCRIPTION DRUGS. SOME MAY AFFECT THE ACTION OF THE MEDICATION.	Talk to your doctor before using any over-the-counter drugs.

The researchers found an 80.3 percent rate of correct interpretation of the standard drug warnings and a 90.6 percent correct interpretation of the revised simplified ones.

Sonicate Until Dissolved. The industry need for simple, direct, and unambiguous instructions is no less important for reducing the probability of misunderstanding in methods, lab protocols, or analytical studies. The threat of lab jargon, assuming stock phrases and language are universally understood as, say, the symbol for benzene, is also no less intense.

In reviewing a method, ask a chemist, does *sonicate until dissolved* need to be explained? You might hear some sighs or a statement like *why should we have to tell an analyst that*? For an SOP, this language leaves the step open to interpretation and one that can be completely differently each time by the same person. And so one analyst will use a the ultra-sound probe (sonicator) to prepare a sample for 15 minutes over a coffee break; another for an hour so it will be ready after coming back from lunch.

QA managers and directors attest that the latitude embedded in *sonicate until dissolved* is prone to error. It can be cited as the cause for low assay results and results out of specification, even though nothing was wrong with the product. The costs from these variances are spending more resources, time and money, for additional testing, delaying the release of product, or, if it's stability testing, reporting the results to the FDA. Why take the chance?

There's not a perfect solution, but there are means to reduce this risk—through language and science, and by making it make it method-specific, not analyst dependent. A possible translation in plain language might be *Prepare the solution using x and z. Sonicate it until the solution is clear and no particles can be observed.* However, for photo-sensitive testing that uses amber glassware, an analyst can't see what's dissolved. A more reliable and consistent approach would be to base the directive on experiments that identify the time required for *this* method to eliminate possible variances in results, and state it in unambiguous language. Method A, therefore, sonicates for 15 minutes; Method B for 45 minutes.

There is no such thing as a good writer.

To allude to a line in the sales profession, writers are only as good as their last written communication. Writing is work, and no simple formula is going to produce the quality product desired every time. Rigorous editing and rewriting will increase the chances. So give yourself a hard time—and ask others who review your work to do the same. As the legal scholar Bryan Garner advises, "Review your writing ungenerously, as a harsh critic might. . . . If you approach your own writing mercilessly, your readers are sure to be merciful" (7). Great advice, too, for professionals involved in the health and safety of the public. Why take a chance?

References

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