2

Connecting Writer and Reader

People who assess it overwhelmingly point to one problem in writing: a lack of understanding of and perception about the audience. Knowing whom your documents address and what response you want is a key to successful technical writing. This kind of writing informs people of past activities, findings, and decisions; it presents data and makes recommendations; it provides records of ongoing projects; it tells people how and why to take certain actions; it tells what kind of outcome is likely from intended actions; and it always has an audience — sometimes immediate and well known, other times projected. Often documents directed to a future audience go to immediate readers who need the information for interim work processes.

> When you write to FDA, the entire industry is a potential audience.
>
> **Monica Grimaldi, Certified Quality Engineer**

You can create grammatically correct and efficient passages that offer the information you need to convey. But overlooking the effects of your words on your readers is all too easy. That's why, when you write, you need to step back and evaluate the readers. Who are they? How will they respond to the information you're giving? Most people run the risk of not being objective about their readers, because when they write they are much more involved with what they have to say than they are with how readers will receive it.

This holds particularly true in the technical disciplines, where an initial reader may have knowledge of a project equal to that of the writer, but the intended audience may not be privy to the underlying details of a project. Other documents, such as technical notes, have no direct or immediate audience, and the intent is to supply a record of a problem resolved or record an issue. Nevertheless, while you may not know *now* who will seek a future record, you can assume someone will, so you will need to include enough background information to make the message understandable to the possible future reader.

The laboratory notebook is a good example of writing that's done for an immediate audience: those persons coordinating projects and overseeing routine activities who are in positions to make decisions. Should the data in the notebook lead to significant discovery, then the data in the notebook

become the foundation for development. So future audiences may include anyone who seeks a record of a project, including a regulatory body such as the Food and Drug Administration (FDA). Thus, information must be clear, complete, and comprehensible to all pertinent, possible readers, not just the immediate ones.

> The palest ink is better than the best memory.
>
> **Chinese proverb**

Similarly, you may write a report to inform a scientific area of the company of a project's progress, but a projected audience may well be a regulatory body who will look at the report at some point in the future. Thus, it's smart to include information that the projected audience may require for complete understanding — but which is, nevertheless, not crucial for your immediate audience. Consider the case of a Quality Assurance (QA) Director who served as the project lead in the validation of a renovated plant facility. He included far more background and information than he had to for the simple reason that the facility would eventually be subject to a compliance inspection. He deemed it best to capture the complete history of the renovated facility, because he did not want to be in the position of having to recreate it at a future point.

A dossier that goes to a regulatory agency for review and product approval usually includes a large number of supporting documents, such as those prepared as the development progressed often over a period of ten years or more. When information is summarized, such as within individual portions of a New Drug Application (NDA) or Common Technical Document (CTD), writers really won't know who the precise readers will be for the sections or their supporting documents. There may be many readers who will read various sections of a submission. For instance, a reviewer at FDA for a Chemistry, Manufacturing, and Controls (CMC) section of a submission will most probably not be the same reviewer as the one who looks at clinical data. And neither reviewer will have seen the supporting study documents when they were actually written. Those will have had a more immediate audience at the time the actual study reached completion. The common link here is usually the project manager at the agency who has been working with the company's regulatory people and providing insight and suggestions for compiling the submission. And that dialog should set the tone for the writing.

Questions to ask before putting pen to paper — or booting up the computer — are the following:

- Who are the immediate readers?
- Who may read this document in the future?
- How much do the immediate readers already know about the topic?
- What do future readers need to know to understand the topic?
- What response do you want?

Consider this passage from a Chemical Hygiene Plan. It is incomplete and vague. What is missing that the readers need to know? How can it be more explicit and direct?

> Where there is no immediate danger to the skin from contact with a hazardous chemical, it is still prudent to select clothing to minimize exposed skin surfaces. A laboratory coat should be worn over street clothes and be laundered regularly. A laboratory coat is intended to prevent contact with direct, chemical dusts, and minor chemical splashes of spills. If it becomes contaminated, it should be removed immediately and affected skin surface washed thoroughly. Employees should wear long legged clothing and avoid short trousers or skirts to cover areas that lab coats do not. Shoes should be worn in the laboratory at all times. Sandals and perforated shoes are not permitted in the laboratory. In addition long hair should be confined.

The above passage falls short because it does not directly address the readers and does not follow through in its directive. Further, the passage does not include related information the readers need. Who launders the lab coats? In the following rewrite, there is no question. The rewrite also gets rid of the conditional ("should be"), speaks directly to the reader, and tells how to follow through.

> Where there is no immediate danger to the skin from contact with a hazardous chemical, it is still prudent to select clothing to minimize the risk of exposure. Wear clothing with long legs to cover areas that lab coats do not. Avoid short pants or skirts to minimize exposure risk. Wear socks and closed shoes at all times; do not wear sandals and perforated shoes. In addition, confine long hair for your safety and to prevent compromising the integrity of the lab work. In addition, do not wear jewelry that can catch in laboratory equipment. Most important, always wear a laboratory coat over street clothes. Laboratory coats prevent contact with dirt, chemical dusts, and minor chemical splashes or spills. Always wear clean laboratory coats and dispatch soiled ones to the hamper bins in the change room.
>
> Note: If you suspect your lab coat has become contaminated, remove it immediately, bag it, and wash all exposed skin surfaces thoroughly. Refer to the MSDS sheet for any additional measures. Call the Chemical Hygiene Officer to collect the contaminated lab coat.

Readers' Language Skills

Whether you are writing for internal distribution or external, you must consider the language skills of your readers. When writing to a regulatory

body, you can be confident that readers will have a degree of sophistication to enable them to understand fairly complex data. These people have read similar documentation repeatedly.

If you prepare a manuscript, you can also be confident that if you write according to the style set forth by the publication, the readers will readily comprehend what you say. These readers are your colleagues and will have comparable language skill sets. The same holds true for posters and slide sets. The audience that reviews posters in an exhibit hall does so because of interest in what others in the industry are doing; they attend presentations for the same reason.

Not all readers possess the same skills. Some documents must be comprehensible to a much lower reading level, and it is critical that they be. Work instructions for a manufacturing environment are best in clear, direct language that speaks to a tenth grade or lower reading level. Informed consent for potential participants in clinical trials is also best written to an eighth grade or lower reading level as well, as is patient literature.

Informed Consent

What Is Informed Consent?

Informed consent is not a signature on a piece of paper. It is a process undertaken to assure that people are fully informed about the choices available for their health care. Informed consent is based on the legal and ethical rights of individuals to direct their own care and the ethical duty of physicians to involve their patients in their own care. Individuals have the right to refuse information about procedures or surgeries, but they must initiate the request, not be offered it. After it is determined that the person understands the proposed intervention and has reached a decision, his/her signature on the informed consent form denotes acceptance of the proposed intervention

When Is Informed Consent Needed?

Informed consents are required for invasive interventions (for example, procedures, anesthesia, and surgeries); before being given certain medications (for example, flu shots) or receiving certain tests (for example, HIV testing); and before participating in research projects.

What needs to be included in an informed consent?

Informed consent needs to include:

- The rationale for the intervention
- The nature of the proposed intervention
- Reasonable and medically appropriate alternatives to the proposed intervention
- The risks and benefits of the proposed and all alternative interventions
- The anticipated outcome of the proposed intervention.

Who Can Give Informed Consent?

Conscious, competent individuals can give informed consent. An incompetent or incapacitated individual needs a surrogate decision maker to give informed consent.

Parents give informed consent for their dependent children.

In most states, emancipated minors can give informed consent. Most states also allow minors to seek treatment for sexually transmitted diseases, pregnancy, and drug or alcohol abuse on their own.

Tips for Writing Informed Consent

When writing informed consent forms, be sensitive to a person's ability to digest complicated or bad news, and be sensitive to personal (cultural or religious) beliefs of the regional population.

Rely on the following when writing informed consent forms:

- Provide alternative language (Spanish, for example) informed consent forms for individuals whose first language is not English.
- Explain the proposed intervention in consumer friendly language, not technical jargon.
- Define all terms and write out phonetic pronunciation of all unfamiliar terms.
- List risks in as nonthreatening a way as possible.
- Put risks in perspective. For example, about 1 in 50,000 healthy people die from general anesthesia; you have about double that chance to die in an automobile accident.

Courtesy of Joan Lorenz

Another consideration is whether readers are native born speakers and writers of English, or if they are foreign born. In most pharmaceutical, device, and biologic environments, the mixture of employees is multinational. The same is true of patient populations for clinical trials. The result is that,

although your readers may have sufficient language skills to comprehend most communication related to activities with which they are familiar, they may not understand a term you consider critical, or they may have difficulty decoding a complex passage. If you suspect that's a possibility, it's easy to give a quick explanation or include a brief glossary if the document is long, or to rewrite to simplify presentation. Remember that it's a rare reader who will confess to "not understanding" if he thinks his lack of comprehension stems from his own inabilities. Provide the meanings you intend your readers to have so that there will be no misunderstanding.

Further, if you are a writer for whom English is a second language, you may be bringing certain conceptions about writing, unfounded in standard American conventions, to your workplace. In some cultures for instance, when a writer sums up information for a reader, it is tantamount to saying, "You probably won't understand the data, so I'll have to explain it." Such a message can seem insulting. In written English, however, the standard is to explain the significance of data. Always tell your readers what you mean and what the significances of certain facts are. Never leave the message open to interpretation.

The average person has three vocabularies:

- Reading is the largest.
- Speaking is the next largest.
- Writing is the smallest.

In writing, words must carry 90 percent of our messages. Punctuation and graphics convey the rest.

Writing Directly to the Reader

Many documents work best when they speak directly to the readers. When you seek an immediate response from specific readers, the best way to make sure the response is what you want is to involve them. You may write directly to fellow employees where you work; you may also write directly to readers external to the company. Sometimes you will write to one person specifically; just as often, your immediate readers may be two or more.

Many pieces of writing address readers directly. Letters, memos, and e-mails certainly do. So does informed consent for clinical trials. Other documents that speak directly to readers, such as methods, instructions, procedures, and operator manuals, usually work best in the imperative voice, which simply means the "you" in the writing is understood. The imperative

voice uses the present tense and is the only instance in English where you can compose a complete sentence without actually writing out the subject. For example, "Write it down" is a directive, and the "you" is understood to be the reader. Understood as well is that the audience for these documents has been trained in the processes. Typical steps in a procedure, such as these that tell how to measure flow rate, have an implied "you":

6.1 Make sure the clamp securing the funnel to the vibrator is properly affixed.

6.2 Open the air valve and adjust the regulator to 16 psi.

(See Chapter Five for more information about procedure writing.)

A Preventive Maintenance Memo

Consider this internal memo about preventive maintenance to a project engineer. Here the author writes directly to the engineer but does not include him in the communication at all.

Original

JORSTAD LABORATORIES Internal Memorandum

DATE: August 16, 2005
TO: Matthew Zarelli
FROM: John Lopez
RE: Preventive Maintenance

At the weekly meeting on August 14, 2005, it was decided to review aspects of the preventive maintenance program to assess its sufficiency. The preventive maintenance for sophisticated components of the fluid bed dryer has been contracted out to Glatt and Co. The in-house work orders for the past month have all been reviewed, and none are related to preventive maintenance.

During the weekly staff meeting, the question of possible "downtime" in production because of simple maintenance needs was not discussed. A meeting should be arranged that includes the maintenance manager. Regular preventive maintenance must be addressed.

While the paragraphs in this memo are grammatically reasonable and present key information, they're not doing the best job they can. The writer has focused on the information that precipitated the memo. Seriously lacking is what the writer expects from the recipient. How does the information relate to the reader? What role has the reader played in the development of events? And who should arrange the meeting that will address preventive

maintenance? Will the reader be involved in making the decision about preventive maintenance?

A rewrite that addresses the engineer directly, using "we," "our," "you," and "your" produces a much clearer message that's more likely to get results. In the first version, the writer refers to himself once, but not at all to the reader. In the second version, the writer includes the reader ten times and directs the engineer to action. The rewritten memo is more effective because the reader knows what action he must take, and he knows it up front.

Rewrite

JORSTAD LABORATORIES Internal Memorandum

DATE: August 16, 2005
TO: Matthew Zarelli
FROM: John Lopez
RE: Preventive Maintenance

Please arrange a meeting and include the maintenance manager so that we can discuss preventive maintenance and devise a plan for action. As we discussed at our weekly meeting on August 16, 2005, we are going to review the work orders for your area to see if aspects of the current regular preventive maintenance program are sufficient.

As you pointed out then, the preventive maintenance for "sophisticated components of the fluid bed dryer" was contracted out to Glatt and Co., and thus that equipment is regularly serviced. However, maintenance of equipment not under contract remains an issue. Since our meeting, I have reviewed all the work orders for the past month, and you are right: Preventive maintenance has not been a priority. In addition, during the weekly staff meetings, we did not discuss whether any equipment has suffered "downtime" because of maintenance needs. I firmly agree that we must address these issues, and our meeting will be the place to start.

> When we give serious consideration to who will read what we've written, what they already know, and what they need to know, we are much more likely to hit the mark.
>
> **Arlene Johnson, Author**

Announcing an Inspection

The following memo effectively addresses several key people who need the information contained therein to prepare for an FDA inspection. Notice how the memo tells people directly what they need to do in preparation for the FDA visit. Further, while it refers recipients to the established protocol, it reiterates what the writer feels is essential. In addition, it refers to the recipients 15 times, with the words "you" and "your" and "we" and "our," as well as with the use of the imperative voice of "you" under-

stood. This technique clearly makes the readers part of the message. This memo is effective.

LEON LABS, INC. **Memorandum**

Date: November 6, 2005

To: Frank Grimaldi
Linda Zwagerman
Lamar Brown

From: Beatrice Solomon

Re: Upcoming FDA Inspection

We anticipate FDA will be on the premises sometime next month. To prepare our facility for the visit, we will be holding a mock inspection on Friday, the thirteenth. Please inform your respective staff. You may want to review the company protocol for handling inspections, as well.

We plan to provide two escorts per inspector. In addition, I'd like to reiterate that our position is to do the following:

- Provide requested documentation to the company inspection leader as quickly as possible.
- Avoid being confrontational.
- Answer only the questions you are asked.
- Clarify all observations.
- Agree to implement corrective action, if any, as soon as possible.

We will evaluate our mock inspection on Monday to identify any potential problems. If you have any questions, please contact me before week's end. Thanks.

Announcing a GMP Audit

The same common-sense approach works when you are writing to readers outside the company: Include them in the message. The following notice to a contractor advises of an impending current Good Manufacturing Practice (cGMP) audit. Notice how it addresses the reader directly and calls for action.

Ronway Laboratories

2323 Ronway Drive Jackson, Wyoming 83001
June 5, 2005

Dr. Calin Cionca
CEO and General Manager
Micro Systems Management, SA
737525 Hundingsland Boulevard
Chelsea, West Virginia 24608

Dear Dr. Cionca,

We at Ronway are pleased with the range of services Micro Systems is prepared to offer us. Our dramatic increase in manufacturing puts us in a position to use contract services, and we believe Micro Systems will augment our operations satisfactorily. As I mentioned to you during our phone conversation, all that remains is a routine GMP audit of your facilities.

We plan to send two auditors to your facilities on Tuesday, July 14th, to perform an evaluation. They will assess your analytical testing to verify your Certificates of Analyses, your manufacturing site, and those processes that concern our manufacturing requirements. Please provide them with the appropriate documentation as well as guided access to your facilities.

Thanks for your cooperation. We at Ronway look forward to a productive working relationship with Micro Systems.

Sincerely,

RONWAY LABORATORIES

Christian Horton
Director of Quality Control

Giving Product Information

The following letter provides information about a product. It speaks directly to the recipient and includes both reader and writer, referring to previous conversations.

Lasentec

15224 NE 95th Street Redmond, WA 98052

August 28, 2005
Benjamin Smith
Professor of Chemical Engineering
University of Maine
6982 Jenness Hall
Orono, ME 04469

Dear Professor Smith,

I look forward to continuing our discussion of your experiences in crystallization research. I have enclosed the latest information available describing the application of Lasentec® technologies in the monitoring and control of batch crystallizers.

The two instrumentation systems we discussed, FBRM© and PVM©, were developed by Lasentec for real-time *in-process* measurement of Particle Count, Size, Shape, and Imaging. Both systems are probe-based for easy installation and application. The probes are inserted directly into your process vessel or pipeline. They do not require material extraction and sample preparation.

LASENTEC FBRM© (**F**ocused **B**eam **R**eflectance **M**easurement) provides a continuous, high-speed measurement of the Particle Population, enabling you to track the rate and degree of change both on a particle count and particle dimension basis. Even at high solids concentration, FBRM© can provide a *sensitive* and *precise* measurement of

- Population in *independent* size ranges
- Rate and degree of nucleation
- Rate and degree of growth, reduction and agglomeration
- Process endpoint
- Batch to batch consistency
- Continuous process stability

LASENTEC PVM© (**P**article **V**ision and **M**easurement) provides a continuous stream of high-resolution microscope images of your particles and particle structures as they naturally exist *in process.*

PVM© images will provide an in-depth knowledge of your particle-to-particle interaction, and gives you the ability to visually track dynamic process changes in real-time. It is a powerful R&D tool for imaging particle, droplet, and bubble systems at full process concentrations.

Lasentec-2

I believe that you will find the enclosed papers relate directly to your planned research project. After you have had a chance to review this material and are prepared to further discuss our collaboration, I would be pleased to carry out a feasibility test to demonstrate the effectiveness of our instruments in your particular application.

Please call me at your convenience, at 1-800 LASENTEC (1-800-527-3683).

Best regards,

Terry P. Redman
Application Engineer
TerryR@Lasentec.com

Enclosures

Courtesy of Lasentec, Inc.

(See Chapter Four for more examples of correspondence.)

Focusing on the Information

Writing directly to readers, when you know who they are and want a specific response, is usually the most effective way to deliver information. However, much of the time, your purpose in writing will be to present information that's part of a larger picture. Such documents as analytical reports, summary reports, and project analyses frequently make little or no mention of the reader, nor do they need to, because their purpose is to provide a history or other information.

Documents that don't call for reader action directly must still present what readers need to know to understand what has happened, what is happening, or what will be happening, as well as the conclusions and recommendations resulting from specific findings. Often, documents are but links in a chain of documents, and getting the overall picture of a project may require understanding of much more than what the document at hand presents.

Even if immediate reviewers and approvers comprehend what's in a report, filling in the gaps can be useful, even if it means repeating some

information the initial readers already know. In the same vein, controlling your delivery so that it is clear and direct also makes sense. Using internal jargon, for instance, in a report that may be subject to future outside scrutiny is foolish, for doing so invites questions that demand answers. How much better to be lucid and complete in the first place!

It's better to err on the side of giving more information than your immediate audience needs than to be sparse in data or detail, which you may be asked to produce at some future point. There's a fine line, here, however. Your written histories should provide the information relevant to certain activities; they should not trigger unrelated questions that arise from the inclusion of inappropriate details. Worse is to make statements that are unsupported; blanket statements without support are sure triggers for queries from readers, and when readers start to question, you may ultimately wind up giving more information than you intend or need to. Good writing gives readers what they need to know. Thus, a writer may deliver the same information in several versions depending on the readers' need to know and level of technical comprehension.

Summarizing an Investigation

Many documents focus purely on events. Investigations, for example, tend to be directed toward activities leading up to a conclusion. Readers play no role other than that of understanding the information and perhaps responding to it routinely. For instance, a manufacturing deviation report will present the findings of an investigation; the result of those findings may provide the basis for deciding whether to rework or discard a batch.

The following technical note does not call for reader action directly because the purpose is to provide a history of an occurrence. Addressed to the Director of Quality Control, the memo summarizes the result of an investigation.

JORSTAD LABORATORIES **Internal Memorandum**

DATE: February 18, 2005

TO: Ellen Measday

FROM: Hal McCornac

RE: 098C3-Q1234RT-18M and 098C3-Q1235RT-18M test failures

February 15 retesting of 098C3-Q1234RT-18M and 098C3-Q1235RT-18M failed to confirm the test results obtained from the dissolution tests performed on January 29 and 30, 200- The February 15 testing showed a higher potency than the earlier testing did. An investigation revealed that the low potency was a result of the vials being previously opened, and consequently the samples had absorbed moisture and increased in weight. Thus, while the weights in the tests were identical, the ratio of active ingredient to total weight was not, since the first test samples had proportionately higher water content, and therefore proportionately smaller active ingredient.

Retesting using a new standard from an unopened vial verified a potency of 947.67 mcg/mg and a standard factor of 0.0671 mcg/ml. Assays LIC-99-0039 and LIC-99-0040 substantiate these results.

Summarizing a Complaint Investigation

The following memo focuses on the events and does not call for action from the reader; its purpose is to inform the recipient, a Regulatory Director, of the results of a complaint investigation. The Director, in turn, will compose a complaint response.

KIM LABORATORIES, S. A. Memorandum Page 1 of 1

DATE: October 11, 2005

TO: Rui Li

FROM: Eugenia Cline

RE: 2 mg/5 mL complaint

Quality Assurance has reviewed the following 0.5 mg/1 mL product complaint and found radioactivity in the excess precipatated material and low final activity in the product.

Site	Lot	Isotope Manufacturer	Isotope Lot
Wellman Pharmacy	66B2	Radiostuff Inc.	456

The isotope from Radiostuff Inc. has periodically become bound in the excess precipitate formed during the labeling of the product. The isotope caught up in the precipitate is a result of isotope colloids forming during the preparation of the isotope-product complex. The formation of isotope colloids is dependent on the lot of isotope. In addition to this product complaint, three additional complaints the same day proved to be related to the labeling of the products with isotope lot 66B2. In addition to isotope lot–related issues, there are several other interrelated variables, including the importance of strictly following the labeling procedure on the package insert. Quality Assurance completed a report on the causes of isotope colloid formation during the labeling procedure in January 2005. It is available in the QA Archives.

A review of the production records found them to be acceptable. The complaint incident does not represent a serious or unexpected drug experience, so a report of the incident to FDA is unnecessary. However, a review of isotope-related complaints from last year is now underway to determine if further clarification of this recurring situation is possible.

Courtesy of Michael Nolan

Explaining Trade Dress Revisions

The thrust of the following memo is to announce a trade dress revision. It does not call for any action on the part of the readers and simply presents information about a change in market image of a product. Ultimately it will become part of a product development outline. It is direct and to the point and uses the corporate "we."

Lily Labs Interoffice Memo

To: Dr. Maureen Conlan
Dr. Kathleen Monroe
Dr. John Tessman

From: Seth Porter

Location: New Product Development

Date: Nov. 22, 2005

Re: Trade Dress Revisions

We have made the following changes to the market image of Nadolol tablets, 300 mg. Labetalol HCI Tablets, 300 mg: The tablet will be coated with an Opadry to match blue 552 in the Opadry color kit. These tablets will be film coated and have no bisect. The imprint "LL" will appear on one side of the tablet.

The Words You Choose

Much has been said about objectivity and subjectivity. Remaining objective is generally the goal for writing, unless we are preparing a piece of correspondence that contains a personal message. What does being "objective" rather than "subjective" mean? Being objective really means focusing on the best, most direct delivery of information for the reader's understanding without interjection from the writer. Subjectivity allows the writer's opinion to come through.

However, many people who teach and assess writing have come to understand that, while some passages can be more objective than others, no writer can rid himself of subjectivity completely. The words writers choose are the results of their thinking patterns and their personalities; so are their language constructions. Thus, the writer's voice really reflects the individual who first composes a document. Perhaps that's why so many eyes see most documents generated within companies developing or manufacturing therapeutic products, at contract research organizations, and at clinical sites. In an effort to be objective, rather than subjective, most technical people focus on the activity rather than the doer of the activity when recording information. However, whereas this approach is logical, it's not law. People, after all, comprise companies. People communicate what they know to others. They present their findings and ideas so that other people can examine them, either immediately or in the future.

Readers generally receive information better if it includes a doer of the action, an active "we did this" rather than "this was done" approach. Studies show that when reading the passive voice the audience tends to turn the information around anyway before digesting it. Thus, it often makes sense to say "we" when you mean your department or area. Indeed, the corporate "we" is a handy device when you speak on behalf of a unit. You can also refer to your department or area directly: "New Product Development (NPD) has completed the formulation." (Chapters 9, 10, and 11 give more information about the passive voice.)

Don't shun using "I" either. Many documents that speak directly to people appropriately incorporate "I," the writer. "I'm sending you the dissolution data you requested yesterday" is direct and to the point in a brief memo. Even in longer reports, it's okay to include yourself. "During July, I completed the validation of the in-house method" delivers information straightforwardly in a periodic report. Howard Kanare, author of *Writing the Laboratory Notebook,* points out that a notebook entry that says "I saw the mixture turn blue after 10 min.," is preferable to what scientists often write: "It was observed that the mixture changed color after a few minutes had elapsed."

A word of caution is probably wise here, however. Many technical arenas have for so long avoided the use of the first person and first person plural in correspondence and documentation that it feels unnatural, and may even seem "unprofessional." Exercise some judgment, but make your decision knowing that including the doer of the action violates no professional writing standards.

The following passage is an excerpt from a Drug Master File from a Pre-Market Approval Application (PMAA). Notice that it is objective and factual, yet the writer here does not choose to eliminate the corporate "we." The result is direct and easy to read text.

> Abrams, Inc. began development of the active pharmaceutical ingredient in 2003. Development was in three phases. An initial small scale processing produced material for toxicology studies and research. In 2003 through 2004, Abrams scaled the process to provide sufficient final intermediate to allow production by an alternate manufacturing source for the final active pharmaceutical ingredient. No manufacturing occurred before 2004.
>
> In 2004, Abrams, under our directive, undertook a major development project to improve process safety and reduce process cycle-time and process waste. The result of this final phase development effort was the drug product which is the subject of this submission.

> We provide the details of the lots produced during development and explain the changes in the processes relative to lot usage in the development studies.

Using Suitable Language

You must also make sure your memos, letters, and reports present your information in terminology your readers will understand. If you are a chemist writing to another chemist, you share expertise, and complex technical terms will probably pose few problems. If you are a chemist, however, writing to an information systems specialist, you may very well run into difficulties, just as you might in conveying information if you are a chemical engineer writing to a line supervisor. Again, awareness of the expertise of the recipient is tantamount to successful delivery and acceptance.

The following excerpt from an engineering department planning a laboratory renovation was addressed to a director of analytical development.

> Enclosed herewith is the laboratory master plan proposal which abandons the one previously proposed by engineering in favor of a proposed master plan for a facility with six additional modified workstations, and one additional door to the corridor to facilitate access and egress and interfacing between the analytical laboratory undergoing restoration and quality control.

Here the writer has forgotten that the reader of his review, a chemist, is not a facility engineer and has not been a party to all the discussions that have gone into developing the original proposal. Even though the director may understand what is necessary in the laboratory, she may not be prepared to work out the difference between a "master plan proposal" and the plan "previously proposed." She can easily become befuddled if the vocabulary impedes the message.

The phrasing "to facilitate access and egress and interfacing between the laboratory undergoing restoration and quality control," means, simply put, "to make going back and forth between the analytical development lab and quality control easier." In his choice of words, the writer betrays either ignorance of the person who will be reading his analysis or carelessness in presenting the information.

You can avoid the grief that will surely befall you if you submit writing such as this. For one thing, look for words such as "proposed" and "proposal" that each seem to be one word referring to two different things or ideas. This is called "equivocation," and here it is confusing—not richly ambiguous as it would be in a piece of literature. Second, if it isn't possible to reduce technical verbiage to concrete terms, supply brief definitions—a

phrase or two—or examples to clarify things for the nontechnical reader. Third, on the assumption that as master plans, such documents are subject to review long after they have been put together and after their authors have moved on to other jobs, ask the reviewer to supply context or briefly repeat background information that other memos might include in more detail—that is, the circumstances of the suggestions under review.

At times it's appropriate to use technical terminology. Most professions have their own "shorthand"—terms that are unique to a particular subject area. Among specialists, this shorthand, or jargon, can save time and even communicate information more precisely than if it were eliminated. When you say "We're working out the 'bugs' in the system," or "The computer is down," you're communicating succinctly to people who are computer knowledgeable but perhaps unclearly to those who aren't. What you must do, then, is evaluate your audience and make sure you're using diction that will do the best job for you. When a chemist refers to "two unknowns," another chemist will immediately understand that two impurities have not been identified. A less technical person might not.

Evaluate what needs to be said and to whom. What can happen as a result of unnecessary jargon is that your reader will think you're trying to put something over on him, or worse, won't understand what's being said at all. In addition, since most companies have their own jargon, you may run the risk of including terminology that means one thing to you, but something quite different to an external reader.

Controlling Acronyms

Acronyms are specialized jargon. They're created from the first letters of a group of words, or from a combination of letters and parts of words. For example, GC is an acronym for gas chromatography; IPA is an acronym for isopropyl alcohol; and SOP is an acronym for Standard Operating Procedure. These acronyms are perfectly clear to most technical people and they probably need no explanation.

Yet acronyms are endemic in this industry—so much so that FDA includes a list of common acronyms on its website. A very real danger of acronyms wreaking havoc can occur when a company uses an acronym to mean a thing easily understood internally, but that means something entirely else to an external auditor, joint-venture manufacturer, or FDA inspector. Even cGMP, which most of the industry understands to mean current Good Manufacturing Practices, can indicate something quite different—cyclic guanosine monophosphate.

So unless you are sure your reader knows that DTA means differential thermal analysis, you'll be better off spelling the words out. It never hurts to handle acronyms the way most technical writing experts advise: Simply

spell out the full term in the first citation and follow it with the acronym in parenthesis.

> We hope to complete the Modified Release Facility (MRF) by June.

In subsequent references within the document, simply use the acronym.

> The MRF facility will be producing solid dosage products.

To prevent confusion and ensure consistency, careful writers follow these guidelines as well.

- In most cases, do not use periods within or after the acronym, except at the end of a sentence.
- Do not use an apostrophe with a plural acronym.
  - CRFs, IRBs, INDs
- When affixing a prefix to an acronym, hyphenate the prefix and the acronym.
- pre-IND submission activities

Most companies have also realized that it's sensible to maintain a list of acronyms specific to the company. This they usually do as part of a style guide or style sheet. Such a tool makes the appropriate acronym available to writers and deflects the possibility of confusion or misunderstanding as to what company writers mean. (Chapter 14 provides a lengthy list of industry-specific acronyms.)

Connotation and Denotation

The English language is such that we have many, many words to indicate the same thing. These are synonyms. And while synonyms will appear in the dictionary as definitions for each other, there are often subtle variations. So the first definition is the primary meaning of a word, the denotation; what follows are usually the connotations of the word. A word like "smell" may be defined as "odor" or "scent," but the three words have different connotations, the associations we place on them, with "odor" being most negative, "smell" somewhat less negative, and "scent" as positive and light, and aroma also positive, but stronger. You must, therefore, choose your words carefully so that the precise understanding of the message is the result.

Defining Terms

Once you know to avoid unnecessary jargon and unidentified acronyms that may baffle and befuddle readers, concern yourself with clarifying the rest of the words essential to the message. Remember, information is useful only if it makes sense, and what makes sense to you may not make sense to your readers.

Readers with technical expertise similar to yours will most likely understand specialized data without lengthy explanation. But readers with less technical expertise than yours will generally have trouble absorbing the information. Therefore, evaluate the appropriateness of your words and select terms so as to make the information readily comprehensible and impossible to misinterpret. In a work environment, only the rare reader will consult a dictionary to read a letter or memo, let alone a long report. In technical writing, terms open to interpretation deserve definition.

For instance, if an engineer writes a report on the safe installation and operation of electrical equipment that includes as its audience new technicians, he may need to include a definition of "grounding." Similarly, an in-house manual that describes an SOP system should include a definition of key terms as they apply to the system. For instance, "Active SOP" can be defined to include the existing version of an SOP undergoing revision. When the revised version becomes "active," the previous version is "retired"; however, a "withdrawn" SOP can denote a document no longer in use in any version. The terms "retired" and "withdrawn" can be easily interchanged unless they are clearly defined. Consider these terms: "current document," "obsolete document," "inactive document," "disabled document," and "enabled document." These designations are common to document control systems and will vary from company to company. Hence, they demand definition.

There are several effective ways to define terms. These include parenthetical, restatement, classification, operation, etymology, background, and negation. Often a definition will employ more than one technique. In essence, here's how they work.

Parenthetical Definition

Parenthetical definitions include an explanation in parenthesis after the word.

> We discarded the effervescent (bubbling) mixture.
>
> Identify the scientific (taxonomic) name of a phylum, class, order, family, or genus.

Restatement Definition

Restatement definitions offer an appositive word or phrase that restates the term. Note that this type of definition calls for two commas when it appears within a sentence to set off the restatement, unless it comes at the beginning or end of a sentence. Sometimes a restatement definition is a separate sentence.

> A polygraph, an instrument used in lie detection, records changes in pulse, blood pressure, and respiration.
>
> The trees outside the new facility are deciduous; that is, they shed their leaves by the end of October.

Classification Definition

Classification tells what family a word belongs to.

> A dog is a member of the canine family.
>
> A tumor is a neoplasm.
>
> Bluetongue II virus is a member of the Reoviridae family.

Operation Definition

An operation definition tells how something works or happens.

> A disorder of the pituitary gland or pancreas causes diabetes, a metabolic disease characterized by excessive urination, persistent thirst, and often, an inability to metabolize sugar.
>
> Air-to-air solar heating circulates cool air from inside the facility, across a collector plate, which is heated by sunlight on the roof, and then back into the facility.

Etymology Definition

Etymology looks back in time to the roots of words. Approximately two thirds of the words in the English language have their origins in Latin and Greek.

> "Biology" comes from the root "bio," meaning "life," and "ology," meaning "study of."
>
> "Chromatograph" comes from the root "chroma," meaning "color," and "graph," meaning "write."

Background Definition

A background definition gives some history.

> Gasohol, a mixture of 90% unleaded gasoline and 10% ethyl alcohol (ethanol), has gained some acceptance as a fuel, since it is comparable in performance to 100% unleaded gasoline with the added benefit of having superior antiknock properties.

Negation Definition

Definition by negation means telling what something is not.

> Adsorption is not a misspelling of absorption. Adsorption causes liquid to adhere to a surface, like dew on a leaf, while absorption pulls liquid in, much like a sponge drinks up water.

Nondiscriminatory Language

Cautious writers take care to avoid using language that sounds discriminatory. Racism and sexism have worked their way insidiously into the American language. It's probably impossible to rid writing of every metaphor that holds meanings for male and female or ethnic affiliation, but you can certainly act to be sure you use the language to promote social equality rather than hinder it. Choose terms and expressions that don't refer to people in ways that can be considered negative or discriminatory.

One way to avoid discriminatory statements is to choose qualifiers carefully. To say "a woman manager" is discriminatory. To refer to "the Hispanic technician on the six o'clock shift" is as well. And to write that "her innovative ideas belie her age," even with the intent to compliment, is foolhardy. Unnecessarily drawing attention to differences without cause is discriminatory.

Be careful, too, not to use "he," "him," or "his" exclusively when referring to colleagues. One way to avoid offending is to use "he or she" or "him or her," for instance. But, as you can see, that can be awkward. Many writers, for that reason, use the plural, or interchange gender pronouns. It's also a good idea to choose the sexually neutral word over the traditional equivalent. For instance, "chair" or "chairperson" works just as well as the commonly used "chairman."

> The geographical distribution of the Germanic languages, of which English is one, has been more extensive than that of any other group of languages.

Living Language

American English, like other living languages, is in constant transition. It is ever adjusting to reflect the changes in society. The alterations in the language can be controversial and have drawn some criticism from purists who wish to retain the form they learned initially. Yet the reality is that English borrows words from other languages incessantly, sometimes with the foreign pronunciation and sometimes without, adhering more to the standards for American English pronunciation. Immigrants bring terminology that quickly gets absorbed into the vernacular; new ideas receive new labels; and words are regularly shortened and combined with other words. And so language alters itself.

Unlike many other nations, the United States has no official organization to prevent the language from changing. Indeed, the language has been called a polyglot; that is, it has a vocabulary stemming from myriad languages, a vocabulary that is ever-evolving. It's easy to let this phenomenon bog you down—even overwhelm you. Try not to let it; concentrate on the logic of what you have to say to whom and strive to write clearly and precisely. Let the language be the common denominator in communication. That means using language your audience understands.