Organizing and Delivering Information

Once you've identified to whom you are writing and assured yourself that your data are acceptable, consider how to put ideas and information together. This is often the most difficult part of the writing process. You may know what you need to say but may be stymied as to how to get it down on paper. This is normal; most people simply don't like to write. There are,

When we begin to write, we may anticipate the result, but writing has a way of taking on its own life.

Alexander Butrym, Ph.D., Professor of English

however, some techniques for organizing information that can help you control your ideas as you commit them to paper. Don't be surprised, either, if you violate your initial concept of how you are going to deliver your information. The act of writing itself triggers new ideas, and this is to the good.

Any time you create a document, look at it from two angles: logic and development of ideas. The distinctions aren't always as neat and clear-cut as they are for the purposes of this book, however, and you may find many different ways of presenting information that work well. These guidelines are merely that: guidelines. They'll help you control your information when you're not sure how to present it.

You will frequently encounter problems in organization—situations where the ideas themselves are good, but not presented in a way that makes their meaning obvious or their purpose clear. In short, how can you best organize your information so that your messages work the way they should?

Categorize Your Information

To effectively organize information, it helps to categorize what you are conveying—is it good? routine? negative? persuasive? If you anticipate the reader's reaction to different categories of information, you'll know better how to present it. Surely you wouldn't respond to a request for an internal job

transfer by saying, right off the bat, "You can't have the job because you lack the necessary skills." Yet, you might begin a note of recognition like this: "Congratulations, Joe. You certainly deserve this promotion." In the first instance, the reaction would surely be more negative than you desire. In the second, the reaction will likely be as positive as you hope. You gain nothing by irritating the recipient—nor do you benefit by working up to a message of goodwill. More important, withholding information or obscuring it can have deleterious effects on the day-to-day activities that make a business run.

Writing is easy. All you do is sit staring at a blank sheet of paper until drops of blood form on your forehead.

Gene Fowler, Author

The majority of the writing you will do in the pharmaceutical industry will fall into the category of delivering routine information. For the most part, you are not eliciting an emotional response; you are presenting information your readers need to have. Use these guidelines for logical presentation. But remember: They are not cast in stone.

Finally, writing isn't easy. Nothing says you have to "begin at the beginning and go to the end." You may be best off getting the details down and then rearranging them for readability and comprehension.

The Direct Approach

I hate to write, but I love having written.

Dorothy Parker, Author

Use this pattern for presenting most of the information you relay in writing. The direct approach is effective for routine information—the work-specific writing you do. When you are writing a short memo or technical note, for instance, let this pattern govern your total

delivery of information. When you are writing a document of length, break it into segments, and use this pattern to help you control your overall delivery as well as your delivery in each part.

The direct approach calls for making the key point first. This way, your reader will immediately know what a document, or portion of a document, is about. Your point logically leads to information that supports it. Unfortunately, when most people write about what they've done or what they're going to do, they tend to approach documenting the past or projecting future activity sequentially, the way they have addressed or will address completion of the task itself. Writing sequentially seems logical, and indeed, it reflects inductive reasoning: A series of facts leads to a conclusion. However, the reader is best served by understanding the point first—whether it is a summary of findings, a strategic decision, or the results of an investigation.

Usually, delaying the point doesn't make a document any more effective. Your reader does not know the purpose of a document the way you did before you even began to write it. Thus, inductive presentation is not the best way for most readers to receive information. With inductive presentation the reader doesn't get the point until he reaches at the end of a document

or passage in a document. Readers understand messages best when a point is followed by a series of facts that support the point.

For instance, by the time an engineer prepares a summary of an installation/operation qualification (IQ/OQ), she has been working on the project for a long time. She has already written a protocol of what she planned to do and has secured the necessary approval. Then she's gone through the testing process. Chances are, she may have had some nonconformances along the way. Once she's assured herself the equipment installation and operation meet qualification criteria for the company's needs-specific purposes, she has gone through a step-by-step process.

Yet there's no benefit in preparing a report for approval of the qualification by saying, "In July it was time to requalify the 200-gallon batching kettle with double motion counterrotating agitator" and then detailing events chronologically. What the readers need here is an immediate statement that asserts that the equipment is qualified, partially qualified, or not qualified as a result of the testing according to the protocol. An IQ/OQ summary report is easy to understand when it begins straightforwardly like this:

The Lee Industries 200-gallon batching kettle with double motion counterrotating agitator meets all the installation/operation qualification requirements. All test functions established in Protocol Q023 are complete and reconciled. In carrying out the testing, we addressed three nonconformances. All test results are attached.

If you have an important point to make, don't try to be subtle or clever. Use a pile driver. Hit the point once. Then come back and hit it again. Then hit it a third time—a tremendous whack.

Winston Churchill

The summary report then can go on to explain nonconformances and their impacts and state requirements for scheduled requalification and so forth. This way, the readers know immediately the results of the qualification testing and are ready for what the report contains. Here's a basic pattern for presenting information:

The beginning: State your purpose. What point do you

want your reader to know?

What, if anything, do you want your reader

to do?

The supporting information: Offer details to substantiate your purpose.

The close: Tell your reader what he or she needs to

know to be convinced.

Restate the point or call for action.

Packaging Specification Change

The information in this short memo isn't as effective as it could be because it doesn't make its point up front. The reader is subject to explanatory details before learning the purpose of the communication.

JORSTAD LABORATORIES Internal Memorandum

DATE: August 23, 2005

TO: Ginger Ogden

FROM: Linda Tanabe

RE: Quinine Sulfate Packaging Specification Change

We decided to make Quinine Sulfate 200 mg capsules dose proportional to the 325 mg strength. For the Quinine Sulfate 200 mg capsules we had been using number 2 size capsules and 100 cc capacity bottles.

However, the number 2 size capsules are inadequate for the 325 mg dose. Therefore we decided to use the number 1 size capsules. Then we determined it to be too difficult to accommodate one hundred number1 size capsules in the 100 cc bottle along with the insert. We also realized that 100 number 1 size capsules and the insert would be difficult to fit into the 100 cc bottle. To accommodate the new capsules, we changed the bottle size from 100 cc to 150 cc and added rayon to fill the empty space on top of the capsules. This solution is satisfactory, and we have changed our packaging specifications accordingly.

Even though this memo is short, it's easier to understand when the key idea comes first. The point is not to explain the decision to make the capsules dose proportional to 325 mg, but to detail the consequences and subsequent decisions about packaging. In the following version, the reader reasonably looks to the information after the first statement to back up that statement, and it does.

Rewrite

JORSTAD LABORATORIES Internal Memorandum

DATE: August 23, 2005

TO: Ginger Ogden

FROM: Linda Tanabe

RE: Quinine Sulfate Packaging Specification Change

For 325 mg strength Quinine Sulfate, we are now using number 2 capsules and 150 cc size bottles with rayon to fill the empty space on top of the capsules. We have changed our packaging specifications accordingly.

For the Quinine Sulfate 200 mg capsules we had been using number 2 size capsules and 100 cc capacity bottles. When we decided to make Quinine Sulfate 200 mg dose proportional to 325 mg strength, we realized that the number 1 size capsules, rather than number 2 size capsules, were necessary, because the number 2 size capsules could not accommodate the new dosage. In turn, we realized it would be difficult to fit 100 number 1 size capsules and the insert into the 100 cc bottle. Increasing the size of both capsule and bottle has proven satisfactory.

Drug Recall Letter

The Code of Federal Regulations (CFR) defines the content of recall letters; it calls for a clear presentation of the point up front. This letter does that effectively and is a solid example of the direct approach for organizing information. The purpose is stated immediately in bold letters, before the salutation, as well as in the second sentence. The reader knows at a glance what's afoot.

Ronway Laboratories

2323 Ronway Drive Jackson, Wyoming 83001

October 16, 2005

URGENT: DRUG RECALL Stability Assay Failure and Unknown Degradant Products Re: 50 mg SUPPOSITORIES, USP, ALL LOTS

NDC 0168-1949-46 Ronway Laboratories

Dear Wholesaler/Retailer:

Recent tests indicate that some outstanding lots of 50 mg suppositories do not meet minimum assay requirements through their expiration dates. Because we are uncertain that all lots will meet assay requirements throughout their shelf life, we are recalling all unexpired lots of this product. These lots have potency assays ranging from 59% to 100%. In addition, we have been unable to identify a degradation product; the concentration levels are unknown. This represents a potential health hazard, but we believe that the probability of serious adverse health consequences is remote.

Please determine if you have any lots on hand. If you do, discontinue distribution of these lots and return the merchandise to our facility promptly, to my attention. Please complete and return the enclosed response form as well. If you have any questions call 306-123-4567, extension 525.

If you have distributed any of these lots, please contact your accounts immediately; advise them of the recall; and have them return their outstanding recalled stocks to you. We are conducting this recall to the retail/dispensing level. Return these stocks as indicated above. We will reimburse you by credit memo for the returned goods and postage.

We have informed FDA of this recall. We appreciate your assistance in this matter.

Sincerely,

RONWAY LABORATORIES

Erin Andreas Vice President, Regulatory Affairs

The Direct Approach in Report Sections

You can apply the same principles of delivery in segments of reports. Even if a report has a clean, comprehensive summary at the beginning, the information within each component of the document is easier to comprehend when it makes a point and logically supports it.

The following is a portion of a product development report. The point is to identify which batch the company will use as the standard to manufacture a product. Notice that the writer has delivered the information in the sequence in which it occurred. Where does the information the reader wants to know lie?

Ronway Laboratories initiated the formulation development for sodium capsules in January, 2005. Our strategy has been to employ exponents similar to those used in brand formulation combined by a dry mixing method. Folles SA manufactured the available active entity.

The goal was to develop 50 mg strength first and then follow up with 100 mg strengths. Appendix A includes the formulation experiments conducted during formulation development.

The formulation lot numbers are five digits. The prefix 123 refers to the laboratory notebook housing the records of the development of this product, and the subsequent numbers refer to the batch.

Lots 123-01 to 123-14 incorporated Lactose Anhydrous DT, and Lactose Hydrous SD Starch P21 in different ratios and combinations with Sodium Lauryl Sulfate, Magnesium Stearate, and, in the case of lot 123-11, Aerosil 200, to achieve good encapsulation properties of the blend and to match the dissolution profile of the brand capsules.

We accomplished this effort with lot 123-14, and manufactured pilot batch PB987 accordingly. However, this batch developed stability problems under accelerated conditions.

Lots 123-15 to 123-28 reflect the attempts to develop a second formulation employing Magnesium Stearate and Aerosil 200 in combination with Starch P21. Lot 123-28 exhibited good encapsulation properties and similar dissolution patterns to the brand product. However, concurrent to development of this batch, material became unavailable for further development.

We then made and tested Lot 123-29, similar in formulation to lot 123-28, but employing Magnesium Stearate manufactured by Nogodawa Pharmaceuticals. Results indicate that this lot is comparable to brand in dissolution behavior and is stable under accelerated conditions. Thus, Lot 123-29 is the base for pilot batch PI988.

The very last sentence is what the readers want to know. All the information is here—but a simple revision, almost a cut and paste, makes this

information easier to digest. Since the key information rests in the last paragraph, moving that information to the beginning both clarifies and allows for logical explanation of what follows. A simple edit to paragraph two and a brief statement of closure completes this section of the development report.

Ronway Laboratories will use Lot 123-29 as the base for pilot batch PI988. Results indicate that this lot is comparable to brand in dissolution behavior and is stable under accelerated conditions.

We initiated the formulation development for XYZ capsules in March, 2005. Our strategy has been to employ exponents similar to those used in brand formulation combined by a dry mixing method. Folles SA manufactured the available active entity.

The goal was to develop 50 mg strength first and then follow up with 100 mg strengths. Appendix A includes the formulation experiments conducted during formulation development.

The formulation lot numbers are five digits. The prefix 123 refers to the laboratory notebook housing the records of the development of this product, and the subsequent numbers refer to the batch.

Lots 123-01 to 123-14 incorporated Lactose Anhydrous DT, and Lactose Hydrous SD Starch P21 in different ratios and combinations with Sodium Lauryl Sulfate, Magnesium Stearate, and, in the case of lot 123-11, Aerosil 200, to achieve good encapsulation properties of the blend and to match the dissolution profile of the brand capsules.

We accomplished this effort with lot 123-14, and manufactured pilot batch PB987 accordingly. However, this batch developed stability problems under accelerated conditions.

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We then made and tested Lot 123-29, similar in formulation to lot 123-28, but employing Magnesium Stearate manufactured by Nogodawa Pharmaceuticals with satisfactory results.

Good News

For most documentation purposes, you will deliver information most effectively using the direct approach. Sometimes, however, you may need to deliver information that is not directly linked to

Reading makes a full man, conference a ready man, and writing an exact man.

Francis Bacon

documentation, but serves to drive everyday activities. You will find that the direct approach works well for good news, too. People, of course, like to receive good news, and when you make your point up front, your readers are much more likely to absorb the details that reinforce the positive point. The following memorandum from a company president announces the appointment of three people to company positions. It follows this pattern:

Paragraph one: States the good news

Paragraph two: Gives details about Gary Williams

Paragraph three: Gives details about Christian Matthews

Paragraph four: Gives details about Stan Syvertsen

Paragraph five: Closes on a friendly note

Letter of Welcome

Ronway Laboratories

MEMORANDUM

DATE: March 2, 2005

TO: All Employees

FROM: Maryann Sorensen

RE: New to Our Staff!

We are pleased to welcome the following people to Ronway Laboratories: Dr. Gary Williams as Vice President, Scientific Affairs; Christian Matthews as Director, Quality Assurance; and Stan Syvertsen as Manager, Methods Development. All three will assume key responsibilities within the company.

Dr. Williams comes to us from Mandal Laboratories, Inc., where he directed the scientific group in methods development, analytical, and quality control. He has over fifteen years of industry experience, and will prove to be an asset to our newly restructured laboratory.

Christian Matthews, formerly with Bergen Drugs, will head up the Quality Assurance unit. He established the Quality Unit at Bergen, and is experienced in ISO 9002. One of his first projects will be to bring ISO 9002 certification to Ronway.

Stan Syvertsen joins us as Manager of Methods Development. With 10 years of experience at Mandal Laboratories, Inc., he will work closely with Dr. Williams in building a dynamic scientific team.

Please join in welcoming the new members of our team!

You can see how starting with your main point lets you logically develop your document by offering appropriate explanatory detail in the same sequence you've established at the beginning.

Submission Approval Memo

The following simple memo posted on a company bulletin board uses the same approach to announce the approval of a submission and to thank the employees for their efforts. This direct, friendly approach is effective in goodwill messages.

JORSTAD LABORATORIES Internal Memorandum

DATE: August 23, 2005

TO: All Employees

FROM: Arnold Johannessen

RE: We Have FDA Approval!

We're pleased to announce we have gained FDA approval to manufacture Indomethacin suppositories. We expect this product to be a significant addition to our over-the-counter suppository line.

This achievement is due to the concentrated efforts of the Indomethacin development team, as well as those of you who attend to the day-to-day activities that make us successful. Thank you!

Indirect Approach

While this book advocates the direct approach as the primary pattern for delivery of information for documentation, sometimes you may find the indirect approach more appropriate. The indirect approach calls for presenting information that leads to a point.

This pattern is useful for certain information. Reports like investigations typically deliver a sequence of events, an assessment, and a plan for action. And less-than-positive information works best when the negative news is delayed a bit.

Negative News

If you are in a position to determine the suitability of contract manufacturers or suppliers, for instance, you may on occasion have to deliver negative news. Suppose you determine an outside laboratory's testing standards have deteriorated and you wish to stop employing the services, at least temporarily, until the laboratory can improve its standards. In such a case, the indirect approach may work well. You can reasonably explain your position before you state it. This provides a better opportunity for retaining goodwill should circumstances change in the future and you wish to reestablish business relations.

Delivering negative news is never easy. People naturally hesitate to come right out and state the message they know will be ill-received, particularly if they wish to retain goodwill. But at times, people do have to bear bad news. This letter to a production team provides a paradigm for delivering bad news:

Paragraph one: Presents mutually agreeable information

Paragraph two: Offers explanatory details that lead to the main

point, states the point, and offers more

information

Paragraph three: Offers further explanation, as appropriate

Paragraph four: Closes on a positive note

Work Cessation Memo

MEMORANDUM

Lyngdal Laboratories

TO: All Employees

DATE: March 21, 2005

FROM: Ingvald Landrud

RE: Third Shift Notice

We appreciate the dedicated efforts of all of you on the third shift. You have been a vital part of our production activities and an integral part of Lyngdal Laboratories.

However, we have lost two significant accounts to competitors who can offer more rapid production because of a significantly smaller product line overall, and newer facilities. That's why we must temporarily suspend our third shift activities while we modernize our packaging equipment to be competitive. You will, of course, receive unemployment compensation and other benefits to which you are entitled. Your supervisors will further explain the impact of our temporary suspension of the third shift and direct you to any additional assistance you may need during this period.

We hope to resume production as quickly as possible; we do not anticipate a prolonged work cessation. We will notify you of shift resumption at the earliest practical time.

In the meantime, please be reassured. This work suspension in no way reflects negatively on the performance of the third shift. We will make every effort to resume production as quickly as possible, and we hope to have you there on the team when it does.

Persuasion

On the occasion when you need to ask a favor of someone but anticipate a negative response, use an indirect pattern. Bear in mind that most requests are routine and the direct approach will

Whatever we well understand, we express clearly, and words flow with ease.

Nicholas Boileau

suffice. A contractor or vendor, for instance, is generally happy to supply a response to a request. Using the indirect approach, however, will help you when you need to convince someone to take action, to respond to a request when you anticipate the initial reaction may be negative. It's human nature to be happy to be asked but reluctant to comply. Consider asking someone to speak at a professional meeting, for example. Most people hate, more than anything, to speak in front of a group. So, in this case, the reader might be flattered but reply negatively, which is not what you want.

The following letter can use revision.

Speaker Request Letter

Ronway Laboratories

2323 Ronway Drive Jackson, Wyoming 83001

March 6, 2005

Dr. Kurt Waldheimer Environmental Systems, Inc. 842-60th Street Casper, Wyoming 83005

Dear Kurt,

As you know, I've been pleased to serve on the program committee for our state Chamber of Commerce. Our next chamber meeting will be held on Tuesday, April 15, and we're hoping you'll consent to be our speaker.

Our topic is "Controlling Pollution in Industrial Areas." Your experiences with the Department of Environmental Protection make you an expert on this topic, and we know you'll be able to contribute enormously to the success of our meeting.

We hope you'll consider this request. We know we can all gain from your expertise.

Sincerely,

Rodney Erickson Facilities Engineer

Make everything as simple as possible, but not simpler.

Albert Einstein

What's likely to happen here is this: The recipient will read as far as the second sentence, and his mind will say "no way." Even though the second paragraph recognizes the reader's expertise, he has already

mentally responded to the request made in the first—very likely negatively. Reworking the request so that interest develops first makes this letter much more effective.

Rewrite

This revised version builds to the request. And by the time the request is made, the reader knows that he has something to offer that no one else has. It's hard to say "no" to that. This letter follows this pattern:

Paragraph one: Gain your reader's interest.

Paragraph two: Offer details and build to your request.

Paragraph three: Close and call for action.

Ronway Laboratories

2323 Ronway Drive Jackson, Wyoming 83001

March 21, 2005

Dr. Kurt Waldheimer Environmental Systems, Inc. 842-60th Street Casper, Wyoming 83005

Dear Kurt,

As you know, I've been pleased to serve on the program committee for our State Chamber of Commerce. Our next Chamber of Commerce meeting is April 15, and our topic is one that we know interests you: "Controlling Pollution in Industrial Areas."

The board has been continually impressed with the expertise you've gained working with the Department of Environmental Protection. Your knowledge can effectively aid us all as we search for ways to control and eliminate pollution at our respective plant sites. That's why we're hoping you'll consent to be our keynote speaker.

I'll contact within the next week to discuss our agenda further. Again, we hope you'll share your expertise with us.

Sincerely,

Rodney Erickson Facilities Engineer

Uniting the Direct and Indirect Approaches

Many documents, especially reports of length, combine the direct and indirect approaches for delivering information effectively. For instance, a technical report may begin with a summary that states the main idea in the first sentence and cites key points to follow. Individual sections then present information that supports those points. Some sections in the report may provide information sequentially, particularly if they discuss procedures or events leading up to a current position.

A Standard Operating Procedure (SOP), for example, uses a mixed pattern of delivery. A purpose or objective statement tells at a glance what the document is about—and the reader is prepared for the sequential steps that will lead to completion of the task.

Using an Outline

Many writers wouldn't venture into the murky waters of writing without an outline, yet outlines aren't for everybody. An outline may indeed help chart your course and serve as your guide as you develop your document, particularly if it is lengthy. But there are some cautionary notes here. While outlines can help, they can also defeat if they prevent you from exploring an innovative idea triggered by the writing process. If you prefer to use an outline, use it as a guide, not a mandate. Some writers work best with no outlines; they impose structure as the document progresses. Still others prefer a rigid outline, which will work for those who do a great deal of mental mulling before they write. Still others work best with a loosely defined outline that expands and contracts as the document takes form. Which method you adopt depends on you as a writer. There's no "must do" here—it's a matter of discovering what works best for you.

Developing Paragraphs

Think of each paragraph you write as a mini-piece of documentation. Generally, give each idea its own paragraph and provide enough information to convince. You can use the direct or indirect approach for your paragraphs as well, depending on the message you want to deliver. In most instances, each paragraph should have one sentence that states the controlling idea. The other sentences should provide proof to support that idea.

Starting with the Controlling Idea

You can present information clearly using the direct approach in individual paragraphs. When you give your readers the controlling idea first, they will be receptive to receiving what is next. The following paragraph discusses a two-tier team effort, and the first sentence sets the stage.

Instituting a program of production equipment maintenance at Ronway Laboratories requires a two-tier team effort. A core team of Maintenance and Engineering employees trained in the aspects of TQM should form the first-tier team, with one employee serving as group leader. Each member of the core team, in turn, will assume responsibility for directing a team in developing the maintenance program for a specific piece of equipment or group of equipment. The intent is to impart "ownership" of the equipment maintenance to designated teams.

Sometimes one controlling sentence can carry more than one paragraph of explanatory information. This is a call you must make. The following paragraph is from an information report generated when a company decided to purchase a new mixer for making a topical product. While it does the job, it is lengthy, with several ideas that support the first sentence, and offers the reader no chance to pause while absorbing the information.

The mixer we purchase must be suitable for our needs. The shape of the mixer and the rigidity of the blades, as well as the effectiveness of scrapers, are primary concerns. Since thorough and consistent scraping of the mixer walls is vital to blend uniformity, internal surfaces must be accessible to receive adequate scraping so that residual material does not become part of the batch and result in nonuniformity. The scraper blades must be rigid enough to effectively scrape the walls, but not so much so as to damage the walls. Another concern is mixing capability; inadequate mixing that permits portions of the batch to remain stationary can result in "dead spots." Overly rigid mixer blades may provide good mixing, but impede scraping. Blades with too much flexibility, on the other hand, may not effectively mix a formula with the viscosity of ours. Blades should therefore be of a firm plastic that will provide adequate mixing and permit scraping of mixer walls during processing without damaging the interior surface.

Readability improves dramatically when this lengthy passage is broken into two paragraphs, both controlled by the first sentence in the first paragraph.

The mixer we purchase must be suitable for our needs. The shape of the mixer and the rigidity of the blades, as well as the effectiveness of scrapers, are primary concerns. Since thorough and consistent scraping of the mixer walls is vital to blend uniformity, internal surfaces must be accessible to receive adequate scraping so that residual material does not become part of the batch and result in nonuniformity. The scraper blades

must be rigid enough to effectively scrape the walls, but not so much so as to damage the walls.

Another concern is mixing capability; inadequate mixing that permits portions of the batch to remain stationary can result in "dead spots." Overly rigid mixer blades may provide good mixing, but impede scraping. Blades with too much flexibility, on the other hand, may not effectively mix a formula with the viscosity of ours. Blades should therefore be of a firm plastic that will provide adequate mixing and permit scraping of mixer walls during processing without damaging the interior surface.

Leading to a Conclusion

Often a paragraph, such as the following one, offers a series of details that lead to a conclusion. This paragraph, from an out-of-specification (OOS) report, details a series of events; it is a causal presentation of information. The result of an OOS investigation is the main point of the paragraph, and it comes last.

As soon as the microbiologicial out-of-specification result occurred, the analyst notified the supervisor. The supervisor then authorized a second analyst to retest the original laboratory sample using a sample triple the size of the original. While the analyst retested the sample, the supervisor reviewed all documentation relative to the OOS. The retest failed to isolate the aberrant data and verified the original result. Analyst error, technical malfunction, and media contamination were ruled out, and an assignable cause proved to be inconclusive. The supervisor notified QA, and QA subsequently rejected the batch.

The following paragraph effectively cites a condition first, with an explanation of subsequent action.

QC discovered that the in-house HPLC/2323/ASI Revision 3 analyses of the related compounds tests were flawed, and the results are invalid. The lot involved was L211; the test stations were one-month accelerated and three-month accelerated. QC corrected the problem at the ninemonth test station. As a result, the 12-month test station results are valid, and the 12-month results show that all the room temperature samples are within specification.

Giving Adequate Information

Even if you organize your information appropriately, your paragraphs may somehow lack the essential ingredients for convincing your reader. This problem is often one of idea development. Ideas need to be spelled out, or enhanced in such a way that they elicit the right response from the reader.

The following paragraph from a chemical hygiene plan would benefit from more detail.

Hot glassware can be dangerous. Be careful when handling it.

Why is hot glassware dangerous? What can laboratory personnel do to minimize the danger? What do they need to do? A good directive includes the answers to questions such as these. Consider this rewrite:

Take care when removing glassware from heat since hot glassware can cause severe burns. Never attempt to hold hot glassware without adequate protection, because the item can fall and break, causing hot liquids to splatter. Use asbestos gloves or appropriate tongs. Use utility tongs to handle small apparatus and crucibles, and beaker tongs to hold and carry small beakers.

This rewrite has the strength of focusing on concrete specifics in an orderly way, and it provides thorough coverage of a procedure. Remember when English teachers told you that paragraphs must have five sentences or seven, or more, or less? Of course, such arbitrary strictures are ridiculous, and writers shouldn't be bound by them. However, short paragraphs can be inadequate. What they may lack most is convincing detail. They're fine for transitions, closings, and some openings, but guard against them when you need to convince.

Using Transitions

When you write, give logical signposts to move your reader through your statements as well. A reader should receive one message, and one message only, from the information you present. The following paragraph, delineating a problem with productivity, fails to make the necessary relationships clear.

Absenteeism ran about 9 percent. People would take days off without notification. Three days' notification is required. The foreman would shut down his operation until he could either reassign employees or call someone in for overtime. Overtime costs for last year amounted to 60,000 work hours.

Watch what happens when these ideas are joined by words that indicate their relationship to each other. Here, time and cause and effect serve as connectors.

Last year absenteeism ran about 9 percent because people would take days off without notification, despite the three-day notification requirement. Consequently, the foreman would shut down his operation until he could either call in or reassign someone for overtime. This pattern resulted in overtime costs amounting to 60,000 work hours.

Even though the original paragraph contains the essential information, the rewrite is easier to read because the transitional terms signal the relationships between the facts and guide the reader along.

Sometimes paragraphs will be purely explanatory. Then you may need words such as "because," "in addition," "further," and "finally." When a paragraph shows causal relations, you may begin with a word such as "when," followed by information connected with "as a result," "consequently," or "finally."

Omitting transitions is never disastrous to meaning, but including them usually makes a passage more fluid and facilitates reading. Further, you may occasionally write a one-sentence paragraph that serves as a transition between key points in a document of length.

Transition words can help you control your writing and assist the flow from idea to idea. First, assess the relationships between your ideas. Is it cause and effect? A phrase such as "as a result" clearly signals that something has resulted from some other action. If the document explains the causes or effects of some event, see that you signal your intentions by using such clear indicators as "because," "grows out of," or "results in." Time sequences, similarly, should be logical: Words such as "initially," "second," "then," "subsequently," and "finally" serve to indicate chronological sequence. When these and other terms—such as "in conclusion" and "thus"—are used, make sure they signal the relations they stand for and not some vague connection you only half convey. In other words, see that each paragraph is tightly coherent in the way it connects details.

Transitions of Sequence

after following that
after that immediately
as immediately after
as soon as immediately before
at first immediately following

at first in conclusion at last at the beginning in time to at the onset initially at the same time just before before last of all conclude by lastly concurrently next continuing on prior to during second finally sequentially

shortly after

subsequently

the next step
then
thereafter
third
to adhere to
to complete
to end
to finish
to follow
to terminate
to wind up
upon completion
when

Transitions of Addition

first

following

a case in point furthermore
a mirror image in accordance
additionally in addition
also in addition to
also important in all
also notable in fact
analogous to in like manner

and a correlative in line with
and again in support of the point
another such in the same vein
as an example in this case
at the same time indeed

besides it encompasses

by association like
by the way likewise
closely related more

conjointly more specifically equally important moreover for one thing namely

further one more example

one sample one such similar to similarly still another such as this too thus

while

to a similar degree to add to that to delineate to delineate further

to exemplify to illuminate

too

yet another

Transitions for Explanation and Restatement

a summation of in other words to confirm above all in particular to elaborate accordingly in retrospect to elucidate again in review to illustrate

all in all in short to look at it another way another way to look at it in sum to paraphrase as noted more specifically to put it differently as stated mostly to recap not only, but also to reconfirm backing this notwithstanding to reiterate clearly for example on the whole to repeat for instance once again to rephrase for one thing once more to restate further one more time to retrace furthermore one perspective is to reword in a nutshell overall to sum up

simply stated in all to summarize in brief still when all is said and done

in conclusion that is in effect that is to say in fact to clarify

Transitions for Comparison and Contrast

a clear difference contrary to larger a conflicting viewpoint conversely less a different perspective counter to like a strong distinction despite likewise after all more

disproportionate to akin to disproportionately nevertheless albeit dissimilar to notwithstanding although distinctly of course an opposing position equally important on the contrary

and yet equivalent to on the other hand smaller

even so as compared with even though the antithesis of as well as faster than though to resemble at the same time for all that

balanced with granted that too

unfortunately but however in much the same way by comparison Versus

by the same token while it is true that in opposition to

comparatively in parallel similarly conforming to in spite of

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consistent with

Transitions for Cause and Effect

a by product is a causative factor a correlative effect a secondary effect a side effect is absent that accordingly after as a consequence as a result as opposed to because because of this

comes to rest at concludes concluding in consequentially consequently due to thereafter therefore

by means of

by reason of

therefore thereupon this began following that for that reason for the purpose of for this purpose for this reason generated grows out of hence henceforth in conclusion

in lieu of
in opposition to
in spite of
incidentally
initiated
it follows that
it launched
it produced
it shakes out as
it winds up as
this created a movement to

in effect

this induced this started little by little on account of otherwise precipitated

resulting directly from

since so

terminates at that results in the aftermath the by-product the end result the impact of the impetus to the long term effect the outcome the outgrowth the primary effect the spoils of the yield then to the end that

to this end with the result that

Types of Paragraphs

Paragraphs play many roles. Their purpose is to fully explain and support a controlling idea. Often they employ different techniques to get the job done. In total, a series of paragraphs comprise a document or sections of documents. Here are some examples of various types of paragraphs. Note that some longer documents can be totally descriptive, totally chronological, or totally comparative; others may require a combination of information delivery methods. Consider a clinical trial protocol: It will have elements of description, such as the study design, the patient volunteer profile, and facilities. It will also have sections identifying procedures, the "how to" of the activities that are to occur. This type of writing is chronological. The following examples show different methods for delivering information effectively.

Descriptive Paragraphs

Descriptive paragraphs create an image of an event, a person, a concept, or a thing. Paragraphs that describe facilities are descriptive. So are those that present conditions, such as what a product in development should be like, or offer narrative information about patients or animals in a toxicology study. The following paragraph gives an overview of standard operating procedures.

Standard Operating Procedures (SOPs) of a proactive company form the backbone of its operations. SOPs delineate processes from vendor qualification to materials receipt and testing, to product manufacturing and packaging, to distribution to the marketplace, and finally, to tracking the product through its shelf life. SOPs must adapt as systems and processes change, and they must undergo rigorous controls to remain accurate and current.

The following paragraph is also descriptive/informative. It is part of a document that gives an overall explanation of the validation process.

Actual users comprise the most effective validation teams for commercial off-the-shelf (COTS) software-driven systems. Teams may have a few or as many as twenty or more members. The number of team members is directly proportional to the scope of the project. If the validation is for software that the entire company will use, a representative from each area should be on the team. A member of the Information Technology (IT) group should also be a team member. And, one person should serve as the Validation Lead.

Extended Definition Paragraphs

Sometimes writers need an entire paragraph or even two to define a person, thing, concept, or event. This type of paragraph is closely related to descriptive paragraphs. For example, an extended definition paragraph about a system may tell what the system is, how it works, what it does, what it looks like now, and how it works with other systems. The following paragraph defines a clinical thermometer.

A clinical thermometer is a narrow, tubular, closed glass device with one bulbous end containing mercury. It works on the principle of heat expansion. When the temperature of the bulb increases, the mercury inside expands, causing a thread to rise within the hollow stem until it stops by a marked measurement. The measurement indicates the degree of warmth.

Cause and Effect Paragraphs

Cause and effect writing usually results when someone tries to figure out what has happened and why. In essence, one thing causes something else to happen, which in turn often causes another event. Consider for example, that diphtheria causes vomiting. Vomiting in turn causes dehydration. Dehydration causes death. Note that diphtheria does not cause death.

Cause and effect writing is useful when there is a deviation or nonconformance and the need is to determine and record what happened. This type of writing is useful for exploring a probable outcome for an activity, or anticipating a result of a planned action. The following paragraph is an example of cause and effect writing. Note that the controlling idea is in the first sentence.

Software modification can have a ripple effect. A simple change request from operations can affect multiple functions of the system. A change to the way a report form displays data on a computer screen can affect every place in the system that uses the same form. So, a seemingly minor change can be a difficult information technology assignment in a complex system.

Chronological Paragraphs

Chronological paragraphs put information into a time sequence. Chronological paragraphs appropriately tell how things happen, have happened, or will happen. Procedures, completed studies, background sections of abstracts, and protocols are examples of chronological writing. The following paragraph gives a history.

As early as the 1980s, pharmaceutical manufacturers started using automated batch record systems. While offering the advantages of paper reduction and increased efficiency, these systems brought new issues. The paper-based cGMP regulations did not address electronic record keeping. So, in 1991, a group of pharmaceutical manufacturers met with FDA to determine how to use paperless record systems and remain compliant with cGMP requirements. This effort led to an FDA task force to look at electronic records in all areas — GMP, GLP, and GCP. The result was the publication of 21 CFR Part 11 Electronic Records; Electronic Signatures Final Rule in the Federal Register. The rule became effective on August 20, 1997.

Comparison and Contrast Paragraphs

Comparison and contrast looks at two or more things, concepts, events, or people for similarities and differences. If a company wants to purchase new equipment, such as a capping machine, a report that compares and contrasts possible equipment may be the fulcrum for a decision. Such a document might compare capacity, size, compatibility with existing equipment, price, service, and ease of validation for each piece of equipment under consideration.

Comparison and contrast typically occurs in identifying test and control articles in studies and results from study to study. It is also essential for evaluating vendors and suppliers. Here is an example of comparison and contrast in two paragraphs. Note that the transition word in the second paragraph is simply "also" and the comparative word is "but."

Deoxyribonucleic acid (DNA), a nucleic acid, forms from a repetition of simple building blocks called nucleotides. Nucleotides consist of a phosphate (PO₄), sugar (deoxyribose), and a base that is either adenine (A), thymine (T), guanine (G), or cytosine (C). In a DNA molecule, this basic unit repeats in a double helix structure made from two chains of nucleotides which link between the bases. The links are either between A and

T or between G and C. The structure of the bases doesn't allow other kinds of links. The double helix structure resembles a twisted ladder.

Ribonucleic acid (RNA) is *also* a nucleic acid, *but* it has a single chain and the sugar is ribose rather than deoxyribose. The bases are the same as those of DNA, except that the thymine (T) which appears in DNA is replaced by another base called uracil (U), which links only to adenine (A).

Writing Headings

Headings are important, whether they are for a journal article, an abstract, or presentation for dissemination of information to the professional community at large or for documents directed to select readers. In disclosure writing, headings serve to attract readers' attention and impel them to read an article, abstract, poster, or other publication. In documents of length, headings assist in guiding readers through the text. They serve to separate elements and identify at a glance those sections of a document that may be of interest to specific readers.

Good headings give information. If, for instance, the heading is for an abstract or professional meeting poster, it's often the first, and sometimes only, thing people read. When writing such a headline, it's even more important to make every word count — and to present the main idea succinctly. Consider the following heading:

CleanBlood™ Pathogen Inactivation of Red Blood Cells

What about pathogen inactivation? A headline that makes a point grabs the reader's interest and can induce her to read the rest of the abstract.

Clean Blood $^{\mbox{\tiny TM}}$ Inactivates Protozoa, Viruses, and Bacteria in Red Blood Cells

The second example is a complete sentence, and it's packed with information about the CleanBlood product.

Writing informative headings is important in documents as well. A good document, whether a long memo or a more inclusive report, benefits from headings where every word tells. To call a section "Supporting Data" is insufficient. That phrase could apply to every report generated! Just as a newspaper wouldn't entitle a feature article "News Story," a report shouldn't label a vital section "New Information" or "Significant Data." Headings work best when they encapsulate what's in the text that follows. "Development of Method 2204" is more precise, for instance, than "Method Development Two" in a report that talks about the development of several laboratory methods.

The same caveat applies to headings for tables. The following table heading is vague and uninformative.

Summary of the Results of Toxicity Studies Conducted with Experimental Drug S-252X

A rewrite gives more information. Further, a table is a summary, so identifying it as such is redundant. Getting rid of words that don't do their duty and replacing them with content delivers stronger information.

Results of In Vitro and In Vivo Toxicity Studies of S-252X in Sprague Dawley Rats

Make Headings Parallel in Structure

Headings don't have to be complete sentences (although they can be), but they should be parallel in structure. That means elements within the headings themselves should be in the same form, and the headings in the entire document should parallel each other. The following report section heading lacks parallel structure.

Using Salt Ice Mixtures and the Employment of Dry Ice for Cooling

The word "using," a verb acting as a noun, and "employment," a noun, are awkward together in that they are different word forms. Selecting one form brings the heading elements together, and, as often happens, eliminates extra words:

Using Salt Ice Mixtures and Dry Ice for Cooling

Similarly, a report should not have several headings that conflict in structure with others contained in the report. These headings, gleaned from a report on plant maintenance, reveal inconsistencies in parallelism.

Estimates of Electric Heating Costs Rate Determination

The System Will Require Semiannual Assessment

Cost Data Have Been Checked by the Supplier

Projection of New Fiscal Year Cost

Allowing for Rate Adjustments, Estimates of Five-Year

Expenditure

These headings work better when nouns, not verbs, control them. Further, some headings are sentences; others are phrases. Making these headings consistent assists in making the report readable.

Electric Heating Costs Estimation

Rate Determination

Semiannual Assessment Requirements

Supplier's Cost Data Evaluation

New Fiscal Year Cost Projection

Five-Year Expenditure Estimation

Organize Headings by Rank

Short documents may require few headings; longer reports may have myriad sections and subsections. Headings for either should follow a pattern that allows delivery of a primary point first, with subsequent support relegated to subheadings. Often, main headings are centered on the page, and subheadings aligned left, but companies use a creative range of positioning. Whether you bold face, capitalize, or change the font size depends on the facilities you have available and the standards within your workplace. Generally, however, for sections of equal weight, use the same heading type size and face. Don't give equal standing to a major section and a subpart of that section.

Tables and Visuals

A picture is "worth a thousand words." This axiom is particularly true in documents dealing with technical or complex data. Consider a report explaining a fire drill procedure. Wouldn't a map assist in defining the designated routes? Or, think about directions for installing a piece of batching equipment. Wouldn't a diagram help "show" how to do it? If you were compiling dissolution data, wouldn't a chart or table be more comprehensive than just words? To illustrate clinical research results, for instance, a table generally works best. Trying to put complex information into words is tricky business; further, doing so can present problems for readers who must make sense of data which is often complex.

Tables are particularly useful to condense or summarize large bodies of data. When data are complex or detailed, tables are almost always the best

vehicle for presentation. Tables allow readers to compare individual values and groups of data. Moreover, tables accelerate the comprehension process of readers.

The style and format of visual information will vary from company to company, but most have these elements:

- A table or figure number
- A table or figure title
- A legend, which often resides beneath the table or visual

When tables or other visuals deliver information, it's preferable not to reiterate in text what the visuals say. Write a simple statement in the text that calls the readers' attention to the visual. "Table 2 shows the results of the rat forced swim test." Then, present the table.

Principles of Table Construction

To communicate quickly and accurately, tables require readers to 1) identify how the information is organized, 2) find the information of interest, and 3) interpret the information once it is found. Experience, convention, and some research studies have identified at least five principles that should guide the construction of tables.

1. Tables should have a purpose; they should contribute to and be integrated with the rest of the text.

Data should not be reported for their own sake. Rather, they should be part of a larger effort to answer the four questions of research: "What did you do?" "Why did you do it?" "What did you find?" and "What does it mean?" Thus, tables should be used only when they can communicate information more efficiently or effectively than can be done in text or figures.

2. The purpose of the table should determine its form.

A table created to collect data is not necessarily the same table that should be used to communicate these data. A table created to organize a large amount of data so that a value can be referenced easily will not necessarily be the same as a table constructed to emphasize patterns in the data or comparisons among the patterns.

Tables may be structured for analytical or reference functions. Analytical tables are designed "from the inside out" by organizing the data field to help reveal patterns in the data. Reference tables

are designed "from the outside in" by organizing the column and row heads to help readers find specific information quickly.

3. Tables should be organized and formatted to assist readers in finding, seeing, understanding, and remembering the information.

A table that contains all the necessary data but forces readers to organize the data before understanding it does everyone a disservice: it increases the time needed for readers to evaluate the data and does not assure that the author's understanding of the data will match the readers' interpretation of it.

4. Values to be compared should be placed side-by-side.

English is read from left to right and from top to bottom. Thus, at least in English language publications, placing values side-by-side is not only the easiest way to compare them, but it also encourages this comparison. In biomedical research, where a treatment group is compared to a control group, values for each group should be given in adjacent columns so that the variables in each row can be compared more easily.

5. Organize the table visually as well as functionally.

Graphic elements, including spacing, should be used to help organize the table visually. Elements such as lines, bold type, outlined cells, spacing, and shading, can help readers make within- and between-group comparisons, differentiate more important values from less important ones, highlight patterns in the data, indicate special circumstances associated with the data, and so on.

Most publishers specify their format for tables, and some may not allow the full use of design elements as recommended here.

6. Data presented in tables should not be duplicated in the text.

Describing in the text data that are also presented in a table remains a common problem, even though most style guides and journals advise against the practice. Duplicate information takes valuable space and so is to be avoided in print publications. Values, groups, or comparisons in tables can be mentioned in the text, of course, but the table should present the data.

Tables should also be kept as simple as possible. Include only the information that is relevant to the purpose of the table.

Courtesy of Tom Lang, MA, from a new chapter in the second edition of his book, *How to Report Statistics in Medicine: Annotated Guidelines for Authors, Editors, and Reviewers*.

Tables don't have to be reserved for complex data. They often present simple information precisely and directly. The following table is effective in a quality assurance SOP that calls for the inspection of packaging inserts. Inspectors can tell at a glance what to look for. They can then enter the results of the inspection accordingly on an inspection form.

Inspection	Specification	Method	Classification
Product Code	Clear, complete, and identical to printer's proof	Visual	0
Batch Number	Clear and complete	Visual	0
Label Copy	Clear, complete, and identical to printer's proof	Visual	0

The following table provides complex information that would be difficult to present verbally and equally difficult to understand were it in another format. Notice how the text of the report directs the reader to the table.

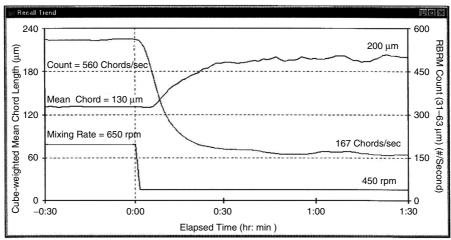
We calculated the percent deviation of five replicate injections of the standard solution, and one injection of additional weighing of standard from the true value, as determined from the linear regression line. Table III shows the results.

TABLE III

Sample	Conc. (mg/mL)	Peak Area	Calculated Concentration	% Accuracy
1	0.16016	3837945	0.15871	99.10
2	0.16016	3876328	0.16033	99.90
3	0.16016	3875795	0.16030	99.91
4	0.16016	3898299	0.16125	99.32
5	0.16016	3881189	0.16053	98.77
6	0.16072	3953200	0.16356	98.23
AVG				99.37
SD				0.65
RSD				0.65

Illustrations, pie charts, bar graphs, scatter diagrams, and the like all work well in relaying information. Visuals often accomplish what words can't. They show patterns of data and trends and allow readers to draw comparisons more readily. They can also condense data more efficiently than text can. The following visual, from a feasibility report, visually presents a process that the text identifies.

The new system will allow us to track the dispersion of mineral oil droplets in an aqueous system with sufficient precision and sensitivity to allow the development of real-time, closed-loop control of droplet dimensions based on manipulation of the mixing rate.



Monitoring the real-time response of a droplet dispersion to a step change in the shear rate (50% Oil/Water mixture).

Courtesy of Lasentec, Inc.

Principles of Figure Construction

1. Figures should have a purpose; they should contribute to and be integrated with the rest of the text.

As is the case with tables, data should not be reported in figures just for the sake of displaying them. Figures should be used only when they can communicate information more efficiently or effectively than can be done in text or tables.

2. The figure should be designed to assist readers in finding, seeing, understanding, and remembering the information.

When designing a figure, its purpose should be emphasized. Is the purpose to show the variability or the stability of data? To emphasize similarities or differences between groups? To show trends over time? To show linear or nonlinear relationships?

3. Figures should contain only those elements that are necessary to fulfill their purpose.

Conciseness is a value in figures, as well as in scientific writing in general. Make sure that all the lines, symbols, numbers, and words in the figure are necessary and sufficient to allow readers to interpret it. In particular, avoid three-dimensional figures unless the data are actually three-dimensional.

4. The data should be emphasized over other elements in the figure.

The advantage of figures is that they focus attention immediately on visual patterns of data. Thus, anything that distracts from this focus reduces the utility of the figure. For example, data points and lines should be larger or heavier than other graphic elements, such as the scales, the borders of the data field, or reference lines.

5. Figures should be consistent with the principles of Gestalt perceptual psychology.

Abstracting and interpreting data from a figure is a process of visual perception. Visual perception, in turn, is influenced by several principles identified by Gestalt perceptual psychology. Following these principles when designing figures should improve the utility of the figures.

• **Primacy:** the larger arrangement ("the Gestalt") is seen before its components.

The overall visual impression of the figure should be consistent with the actual meaning of the data. This principle can be used to manipulate readers' perceptions: the four most common examples are the "suppressed zero," the "elastic scale," the "superfluous dimension," and the "double-scale" problem (see below).

• Proximity: objects near each other tend to be seen as a group.

The characters string, ••• •••, is seen as two groups, whereas •• •• •• is seen as three. Thus, put data to be compared close to each other, and separate data that are not to be compared. This principle is especially important for placing labels with respect to the data they identify.

• Similarity: similar objects tend to be seen as a group.

The characters string $|\ | --$ is seen as two groups, rather than as four lines. Thus, display data from the same group in an obviously and uniquely consistent way, and display data from different groups in obviously and uniquely divergent ways. This principle is essential when graphing three or more variables on the same graph. Plotting marks and data lines from the same group should look alike. They should also differ enough between groups that the groups are not confused with one another.

• **Continuation:** data arranged in an obvious pattern tend to be seen as a group.

The character string, ----, is seen as a single group, whereas ---_ is seen as two. So, when possible, indicate data from the same group by providing an obvious pattern, and disrupt any patterns that are coincidentally comprised of dissimilar data.

• **Closure:** a break in a pattern is automatically "filled in" to complete the pattern.

For example, in the sequence, _- - _, readers usually imagine the missing symbol that would complete either the pyramid: _ - _ _, or repeat the sequence: _ - _ - _. So, emphasize any breaks that represent actual discontinuity in a pattern, and make the pattern clear when the data actually form a pattern (so readers do not have to "fill in" to complete the pattern).

6. Data presented in figures should not be duplicated in the text.

As is the case with tables, do not describe in the text data that are also presented in a figure. Rather, identify in the text the important aspects of the figure to help readers interpret the data.

Courtesy of Tom Lang, MA, from a new chapter in the second edition of his book, *How to Report Statistics in Medicine: Annotated Guidelines for Authors, Editors, and Reviewers*.

References, Works Cited, Works Consulted

Good writing credits sources. To use someone else's words without credit is plagiarism. Even when you paraphrase someone else's information, that is rephrase in your own words, you need to give credit where credit is due. When you are writing for a journal, the guidelines for authors will tell you how to include references. Many companies use a software program like Endnotes, or simply employ the Endnotes feature built into Word. Some companies have style guides that show how to handle references. If that's the case where you work, simply adhere to the style guide. Within many companies, however, such guidance is often lacking.

If no such guidance exists where you work, it's best to consult a style reference book. The American National Standard for Bibliographic References (ANSI) provides guidelines for referencing information. Other style guides do so as well.