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Writing Within the Regulated Environment

As far as most regulatory bodies are concerned, if you didn't write it down, it didn't happen. Working in the pharmaceutical, medical device, or biologic milieu is tantamount to journal keeping. In fact, "Write it down" sums up what it takes to get the job done properly. Successful operations require a working union of the day-to-day activities that keep the wheels of the business turning and the documentation that affirms those activities.

Documents show the framework of a company's varied activities. When the development process for one product is winding down, for example, and a submission is forthcoming, development processes for other products may be in various stages of development, from discovery through final testing in clinical trials and launch. Concurrently, other company products may be in various stages of scale-up or production. For each product in each phase of development or production, there must be a written history that shows control of all activities related to that product. Thus, the answer to "What did the company do in March (or on Tuesday) in the production of acetaminophen?" should be easily available in the records the company keeps.

The sheer volume of documentation that takes place makes writing well a critical skill, one that is essential for success. It is also true that writing is intimidating for many people. Perhaps because writing is so closely scrutinized, people are loath to commit their words to paper. If writing is on your list of job responsibilities, there are some avenues you can take to make the task less formidable. The first is gaining an understanding of why you are writing and how that writing works in conjunction with other documentation. The next is obtaining the tools you need to deliver clear and complete messages that are grammatically correct and consistent. Acquiring the requisite tools is what this book is all about.

Writing for Compliance with Binding Regulations

Why does writing play such an integral part in companies that develop, manufacture, and market therapeutic products? The answer lies largely with the regulatory forces that drive the healthcare industry in the United States and abroad.

The regulations state what companies must do. Their documentation tells how they do it and what the outcomes are. In a pharmaceutical company, for instance, documentation is the proof that a company's activities meet the regulatory demands of Title 21 of the Code of Federal Regulations Part 211, *Good Manufacturing Practices for Finished Pharmaceuticals*. In this environment, documents delineate such diverse activities as facility and equipment qualification, cleaning, and maintenance; control of materials, from incoming components to finished goods; validation of manufacturing processes; sampling and testing activities; nonconformance and out-of-specification (OOS) investigations; and employee training. They provide the "how-to" for auditing vendors and contractors, handling complaints and recalls, and conducting annual product reviews. In short, documents substantiate that a company has complete control of all of its activities in compliance with the regulations.

In the United States (US), 21 CFR Part 820 *Quality System Regulation* delineates the Good Manufacturing Practices (GMPs) for medical devices and Part 606 *Good Manufacturing Practice for Blood and Blood Components* delineates them for biologics. Most countries have similar regulations to ensure the safety and efficacy of products. Canada, for instance has the Canadian Health Protectorate Branch (CHPB), Ireland has the Irish Medicines Board (IMB), the United Kingdom has the Committee on Safety and Medicine (CSM), Australia has the Australian Code of GMP for Therapeutic Goods, and Japan has the Ministry of Health and Welfare (MHW). In numerous other countries, regulations come from the Ministry of Health (MOH).

While countries have their own regulatory authorities for ensuring safety and efficacy in drugs, devices, and biologics, they are also recognizing that internationally acceptable standards can help put products into world markets. Companies conducting clinical trials worldwide embrace the International Conference for Harmonisation (ICH) Guidelines, established in 1964 and revised in 1975 and 1986. These guidelines, which have their origins in the Declaration of Helsinki, present an international standard for designing, conducting, recording, and reporting clinical trials in which human subjects are participants. They were developed in consideration of the clinical practices of the European Union (EU), Japan, the United States, Australia, Canada, the Nordic countries, and the World Health Organization.

In Europe, the European Medicines Evaluation Agency represents 15 member nations. The International Organisation for Standardization (ISO) pro-

mulgates standards for quality worldwide and offers certification. And Mutual Recognition Agreements (MRAs) between nations also attest to the drive toward uniform, internationally accepted standards for therapeutic products development.

One manifestation of this sort of standardization is the Common Technical Document (CTD). Many nations now mandate the CTD as the vehicle for gaining approval to market a drug, biologic, or device. Some countries recommend and will accept the format, but until they change the regulations in place, they do not make it a formal requirement. Until FDA, for instance, makes a revision to 21 CFR Part 314, *NDA* it won't be mandatory to submit a New Drug Application (NDA) in the CTD format. The outline for the CTD allows companies to devise one document that they can submit to many countries for product approval. The variable piece is the section on Quality Assurance. (See Chapter Eight for more information about the CTD.)

Few, if any, companies are driven by just one set of regulations. A typical US pharmaceutical company may be subject to the regulatory guidelines set forth by the Food and Drug Administration (FDA) in Title 21 CFR Parts 210 and 211 as well as those set forth by the Environmental Protection Agency (EPA), Drug Enforcement Administration (DEA), Occupational Safety and Health Administration (OSHA), the Department of Transportation (DOT), and various other state and federal organizations. If it seeks to manufacture or market a product outside the US, it must look to the binding regulations in targeted countries.

Once in place, regulations don't change all that rapidly. However, it takes about five years for industry standards to develop. Once a regulatory agency issues a regulation, dialog among companies and FDA takes place, and industry "best practices" develop. Consider, for example, 21 CFR Part 11, *Electronic Records; Electronic Signatures.* This regulation, vague in nature, has generated tremendous discussion, and FDA has issued many guidances as to how the law is to be interpreted. Industry standards are now in place for this regulation, although discussion continues. More recently, the US Department of Public Welfare and Human Services issued 45 CFR Parts 160, 162, and 164 for electronic record keeping of patient records. This regulation bridges into FDA-regulated industries, since developers of therapeutics engaged in clinical trials manage patient data. These regulations, part of the Health Insurance Portability and Accountability Act (HIPAA), are new, and industry standards are developing. However, companies seeking to comply will do well to understand industry standards for Part 11, since the regulations are parallel, even though issued by separate agencies.

Further, companies must also understand that new regulations don't supersede existing ones. Predicate rules, those already in place, still apply. Thus, companies complying with 21 CFR Part 11 must continue to follow the regulations that drive their operations. If a medical device manufacturer

goes to electronic record keeping, the guidelines for the records themselves reside in 21 CFR Part 820. This is the way most regulations work.

Managing the regulatory maze is not easy. Yet keeping abreast of the regulations and remaining compliant makes good business sense. Monthly publications for industry, available by subscription, detail issues in the industry and governmental rulings. Industry forums, conferences, and courses offered by professional training organizations offer opportunities to remain current. It's not enough to adhere to the regulations. Companies need to understand the direction in which compliance is moving and keep in step. The last thing a company needs is a routine investigation that discovers nonstandard practices. The result will be a discrepancy observation, citing what needs to be fixed. It's always better to have everything in place, with documented proof that it is, rather than to scramble to fix what the company has been cited for—this slows productivity and makes poor business sense. One thing is abundantly clear: Documentation will continue to be critical to every facet of doing business within this highly regulated environment.

Regulatory Evolution in the United States

Laws governing therapeutic product development and marketing have evolved over time with specific laws marking milestones over a period of 100-plus years. The first US federal regulation dates back to 1884 when American soldiers died after ingesting adulterated quinine. As a result of these deaths, the government passed the Drug Importation Act, which required customs inspections on drugs coming from overseas. Then in 1901, The Biologic Control Act became law after 13 children died from a contaminated antitoxin for diphtheria. This act gave the government regulatory power over antitoxin and vaccine development. Shortly after, in 1906, the government passed the Food and Drugs Act to authorize the government to monitor food purity and safety of medicines.

In 1931, the Food and Drugs Act was renamed the Food and Drug Administration. Several other events were significant in developing binding regulations designed to protect humans and animals. The 1932 Tuskegee Study of Untreated Syphilis in the Negro Male, conducted under the auspices of the US Public Health Service, deprived infected men of effective treatment so as not to interrupt the project. Then in 1937, 107 people died after taking "elixir of sulfanilamide," which turned out to be an antifreeze solution. FDA removed the product from the market, not because it caused fatalities, but because it was mislabeled. In 1938, the government passed the Food, Drug, and Cosmetics Act. This Act expanded the role of FDA to control of cosmetics and devices.

It was during World War II, however, that experiments were done in large scale on unconsenting humans. The Nuremberg War Crime Trials brought these atrocities to light, and the result was the Nuremberg Code, which cited ten standards for ethical human research.

A wake-up call for even better monitoring came in 1962, when thousands of babies were born with defects, the result of their mothers taking thalidomide while pregnant. The drug had never been approved for marketing in the US, but was undergoing research in American women. Of these women, nine gave birth to defective infants. This event induced FDA to require notification of investigational use of drugs, which up until this time, had not been required. The result was the Kefauver-Harris Amendment to the Food, Drug, and Cosmetic Act.

At about the same time, President John F. Kennedy announced the Consumer Bill of Rights in a message to Congress. This Bill of Rights said that people have the right to safety, the right to be informed, the right to choose, and the right to be heard. In the same period, in 1964, the World Medical Association issued the Declaration of Helsinki, and physicians were tasked with embracing this statement: "The health of my patients will be my first consideration." The declaration has been amended four times, and the Code of Federal Regulations (CFR) has incorporated the basic elements.

In 1972, the National Institutes of Health transferred the regulation of biologics to FDA. This was followed by the National Research Act, which created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Additional legislation has continued to promote ethical treatment of healthcare recipients. In 1978, FDA published the current Good Manufacturing Practices, 21 CFR Parts 210 and 211.

In 1988, the FDA became an agency of the Department of Health and Human Services. Since that time, the ICH has been formed. A significant ICH goal is to maintain safeguards on quality, safety, efficacy, and regulatory obligation for the protection of the public. The 1997 Food and Drug Administration Modernization Act reauthorized the Prescription Drug User Fee Act of 1992 and instituted reforms in agency practices. In 1996, medical devices became subject to Quality System Regulation (QSR) 21 CFR Part 820. In 1996, as well, the Department of Health and Human Services enacted HIPAA into law. This provided the forward momentum for broad changes in the healthcare industry, but the specifics of the regulation were still being written. Shortly thereafter, in 1997, 21 CFR Part 11 *Electronic Records; Electronic Signatures* was enacted.

The government does not issue laws without forethought. The Office of the Federal Register issues the Federal Register (FR), a weekly disclosure publication that informs citizens of their rights and obligations by providing access to the official text of approved regulations and descriptions of federal organizations, programs, and activities. It also publishes texts of proposed regulations and changes to existing regulations. This gives industry the opportunity to react and share dialog with the government agency that has ownership of the proposal. Reviewers can comment on content and wording, the date the regulation goes into effect, and the penalties for non-compliance. Comments are reviewed in a government forum, and the final text becomes the "final rule."

Once enacted, laws are published in the CFR, issued annually on April 1. Laws are enforceable by the respective divisions within the Department of Health and Human Services. It's important to note, however, that once a final rule appears in the FR, companies are responsible for instituting compliance. Thus, keeping abreast of the regulations requires constant vigilance.

The CFR contains regulations of specific government departments and agencies. The CFR has 50 "Titles," each assigned to a different unit of government. Title 21, Food and Drugs, contains regulations mandated by FDA. Title 45, Public Welfare, falls under the auspices of the National Institutes of Health (NIH). Each title of the CFR is then divided into chapters, and each chapter is divided into parts and subparts.

Remember, too, that as new regulations are enacted, they do not supersede existing regulations unless the government has rescinded them. New regulations in essence become adjuncts to the ones already in place. Companies must adhere to predicate rules and remain vigilant about industry best practices for compliance.

Document, Document, Document

Documents work with each other either concurrently or in tandem. Documents tell how things happen on a regular basis and present a "big picture" of a company's operations, usually in standard operating procedures (SOPs), quality manuals, plans, and other such documents. Documents such as protocols and proposals tell what the company plans to do. Ongoing assessment and data recording occurs as activities progress. Process reports give the results of projects. Finally, summary reports bring it all together — what is the outcome of a significant set of activities?

A single product's history may start with source data for the concept, usually a laboratory finding. After the initial discovery recorded in the laboratory notebook comes testing to see if the concept is viable. Countless studies, performed in accordance with binding regulations, such as Good Laboratory Practices (GLPs), result in decisions to pursue the product development or to abandon it. When a company determines to develop a product, preclinical testing helps to confirm the potential product's value and determine whether the company should file for approval to test the product in humans in controlled clinical trials.

If the product moves through clinical trials, the company files for approval to manufacture and market the product. At every step in this process, which can easily take a decade, documentation captures what happens. Once a product is in the marketplace, record keeping continues, and stability studies confirm continuing efficacy through the expiry date on the product. Careful and continual monitoring must occur, and if a product loses its efficacy or has other problems, the company may issue a field alert or recall. The company keeps the product records at least two years beyond the shelf life of the product itself.

> Companies need to keep extensive records of everything they do, whether it becomes part of the final product development or not. They need to know what didn't work so they don't go down the same road twice.
>
> **John Cline, Ph.D.**

Companies must show their control of systems, processes, and products in documentation. This means self-monitoring and assessment, as well as change management. There is no "magic formula" for documentation for all companies, but the common denominator is this: Companies must have controls in place, and they must have records of what they do, have done, and plan to do.

Critical to successful operations are trained employees, so training must also be a documented part of operations. In addition to the orientation employees receive about their jobs when they are hired, they must receive regular "refresher" training, as well as retraining as procedures change or as they move from position to position within a company. Similarly, companies must verify that consultants have the appropriate training for the roles they fulfill and that vendors and contractors meet the criteria for the quality standards set by the company.

In sum, compliance with the binding regulations requires extensive documentation, all of which reflects the activities a company carries out daily. As companies find better and better ways to do things, gain new technologies, and decide to manufacture products that require different formulas and procedures, they must both continue to meet current standards and verify, through records, their adherence.

Keeping the House in Order

Compliance with the binding regulations and clear and complete documentation should be the goals for all companies operating within regulatory statutes. Who will determine if they are being met? Companies can expect audits and inspections from many sources. FDA, for instance, sends investigators on site for two primary reasons: a general GMP inspection or a new product inspection. In a general GMP inspection, FDA is present to assess overall operations and determine a company's adherence to GMPs. In this type of inspection, investigators may ask to observe production — but not developmental — processes. A preapproval, postapproval, or scale-up inspection, on the other hand, focuses primarily on facilities and processes relative to a new product. Preapproval, postapproval, and scale-up inspections comprise much of the FDA's focus.

Companies that successfully undergo inspections know that it's difficult to anticipate the direction they may take; thus it's always wise to have everything in place and running effectively. If, for instance, a company employs electronic signatures, how the company has achieved compliance and maintains it will surely be a focus. Written records attest to what the company has done and what it continues to do.

What an inspector does or doesn't find marks the caliber of the company. Violations are not to be taken lightly. FDA considers a violation of cGMPs during an inspection an "incident." If, upon reinspection, the same violation is present, FDA considers the violation a "practice," and the product subsequently adulterated. These are serious issues, ones that good documentation reflecting good practices can very often prevent.

Companies must thus understand what controlled documentation they must have in place and accessible. For instance, to undergo a successful approval inspection, companies manufacturing drug products usually make the following core records available; other documents may accompany these, depending on the product and processes.

1. Manufacturing and controls segments of the application
2. Master formula
3. History section of the application
4. Development data, including product characteristics and physical properties, manufacturing procedures, finished product test results, dissolution profiles, and results of pilot and preliminary production-size batches that confirm formula ranges, specifications, in-process variables, and stability testing.
5. Materials analyses
6. Laboratory data
7. Equipment qualification and cleaning validation

8. Standard Operating Procedures, including those for change control, QA/QC investigations, field alerts, and validation
9. Finished product test results
10. Stability studies

Note that a visit by FDA or another government agency is not the only time a company receives an inspection. A company may be the subject of an audit by a firm seeking contract services or a joint venture. Such an audit will likely be every bit as strenuous as other inspections, and, once more, having documented practices in place translates to doing good business.

Document Control

While this is not a book about document control, it's important that writers understand that companies must control their documents and that writers must conform to the process in their companies. The systems vary from company to company, but effective companies know which documentation is drafted, written, under review, beginning revision, or moving into obsolescence. The degree of sophistication that characterizes the system is relative to the degree of sophistication of the company itself. A company with many sites needs systems that are more complex than those required by smaller companies.

While there are many excellent systems, most share common ground. There are fixed procedures for introducing and approving the concept for a document, and drafting, reviewing it, and giving it final approval. Documents generally have other controls and are searchable by number, title, author, and key words. In addition, documents have revision histories, so a review of the document tells the life of the document from conception to retirement. Finally, who signs what type of document needs to be spelled out. Usually companies develop a minimum required signature list that tells who has authority to sign what type of document and how many signatures are needed to approve the document. Companies typically detail how their systems work in an SOP on document management. They may also have instructions for writing specific documents such as study reports, audit reports, and submission documents.

Effective document management systems ensure that documents maintain their integrity. For instance, hard copies of documents — such as those in SOP manuals — are controlled, and when new documents are issued, previous versions are accounted for and destroyed. Approved, official copies of documents must reside in controlled environments with limited access — in

a limited access area for manual systems or in software system vaults for electronic systems.

Companies must all define how their systems work. Documents in a manual system review process, for instance, may route through the system in colored folders, so reviewers know at a glance that the document in a yellow folder is a qualification, a document in a red folder an SOP, and a document in a purple folder a laboratory method. Other systems may send documents as pdf files as attachments to e-mails for review with a scheduled concurrence meeting.

Electronic record keeping (ERK) is now mandated for patient records. Many small companies rely on manual systems, while others have implemented electronic document management systems. Electronic systems are necessary for electronic submissions to many regulating agencies, so the impetus is to go electronic. But more importantly, ERK provides more efficient document management overall and cuts down on the amount of paper companies must manage in their archives.

ERK systems require extensive controls. They must be validated for the intended use of the system. There must be controls in place to ensure security, user accountability, and audit trails. Many companies have put Computer Software Validation (CSV) teams in place to ensure that validation of software-driven systems happens effectively. Once a system has gone live, it undergoes audits, and when major changes occur, it undergoes full or partial revalidation.

The bottom line for document management is this: Companies have to determine how their document management system works and then document it. Further, anyone working with documentation within the system needs to understand how the system works. That means system users must have training in the system and not deviate from it.

Standard Formats

Standardized formats also make documents easier to write and process for most companies. These formats can guide writers through the tasks of drafting and revising; they can guard against zealous rewrites by reviewers and can facilitate the approval process. Many companies have stylebooks that specify the presentation of certain information: These guides may call for a serial comma or not or direct certain SOP phraseology in delivering information common to many procedures, such as securing QA approval and signature. The extent to which companies control the details of documentation depends on each company's resources. (See Chapter Nine for more information about style.)

Document control staff should be able to identify the location of a document in a system at any given time. Staff may also write documents relative to their area or serve in the review process. They may have license to make mechanical, but not content, changes before final approval. Once a document

receives final approval, through either a series of review cycles or a concurrence meeting, document control staff should issue the document with no further change. The group should also retrieve previous versions of documents, if any, and provide a history of the document's development. Document control involves exhaustive attention to detail but does not infringe on the integrity of the documents.

The Writing Task

Writing is hard work, and it is high on the list of what people hate to do most. For many, it's an intimidating task. In regulated industries this can be especially true: You may find yourself in the position of having to document what has happened, what happens regularly, what will happen. Regardless of the focus, writing always requires accuracy, attention to detail, and clarity.

In this industry, few people write in solitary. You may be called upon to prepare a report, write a technical memo, review any number of documents, draft a report that requires the participation of several people, or compile information from many sources as a basis of study. How you tackle these tasks requires some foresight. Understanding the writing project you are about to undertake is the place to begin. You may be the primary author of an SOP, a collaborative author of a dossier, or one of several authors involved in a project such as a facilities validation. You may be the primary author of an activity, such as an audit, that requires a bevy of writing to reach a conclusion. (See the text box *Put It in Writing*.)

Put It in Writing

A good audit report results from good planning. Each audit should have a record of activities, from the decision to audit through the audit review. Each step of the process requires writing it down. Here's a sequence that helps ensure each audit a company conducts gives optimal results.

1. Determine what the customer wants
   - Internal audit to determine GMP compliance
   - Focused audit of manufacturing process to determine compliance gaps or reason for a nonconformance
   - Supplier audit to determine suitability
   - Manufacturing record audit for errors, omissions, deviations

- Stability data for a product

2. Determine the audit scope
   - An entire company
   - One department within the company
   - Manufacturing records of a defined time or product
   - All product packaging operations for one week

3. Determine the type of audit
   - Planned inspection
   - Unannounced inspection
   - Document desk audit

4. Determine the governing documents
   - FDA regulations
   - ISO standards
   - Corporate procedures
   - OSHA standards
   - Departmental procedures and required documentation
   - Process maps and diagrams

5. Determine who to interview
   - Employees conducting the process
   - Newly hired employees
   - Department managers
   - All nightshift analysts conducting stability testing

6. Determine a statistical sample size
   - How many lots are manufactured in one week, month, year
   - How many complaint files in the past three months
   - How many employees in the company

7. Determine the audit duration if not predetermined

8. Conduct the audit
   - Know what should happen
   - Observe what is happening
   - Verify what happened through documentation

9. Meet with audited groups to confirm deficiencies and observations to eliminate misunderstandings and auditing errors
10. Write the report
11. Report the findings to the original customers and auditees
12. Review corrective and preventive action plans
13. Follow-up on the effectiveness of corrective action plans after implementation

Courtesy of Monica Grimaldi, Certified Quality Engineer

The good news is that for many types of writing there are clear guidelines. For writing documents such as SOPs, you need to look to the company standards; the same holds true for validation documents. For other types of writing, you can look to the regulations, industry practices, and government-issued guidances. Consider for instance, preparing a Chemistry, Manufacturing, and Controls (CMC) section of a submission for approval to market a solid-dose drug product. How will what you are to write fit into the big picture? The guideline for CMC breaks down the components into manageable groupings of information including (1) the drug substance, (2) the drug product, (3) methods validation, and (4) environmental assessment. Within each of these groupings are subgroupings. You can thus prepare components of each and assemble them accordingly. Of course, you'll have to do your homework first. Make sure you fully understand what it is that you have to say.

The preliminary work can be tedious, to be sure, but starting the actual writing is usually the toughest part. Many people complain of "writer's block," or the inability to get words down on paper. If you suffer from bouts of writer's block, there are some steps you can take to overcome these down periods. See the following.

Arnold Melnick, author of *Melnick on Writing,* a column in the *AMWA Journal*, the publication of the American Medical Writers Association, offers five questions to help writers understand their writing patterns.

Only You Can Solve Your Writer's Block

Writer's block is the "temporary inability by a writer to put words on a page." It's a common experience for writers, but there are things you can do about it. Answering five simple questions accurately and intelligently can provide an answer to this affliction.

1. Do you struggle vainly to "write" something instead of communicating information or ideas to the reader?

   According to Joel Saltzman, author of *If You Can Talk, You Can Write*, write anything as though you are talking to a friend. Write whatever words might be associated with your document, without pausing to criticize or edit. Intersperse it with whatever random thoughts come to your mind. Then, edit and edit carefully. Good writing is good editing. Very few writers can get their desired effect in the first draft. For writers, how they edit determines whether the writing is good or not.

2. Do you know your own patterns of creativity?

   What are the most favorable work conditions for you? Do you write best early in the morning, late in the day, or at night? Do you do better work with a dish of candy next to your computer or while abstaining from sweets? Do you work better alone or with people nearby? To get the most out of your writing, observe and respect your own personal idiosyncrasies. They guide creativity — or at least they don't block it.

3. Do you work best with notes or without notes?

   Writers work in different patterns. Some do better with copious notes, others with outlines, others with sketchy notes, and still others without any notes at all. In some cases, writers do better using notes for factual documents (as in reporting data) and without notes for less concrete material (as in light correspondence) — or vice versa. People have different patterns of behavior for different types of writing.

4. Is your problem ideas or words?

   If your difficulty is in ideas, it means that you have no concept of how to get where you want to go. In such a case, here are two recommendations. First, just scribble some notes or words about your idea and about your concepts. Later on, you can flesh out these notes. Second, handwrite some of your thoughts because in the extra time it takes to write out concepts you will probably be able to fill in some of the creative thoughts you had in the first place.

   If your difficulty is in words, it means that you know what you want to say, but can't quite say it. One of the better ways to approach this difficulty is to determine which section of the document you are most sure of, then write it first, even if it is out of order. Everything does not have to be written in sequence.

   A second approach is to write down a few of the key words of your document and then expand them by word association. For

example, if you are writing a report on a meeting, you might jot down "meeting," "election," "conference room," and "Tuesday morning." You can then add other words to each of those original words until you have sketched an outline that will permit you to start writing. Next, add material to it. Remember, you can edit out all the extraneous material.

5. Are you a procrastinator?

   Procrastination may well be a genetic thing: some people are procrastinators, some are not, and some swing back and forth. What is important is that each writer recognize personal patterns of procrastination. When given a task, do you attack it immediately, or almost immediately, regardless of when the deadline is or what the import? Or, no matter how serious the job, do you put it off until almost the last minute? Look at how you shop. Look at how you pay bills. Look at how you study for examinations. Good examples, all. Examine your behavior in writing situations and determine whether or not — or how much — you are a procrastinator.

   Here's a recommendation to help procrastinators: sit and sit and sit. Station yourself in front of your computer and do not yield to the temptation to get up and walk around or do anything else. Stay seated for a reasonable period until your thoughts start to flow. Others recommend two other approaches. Interestingly, they are opposites. Some experts say start with the most difficult task and get it out of the way, noting that the rest will then be easier. Others recommend the reverse: start with the easiest things because they can be done quickly, and then gradually work your way up to the most difficult task. Meanwhile, you will already have written much of the work. Still another recommendation is to "take five." Walk around the building, take a short coffee break, do some deep breathing. But, if you "get away" like this, try not to substitute something you enjoy, such as eating ice cream. In essence, don't reward behavior that you shouldn't encourage.

   It's also wise to get a sounding board if you have difficulty organizing your thoughts or words. Use a dictating machine, or find a colleague who will act as a sounding board so you can tell what you want to say. You will then probably have created your own first rough draft. This process ties in with natural law that you can talk or dictate about ten times as fast as you can write, so when an idea strikes your brain you can record it in a shorter period of time by speaking, losing far less of the thought. Then transcribe what you've said.

   In essence, to get rid of writer's block, or at least reduce it, study your own style of writing and your own personality. Once you

understand yourself, you will be well on the way. Stay with who you are, and you will be rewarded.

Excerpted from *KYOS—Five Easy Questions to Erase Your Writer's Block,* the AMWA Journal, Vol. 17, No. 1, 2002.

Courtesy of Arnold Melnick

Writing and Revising

The best motivation for writing is a deadline.

Kristine Ogozalek, Regulatory Manager

Just about anyone can write *something* — it's what happens to it after the first draft that makes it good. In short, pretty much everything that's written can use some skillful editing and revision. Unless you are a genius, good writing doesn't just happen. It's the result of drafting, revising, reassessing, and revising again. Further, the more eyes that see a piece of writing, the better it usually is. This is especially true of the highly technical writing that's the norm in regulated industries.

Most writers have had the experience of proofreading their own words and giving the copy an okay, only to discover too late that they overlooked glaring errors because they did what humans tend to do: They saw what they expected to see and not what was there. On the other hand, a writer may spend hours developing an idea or researching a detail, then notice that to include it would confuse or mislead. In such circumstances, the only recourse is to cut the passage. Developing your own writing is no easy task, for you are dealing with yourself as a writer. You may know exactly what you mean, whereas your readers may not. That's why review and revision play a strong role.

If you write simple memos, e-mails, faxes, and letters that no one but you sees before distribution, it's best to draft the document and let it rest, if you can. Come back to it and look at it again. Read it out loud if you have the luxury of time. (This helps you "hear" as well as "see.") If the piece is important, ask someone else to read it through, and be open to suggestions. Be appreciative when a typo or misspelling comes to light, so you can make changes to improve your writing for the better. Do the best fine-tuning you can; draft and revise until the document is as good as you can make it.

If you are writing a document for a formal review, remember that the better the quality is prior to the review process, the quicker the approval will be forthcoming. Your reviewers, in particular, will thank you for your diligence, because their task will be easier. And in the long run, you may spend less time trying to get the text through final approval.

Collaborative Writing

Collaborative writing means that two or more people conjointly contribute information to the draft and completion of a single document. For example, work that runs continuously, such as pilot plant operations, requires systematic record keeping across shifts. Those records may ultimately feed into reports, with several people preparing sections. Certainly, equipment installation and operation protocols and qualification reports require the expertise of all who work on a specific project. Clinical trial reports may have more than one writer, and certainly dossiers headed to regulatory agencies have a host of authors who have provided input.

> Common sense is not so common.
>
> **Voltaire**

Writers working collaboratively on documents must offer information that ultimately serves one purpose, and although that can be difficult, it's common. What's needed when people embark upon a joint writing venture is a clear understanding up front and a sense of document ownership. Many a collaborative writing project has gone awry because none of the writers assumed ownership, and the end product became a document with no clear purpose, simply a compilation of information without unity.

Writers need to agree on the main purpose and supporting points for the document. Often each writer can clarify the others' thoughts because all have a solid — but somewhat differing — vision of the main idea. Discussion helps clarify the purpose of the report, and this discussion is best done up front before the writing process begins. The next thing to do is to decide who is going to write what. If you write collaboratively, work with your coauthors to define the process that's easiest for all involved. The two approaches that follow are equally workable, and both require some negotiation skills.

The First Approach

The first approach calls for a designated person to draft the document and for the others to add and amend. That's not to say the first person shouldn't review and be permitted adjustments to the text before submission of the finished product. The strength of this system is that the person with the strongest language skills does the "cleaning up," while the writers with the strongest technical expertise have their say. Alterations in the text are with the approval of all writers. You'll find this approach to be particularly efficient in the composition of short documents.

The Second Approach

The second approach requires more planning than the first approach. In this approach, the writers assess needs of the document and assume ownership of specific portions. All writers need to understand the components of the

planned document and what needs to reside where. They then agree on the formatting conventions and the time for text completion.

Writers then meet to combine the elements and polish the document, with each reading and making comments on the entire text. Revision and refinement should come through tactful commentary and with the consent of the writer responsible for each individual section. This approach is usually the most effective in the composition of reports or other documents of length.

Reaching Agreement

Trust in other people's expertise and a willingness to accept their judgment are crucial to collaborative writing. Remember also that two or more people will have distinct writing styles, and that those styles may vary dramatically; yet sometimes the style distinctions will be barely discernible. Try not to make arbitrary alterations in your coauthors' work; similarly, be tolerant of any minor changes a coauthor may make in your writing, and reach agreement as to the clarity and completeness of the message. And remember, nothing does as much for a common goal as conversation. If you feel a change is necessary, discuss it. Chances are greater that your collaborators will agree after they've heard your explanation. Similarly, you'll feel better about text adjustments after you've had the opportunity to hear why your coauthors feel they should be made. Discussion, after all, is the bond that makes collaboration workable in the first place.

Finally, when writing collaboratively, make every effort to present a document that's cohesive, clear, and grammatical. Getting a document to this point may take many readings, discussions, and revisions. Your collective goal should be the end result: a quality document ready for either immediate distribution or formal review that will be well received.

It doesn't matter what kind of writing you are collaborating on. The following is an abstract written by three people: a vice president of development, a regulatory manager, and a consultant. In preliminary discussions, the three determined to submit an abstract to present at an industry conference. The requirement called for a maximum of 300 words. They had several ideas, then narrowed them down to defining how a company can make the transition from discovery to a compliant development operation. The regulatory manager tackled the task of getting the idea down on paper. Here is the first pass. Notice that the manager asks a few questions of her coauthors, and that this draft is far from complete. It has 114 words

The final word count is 300, and the message is succinctly delivered. Here's a happy note: The abstract was accepted and the authors presented at the conference.

First Draft/Idea Stage

ABSTRACT TITLE:

From discovery to development

SUMMARY:
Session focuses building a development organization from the ground up. It includes how to build project management, regulatory, and document functions to take a product from discovery to market.

LEARNING OBJECTIVES:
Basics for managing development activities with project management, regulatory expertise, and documentation functions.

ABSTRACT:
Newer companies are entering a new arena – development. Different skill sets are required for development than are required for research and discovery. Contract organizations and consultants are often used to acquire the expertise that the company itself doesn't have. When consultants are used, companies may not have the knowledge they need.

In-house vs. farmed out?
Documentation?
Main force is all three?

The consultant then reviewed the text and added some information to address the manager's queries and to refine the writing.