ABSTRACT

TECHNICAL WRITING INTERNSHIP AT A MEDICAL DEVICE COMPANY

by Mark R. Weflen

From January to July 2010, I worked as a technical writing intern at a medical device company where I gained experience developing a wide variety of departmental and product documentation. The most comprehensive project I worked on involved developing instructional inserts for two new surgical devices. Through my participation in this project—and other projects during my internship—I learned to leverage the knowledge of subject matter experts more effectively by closely collaborating with them throughout the document development process rather than treating them as isolated technical resources. Consequently, I gained a deeper understanding of the role of subject matter experts in the document development process and, as a result, will be better at determining how and when to leverage their skills and knowledge in my future endeavors.
TECHNICAL WRITING INTERNSHIP AT A MEDICAL DEVICE COMPANY

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Chapter 1: Introduction
I performed a technical writing internship at a medical device company during a six-month period from January to July in 2010. The company develops and manufactures minimally invasive surgical and diagnostic devices. Minimally invasive surgery refers to surgical procedures through one or more small incisions rather than a single large incision. These procedures typically result in less pain, reduced hospital stays, faster recovery, and fewer scars than traditional open surgical procedures.

Organizational Structure
The medical device company is a subsidiary of a larger health care company. Although the medical device company operates independently, it is subordinate to its parent corporation. The medical device company president reports to the company group chair, and the company group chair reports to the worldwide chair who reports directly to the corporate Chief Executive Officer (see Figure 1, Corporate-company hierarchy).

Figure 1: Corporate-company hierarchy

Author’s note: To protect classified, confidential, and/or proprietary information, company and product names have been excluded from this report.
Work Environment
The medical device company operates in an FDA-regulated environment. Consequently, quality and accuracy are paramount considerations in all the company's activities. The cost of settling a lawsuit or delaying a product release to implement unexpected, FDA-enforced revisions outweighs any reduction in efficiency or increase in labor costs arising from ensuring that quality and accuracy are maintained. As a result, the company is highly bureaucratic with fixed processes governing nearly every aspect of its operations both to ensure quality control and to carefully document activities for possible audits. Employees work under pre-established protocols and must cite and follow these protocols for each official project.

Labeling Team
I worked at the medical device company as part of the labeling team. The labeling team, as one might assume, is responsible for the labeling and documentation associated with the medical devices. Along with the package engineering and sterilization science teams, it is a subdivision of the packaging department.

The three primary positions within the labeling department are technical writers, graphic designers, and labeling specialists. Technical writers are responsible for developing product instructions for use (IFUs) and guiding projects through the team's development process. Graphic designers develop labeling graphics, including those in the IFUs, and transmit labeling files to suppliers. Labeling specialists generally perform an array of administrative tasks associated with labeling operations.

As previously mentioned, protocols and paperwork are a prominent aspect of nearly all work performed at the medical device company, and this prominence extends to the labeling team. All labeling documents must go through a rigorous approval process before they can be released to suppliers and, eventually, to the market.

When the initial English version of a labeling document is developed, it must first gain domestic approval. A technical writer circulates the document to specialists from various departments within the company and solicits their approval of the quality and accuracy of the document, denoted by their signature. Once all approval signatures have been obtained, the document is approved domestically, meaning the English version of the document is finalized and, under normal circumstances, will not undergo further changes. However, if the document is intended for an international market, it is outsourced to a supplier for translation.

After the international labeling documents have been translated, they must be approved by the supplier and technical writer. Because the company's technical writers are typically not fluent in multiple languages, their approval is limited to ensuring that the content appears correct from a formatting perspective; by comparing the number and location of bullet points, instructional steps, bolded warnings, and graphics. The technical writers are at least able to assume that all content is present. However, some countries require that their languages also be approved by the medical device company's translation affiliates located in those countries.
When documents intended solely for the U.S. market have gained domestic approval and those intended for international markets have gained domestic and translation approval, the documents are ready for final approval. This approval is expected to catch any errors that may have slipped through the other approval stages. It is conducted similarly to the domestic approval, with the technical writer and other specialists providing approval signatures, but fewer signatures are required for the final approval. Once a document has passed the final approval, it can be sent to a supplier for printing and, eventually, be released to the market (See Figure 2, Document approval process).

Figure 2: Document approval process

Technical Writing Intern
As a technical writing intern, my responsibilities were similar to those of the technical writers—developing IFUs and guiding documents through the approval process. However, I usually performed a more supportive role with assistance and supervision from my supervisor and mentor. My supervisor and mentor, with whom I worked on the majority of my projects, were both experienced technical writers at the medical device company. My supervisor initiated most of my projects, while my mentor typically provided advice and assistance; however, there was significant overlap between their two roles. I met with one or both of them for an hour each week to discuss my projects, internship goals, and any questions or concerns I or they had.

I performed such a wide variety of tasks during my internship that it would be difficult to list them all here; however, the following activities occupied the most time during the internship period:

- Editing
- Proofreading
- Document management
• Interviewing subject matter experts

In addition to these tasks, I gained significant project management experience by guiding project teams through the labeling team’s document development processes and by coordinating with other team members and technical resources to fulfill requirements, resolve problems, and meet deadlines. Because the MTSC program at Miami University primarily focused upon “hard skills” such as writing, designing, and interviewing, I appreciated this emphasis on “soft skills” as I felt they complemented my previous training and, consequently, helped me become a more well-rounded technical communicator.

The next chapter provides a brief description of some of the major projects I worked on, including many of the challenges I encountered and experience I gained.
Chapter 2: Project Overview

During my six-month internship at the medical device company, I worked on a wide range of projects and completed many other minor day-to-day tasks. Several of the major projects I worked on are as follows:

- editing a medical device operator’s manual
- merging two separate medical device instructional inserts into a single insert and updating another medical device insert
- comparing three sets of medical device instructions and documenting the differences between them
- conducting a legibility study on text in an instructional insert and on two medical devices
- developing and updating department procedures for electronic labeling delivery
- developing department goals, including plans for redesigning electronic IFU templates

In this chapter, I briefly describe my contributions to these projects and how they helped me develop as a technical communicator.

Editing a Medical Device Operator's Manual

For the medical device operator’s manual edit, I was asked to adapt a medical device operator’s manual from a recently acquired company to meet the requirements of the medical device company for which I was working. The project was conceived of as a risk mitigation project; therefore, the medical device would only be released in the event the release of another product was delayed.

When the operator's manual was acquired, its previous owners described it as being nearly ready for release. This assessment dictated both the project schedule and the expectations of the team. However, although the information in the manual was nearly complete, the overall quality of the manual was very poor. I received the manual as a Word document with images embedded into it, and, because the file was corrupted, it was prone to crashing and the images could not be extracted into separate files. Most instructions were written in the passive voice and in paragraph form, in addition to numerous grammatical errors and formatting inconsistencies (see Appendix I, Medical Device Operator's Manual before editing).

I described the state of the manual to my mentor, the technical writer overseeing my work on this project, and she asked me to lightly edit the document and transfer it into the medical device company’s InDesign template; because the project was only a risk mitigation project, the team thought that conducting lengthy technical reviews of the material with the engineers, which would be required for an extensive revision of the manual, would not be a prudent use of resources. Additionally, we needed to request new images from the industrial design department because we were unable to import the existing ones into InDesign from the corrupted Word document.
I edited the document in Word before transferring it into InDesign, so I could use Word’s Track Changes feature to record my work. Attempting to stay within the scope of the project, I refrained from making any structural or organizational changes to the content and limited my revisions to the following:

- correcting grammatical errors and typos
- making heading formats and image placement consistent
- adding captions to images (some had captions; some did not)
- changing descriptive text to instructional text (i.e., addressing the user directly)
- rewording sentences that were particularly confusing or awkward

Upon completing these revisions, I recreated the manual in InDesign and adjusted its format to fit the medical device company’s template.

However, when I presented the revised manual to the engineering team, they were displeased with my revisions and asked why I had made them. I explained that I felt the original manual was very difficult to use in its current form and, due to myriad inconsistencies and errors, would reflect poorly upon the company if it were released. Although the engineers agreed that the manual could be improved, they insisted that I revert it to its original form and only correct typos and easy-to-fix grammatical errors, such as punctuation and subject-verb agreement. From a project management perspective, making significant revisions would have required additional reviews from the engineers and, consequently, delayed the completion of the project. I followed their direction and undid my revisions; however, because image-heavy documents are easier to manage in InDesign, my mentor and I were able to convince the team to keep the document as an InDesign file—and, as a result, retain a few minor formatting changes—rather than recreate it in Word (see Appendix II, Medical Device Operator’s Manual after editing).

During the two months that I worked on this project, I received frequent updates from the team via email, phone, and face-to-face visits requesting additional changes to the manual. Also, because the industrial design department was unable to obtain new files for some of the corrupted images, I worked with them and the team’s graphic designer to develop new ones, and even made some simple graphical symbols and minor image alterations myself using Photoshop.

Through this project, I gained experience editing instructional text and working with subject matter experts and also improved my proficiency in InDesign. Although most of my revisions were not used in the final manual, I was still able to gain experience converting descriptive, system-centric text written by technical experts into instructive, user-centric text—a task I expect to perform throughout my career as a technical communicator. Aside from the technical skills I improved through my participation in this project, I also gained experience working with technical experts who did not share my opinions—another circumstance I expect to encounter frequently as a technical communicator.
Merging Medical Device Inserts

The merger of the medical device inserts involved combining two separate medical device instructional inserts into a single insert as well as updating the instructional insert for another similar medical device. My supervisor assigned me to this project very early in my internship, and the project lasted roughly five months; however, there were significant periods during which I was simply waiting for other members of the project team and did not perform any work. At the onset of the project, my supervisor would consult with the team and pass along assignments to me second-hand, but later on I collaborated with the team directly and was largely able to assume direct control over my work, albeit under my supervisor's direction.

At the beginning of the project, my supervisor gave me two medical device instructional inserts and asked me to attempt to combine them into a single insert. The two inserts were very similar though there were several distinct differences. Because of the similarity between the inserts, my first inclination was to compress the inserts as much as possible to save space and, thereby, money. For instance, if a section in each insert had 14 steps, of which 11 were identical between the inserts, I combined the two sections into one and merely noted the differences within the individual steps in which they occurred. However, because I was unfamiliar with the technical material and the intended audience, I asked my supervisor for his advice concerning this approach. He acknowledged that my approach would save space, but also noted that it would be more difficult for a user to determine which action to take—depending upon which device configuration they were using—within individual steps than it would be to simply determine at the onset which section to read. Consequently, he asked me to make several prototypes emphasizing different approaches and allow the team to choose the one they preferred.

I designed three different prototypes: a Separation Prototype, which focused on clearly delineating between different device configurations, even if doing so increased the length of the insert; a Combination Prototype, which focused on saving as much space as possible by combining sections; and a Combination/Tables Prototype, which, like the combination prototype, focused on saving space but attempted to more clearly distinguish between device configurations in individual steps by using tables. While designing these prototypes, I used a color-coding system to record which information came from which insert and which information was added after the initial merger.

My supervisor decided to use the Separation Prototype, due to its usability advantages, and we presented it to the team. Thereafter, I collaborated with the team to make regular updates and revisions to the insert. After the initial merging, most of the work I performed for this project involved editing and analyzing text for inconsistencies, though I also performed a very limited amount of graphic design work.

Near the end of the project, I was given the opportunity to lead the final document review meeting with representatives from the marketing, regulatory,
quality/engineering, and medical affairs departments. These meetings are typically held just prior to the signature approval process to help ensure there are no outstanding issues that may compel reviewers to withhold their approval, which would result in unexpected project delay. The team and I were able to resolve the last few lingering issues that arose during the meeting within the next few days, and we circulated the document for approval signatures shortly thereafter.

The project team and I continued to make updates to the other medical device insert for the next few weeks. These updates were generally rather minor and usually involved my simply receiving text from the team and inserting it into the manual. Nonetheless, these simple updates did give me additional experience managing documents by organizing different revision files and proofreading after each iterative update to maintain accuracy and consistency.

Through this project, I gained experience integrating and managing documents, editing, and analyzing medical information. Additionally, I had the opportunity to work with experts from various departments, and found it beneficial to gain insight into the varying perspectives of reviewers from different fields and to gain experience synthesizing those perspectives into a single document.

**Comparing Medical Device Instructional Manuals**

This medical device instructional manual comparison was initiated to determine the feasibility of integrating the US and international versions of three medical device instructional manuals into single, global manuals for each device. To determine whether this merger should take place, the medical device team wanted to know how extensive the differences were between the two versions of each manual. Consequently, they asked me to perform a document comparison recording the differences between the US and international versions of these manuals.

To complete this document comparison, I used Adobe Acrobat’s Text Edits feature to document where the two versions of the manuals diverged from one another. The primary challenge of this project, aside from the tedium, was determining which differences should be documented. Only a small fraction of the text and images were identical between the two versions of each manual, so I often had to determine whether differing sets of text and images were still communicating the same information. Because I did not understand most of the medical information in the manuals, I had to make these judgments by cross-referencing information between the manuals or breaking down paragraphs grammatically—matching up nouns, verbs, etc.—and reassembling them to assess whether their communicative intent was the same.

I think gaining experience analyzing complex technical information was the primary benefit I derived from completing this project. As a technical communicator, I expect to often work with complex information outside my field of expertise, so developing strategies for rapidly analyzing or interpreting such information will likely continue to be an integral component of my work.

**Conducting a Legibility Study**
The legibility study was initiated by my supervisor to fulfill usability requirements for legibility as defined in applicable external standards for medical device labeling. The study was designed solely to test text legibility (i.e., are the textual characters discernible in their current typeface and font size?), not reader comprehension. My involvement in this test included proctoring the test and discussing the testing methods with my supervisor to affirm that they would yield the needed data.

The test itself was quite simple: Participants were asked to read text printed on two medical devices and text in a sample IFU under premeasured lighting conditions. Then I, as the proctor, would record whether the text was read correctly. We tested 15 participants in accordance with the statistical requirements of the test. Most were nurses from the medical device company’s call center, who closely conformed to our target audience; however, to obtain the needed number of participants, we had to test a few members of the labeling department as well. The test was concluded in four days and met the statistical requirements for success.

I appreciated having the opportunity to participate in this test because it gave me additional insight into the potential variety of objectives and methods involved in usability studies: this test was rather rigid and focused solely on obtaining a single type of information, while the tests I developed in the MTSC program at Miami University were purposefully flexible and aimed at obtaining as much relevant user feedback as possible.

Developing Department Procedural Instructions
For the department procedural instructions development project, I helped develop two new procedural work instructions related to electronic labeling delivery. These work instructions are used to establish approved workflow processes for the company’s employees. The work I performed on this project consisted of updating and editing pre-existing work instruction drafts, designing and redesigning four forms associated with these work instructions, and developing flow charts to supplement the work instructions.

For the first work instruction I worked on (Work Instruction A), my supervisor provided me with drafts of the work instructions and two forms. I reorganized the work instructions to more clearly delineate procedural steps, copyedited them, and added flow charts to their appendices. Because I began work on Work Instruction A during the first week of my internship and, thus, was still unfamiliar with the company’s procedures, my first flowchart draft failed to accurately reflect the procedures from which it was derived. However, after my supervisor pointed out these inconsistencies and more thoroughly explained the work instructions to me, I was able to produce an effective final draft. I redesigned the forms associated with Work Instruction A using fundamental design principles such as contrast, alignment, and balance with the intent of making them more attractive and easier to use (see Appendix III, Work Instruction A flow chart).

The second work instruction I helped develop (Work Instruction B flow chart) was initiated by my manager. She provided me with an existing draft of the work instructions and asked me to supplement it with two forms and a flow chart. She
explained the intent of the forms and gave me suggestions on how I might design them but also left me some liberty in designing them. After drafting the forms, I edited the work instructions for spelling and grammar errors and content inconsistencies. Thereafter, I met with my manager periodically to update and discuss improvements to these documents. Additionally, I met with other department team members who would be using these documents and asked for their feedback (see Appendix IV, Work Instruction B).

Perhaps the most challenging aspect of this project was implementing these new work instructions into the company’s Quality System Procedures. The form submission and approval process for issuing new procedures at the medical device company is very complex and involves coordinated cooperation from people in multiple departments. While I was able to develop Work Instructions A and B in about two weeks each, it took me and my supervisor roughly two months to complete all the appropriate paperwork to submit them into the protocol system.

In addition to refining my editing skills, however, developing these new work instructions gave me valuable experience analyzing processes and mapping them visually. I had little experience creating flow charts prior to my internship, so I had to experiment a bit with different approaches before I found an effective design for each work instruction. This task gave me both a better appreciation for the value of visual aids in documents and additional strategies for educating readers about complex tasks or procedures—following this task, I often made rudimentary flow charts for other work instructions simply for my own benefit in understanding them.

Designing supplemental forms for these work instructions was an excellent opportunity for me to apply many of the design principles I learned in my Information Design course as well as much of the information I learned in my Technical and Scientific Writing course regarding document usage and purpose. I am confident that this knowledge will serve me well throughout my career as a technical communicator.

**Developing Department Goals**

The department goals development project was initiated during a department goals and objectives meeting. At this meeting, the department team conducted a SWOT analysis under the direction of a contract consultant. A SWOT analysis is a strategic planning methodology wherein an organization identifies its **Strengths**, **Weaknesses**, **Opportunities**, and **Threats** and uses those factors to formulate its goals and objectives.

Upon concluding this analysis, the department team was divided into groups. Each group was assigned a specific aspect of the department (e.g., technology) and tasked with developing goals and objectives for the next five years for that aspect. My mentor and I comprised the group assigned to department processes.

My mentor and I met several times to develop our goals and objectives, but these meetings yielded limited results. Consequently, we decided to develop several goals individually and then work together to refine them before presenting them to the
rest of the department team. I prepared and updated our PowerPoint file prior to our presentations, and my mentor and I took turns presenting our ideas to the department team. After each presentation, we received feedback from the team and revised our plans and ideas accordingly.

One of the goals I proposed was to re-design the current IFU template by experimenting with more usable print designs and taking advantage of the electronic medium for online IFUs. My intention was that the department team would design two new templates: one for print IFUs that would respect current cost and size limitations, and one for online IFUs that would capitalize on the Web’s cost-less environment by including larger font sizes, more white space, color, hyperlinks, and other features to improve usability. Here is a brief overview of my proposed plan for this project:

<table>
<thead>
<tr>
<th>Milestone</th>
<th>Deadline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Locate/develop information regarding usage of current IFUs (e.g., voice-of-customer data, expert opinions)</td>
<td>Day 20</td>
</tr>
<tr>
<td>Obtain and analyze competitor IFUs</td>
<td>Day 20</td>
</tr>
<tr>
<td>Determine/develop firm boundaries for length, image usage, and color usage (for printed and online IFUs)</td>
<td>Day 50</td>
</tr>
<tr>
<td>Technical Writer(s)/Graphic Designer(s) develop new IFU prototypes</td>
<td>Day 70</td>
</tr>
<tr>
<td>Department team members select/revise the best prototype(s)</td>
<td>Day 90</td>
</tr>
<tr>
<td>Implement revised print IFUs into IFU development process</td>
<td>Month 9</td>
</tr>
<tr>
<td>Develop process for easily converting print IFUs into online ones (if formatted differently) using templates</td>
<td>Month 12</td>
</tr>
<tr>
<td>Implement revised online IFUs into IFU development process</td>
<td>Month 15</td>
</tr>
<tr>
<td>Repeat IFU revision process to adapt to technology changes and to further improve usability</td>
<td>Year 5</td>
</tr>
</tbody>
</table>

The department has not yet decided which ideas to implement and which to put on hold or reject. However, my plans for redesigning IFU templates coincided with my supervisor’s intention to develop a more visual approach to the company’s IFUs. As a result, he asked me to use a flowchart design to create an IFU prototype that would meet the following objectives: increase usability, reduce length, and improve visual appeal. I created several prototypes using InDesign, but, unfortunately, was not able to find a way to reduce (or even maintain) IFU lengths using this approach, and my internship ended before we were able to explore this issue any further.

Through my participation in the department goal planning process, I was able to apply many of the analytical skills I developed in my Organizational Communication class at Miami University, and I gained additional experience planning projects and giving presentations. Finally, working with my supervisor to develop new IFU templates gave me an opportunity to improve my proficiency in InDesign and to develop creative approaches to a challenging task—even though my approaches were ultimately unsuccessful.

The next chapter describes in more detail another project I worked on during my internship that, like the department goal development project, allowed me to draw
from skills I learned at Miami University but also presented unique challenges that I had not encountered in school.
Chapter 3: Developing Instructional Inserts: Major Project

One of the most substantial projects—and perhaps the most challenging—I worked on during my internship was developing instructional inserts for two new surgical devices. Through this project, I had the opportunity to gain additional experience performing the following tasks:

- collaborating with subject matter experts
- writing instructions based upon a device prototype
- editing
- merging and reorganizing content

Initiation
I began my involvement in this project by meeting with the regulatory affairs representative on the project team. He briefed me on the background and objectives of the project and allowed me to ask questions to gain more insight into the regulatory approval process for surgical devices, particularly as it applied to this project.

The project involved the development of instructional inserts for three new surgical devices: one was assigned to my supervisor, and the other two were assigned to me. Our task was to produce the instructional inserts for these devices as early in the device development process as possible. Although these devices were based upon preexisting devices, they possessed several unique features that made them ideally suited to their target markets. Therefore, while much of their content could be derived from preexisting inserts, the content required significant modification and creation of some new content as well.

Development
After meeting with the regulatory representative, I set up our first meeting with the team, which consisted of the regulatory representative, two engineers, one industrial designer, my supervisor, and me. During the meeting, I read through a pre-existing insert line-by-line with the team and collected their feedback regarding which information was missing, which needed to be added, and which needed to be changed for the new insert. The next day I held a similar meeting for the other insert.

Following these initial meetings, I created my first drafts of the new inserts. Using the feedback I obtained from the team, I made significant revisions to the pre-existing insert and imported information from other existing inserts. I then surveyed the insert drafts for newly created inconsistencies and for information that seemed likely to change in the final version and highlighted these sections for further discussion with the team.

In the following weeks, I scheduled periodic meetings with the team in which I would present my latest draft of an insert, ask questions, and note any additional changes that needed to be made. Occasionally the team would also send me revisions or request information via email. I also routinely followed my supervisor’s progress
on the third insert to ensure that my inserts conformed as much as possible with the format and content of his.

Near the end of my involvement in this project, I was given the opportunity to develop new content for one of the inserts—one of few such opportunities during my internship—to describe the assembly and disassembly of the device. To develop this content, I arranged a meeting with the team in which they demonstrated the assembly and disassembly of a preliminary device prototype. I took notes on their procedure and suggestions and assembled and disassembled the prototype myself.

Because this device prototype was missing several components, I was initially only able to draft about half of the assembly and disassembly instructions. To draft these instructions, I used my notes from the meeting and several preliminary illustrations that were provided to me. The prototype itself was in high demand, and, thus, could not be reliably accessed as a visual aid or testing tool.

Once a further developed prototype was available, I met again with the team’s industrial designer—other members of the team were unavailable due to scheduling conflicts—to add the rest of the assembly and disassembly instructions and to review my existing draft.

During this meeting, the industrial designer reviewed my draft instructions and gave me some additional suggestions for specific terms to use as well as additional information regarding how the final device would differ from the prototype. He also demonstrated how the previously missing components fit into the assembly and disassembly processes. Using this new information, I was able to complete a draft of the assembly and disassembly instructions.

My internship ended before I was able to further develop and review these inserts with the team. As a consequence, my supervisor will assume responsibility for the completion of this project in my absence.

Benefits
I found this project to be challenging and very beneficial for my development as a technical writer. Because this was the first major project that I was responsible for from inception, I needed to familiarize myself with the device very rapidly. Additionally, I had little experience describing physical objects and actions—as opposed to more conceptual information—and found it quite challenging, particularly when I could not see the actual object I was describing and had only limited access to the prototype.

To overcome these difficulties, I had to rely heavily upon the subject matter experts on my team. Not only did they possess more technical knowledge than I, but they also had a clearer understanding of the intended usage of the inserts and their target audience. Consequently, I often had to solicit their input regarding matters such as presentation format and term usage—areas which, as a technical communicator, I am accustomed to having the most insight into.
Through this experience, I learned to leverage the knowledge of my team members more effectively by closely collaborating with them in the document development process rather than treating them as isolated technical resources divorced from the actual development of the document itself.

While gaining additional experience working with subject matter experts was the most significant benefit I derived from this project, I also gained additional experience editing, drafting instructions from prototypes and illustrations, and synthesizing information from multiple sources into a single, cohesive document.
Chapter 4: Analysis
Gareth Morgan, in his book *Images of Organization*, uses the metaphor of a brain to describe how certain organizations are able to learn and adapt in a complex environment. He draws parallels between the decentralized way neurons produce intelligence and the way some organizations are able to operate through a decentralized organizational structure that allows knowledge to coalesce and develop from the bottom-up. This metaphor offers an effective means of analyzing the document development operations of the medical device company where I performed my internship.

The two aspects of Morgan’s brain metaphor that closely correlate with the documentation process at the medical device company are the following:

- **Cybernetics**: Morgan explains that cybernetic intelligence arises from a cumulative exchange of negative feedback, “whereby deviations...are reduced at each and every stage of the process, so that in the end no error remains.” In other words, success is achieved through feedback that reduces and eventually eliminates error (77).

- **Holography**: Morgan describes holography as “everything enfolded in everything else” (71): because every piece of a holographic plate has the entire holographic image imprinted into it, any single piece of the plate can be used to reconstruct the entire image. This principle applies closely to the physiology of the brain. Because memory is diffusely distributed throughout the brain, it can be derived from any of the parts; thus, neurons are extremely versatile, able to perform each other’s functions. However, the brain is also highly specialized with certain hemispheres and lobes excelling at particular activities (99).

The medical device company’s team-based document development process uses the cybernetic principle of negative feedback to maintain quality control. This use of negative feedback is most prominent in the document approval stages when a draft of the document is circulated among reviewers from various departments for approval or revision; however, it is also evident throughout the document development process with content and organization decisions being made in a decentralized, collaborative manner.

This process closely relates to the cybernetic decision-making process of *ringi* as described by Morgan:

Under *ringi*, a policy document is circulated among a group of managers or other personnel for approval. If a person disagrees with what is being proposed, he or she is free to amend the document, and it is circulated again. The process explores the values, premises, and details relating to a project from multiple points of view until an agreed-on position that satisfies all critical concerns and parameters emerges. It can be extremely time consuming. But when a decision is made, one can be fairly certain that key
assumptions will have been challenged and that most errors will have been detected and corrected (88).

Like *ringi*, the medical device company's document development process "mobilizes disagreement to create consensus" (89). By conferring authority over document approval to individuals within their areas of expertise, all team members are given roughly equal input into the document and, thus, by virtue of their capacity to delay document approval, are granted leverage to challenge the decisions of other team members, including the project team leader. Like *ringi*, this process can be tedious and time consuming, but, in an FDA-regulated environment, the quality assurance it provides outweighs its relative inefficiency.

As the document manager, the technical writer's role in this process is unique. Like other team members, the technical writer is able to hold sway over her areas of expertise (e.g., document design, grammar, syntax, etc.), but she is also responsible for maintaining cohesiveness and consistency through the document as a whole. The technical writer must logically analyze each section of the document to help ensure that revisions from other team members do not produce unforeseen contradictions elsewhere.

In this way, the technical writer assists other team members in their specialized areas, and they each assist her in hers. Because the medical devices produced at the medical device company are intended for use by highly trained physicians, surgeons, and nurses, subject matter experts on the document development team typically have more knowledge about the documents' intended audience and their needs and areas of expertise than do the technical writers. Consequently, the technical writers must rely upon subject matter experts not only for technical information but also for insight into how the document itself should be written for its intended audience.

This shared responsibility among the team for both the content and language in medical device IFUs is analogous to the principle of holography within a brain. Morgan notes that, "at any one time many parts of the brain may be involved with the same activity or information. This redundancy allows initiatives to be generated from many locations at once, reducing dependence on the activities of any single location" (102). The use of specialized, multidisciplinary teams with significant redundancy of knowledge and functions allows for IFUs to be analyzed holistically from multiple perspectives. As a result, errors and deficiencies are more likely to be noticed and corrected through the crossfire of a multilayered analysis than if individuals were only able to analyze their own area of expertise.

I found the incorporation of the principles of multidisciplinary negative feedback and redundancy to be a useful strategy for document development. Prior to my internship at the medical device company, I tended to treat subject matter experts as inert resources, like databases or textbooks. I gathered needed technical information from them and then completed the rest of the document development process in isolation until the subject matter experts were needed again for a final review. As illustrated by Figure 3, within this model, the technical writer serves as a mediator among the subject matter experts and the document itself.
This approach is highly specialized and, thus, resource-efficient: each team member does what he does best.

However, upon completing my internship, I have come to appreciate the value of involving subject matter experts more directly in the document development process. As a result of their technical expertise, subject matter experts may have special insight into the intent of the document and, in the case of the medical device company, the target audience. Consequently, they are often able to make valuable contributions beyond simply providing and verifying technical information. When using this more collaborative approach, the technical writer acts as simply another contributor, albeit one with a closer relationship to the document, rather than a mediator (See Figure 4, Technical writer as contributor).
However, along with its advantages, there are a few drawbacks to this approach. First, as mentioned above, this process is more time consuming as it requires buy-in from and negotiation with more individuals. Also, some subject matter experts may not appreciate the value of good communication as much as the technical writer, so it is vital that the technical writer possess sufficient leverage to successfully advocate for the need to produce a quality document, if that need should be called into question by a subject matter expert. Last, because this approach requires significant redundancy within the team to be successful, it may not be as resource-efficient as the mediator model because many specialized skills possessed by team members will not be used regularly. For instance, as an intern at the medical device company, I only used a fraction of my technical communication skills on a regular basis and sometimes felt that my job could have been performed almost as well by someone with significantly less training and fewer capabilities.

The appropriateness of either the mediator or contributor model will largely depend upon the circumstances surrounding the document’s creation. In an FDA-regulated environment, like that of the medical device company, the contributor model affords excellent quality control; but for a small company that lacks the resources to maintain teams with high levels of redundancy, the mediator model may be preferable. Thus, while I may not necessarily employ the contributor model throughout the rest of my technical communication career, I have gained a deeper understanding of the role of subject matter experts in the document development
process and, as a result, will be better at determining how and when to leverage their skills and knowledge in my future endeavors.
REFERENCES

Appendix

I. Medical Device Operator's Manual before editing (p. 22-23)

II. Medical Device Operator’s Manual after editing (p. 24-27)

III. Work Instruction A flow chart (p.28)

IV. Work Instruction B flow chart (p.29)
Bipolar Cut: Bipolar Cut is the default setting. Coagulate mode is not available.

Bipolar Cut / Monopolar Coagulate: Monopolar coagulate feature is added by selecting from this menu. A patient return pad must be in place [read return pad cautions].

Monopolar Cut / Monopolar Coagulate: Cut and Coagulate will be monopolar. A patient return pad must be in place [read return pad cautions].

93. Bipolar Cut

93.1. Cutting power will be delivered while the YELLOW footswitch is depressed. A tone will be heard indicating the delivery of bipolar cutting RF energy. The display will indicate cutting power delivery.

93.2. Cutting power is always available by pressing the trigger on the device (see section on Mode).

93.3. Cutting Tip: The Cutting tip function uses an electrode that extends out from the distal tip of the device. The default mode is bipolar and the use of a grounding pad is not required. To cut, touch the end of the lower jaw to tissue and apply power. Output can be increased or decreased using the touch screen.

93.4. The Cutting tip electrode is completely isolated from the electrode and uses the Jaw structure as the return path. Tissue can be cut or scored with the jaws in the open position as well as the closed position.

93.5. Care should be taken to minimize the amount of time the device is fired without contacting tissue.
9.1.7. **Footswitch or Trigger Mode ["Tap, Tap/Hold"]**

If the Footswitch or Trigger is pressed twice and held down within the first second of RF Power Delivery the generator will deliver RF Power for as long as 2 minutes. RF Power delivery can be terminated at any moment by releasing the Footswitch or Trigger. During Mode (by Footswitch or Trigger) the Tone (faster beeping) is heard and elapsed time is indicated on the display.

9.2. **RF Power Delivery**

9.2.1. **Cut-Coagulate Mode**

device attachment will bring up the Cut screen.

Tissue Sealing Mode (trigger only) and CUT (yellow footswitch) Mode are now available. mode is effected between the jaws. Cut and Coagulate are effected at the electrode located at the distal tip of the lower jaw. The jaws can be open or closed when using cut and coagulate power.

Polarity options (bipolar/monopolar) are available through the POLARITY button. Pressing the POLARITY button brings up the following menu choices.

Remember:

- **Bipolar** means that power return through the device
- **Monopolar** means that power returns through the patient to the patient pad
APPENDIX B: Product Specifications

Specifications

Mode of Operation:
- **Input:** 100 VA to 400 VA, 50 Hz to 60 Hz
- **Dimensions:** W13.5in, D13.5in, H8in (34cm x 34cm x 20cm)
- **Weight:** 13.5lbs (6.1Kg)

**Output:**

- **Tissue Sealing Mode** - Pulsed, Quasi-Sinusoid, 480kHz, 45W +/-20% into a 75 Ohm load, 85 V_{RMS} (Open Circuit), duty cycle intermittent; 15 seconds on 1 second off
- **Monopolar Cut mode** - Pure cut, Quasi-Sinusoid, 480kHz, 45W +/-20% into a 400 Ohm load, 323 V_{PEAK} (Open Circuit), duty cycle intermittent; 10 seconds on 30 second off
- **Monopolar Coag mode** - Pulsed, Quasi-Sinusoid, 480kHz, 50W +/-20% into a 400 Ohm load, 466 V_{PEAK} (Open Circuit), duty cycle intermittent; 10 seconds on 30 second off
- **Bipolar Cut mode** - Pure Cut, Quasi-Sinusoid, 480kHz, 40W +/-20% into a 400 Ohm load, 326 V_{PEAK} (Open Circuit), duty cycle intermittent; 10 seconds on 30 second off

**Fuses:** 5 mm x 20 mm Type "T" 6.3 A/250 VAC (Qty. 2; Schurter or equivalent)

Weight and dimensions indicated are approximate. Specifications are subject to change without notice.

**Protection**
- Class 1, Defibrillator Proof – Type CF, intermittent operation; Enclosure IP X0, E-DF IP68

**Operating Conditions**
- **Temperature:** 32°F to 122°F (0°C to 50°C)
- **Relative Humidity:** 30% to 75% non-condensing
- **Atmospheric Pressure:** 86 kPa to 106 kPa

Whenever the temperature goes above 50°C or below 0°C RF power will not come on and the generator will report a fault until the temperature condition is met.

**Storage Requirements**
- **Temperature:** -4°F to 140°F (-20°C to 60°C)
- **Relative Humidity:** 30% to 75% non-condensing
- **Atmospheric Pressure:** 86 kPa to 106 kPa

APPENDIX C: Conformance to Standards

**RF Generator conforms to the following International Standards:**

- IEC60601-1, 2nd ed.
- UL60601-1, 1st ed.
- CSA C22.2 No.601.1-M90
- EN 60601-1-2 2001
- Collateral Standard:
- IEC 60601-1-4
- Part 1-4:
- IEC60601-2-2, 4th ed.
- ANSI/AAMI/IEC TIR60878:2003 Graphical symbols for electrical equipment in medical practice
- EN 60529
- ASTM D 4169 - 05
- MDD 90/42/EEC

Medical Electrical Equipment. Part 1: General Requirements for Safety
Medical Electrical Equipment. Part 1: General Requirements for Safety
Medical Electrical Equipment. Part 1: General Requirements for Safety
Electromagnetic Compatibility
Medical Electrical Equipment General Requirements for Safety
Collateral standard: Programmable Electrical Medical Systems
Medical Electrical Equipment, Part 2: Particular Requirements for the Safety of High Frequency Surgical Equipment
Degrees of Protection Provided by Enclosures (IP Code)
Standard Practice for Performance Testing of Shipping Containers and Systems

LBL 700207RE_P43558P01
Remember:
Bipolar............means that power returns through the device
Monopolar........means that power returns through the patient to the patient pad

**Bipolar Cut**

Bipolar Cut: Bipolar Cut is the default setting. Coagulate Mode is not available.

**Bipolar Cut/Monopolar Coagulate**

Monopolar coagulate feature is added by selecting from this menu. A patient return pad must be in place [read return pad cautions].

**Monopolar Cut/Monopolar Coagulate**

Cut and coagulate are monopolar. A patient return pad must be in place [read return pad cautions].

### 9.3. Bipolar Cut

9.3.1. Cutting power will be delivered while the YELLOW Footswitch is depressed. A tone will be heard indicating the delivery of bipolar cutting RF energy. The display indicates cutting power delivery.

9.3.2. Power is always available by pressing the trigger on the device (see section on Mode).

9.3.3. Cutting tip: The cutting tip function uses an electrode that extends out from the distal tip of the device. The default mode is bipolar, and the use of a grounding pad is not required. To cut, touch the end of the lower jaw to tissue and apply power. Output can be increased or decreased using the touch screen.

9.3.4. The cutting tip electrode is completely isolated from the electrode and uses the jaw structure as the return path. Tissue can be cut or scored with the jaws in the open position as well as the closed position.
9.3.5. Care should be taken to minimize the amount of time the device is fired without contacting tissue.

9.4. Bipolar Cut/Monopolar Coagulate

9.4.1. Bipolar Cut operates as above.

9.4.2. Tissue Sealing Mode is always available using the Trigger on the device. Mode is always bipolar.

9.4.3. Coagulate Mode is now available using the BLUE Footswitch. A patient return pad must be in place [read return pad cautions]. When activated, a tone will sound and the display will indicate coagulate power delivery.

9.4.4. The output may be changed in both cut and coagulate modes to increase or decrease the effect at the electrode.

9.4.5. Care should be taken to minimize the amount of time the device is fired without contacting tissue.

9.5. Monopolar Cut/Monopolar Coagulate

9.5.1. Cut mode is now monopolar and activated using the YELLOW Footswitch. A patient return pad must be in place [read return pad cautions].

9.5.2. Tissue Sealing Mode is always available using the Trigger on the device. Tissue Sealing Mode is always bipolar.

9.5.3. Coagulate mode is now available using the BLUE Footswitch. A patient return pad must be in place [read return pad cautions]. When activated a tone will sound and the display will indicate Coagulate power delivery.
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Specifications

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EnSeal Tissue Sealing Mode - Pulsed, Quasi-Sinusoid, 480kHz, 45W +/-20% into a 75 Ohm load, 85 VRMS (Open Circuit), duty cycle intermittent; 15 seconds on 1 second off
Monopolar Cut Mode - Pure cut, Quasi-Sinusoid, 480kHz, 45W +/-20% into a 400 Ohm load, 323 VPeak (Open Circuit), duty cycle intermittent; 10 seconds on 30 seconds off
Monopolar Coag Mode - Pulsed, Quasi-Sinusoid, 480kHz, 50W +/-20% into a 400 Ohm load, 466 VPeak (Open Circuit), duty cycle intermittent; 10 seconds on 30 seconds off
Bipolar Cut Mode - Pure Cut, Quasi-Sinusoid, 480kHz, 40W +/-20% into a 400 Ohm load, 326 VPeak (Open Circuit), duty cycle intermittent; 10 seconds on 30 seconds off

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Protection
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Operating Conditions
Temperature: 32°F to 122°F (0°C to 50°C)
Relative Humidity: 30% to 75% non-condensing
Atmospheric Pressure: 86 kPa to 106 kPa
Whenever the temperature goes above 50°C or below 0°C RF power will not come on and the generator will report a fault until the temperature condition is met.

Storage Requirements
Temperature: -4°F to 140°F (-20°C to 60°C)
Relative Humidity: 30% to 75% non-condensing
Atmospheric Pressure: 86 kPa to 106 kPa

APPENDIX C: Conformance to Standards

The EnSeal Universal Energy Generator conforms to the following International Standards:

IEC60601-1, 2nd ed. Medical Electrical Equipment. Part 1: General Requirements for Safety
UL60601-1, 1st ed. Medical Electrical Equipment. Part 1: General Requirements for Safety
CSA C22.2 No.601.1-M90 Medical Electrical Equipment. Part 1: General Requirements for Safety
Collateral Standard: Electromagnetic Compatibility
IEC 60601-1-4 Medical Electrical Equipment General Requirements for Safety

UGEN02
ELECTRONIC DELIVERY USING

PLI form submitted

Does PLI form affect e-labeling?

Yes

Revised document is completed and approved

No

Complete update under normal process

Other E-labeling

Implementation timing determined

Document sent to Website Content Administrator

PLS informs appropriate resource of update

PLS logs implementation date

Website Content Administrator uploads document into system per implementation date