ABSTRACT

REPORT ON A MTSC INTERNSHIP AT A MEDICAL DEVICE COMPANY

by Laura Marie Cagley

This four-chapter report describes the work I completed as a technical writer intern at a medical device company during the spring of 2007. It provides an overview of the company organization; an overview of my role and the projects I worked on at the company; a detailed description of an instruction manual I created for a contracted on-site replacement and diagnostic service for a medical testing system as my major writing project; and an analysis of the internship experience that compares the expectations I had from my classroom training in technical communication and the reality of the job functions of a technical writer at a medical device company.

Author’s note: Due to the need for companies to protect classified, confidential, and/or proprietary information, product and company names in this report have been altered or excluded.
REPORT ON A MTSC INTERNSHIP AT A MEDICAL DEVICE COMPANY

An Internship Report

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DEDICATION AND ACKNOWLEDGEMENTS

As John Donne wrote, “No man is an island entire of itself.” As I complete my graduate degree, I understand that I did not get here alone. Without the support of some wonderful people in my life, this accomplishment would not have been possible. It is to those wonderful people that I dedicate my report.

To my parents, Allen and Carol, who have given me nothing but their unconditional love and support my entire life. I could not have been blessed with a better mama and papa. I appreciate all you have given me beyond words. You always taught me to do the very best I could, and I live that lesson every day. I love you so very much.

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And to my best friend and love, Michael Katzen, who offered his constant love and support to me through every panic attack and stressful moment I had while completing this report. Your motivational powers are unmatched. I love you dearly. Now let’s go find a gigantic frame for my diploma.
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Chapter 1 | Internship at a Medical Device Company

Introduction
I performed my internship at a medical device company, a subsidiary of a larger parent company, during the spring 2007 semester. The medical device company develops, markets, and manufactures minimally-invasive medical devices, specializing in designing medical devices for laparoscopic, breast care, and gastrointestinal procedures. Minimally-invasive surgery refers to surgery performed in ways other than through large “open” incisions in the body. The Food and Drug Administration (FDA) has three regulatory classifications for medical devices, which are assigned to a product based on the “level of control necessary to assure the safety and effectiveness of the device” (FDA.gov: Device Classification). This particular medical device company predominately designs and markets Class II medical devices, which are subject to special controls, including special labeling requirements.

Organizational Structure and Culture
The medical device company where I performed my internship has a dynamic organizational structure. The company operates independently and thus has its own organizational hierarchy (company president, vice president, etc.), yet the company is part of a larger corporation. As shown in Figure 1.1, the company president reports to the company group chair. The group chair reports to the parent company surgical care worldwide chair who reports to the parent company CEO.

Figure 1.1 | Organizational Link to Corporate Headquarters
The organizational culture of all the subsidiary companies is defined by the company’s guiding philosophy, which describes the company’s business responsibilities.

**Business Environment**

The company with which I performed my internship is exceptionally bureaucratic, with fixed business processes and defined paths through professional levels for communication hierarchies. With few exceptions, managers and employees follow the chain of command, sending communications through their management, who then will pass information to the next level as needed.

The working environment shows a mixture of business norms. The company is moving toward a more business casual work environment. “Jeans Friday,” a company-wide initiative allowing employees to wear denim jeans to work on Fridays was introduced during my internship. Even so, many employees, especially those who have worked with the company for several years, still wear formal business attire despite having relaxed dress code rules.

**Internship Job Description**

For my internship, I worked as a technical writer within the medical device company’s labeling unit department. As shown in Figure 1.2, the labeling unit department is a part of the operations department and is comprised of three groups: packaging engineering, sterilization science, and labeling. The labeling group consists of technical writers and graphic designers. The technical writer’s main role is to facilitate the creation of new and updated product inserts and instructions for use (IFU) in collaboration with a graphic designer and the Regulatory Affairs department to make sure the IFUs comply with all FDA guidelines for Class II devices. The technical writer is also the key contact for any translation work and the final proofing of the IFU.

*Figure 1.2 | Labeling Unit Department Organizational Structure*
Mentorship
My internship mentor was a technical writer at the medical device company. I had weekly one-on-one meetings with my mentor to discuss my projects, my progress, and my internship goals. For many of my projects, my mentor was the project initiator.

During my internship, I focused on three main technical writer tasks:
- Creating text for marketing-directed programs that contracted outside companies to perform equipment delivery or service functions,
- Designing the layout of instruction manuals, and
- Proofreading the final copy of an IFU (developed by Research and Development (R&D) personnel and medical personnel) prior to its release to the printer.

In addition to these technical writing tasks, I spent the majority of my time managing projects and directing them through the company’s document approval process. A breakdown of the time spent on these tasks is shown in Figure 1.3.

![Internship Technical Writer Tasks](image)

This report will highlight the major projects I completed during my internship and show how I applied principles of scientific and technical writing in the workplace.
Chapter 2 | Internship Projects

Introduction
During my seven-month internship, I worked on five major projects:

- Medical device system IFU and patient booklet
- Equipment service manual
- Equipment installation manual
- Contracted on-site replacement and diagnostic service manual
- Medical testing system consolidation manual

In this chapter, I briefly describe each of these major projects.

Project Background—Medical Device System
The FDA was evaluating a medical device system for sale in the United States at the time of my internship. The device had been available in Europe for several years (marketed under a different name). The labeling unit department needed to prepare the IFU for submission to the FDA and I was asked to join the team.

Medical Device System Initial Approval IFU and Patient Booklet
I joined the medical device system team to help create the IFU document in Adobe InDesign CS2 as the labeling unit department was converting from QuarkXPress to InDesign. The IFU document was created to guide surgeons through appropriate surgical techniques for the device. After I had placed the text and graphics into InDesign, I was asked by a technical writer to continue working on the project and help incorporate edits into the InDesign file. Due to the high-priority nature of this project to the company, the actual text of the IFU went through approximately 20 revisions (from marketing, regulatory, other subject matter experts, and the FDA) before final text was approved.

After the project received initial approval, the technical writer and I met with the marketing team. I was asked to copy edit the patient booklet (Appendix A). The patient booklet, which was produced by the marketing team, centered on the patient experience before, during, and after treatment with the product. The errors in the booklet were minor and included inconsistencies in the table of contents with actual headings, incorrect page numbers, and inconsistent use of serial commas. I met again with representatives from the marketing department to review my edits. The marketing lead on the project sent my edits to the design agency for incorporation into the document. The booklet underwent additional changes to reflect changes in the project scope. Since the booklet was printed after my internship ended, I was not able to review the final draft.

Project Background—Service Manual Update
The medical device company manufactures and markets devices for both laparoscopic and open surgical procedures. These devices are frequently used in plastic surgery, gynecological, and colorectal procedures. There are several unique devices available in the product line, each using a generator as the energy source.

Service Manual Update
The service manual update was assigned to me in late March 2007. The manual is used by
biomedical service personnel while troubleshooting and repairing system generators. It was originally a project assigned to my mentor in 2004, but little work had been completed on the requested revisions due to conflicting project priorities. The project was exceptionally challenging in that by the time it was assigned to me, three years’ worth of additional revisions had accumulated. The QuarkXPress file of the original document had also become partially corrupted, so no new work could be saved. The existing information had to be recreated into a new Quark file before any edits could be made.

I worked primarily with two reviewers, a staff engineer who was the project initiator, and a principle design engineer. This project showed me the difficulty of working with teams that have larger, high-profile projects in their queue because I had to overcome a general lack of focus on the project caused by team members’ busy schedules. I would often need to schedule working meetings with the team, as I found people would show up to scheduled meetings without having read any of the materials I had sent out in advance. In the working meeting format, I would have the team members read the manual page by page together so that I could capture all the required revisions and formatting changes.

Many parts of the manual needed to be revised. I divided the revisions up into two types: minor revisions that I could resolve myself and major revisions that would require input from the larger team before incorporating them into the final text. The minor and major revisions were as follows:

**Minor Revisions**
- Reformatted Table of Contents with correct page numbers added
- Made headings in Table of Contents consistent with headings used in manual
- Added new warning and precaution statements
- Added new part numbers in service section

**Major Revisions**
- Recreated front and back panel diagrams due to QuarkXPress file corruption
- Reorganized troubleshooting chapter content
- Created worksheets for service engineers

The manual was scheduled to print after my internship ended. I provided the updated files to my mentor so the project could be completed.

**Project Background—Medical Testing System**
Three projects, the equipment installation manual, the contracted on-site replacement and diagnostic service manual, and the consolidation manual, all involved a medical testing system. The medical testing system is a device designed to conduct minimally invasive medical tests under various imaging forms. A physician uses a probe to collect samples. The device is considered minimally invasive because the probe leaves only a 0.25 inch incision at the testing site.
The system works by using different imaging methods to detect abnormalities or lumps. It can be purchased in four different platforms or versions. While each system consists of a computer and a cart, each version differs slightly in software, design, technique, and peripheral devices.

System Equipment Installation Manual

The company had recently contracted a moving company to deliver and install the medical testing system cart and equipment in hospitals and clinics. The equipment installation manual was comprised of two deliverables, an instruction manual and an installation checklist. The documents were created for employees of a moving company to use during all steps of the installation process and described proper handling, setup instructions, and safety information.

The students enrolled in the Fall 2006 Introduction to Technical and Scientific Communication course (ENG 692) from Miami University’s Master of Technical and Scientific Communication (MTSC) program became involved in the equipment installation manual project as a course assignment. These students worked with my mentor under Dr. Jean Lutz’s direction to create the instruction manual. At the start of my internship, I was briefed on the equipment installation manual project initiative. I was given the student paper selected by my mentor and other labeling unit department employees to use as a template, along with a list of items to include in the checklist. The student paper was a Microsoft Word file, so my first task was to move the document into Adobe InDesign CS2 to have more flexibility and control over the manual design. I then began editing the text for accuracy and consistency by using the student-created instructions with the system equipment.

Within the labeling unit department, I had to work closely with my mentor to learn the protocol and document approval process. I also worked with a graphic designer to coordinate the creation of several illustrations for the instruction booklet in Adobe Illustrator CS2. Outside of my department, I worked closely with a breast care sales training manager to resolve manual content issues, such as the orientation of the shipping box and its contents, and with a safety manager, who had arranged the installation contract with the moving company.

The instruction manual and checklist would not be included with the medical testing system packaging; therefore, these deliverables needed to follow a different process than what is usually followed with documents that go through the labeling unit department. As shown in Figures 2.1 and 2.2, the protocol process has more involvement from the technical writer than the Bill of Materials (BOM) process because, in addition to the official approval form, two other documents need to be created and approved by the review committee: the protocol approval form and the completion report.

Protocol Approval Form

The protocol approval form describes the purpose and scope of the new document, how and under what company guidelines it will be created, and how it will be tested for accuracy. A cross-functional team of employees (e.g. quality engineers, lawyers, regulatory affairs partners, etc.,) review and approve this protocol. My mentor provided me with examples of past protocol forms and helped me create the text for the form we would use.
**Official Approval Form**

Once the protocol was approved, the final draft of the instruction booklet and checklist were sent along with the official approval form to those employees who needed to review and approve the content. The official approval form lists the required reviewers for approval as well as each functional area’s review responsibilities. If the document is approved, the reviewer signs the official approval form and returns it to the technical writer. If the document is not approved, the reviewer will send needed revisions back to the technical writer and the official approval review process will be repeated.

**Completion Report**

After I had received official approval via the review process on the instruction manual and checklist content, My mentor and I made arrangements (as stated in the protocol) to print 50 copies of both documents at the company’s print center and inspect each copy for legibility, page order, and any other pagination errors. After this task was completed, I began finalizing the completion report.

The completion report is sent to the same people who receive the protocol approval document. The completion report is intended to verify that document creation was carried out in the manner stated in the protocol form. To create the completion report, my mentor gave me an example of a past completion report, but I produced all the text for this new form.
Figure 2.1 | Protocol Document Approval Process Workflow
Figure 2.2 | BOM Document Approval Process Workflow
Contracted On-site Replacement and Diagnostic Service Manual

My second project was to create an instruction booklet and checklist for contracted on-site replacement and diagnostic service representatives who provide services for medical testing systems. When equipment malfunctions, a representative brings temporary, or “on-loan,” equipment to the customer so that there is no interruption in system use while the customer’s unit is being repaired.

The representatives needed to be able to unpack and install loaner equipment and remove and ship the customer unit back to the medical device company for repair. The representatives then needed to be able to perform a diagnostic check on the loaner equipment to ensure functionality. The representative would need to repeat this procedure when returning with the serviced customer unit.

The previous version of the manual being used for this program only included information for a diagnostic check on one of the system versions. A new manual needed to be created to include the other three system versions as well.

I used much of the information I learned from preparing the equipment installation manual for the biopsy system to write effective documentation for unpacking and installing the equipment. I met with a medical testing system sales representative to go over the differences in each of the system versions to make sure my steps and system response information was accurate. To make the documents look like members of the same document family, I incorporated design features from a checklist currently being used by the contracted representatives. I also created two flow charts to outline the service procedure for the representatives.

Rather than make the representatives carry the instruction manual for each system version, the manual would act as a single-sourcing project that would bring together a lot of information about the different system versions into one document. While much of the instructional text for each version is the same, the reader would need to be shown the differences clearly. To help create a uniform document, I created a style sheet for the manual. The style sheet included sizing for images, a verb guide (e.g. press for physical buttons, push for on-screen buttons; and select for decision buttons), and consistent spacing.

I wrote the protocol approval page form for the manual and electronically delivered that form and an official approval form to all recipients on February 8. All necessary signatures were received on February 22. After making the suggested changes from my reviewers and receiving final approval on the official approval form, I had 100 copies of the manual produced at the company’s print center. I inspected each copy for any production or pagination errors and then wrote the completion report. The manual client then asked to have an additional 200 copies made, which required a new production protocol/completion report signature process. I wrote both the documents and sent them electronically to the necessary reviewers. After signatures were collected, I repeated the same process of production and inspection as I did for the first 100 copies.

Medical Testing System Consolidation Manual

The third project of my internship was to compile all the medical testing system user manuals
into one consolidated source. This undertaking was the largest project I worked on during my internship. While much of the information in the manuals for different product versions is very similar, some is platform specific. Early releases of the system included separate manuals for software, probes, and hardware setup. The push for a consolidated user manual came from the BOM department because a consolidated manual reduced complexity within the supply chain. With a consolidated manual, only one document would need to be printed and packaged, and the consolidated manual would remove the need to track multiple documents.

Working closely with my mentor, I put together a consolidated user manual that contained all the similar information for each platform as well as all of the essential information to guide a user through operating each system platform. My mentor provided hand-written mock-ups of the first three chapters as well as the troubleshooting chapter in a Word document to include in the manual. I compiled the rest of the information to build the remaining nine chapters and appendices.

The graphics for the manual were taken from previously published manuals and were formatted using Adobe Illustrator CS2.

Since the manual was going to be listed by BOM for distribution into the medical testing system’s packaging, the normal document approval process was followed. After I received the completed official approval form with all required signatures, the manual was then moved into the translation phase.

The approved English document needed to be translated into the 16 languages that the medical device company supports, including French, German, Dutch, Italian, Portuguese, Spanish, and Greek. The contracted translation house required the file to be formatted according to their specifications, which included intensive use of paragraph styles, character styles, and auto bullets/numbering. The translation process took approximately six weeks to complete. The final English portion of the manual (excluding front and back matter) consisted of 12 chapters and three appendices, each approximately 12 pages in length.

To complete the project, the graphic designer readied the files for pre-flight before sending them to the printer. The pre-flight process helps reduce problems in the document printing process that can cause production delays. The graphic designer verifies the materials included in the manual meet production requirements, such as:

- fonts are accessible and not corrupt
- required color profiles are included
- embedded images and graphics are available and not corrupt
- image files are not corrupt
- page layout, document size, margins, bleeds, marks and page information all fit within printer specifications

**Educational Experience**

While I was able to use at least some part of my MTSC education on all of the above projects, the contracted on-site replacement and diagnostic service manual project was the only project that incorporated all of my technical communication skills and helped in my development as a
technical communicator. Chapter 3 takes an in-depth look at that project and the steps involved from project initiation to completion.

Introduction
The contracted on-site replacement and diagnostic service manual project was the second project assigned to me during my internship, and one of the more intricate projects I have worked on as a technical writer. This manual project allowed me to use and develop the following technical writing skills:

- Problem solving
- Instruction writing
- Editing
- Page layout/design
- Graphic development

Project Background
The medical device company wanted to launch a medical testing system equipment repair service in February 2007 and had contracted service representatives to pick up equipment requiring service. The contracted service representatives would also replace the customer’s equipment with a loaned unit for the length of the service period and verify the operability of the loaned unit at installation. Following repair of the customer’s equipment, the service representative would return to the customer, disconnect the loaner unit and install the customer’s repaired equipment. The service representative would then verify the operability of the repaired unit and return the loaner equipment to the loaner pool provided by the company.

I was assigned the task of developing an instruction booklet and installation verification checklist for the contracted service providers to ensure a quick and error-free installation of the on-loan equipment for all versions of the system.

The representatives needed to be able to complete three tasks:

- remove and ship the defective customer unit for service,
- unpack and install the on-loan equipment, and then
- perform a diagnostic check on the on-loan equipment to ensure proper functionality.

The representative would need to repeat this procedure when returning with the serviced customer unit.

Initial Planning
Before I began the creation of an updated instruction manual, I needed to learn more about the program and the manual’s target audience. I began the assignment by contacting a medical device technician and program coordinator to find out the details of the level of service being provided by the contracted representatives and collect any documentation currently being used. I learned that a pilot of the service program was conducted with customers in 2006 for two system platforms and that the other two platforms were going to be added to the 2007 program launch.

The medical device technician needed a manual that was a comprehensive guide that included all system versions as well as an accompanying installation verification checklist, to be used by the service representative to make sure no step in the process was missed before leaving the customer.
I was given the manual used for the 2006 pilot, which was eight pages long and included 13 images (two photographs and 11 screen captures). I was also given a copy of the medical device company’s Customer Support Product Return Flowchart, which was distributed to the service providers, to help me understand the overall process.

There were several reasons why the manual needed to be updated before the program launch:

- images were of poor quality and would not reproduce well,
- instructional steps did not adhere to accepted technical writing practices and standards,
- instructions for the version system checks referred the reader to the equipment operator’s manual, creating the need to distribute and reference a second document, and
- the manual also lacked equipment descriptions and cautionary statements.

As I began creating the manual, my overall strategy was to reuse as much information as possible from previously completed projects.

**Document Creation**

To implement my strategy, I compiled all the information I had available and noted the information I would need to move forward with the project. I referred back to many previously created documents to begin drafting the manual. Instructions for unpacking and hardware setup for the medical testing system could be pulled from the equipment installation manual I had created in my first internship assignment. Descriptions of the equipment and holster connection instructions could be found in the individual platform’s operation manuals.

An extensive portion of the manual centered on the functionality of the equipment. In order to write instructions to guide a user through a diagnostic test of each system version, I would need to learn the following information:

- how each version works,
- how each version differs from another (screens/system functions), and
- how users interact with the system interface.

To gain this information, I would need to consult a subject matter expert. I contacted a medical testing system sales representative to set up one-on-one training. The sales representative walked me through the use of each version and I took notes on the software interface and listed the screens the system would show before and after completing a step. I made sure to document the sales representative’s interaction with the software, recording where she would press a button on the screen or on the physical equipment.

The sales representative also invited me to attend two sales training workshops held for new hires in the sales department. These workshops focused on performing breast biopsies with the system. In this setting, I was able to watch a group of new sales employees interact with the system interface. This interaction allowed me to gauge the audience’s needs and see what portions of the interface were intuitive and which were confusing and needed more clarification to perform correctly.

**Page Design and Layout**

The contracted service representatives would be interacting with the medical testing system
equipment and software while using the manual. The layout of the manual proved to be challenging because it had to contain a large amount of information but needed to be structured to ensure usability. My key goal in creating the page layout for the manual was to minimize the user’s need to turn pages. This type of layout would help the user find his or her place as quickly and easily as possible since the user would be shifting his or her attention between reading and doing.

Before formally writing the instructional steps, I outlined the information that was common to all four versions. The information that was unique to a version was placed in order of the most common version first. Using the flow charts, I put together a draft document that outlined what information the chapters would need to contain as well as the order in which the chapters should appear. I needed to select a layout that not only provided enough room to make the graphics large enough to be easily readable and reproducible but that also provided room to have enough information on a page so that users would not have to be constantly turning pages. My early drafts tried to implement a horizontal/landscape page design, but I did not feel that the layout allowed enough room for text/graphics on a page. In order to display an appropriate amount of information on a page, I changed to a vertical layout with two columns, one for text and the other for graphics.

**Instructional Text**

I wrote the text of the instruction manual following Paul Anderson’s superstructure for instructional documents. As shown in Anderson’s *Technical Communication: A Reader-Centered Approach* (644-5), the conventional superstructure for instructional documents contains the following elements:

- Introduction
- Description of equipment
- List of materials and equipment needed
- Directions
- Troubleshooting

To keep with company style conventions, I moved the troubleshooting information into the introductory material. In my introduction, I outlined the aim of the document and introduced the verification checklist as supplemental material. I included descriptions of the equipment and the vacuum canister, as they are the most complex items the service representative would need to use. I did not describe the cart, as its parts are minimal, and the user’s interaction with the cart could be described within the body of the instructions. No additional tools were needed to perform the tasks described in the instructions. The table of contents was placed on the cover of the document to eliminate extraneous pages from the manual as well as give the user a quick place of reference. To ensure that the reader will not skip ahead, the introduction to each section cross-referenced the previous task that needed to be performed before starting the current section.

The instructions all begin with action verbs for a clear, concise writing style and immediately tell the reader what action they will be performing. For further clarity, I created a style guide for verbs and conventions within the document. The style guide set standard sizing for images, a
verb guide (e.g. *press* for physical buttons, *push* for on-screen buttons; and *select* for decision buttons), and consistent spacing. I used two conventions throughout the document:

- caution statements containing safety information for the user appeared in a box to help them stand out from the text
- notes were distinguishable by appearance and displayed below the step to which they add additional information

After writing the sections that contained information relevant to all four versions, I included a step that sent users to a page with version-specific steps. This format allowed me to save room on a page and avoid repeating information.

**Graphics**

The manual contained three types of graphics: line drawings, photographs, and screen captures. The combination of graphics allowed me to guide the reader through many different tasks and display relevant information in a concise, easy to follow format.

**Line Drawings**

Line drawings were used for the equipment description portion and the unpacking the equipment portions due to their clean look and simplicity. They also would retain their readability after reproducing the manual in black and white. Since the information was the same, I used drawings from the unpacking section of the equipment installation manual; the description of equipment drawings were taken from the system operator’s manual. The line drawings were particularly useful during the unpacking segment because the drawings could easily be augmented by adding arrows to show the correct box orientation.

**Photographs**

Only one photograph was used in the manual because I was concerned with image clarity after reproducing the manual in black and white. The photo was used in the unpacking segment where the reader must unpack the equipment from its shipping container. I used the photograph here because it clearly showed the styrofoam packaging the equipment is shipped in and the proper way to remove it without damaging the unit.

**Screen Captures**

To obtain the screen captures I needed, I worked with a system sales representative to create a list of the screenshots that I would most like to incorporate into the design. I then asked my mentor for the discs that came with the system’s CD-ROM manual and pulled what I needed from that. Some images were only available in certain versions, even though nothing else differed on the screen. For these screens, I used Adobe Photoshop to create screens that matched the version. In addition to incorporating the full screenshots, I also created close ups of the icons the reader would need to press on screen. All the screenshots were converted to gray scale to help them retain readability after printing.

**Document Testing**

Once the draft was complete with all steps and graphics, I went back to the lab and a sales representative and I walked through my instructions to make sure I was not missing any steps and that the flow was correct for all versions. While there was not enough time for a full
usability test, I felt that even this limited walk through was beneficial to my final product. The sales representative and I found a few steps where additional information or the use of a graphic would make the instructions clearer.

**Document Approval**
I wrote the protocol approval page form for the manual and electronically delivered the form and the official approval form to all reviewers (Regulatory Affairs, Quality Engineering, Sales, labeling unit department, and project sponsor) on February 8. I received all feedback on the documents on February 22. After making the suggested changes from my reviewers and receiving final official approval form approval, I had 100 copies of the manual produced at the medical device company’s print center. I inspected each copy for any production or pagination errors and then wrote the completion report.

The client then asked to have an additional 200 copies, which required a new production protocol/completion report signature process. I wrote both the documents and sent them electronically to the necessary reviewers. After signatures were collected, I repeated the same process of production and inspection as I did for the first 100 copies.

While the contracted on-site replacement and diagnostic service manual gave me an opportunity to grow as a technical communicator, I learned that projects like these are rare at this medical device company. The main function of the technical writer role within the labeling unit department is to act as a project manager for IFU projects. Chapter 4 discusses how my activities as a project manager initially conflicted with my internship expectations.
Chapter 4 | The Technical Communicator in a Highly Regulated Field

Introduction

Michael Hughes characterizes technical writers as “professionals [who] take technical information and make it understandable to those that need it” (275-85). As a student of technical writing, I thought my internship would focus on the “information bridge” role between SMEs and the target audience. Given the importance of writing and the types of projects I completed during my MTSC coursework, I went into my internship with the assumption that the projects I would complete in the workplace would concentrate on the use and development of the following abilities of a technical writer:

- interacting with SMEs
- writing and editing text
- designing documents

The importance of this role as information bridge was implicitly acknowledged by my internship mentor and supervisor as they constructed assignments that would help to develop my technical writing abilities. The medical device company where I interned, however, does not utilize the technical writer in this way. While the projects discussed previously in this report did allow me to develop these technical writing bridge skills, the reality for the company was that had the labeling unit department not had a MTSC intern, the equipment installation manual and the equipment service manual projects most likely would have been outsourced and created by an agency.

As I progressed in my internship and began to take on the IFU documentation projects that the full-time technical writers were assigned, I found that the definition of “technical writer” as bridge between novice and expert that I practiced in my class projects only partially represented the scope of work a technical writer can perform. The technical writers at the company normally do not engage in any writing activities, per se, in creation of a product IFU document because FDA regulations govern the verbiage and layout of IFU documents, also minimizing the need for document design skills. As a result, the technical writer acts as a project manager and guides documents through the review and language translation process.

The everyday role of the technical writer differed greatly from my internship expectations and for a long time I struggled to see the how these project management “soft skills” would help me grow as a technical communicator.

The last project I worked on during my internship was a clear example of this shift to a project management role. I was assigned to update a medical stapling device IFU after a manufacturing defect was discovered. Our Regulatory Affairs department reviewed the product’s IFU and decided to update the device firing instructions to help prevent future misuse of the instrument. Updating the IFU put me into the more typical role of the technical writer at the medical device company, and due to the strict FDA regulations regarding the manufacture and documentation for medical devices, my experiences during this part of the internship differed from the information bridge role of the technical writer that Hughes and others describe.
Using the medical stapling device IFU update project as an example, this chapter explores the reasons why I believe the technical writing role where I interned has taken on project management responsibilities and how this transition from information bridge to project manager can be considered a natural career progression for technical writers.

Revising the IFU: The Technical Writer as Project Manager
After the Regulatory Affairs department identified an issue with the device IFU, the labeling unit department was brought into the project to update the IFU. I worked with a technical writer to update the IFU. We first met with our regulatory affairs contact, to discuss the scope of the changes and set timing to complete the update to the English section of the IFU for review.

My job was to keep the labeling portion of the overall project on track and facilitate the meetings between Regulatory Affairs and R&D, who both give final approval on the instructional verbiage and graphics used in the IFU. While I began to learn about regulation standards, the general nuance of surgical procedures, and the overall “lingo” of the profession during the project, I could never attain the level of skill a surgeon has to truly be the knowledge “gatekeeper.”

As I previously mentioned, the medical device IFU genre creates a shift in the role the technical communicator must play. The audience for the IFU is surgeons, doctors, and nurses, all of whom have more knowledge on surgical procedures and devices than the writer. Surgeons are both key SMEs in IFU development and the primary target audience for new products, thus the audience is in many ways equivalent to the information source. The idea of the technical writer as the bridge of knowledge from SME to audience applies less accurately in this context.

The actual text of the IFU is team-written by highly skilled professionals who are actively involved with the documentation process and responsible for approvals. The text is merely provided to the technical writer on the product team for layout into the document template. The technical writer then has to get final approvals from the other members of the product team (regulatory affairs, marketing, etc.) and then order translations of the approved text. In this situation, the technical writer predominately fills the role of project manager rather than knowledge creator.

I believe the medical device company where I interned has constructed the role in this way for two reasons:

- to reduce company liability for any surgical malpractice caused by errors or misunderstandings of the IFU verbiage, and
- to account for the gap in medical and surgical knowledge between the technical writer and the SMEs.

I explain both of these reasons in the following sections.

FDA Regulations and Legal Implications
The FDA defines medical devices as “articles intended to affect the structure or any function of the body without achieving its principal intended purpose through chemical action in or on the body and is not dependent on being metabolized” (Federal Food, Drug, and Cosmetics Act). There are three FDA regulatory classifications of medical devices: Class I, Class II and Class III devices. The risk the medical device presents to the patient and the level of regulatory control
needed to legally market the device determines the classification. Accessories to medical devices, devices used with a medical device to support use of the device, are considered the same classification as the medical device (FDA.gov:Regulatory Information).

Legal Scrutiny of Technical Documentation
The potential negative exposure to any company during a product recall is enormous, both financially and publicly. As reported in September 2004, Merck voluntarily recalled their arthritis drug Vioxx after medical studies showed an “increased risk of cardiovascular complications” from its use (Eustice). After the recall, Merck’s stock price fell 40% and Merck eventually settled a 3-year lawsuit that included multiple plaintiffs for $4.85 billion (Smith). Events such as these cause more than just monetary damages. No healthcare company wants to see its public image tarnished and turned from healer to killer overnight. To reduce this risk, companies such as the medical device company put processes in place that protect them from potential liabilities, which John Caher explains in three theories regarding liability (5-10):

- Contract-binding agreement to perform or provide a service,
- Due Care-a manufacturer knows more about a product the consumer and therefore has a weightier responsibility, and
- Strict Liability- manufacturer or employer can be held responsible for damages regardless of fault.

An injured person can proceed against any or all persons who had a hand in placing the product into the stream of commerce. A defect in a product may consist of a faulty design or the absence and/or inadequacy of warnings for the use of the product (Pieper T-107).

Thus, courts have determined the technical writer has a responsibility in the documentation and shares a part in liability. As Caher explains, “unsatisfied to merely scrutinize the package inserts from arm’s length, the panel dissected the work of the technical writer and considered at the micro and macro levels not only what was said but what may have been implied or suggested in whole and in part” (5-10). If courts can find fault with the technical writer’s work, it is understandable to see why a company such as a medical device company would commit the creation of the highly sensitive material contained in the IFU to those with medical backgrounds and the same specialized experience as readers. While this practice does not remove the medical device company from potentially being found liable for damages, having trained medical professionals crafting the language used in the IFU documentation does mitigate some of the risk.

Reconsidering the Bridge Role in Technical Communication
Technical writing has found its way into numerous workplaces due to the ability of the writer to act as a bridge between highly technical information and lay audiences, explaining highly specialized technical information into language that is easy to understand.

So common is this bridge role that the Occupational Outlook Handbook describes the ability of the technical communicator to collaborate and interact with subject matter experts (SMEs) as key to preparing “written interpretations of technical information for a general readership” (United States Department of Labor). In its definition, the Society for Technical Communication also focuses on the technical communicator as one who has an “ability to communicate information
in a clear and usable way to different groups, from consumers to end users. Technical communicators have the crucial job to plan, design, organize, write, edit, and test information” (Society for Technical Communication: Telling Our Powerful Story). Based on these definitions, we might conclude that in the workplace, SME Knowledge is greater than Technical Communicator Knowledge, and both are greater than the Target Audience Knowledge as shown in Figure 4.1 below.

**Figure 4.1** | SME Knowledge > Technical Communicator Knowledge > Target Audience Knowledge

This construct of the technical communicator can readily be applied to businesses where the technical communicator role acts as an intermediary between SMEs and the public. If we look at a software firm, for example, the technical information is created by software developers who are highly-trained and specialized employees. The information they create must be used and understood by end users whose technical abilities and computer skills widely vary. The technical communicator in this example has less knowledge than the software developer, but more knowledge than the average end user. This knowledge allows the technical communicator to take the technical information and translate it into instructional documents, an online help system, etc. Thus Software Developer knowledge is greater than Technical Communicator knowledge and both are greater than the Target Audience knowledge in this example, as shown in Figure 4.2.
As students in the MTSC program we practiced this model in the Fall 2005 Introduction to Technical and Scientific Communication course (ENG 692). We were assigned to create a Deep Vein Thrombosis (DVT) brochure for McCullough Hyde Hospital in Oxford, Ohio. The brochure would be distributed in the hospital to patients. Each student took a large amount of highly technical information about DVT from various technical sources and was able to edit and format it down into a single document that the general public could understand. While we studied a broad array of theories on technical communication, we practiced and applied the bridge model.

The **SME > Technical Communicator > Audience** model relies on two constants:

- the SME who creates the material has more specialized knowledge than the end user (expert knowledge > public knowledge)
- the technical communicator has more specialized knowledge than the end user, but less specialized knowledge than the SME

In a highly-regulated medical field, such as at a medical device company, the SMEs (staff doctors and surgeons) who create the technical information and the audience (doctors, surgeons, and surgical nurses) share approximately the same level of medical and surgical knowledge. In this situation, the balance shifts as shown in Figure 4.3: Expert Knowledge is equal to and shared by the Target Audience Knowledge and both are greater than the Technical Communicator knowledge.

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**Figure 4.2** | Software Developer Knowledge > Technical Communicator Knowledge > Target Audience Knowledge
Instead of content knowledge, the technical writer’s main value within the department is to gain depth of understanding of the IFU genre, or as Anne Beaufort calls it, the “accumulation of experience within the discourse community” (133-7). Beaufort goes on to suggest that mastery of the genre, as described in her “Learning Curve for Genre Acquisition” (Figure 4.4), is gained through full participation in the discourse community in which it is used and that the technical writer’s personal involvement within a community enables understanding of that community’s values and goals. While involvement within the “discourse community” often would allow the technical writer to manipulate aspects of the text for rhetorical effect, in my internship the role lends itself instead to the development of basic project management skills. Here, a technical writer at the medical device company may eventually learn certain terminology used by the SME and target audience, but can never add medical expertise knowledge to the documents produced by the group.
Benefits of the Technical Communicator as Project Manager

Adapting to a project management role after expecting my internship to fit the bridge model of technical communication was initially frustrating. Now that I am farther along in my career, I can understand how the project management skills I acquired at my internship made me a more valuable employee and will help me in my future career aspirations. My exposure to project management during my internship allowed me to gain or improve the following skills:

- cross functional team leadership
- process improvement identification
- proactive communication practices

I believe that one of the advantages to the technical communication role is the ability to fill a multitude of needs based on the nature of the business and these project management skills are easily transferable to several different careers.

Cross Functional Team Leadership

The greatest problem I had initially with the project management role is that it felt as though there was very little that I was actually responsible for delivering and that most of my time was spent waiting on information from other functional partners. Over time, I learned that the project manager is seen as the project team leader and as such is responsible for delivering against the timeline. Leading a project team requires excellent communication and organizational skills and the ability to influence and constructively challenge cross-functional team members to achieve the project goals within the approved process.

Process Improvement Identification

As the team leader, the project manager identifies process gaps and keeps the project on schedule. At the medical device company, many technical writers chose to allow the review team to perform an individual review of the IFU material. I used this method once and found many members of the team unresponsive and not providing feedback by the due date I had communicated. I also found that it took longer to resolve questions that one reviewer would have because I would have to contact a different review member for the answer. I decided to facilitate
a review meeting for future projects because it brought the entire team together at one time to
discuss IFU content. In her book *Information Development: Managing Your Documentation
Projects, Portfolio, and People*, JoAnn Hackos states that review meetings are more effective at
resolving problems than independent reviews “because other reviewers get to hear what other
reviewers have to say about the content” (521). Rather than leaving the project manager to search
for information, the review meeting allows for immediate discussion with the SMEs for
resolution.

The project manager also maintains performance metrics, which are then used to improve the
efficiency of processes moving forward. As a project manager in my current job, I conduct a
“Lessons Learned” meeting after each major project I complete to identify areas where the
project team excelled and address issues that negatively impacted the project and work with
management to implement solutions prior to starting the next project.

**Proactive Communication Practices**
Clear communication is important to the success of a project. As the timeline owner, the project
manager ultimately holds team members accountable for their individual roles and
responsibilities. Each member of the team is vital to the success of the project and must work
together toward the goal. Project managers need to facilitate productive meetings by, as Hackos
writes, “ensuring that disagreements about the content are resolved either on the spot or soon
afterward, taking responsibility for action items to resolve questions” (521). The project manager
must keep a constant flow of communication throughout the project.

**Conclusion**
The medical stapling device IFU project example demonstrates that while the technical writer
works closely with SMEs, the content in the IFU for medical devices places too much legal
liability on the technical writer, preventing him or her from assuming a knowledge gatekeeper
role. In this situation, the technical communicator makes a natural transition to project
management. One consequence of this transition is specialization: a project manager uses less
knowledge and fewer skills than the wide range we acquired as students in the MTSC program.
Because acting as a project manager fulltime does not allow me to utilize all of the skills that I
feel I excel at as a technical communicator, I proactively search for projects that allow me use
the different parts of my technical communication abilities in the workplace. Through my work
experience, I have learned it is the responsibility of the individual technical communicator to
utilize the wide spectrum of skills the role provides and resist the pressure to be typecast into one
function.
References


FDA.gov: Device Classification. 18 June 2009 <http://www.fda.gov>. Path: Medical Devices; Device Classification


Appendix A
System Patient Brochure Sample Page with Edits