Running head: FENDLEY LABELING ARCHITECTURE

The Impact of Labeling Architecture on Document Translation in a Regulated Medical Device Company

Ann Elizabeth Fendley

University of Minnesota

Abstract

This study explored the impact of labeling architecture on document translation within a regulated medical device company. Labeling, as defined by the Food and Drug Administration (FDA), is "any written, electronic, or graphic communication on the package or on a separate but associated label" (http://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/ March 2016). Labeling is a key deliverable, and many countries require that it be in the local language. Audiences for labeling include patients and clinicians. Labeling architecture refers to the ways in which the components of labeling content are organized for use and reuse. In the organization I studied, the Labeling Department produces an English document source first, and then it sends this to an in house Translation Department prior to release to the public. Medical device companies need to deliver all of this in a useful and economical manner in order to meet client needs and remain competitive in the marketplace. This study utilized unstructured interviews of technical communicators to learn about the current state of labeling architecture within one department at one medical device company, and how the architecture affects the translation of its documents. Recommendations are discussed including studying and perhaps expanding the labeling re-architecture, creating avenues for regular communication between the Labeling and Translation departments, increasing the consistency of Global English training for Technical Writers, and emphasizing the importance of cultural intelligence across departments.

Introduction

The challenges of a regulated medical device company that conducts business on a multinational basis include meeting the translation needs of its users, fulfilling the regulatory requirements for each nation where it does business, and completing these tasks in the most useful and economical ways possible. I explored the current state of labeling architecture and translation with respect to these issues within in a regulated medical device company, and I will discuss recommendations for the future. This project builds upon the work of Frush (2015) that addressed possible benefits of labeling architecture in a regulated medical device company.

The web of regulations that must be met by a global medical device company is a complex one. A medical device must meet the regulatory requirements for each country in which it is sold. The Food and Drug Administration (FDA) must approve medical device labeling for all medical devices sold in the United States. In regards to the medical device industry, "labeling" is different than what most of us think when we hear the word. The FDA defines labeling as "written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article at any time while a device is held for sale after shipment or delivery for shipment in interstate commerce." (http://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/ March 2016). The FDA interprets "accompanying" broadly. Published materials including technical manuals, user guides, device labels, written warranties, and advertising are all considered to be labeling. In his article which was aptly titled "Fit the Manual on a Sticker," Dan Goldstein said that labeling "means everything that the manufacturer has ever said about the device, including advertising, promotional coffee mugs, and (wake up tech writers!) user manuals" (Goldstein, 2015).

A medical device company must meet all regulatory requirements for each country in which it sells its products. For this study, I will confine this to a brief overview of regulatory bodies in the United States, the European Union (EU), and Japan.

Regulations for the safety and performance of medical devices were harmonized in the EU in the 1990s (http;//ed.europa.edu/growth/sectors/medical-devices/regulatory-framework/index_en.htm). The core framework consists of three directives: the Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) (1990), the Council Directive 93/42/EEC on Medical Devices (MDD) (1993), and the Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDMD) (1998). These directives have been amended over time. Although the details of the directives are beyond the scope of this study, taken together they create a framework of regulation that addresses the 28 countries in the EU.

Medical devices that are sold in the EU and some other specific countries outside of the United States must have a "CE Mark". This is a certification that verifies that a device meets all regulatory requirements of the three directives as they apply to the specific product, as well as complying with various other standards. The medical device company that places the product or equipment on the market is responsible for ensuring that all applicable directives are complied with and that the device is properly marked. The TÜV SÜD, an international service corporation, is one organization that assists medical device companies in demonstrating that their products comply with the directives by offering testing and certification in line with these requirements.

Japan's medical device regulation differs significantly from both requirements in the U.S. and the EU. It is based on Japanese medical device nomenclature codes. In 2014, the Japanese put into effect "Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics"

(abbreviated the PMD Act). Administration and oversight of the PMD Act is the responsibility of Japan's Ministry of Health, Labor, and Welfare (MHLW). The TÜV SÜD Japan is registered by the MHLW and provides marketing certification processes to medical device companies ("TUV SUD America Website,", www.tuv-sud-america.com, March 2016).

Labeling Architecture:

All labeling and documentation have architecture (even when that architecture is simply one monolithic document). Some labeling architecture organizes documents by modules of information. It splits the information needed across different labeling pieces based on specific criteria. As Frush (2015) states with respect to this type of labeling architecture, "Labeling architecture is beneficial to a medical device company for a number of reasons." She lists them as:

- Limits the number of times a manual needs to be updated
- Quarantines changes to one manual or another depending on changes made to the device
- Promotes content reuse, crucial for effective technical writing
- Limits human error
- Reduces costs

For this study, I will share an example of one type of product, deep brain stimulation for movement disorders, for which the labeling department in this business unit creates documents. Prior to the labeling re-architecture of 2005, the physician's manual contained 18 separate topics of information. After the labeling re-architecture was applied, these 18 topics were separated into 6 different documents. When information needed to be updated before the labeling re-architecture, the entire manual would need to be updated. Afterwards, a smaller piece of information could be updated, and the rest of the pieces could remain unchanged.

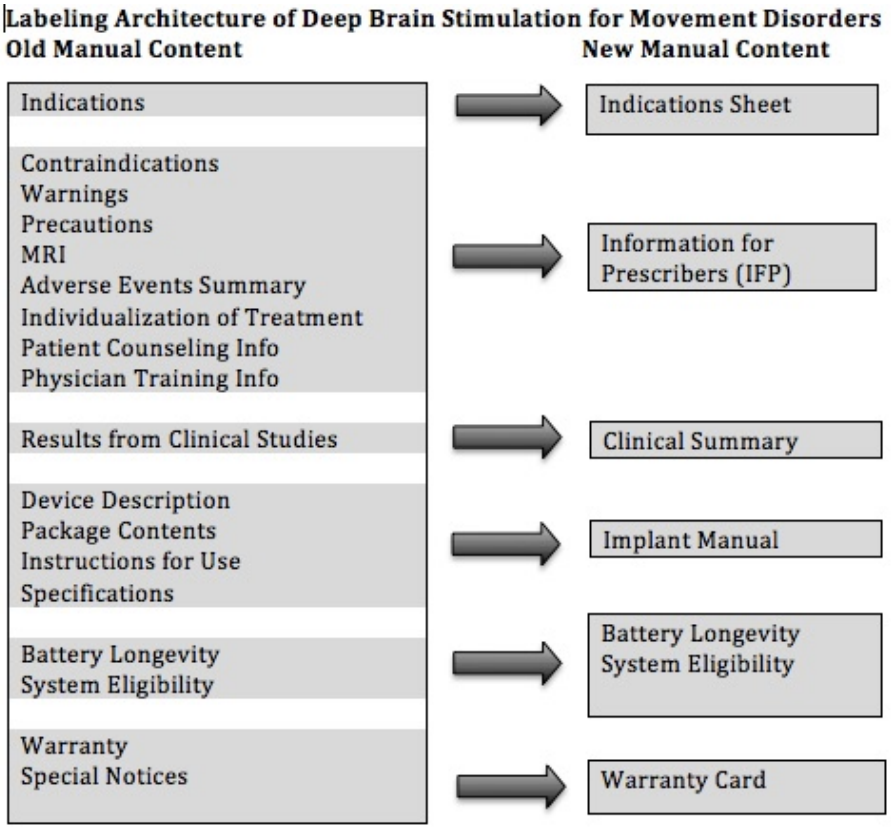

Figure 1. Example of Labeling Architecture and Re-architecture

Because of the technical nature of this example, I have included a glossary of terms below:

Table 1. Glossary of Terms for Deep Brain Stimulation System for Movement Disorders

Component	An individual piece of the deep brain stimulation system (e.g. a neurostimulator, a lead, an extension, a patient programmer, etc.).
Document	An individual piece of labeling that covers a specific topic (e.g. an indications sheet, an Information for Prescribers manual, an implant manual, etc.).
Procedure	A surgical procedure to implant or explant the deep brain stimulation system.
Product	The deep brain stimulation system. A collection of components that (when implanted into the human body) can deliver electrical pulses to specific areas of the brain to reduce or alleviate symptoms of specific disorders.

Therapy	The deep brain stimulation system when it is applied to a specific medical condition (e.g., deep brain stimulation for Parkinson's disease).

In the labeling re-architecture completed in 2005, the Information for Prescribers (IFP) became a separate piece of labeling. This was a particularly helpful change with respect to reuse. The same IFP is used across all DBS Therapies. This means that the IFP is the same for all Deep Brain Stimulation (DBS) components (i.e., specific models of neurostimulators used in deep brain stimulation) for all indications (i.e., specific medical conditions that meet the criteria for DBS therapy). The DBS IFP covers four different products and four different medical conditions. If a separate IFP had to be written for each of these, there would be sixteen documents required instead of one. Each of these sixteen documents would need to be updated and receive regulatory approval when changes needed to be made.

Studies related to labeling architecture

Although few studies are available on labeling architecture specifically, several studies on information architecture and content address the same issues.

Able and Bailie (2014) assert that information architecture is both a process and a product, wherein the process "involves analyzing a body of content—domain—to understand its components, the relationship among them, and their behavior; identifying the organizing principles; and designing a conceptual model that captures the underlying structure" (Frush, 2015). Design, organization, and navigation are critical pieces to both information architecture and labeling architecture. According to Content Strategy for the Web (Halvorson & Rach, 2012), substance, structure, workflow, and governance are all affected by content strategy. These factors affect labeling architecture as well.

Translation:

Byrne noted in her book, *Technical Translation Usability Strategies of Translating Technical Documentation*, that "...the challenge for technical translation is to ensure that all of the relevant information is indeed conveyed but also that it is conveyed in such a way that the readers can use the information easily, properly and effectively. Indeed, this aim is precisely the same as that of technical writing,"(Byrne, 2005). Clearly, labeling departments and translation departments need to have goals and processes that are aligned.

Medical device labeling at the company in this study is first produced in an English source document that meets all FDA requirements by the Labeling Department. Then it is sent to an in-house Translation Department for translation and localization prior to release to the public. Most documents are translated into 26 languages. A native speaker for the language into which the document is being translated translates each document, and then the document is reviewed and if necessary revised by a second person who is also a native speaker of the language into which the document is being translated. The Translation Department uses their employees as translators and revisers for most languages, but they also employee freelance translators and revisers as necessary to create labeling in any language required.

The Translation Department uses Translation Memory (TM), a database that stores "segments" of text that have been previously translated. For example, if a document with 100 sentences is being updated to include 5 new sentences and 95 previously translated sentences, TM will identify the previously translated sentences. The translator and reviser know what new translation needs to be completed and what portions of a document can simply be reviewed.

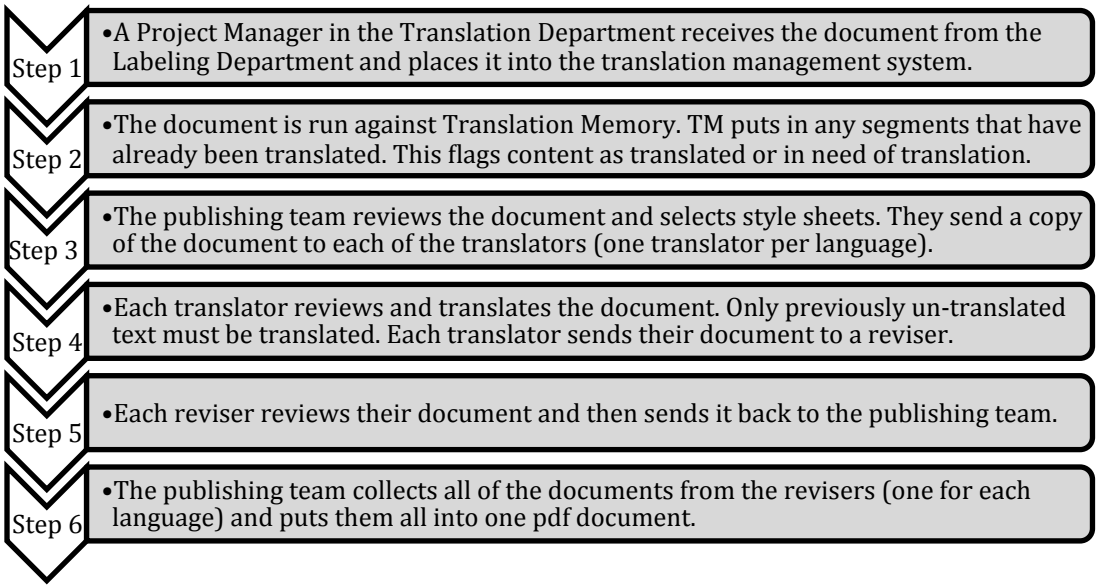

Figure 2: A brief summary of the translation process

Method

This study explored the impact of labeling architecture on document translation in a regulated medical device company. This was a qualitative study in which I conducted unstructured interviews. According to Edwards and Holland,

"All qualitative interviewing has certain core features in common:

The interactional exchange of dialogue (between two or more participants, in face-to-face or other contexts).

A thematic, topic-centered, biographical or narrative approach where the researcher has topics, themes or issues they wish to cover, but with a fluid and flexible structure.

A perspective regarding knowledge as situated and contextual, requiring the researcher to ensure that relevant contexts are brought into focus so that the situated knowledge can be produced. Meanings and understandings are created in an interaction, which is effectively a co-production, involving the construction or reconstruction of knowledge. [Adapted from Mason 2002: 62]

In conducting unstructured interviews, I started with a set of open-ended questions for the participants, but tailored the interviews with follow up questions. I adapted the questions for future interviews based upon the content shared by each participant. Thus, I was able to take advantage of the expertise of the participants by allowing the process to evolve based upon their input.

I conducted seven unstructured interviews with Technical Communicators from a global regulated medical device company. These individuals included professionals from a Labeling Department for one of the business units at the company, as well as individuals in the Translation Department for the company. The Labeling Department is located in the United States and the Translation Department is located in the Netherlands.

Two of the participants were men and five of the participants were women. Five of the participants were native speakers of English. One of the participants spoke Dutch as his native language, and one participant spoke Czech as her native language. Six of the seven participants were employees of the company, and one was a contractor. Their tenure at the firm ranged from 2 years to 20 years.

I interviewed a Linguistics Services Manager and a Project Manager from the Translation Department. They shared information about the translation process, the roles and tools involved, and suggestions for improvement with respect to labeling architecture and communication across departments. I interviewed two Technical Writers and three Program Managers from the Labeling Department. One of the Program Managers works with international and emerging markets within the company. All participants from the Labeling Department have written or edited English source documents that were later translated. These participants shared their

perspectives on the current labeling architecture being used in the department, what was working well, suggestions for improvement, and communication across departments.

I conducted the interviews in person, via WebEx, and via telephone.

Interview questions included:

- Tell me about your professional role.
- Does document labeling affect your role? If so, how?
- Does labeling architecture affect your role? If so, how?
- Does translation of documents affect your role? If so, how?
- What would you like to see changed in any of these areas?
- Are there efficiencies to be gained in any of these areas? If so, what are they?
- Tell me about your experience with respect to Global English in labeling documents.
- How does technology affect your labeling architecture and translation?

With the permission of the participants, I made an audio recording of five of the interviews, and for the remaining two interviews I took notes by hand. I then reviewed and transcribed the audio files and handwritten notes. I captured participant comments from the interviews and performed an affinity mapping exercise to discover underlying themes to be reported and discussed in the paper.

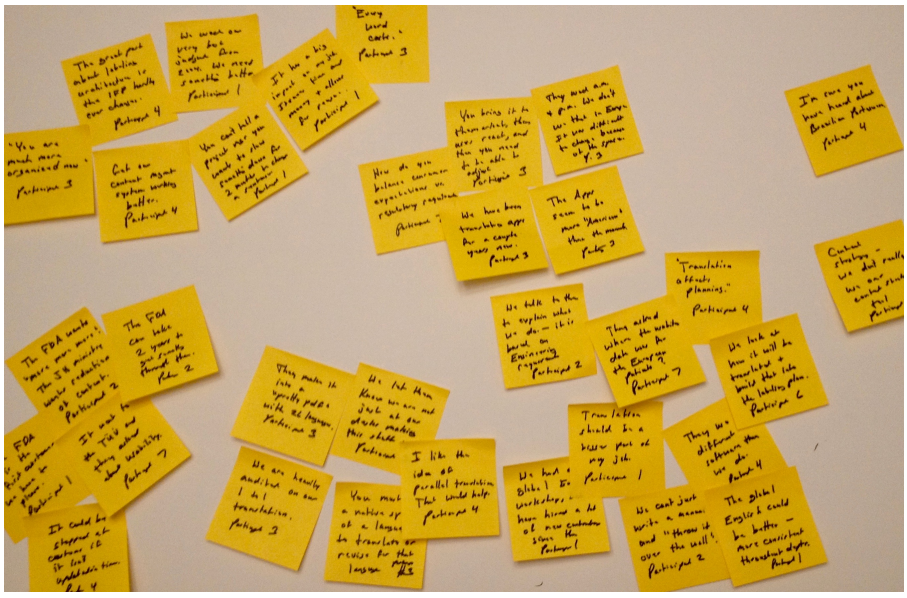

Figure 3: Affinity mapping in process

Please see the data sample below. This is a portion of an interview transcript with coding. "L.A." refers to "Labeling Architecture. "01" is the participant number. The notes after this designation shares additional contexts about the possible theme.

Participant 1 Data Sample with coding

"I think it was around 2005 our department did its first orchestrated deliberate labeling architecture project on our pain stem labeling. We moved from a paradigm where we had large amounts of repeat information in different product manuals — our INS manual had all of these therapy warnings and precautions — the same info repeated in the lead manual and extension manual and in the program manual and it got to a point where we have to do better than this." Labeling Architecture — (L.A. 01) — History of Process
"If we have to change a statement that is found in all four of those manuals we would not only have to update all 4 manuals but update the PINs or packages of those. We were updating entire packages to update a sentence." (L.A. 01) — Reuse of Content
"We kept those product manuals, but skimmed out all of the therapy-wide information and kept it to just product specific information within those product." (L.A. 01) — Reuse and Cost Savings

Table 2: Data Sample from Participant 1, Senior Technical Writer

Results & Discussion

Four distinct themes emerged from the interviews. All participants expressed that the labeling re-architecture that now existed was helpful in saving time and money as well as promoting reuse of content. They also agreed that the changing technological landscape poses new challenges for labeling architecture, translation, and human factors. The participants all noted the underlying importance of the regulatory requirements. Finally, all participants expressed the importance of communicating clearing across the departments and understanding each other's roles and processes. I will review each of these in depth.

Theme one: The New Labeling Architecture promotes reuse of content, which saves time and reduces translation costs.

The current labeling re-architecture within the department was introduced in 2005. Prior to this time, content was repeated across as many as seven different labeling pieces for one product. All of the labeling pieces for one product comprise a package or Product Identification Number (PIN).

> One Technical Writer summed labeling architecture up by saying, "It has a big impact on my job because it saves me time and effort and saves complexity. It creates cost savings."
>
> He went on to explain the environment before labeling architecture was introduced, "If we had to change a statement that was found in all of those manuals we

would not only have to update all of manuals but update the PINs or packages of those. We were updating entire packages to update a sentence."

With the introduction of the labeling re-architecture, the therapy-wide information was taken out of the manuals and placed into an Information for Prescribers insert (IFP). The IFP included contraindications, warnings, precautions, individualization of treatment, adverse events, and patient counseling. To update a manual is not a small investment of time and resource and capital, but to change a package was many times more so.

As the Project Manager in the Translations Department said, "The good thing about the new labeling architecture is that the IFP hardly ever changes."

The Technical Writers whom I interviewed expressed a greater interest in updating the current state of labeling architecture than did the employees of the Translation Department, perhaps because they are the first professionals who work with it.

As one Technical Writer put it, "Our current labeling architecture is based on our very good judgment from 2005 and it hasn't changed since — that is 11 years old. Technology has moved a little bit in those 11 years, and we haven't yet gone beyond thinking about that. To change our labeling architecture again would be no small project and in our current development environment it is hard to get funding for a labeling improvement project."

All seven participants mentioned the importance of cost savings that labeling architecture and content reuse promotes. This directly impacts both the production of English source documents and translated documents.

> As the Manager of Linguistic Services expressed it, "Every word costs." She further explained, "We are required as a company to be more agile, to be faster, to be more cost efficient. We are constantly working on ways to make things faster, cheaper, more efficient such as developing style sheets that will do the work for us or developing cleaner, leaner processes."

Theme two: Regulations are complex and a prerequisite to everything.

When referring to "users" of medical device products, four different participants mentioned regulatory authorities in the same sentence with patients. This underscored how important regulatory approval is within the industry.

Medical device companies must satisfy the regulatory authorities in every market where their products are sold. This requires rigorous attention to detail on the part of both Technical Writers and Translators, and regulations differ based upon the country.

> A Project Manager in the Translation Department said, "The EU works together. The laws are harmonized. Japan has different laws."

> The International Program Manager expressed, “The FDA tends to ask for “more, more, more” where the JHA (Japanese Health authority) wants to “significantly reduce the content.”

Theme three: Users expect apps with localized interfaces and timely updates.

Changing technology poses interesting challenges within the medical device industry. Today electronic applications are part of medical device labeling. This creates challenges with respect to timeframes for patients who are accustomed to quick electronic updates for consumer products.

> As the Linguistic Services Manager said, “You bring it to the market, and then the users react, and then you need to be able to adjust it very quickly. We didn’t used to have that loop.”

> A Technical Writer shared, “Users didn’t use to have expectations that they can download a new app or an update of the app a couple of years ago. We definitely feel in Translation what all of society feels.”

Theme four: Working well across business units and cultures is key.

Both a Senior Technical Writer and the Linguistic Services Manager suggested that greater consistency of Global English training for Technical Writers could be helpful to the

writing and translation processes. The Technical Writers in the Labeling Department have diverse educational backgrounds. They are all college graduates who are skilled in writing and editing, but not all of them have formal training in Global English. An in-house style guide addresses this to some degree. The department also had a Global English workshop onsite within the last year, but a number of Contract Technical Writers have been hired since it was delivered.

Understanding each other's job functions and communicating on a regular basis are key. Geographic distance and cultural differences are inherent in the relationship between the Labeling Department and Translation Department. Bridging this distance with strong cultural intelligence and creative teamwork are part of the job.

> The International Program Manager said, "How do you start from a place of respect for the business unit or the culture —not just empathetic but in their shoes. That is the strongest way to develop partnerships. This approach takes time."

Recommendations

Labeling architecture

- Study/revisit the specific cost savings of the labeling re-architecture to help lay the groundwork for a labeling architecture expansion.
- Expand labeling re-architecture to include all products within the business unit as it becomes economically viable to do so.

Cross-Functionality

- Include the Translation Department in the planning stages of human factors studies and labeling development plans.
- Create avenues for regular communication between Labeling and Translation including a fuller understanding of each other's roles, responsibilities, and challenges.

Training and Education

- Increase the consistency of training in Global English for Technical Writers. Ensure that all employees and contractors complete Global English training and have ongoing access to reference materials. Include Global English training in new hire training.
- Emphasize the importance of cultural intelligence through coursework in International Professional Communication and foreign language studies.

Bibliography

Byrne, J. (2005). *Technical Translation Usability Strategies for Translating Technical Documentation.* (Vol. 50). Dordrecht: Springer.

Frush, K. (2015). Labeling architecture in a regulated medical device company, (May), 1–16.

Goldstein, D. (2015). Fit the Manual on a Sticker : the FDA & Labeling. *TechWhirl*, *August*.

Halvorson, K., & Rach, M. (2012). *Content strategy for the Web*. *New Riders*. Retrieved from http://capitadiscovery.co.uk/mmu/items/2028450

TÜV SÜD America Website. (March 2016). Retrieved from www.tuv-sud-america.com

Varner, L. B. & I. (2002). *Intercultural Communication in the Global Workplace*. doi:10.1057/9781137381040

Www.fda.gov. (March 2016). Medical Device Labeling Requirements. Retrieved from http://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/devicelabeling/default.htm