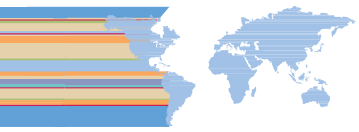


Labels, Packages, Documents --
A Global View

Key Points

- **Developing and delivering labels, packaging and regulatory filings involves multiple, compounding steps - creation, translation and production.**
- **Many life sciences organizations fail to tightly align these workstreams organizationally, procedurally and technically.**
- **Cost savings are often pursued within each discrete production area, yet much greater opportunities could be found by addressing the development lifecycle holistically.**
- **Understanding the "downstream" impacts of each step in the work process enables more effective planning and revolutionary, versus evolutionary, gains in efficiency.**
- **Utilization of emerging authoring techniques and supporting content technology facilitate rapid migration to best-in-class documentation.**

Executive Summary

Unlike the manuals that are shipped with a DVD player or cell phone, product documentation in the life sciences industry is held to a higher, often regulated standard. If the instructions for a DVD are unclear, the risk to the user is minimal. If the labels, packaging or IFUs for your medical device or pharmaceutical treatment are unclear, the results can be fatal. In spite of this, product documentation often goes unread, stored neatly on a shelf far removed from products and patients. In many cases, users find it easier to contact their sales rep or technician to address a question than to scour through tens or hundreds of pages and diagrams searching for a quick answer.

This creates an interesting paradox: although product documentation may rarely be read, quality and accuracy remain paramount, as any error can have devastating effects. The challenge therefore is to achieve the required levels of depth and accuracy while containing costs and accelerating production. This challenge is further compounded when your product is distributed in multiple countries. Serving buyers in these markets means delivering your support content in multiple languages, driving a need to efficiently translate, produce and maintain this content in order to control overall cost. Unfortunately, your ability to contain production costs at these end stages is limited since they are a derived factor of the quantity and nature of the source content.

As result, to achieve the cost gains necessary to affect the real bottom line, a more comprehensive perspective is needed, one that considers the downstream effects of small changes in the creation stage. For example, saving 1-2% per translated word or per printed page will not help if the number of pages increases each year by 10%. What is needed is a way to shrink the volume of content to be translated and produced without sacrificing accuracy or coverage. To achieve this degree of re-engineering, you must focus on integrating the three primary production phases into a single cohesive event:

- Creation - How you author, the tools you use, the style, words and structure guidelines you follow dictates the overall efficiency of your global documentation.
- Translation - The vendors you select, the processes they follow, their interaction with authors, and the technology they deploy determines the degree of translation "bloat" your documentation must endure.
- Production - How you structure your materials, the number of addendums and inserts, the use of print versus digital media, impacts your shipping costs and must therefore influence how you author and translate.

This paper will outline the various challenges in each of these areas and offer a new perspective on ways they can be leveraged to drive measurable, long-term savings.

Making the Case for "Good" Documentation

There is an old business joke that states "you can have it good, you can have it fast, and you can have it cheap, just pick any two." Product documentation, like many other production processes, succumbs to this same paradox and, like the other efforts, managers and companies strive every day to optimize the balance between these three conflicting goals. The challenge is that the priority order can change almost hourly. The head of regulatory affairs, tasked with securing agency approval, stresses that the documentation quality and coverage must be improved to take the product to market. Attempting to improve the quality prior to submission, however, may delay the global launch which marketing states must happen by a certain date or else you lose substantial market share in five target countries. They have substantial research data to prove this. Finally, the head of product development says she must cut the cost of everything in the box by 10% and the international shipping weight by 5%, and streamlining documentation is key to both. She has margin analysis data to support her claim. Each case has merit, so why do firms so frequently sacrifice "good" documentation in favor of "faster and cheaper," seeking to do the bare minimum that will pass inspection in order to save a few weeks or a few dollars.

While it is generally accepted that "good" documentation can reduce service calls and returns, producing "good" manuals and instructions is time consuming. In today's hyper-competitive markets, companies often resort to "good enough" in order to get a new product to market a few days faster. They may employ multiple authoring groups

5 Common Points of Frustration

- Inconsistent terminology
- Use of symbol "8 " vs. word "Enter"
- Shifts in verb tense
- Use of both active and passive voices
- Shifts between bullets or paragraphs

with limited guidance on style, structure, and "voice" resulting in an end product that seems disjointed and may be wrought with terminology inconsistencies that, though minor, will frustrate and confuse reviewers and end users. These issues are then compounded exponentially when translating this content into other languages. The challenge here is that such issues are rarely cited as the reason for failing to secure approval or eventual returns or failures in the field.

Truly "good" documentation is also seen as being expensive, involving teams of highly skilled authors, product developers, and translators creating detailed, graphical content in multiple formats to meet the varying needs of the target consumers. With off-shore competitors quickly developing and distributing alternatives to many products today, the cost of each production element must be continually reviewed to identify new sources for savings. With "good enough" documentation passing the regulatory lens, it is no wonder why firms are eyeing their teams of authors and translators and making comments about "reducing non-core functional expense." After all, if the documentation isn't perceived as being core to approval or customer satisfaction, the teams and processes in place to produce it can't be core to the organization.

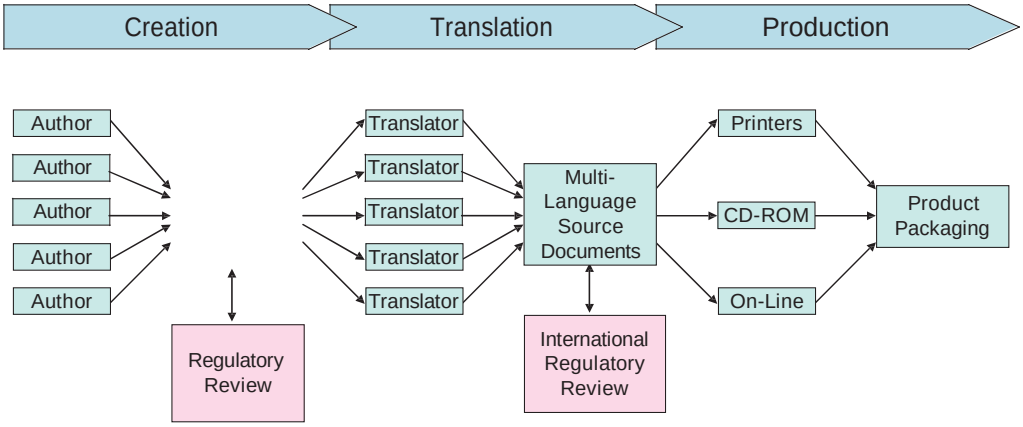
But what if we were able to redefine "good" documentation and shift the focus away from just the quality of the end product and place the emphasis on the total development cycle:

- What if "good" documentation did more than just clear agency reviews?
- What if "good" documentation was able to be produced faster?
- What if "good" documentation could be translated more easily?
- What if "good" documentation could reduce production costs and shipping weight?

In this light, "good" is no longer a discrete goal at the bottom of a list of competiting priorities, but instead is seen as the means to achieving those goals. Recognizing the broader role of documentation and the dependencies across each element of its development is what we mean by adopting "a global view" of product documentation.

A Global View

To adopt the global view of documentation, we need to look at the total lifecycle of production as it occurs across three primary areas: Creation, Translation, and Production. As indicated by the simplified depiction of the process shown below, each of the three primary process phases involves multiple resources working simultaneously towards a common end point. The challenge, however, lies not in each of the discrete phases but in the failure to properly align these disparate work efforts:



In most organizations this disconnect occurs on both an organizational and philosophical level. Organizationally, these processes tend to report into different functional areas. Creation will tend to be managed within the product development function, either loosely or as a formal documentation team. Translation is often outsourced to several language vendors who may be engaged by in-country marketing teams or some central translation team within the company. Finally, Production is often treated like manufacturing and may be managed by the plant manager assembling the product, or it is bid out to multiple vendors as a commodity from a corporate purchasing organization.

Regardless of the actual implementation, the reality is that few organizations adopt a true global perspective on the development and deployment of their documentation. Instead, each of these functional areas is tasked with optimizing their own spend and efficiency. Creation teams may focus on pages-per-hour or cost-per-page to determine the value of their authors. Translation managers will emphasize price-per-word and words-per-day to gauge the contribution of their vendors. Production teams will look at unit cost and inventory turns to measure their results.

By focusing at the unit level in each of these areas, the company assumes it is obtaining the lowest possible cost and fastest possible turn around time. The fallacy here is that such analysis fails to consider the impact of the original source material on the downstream efforts. For instance, a firm that has reduced the unit cost of printing by 10% in a year will see no net savings if, in the same year, the number of pages in a given product's manual increased by 20%.

By this example we see that the true cost of Production is not determined by the cost of paper or CDs, but by the nature of the content it conveys. Given this dynamic, we will therefore focus our attention on the synergies and opportunities that exist through greater integration of the Creation and Translation efforts, expecting that such gains at the source will have a compounding impact on Production efficiency as well.

"Good" Documentation Means Controlling the Source(s)

With the expansion of the EU and the scope of its Directives, it is almost a given that your product documentation will be translated at some point in its life. While this reality is generally accepted by companies today, it is rarely considered when developing the source content. Firms tend to rely on their traditional approaches and teams and fail to consider the dramatic impact these processes can have on the total cost and time to produce the various multi-lingual editions. As a rule, there are five key factors that must be taken into account when authoring for a global audience:

1. Source language.
2. Adherence to common "content principles" by all authors.
3. Consistent terminology.
4. Globally acceptable authoring technology.
5. Use of content management and translation memory systems.

The next sections will examine these areas in greater detail and demonstrate the value of integration between Creation and Translation.

Source Language

Not every company originated in an English speaking country and not every product division in these organizations resides in an English speaking country. As a result, many companies today create content in multiple source languages. This is done primarily because of the preference to closely align authors with developers (assuming they are not the same individual). While this kind of teaming may initially appear highly efficient, in fact it is one of the leading cost drivers in the entire process.

The reason? English has become the accepted "base language" for translators around the world and as such the cost to translate to and from English is substantially less than most other language combinations. For instance, an automotive manual created in German will likely be translated in English before conversion into Japanese or Spanish. This is due mainly to the limited availability of qualified translators. While there are thousands of individuals capable of translating English to Japanese, there may only be a few hundred in the world with the linguistic and technical skills necessary to make the leap from German to Japanese. Failing to author in English will effectively double your translation time and cost. In addition, with each step away from the source content, the risk for error is greater.

Adherence to Content Principles

Authors, by their nature, are creative individuals. Each has his/her own "voice" and approach to creating content. Though necessary to author novels, such individuality is undesirable in technical manuals. When you have a team of authors collaborating on various elements of a manual, you must either be prepared to spend weeks in diligent

editing and rewriting efforts or seek to gain more control of the original creative process. Most firms are pursuing solutions around the latter, either through detailed educational programs or new authoring systems which force compliance to a strict set of guidelines around such elements as:

- No more than 25 words per sentence.
- Seven sentences per paragraph.
- No use of slang or words ending in "ing".
- Use of the active voice.

Failing to apply this degree of structure to the authoring process can create havoc during the translation stages, as translators attempt to reconcile the various styles and constructs. The example on the next page depicts the value of "principled" authoring. It is easy to imagine why sample may "go global" with less difficulty:

Without Principles

INTRODUCTION
This section gives full details of the service procedures necessary to maintain your tractor at peak efficiency. The lubrication and maintenance chart on page 7 provides a ready reference to these requirements. Each operation is numbered for easy reference.
In addition to the regular maintenance operations listed, check the following items every 10 hours or daily during the first 50 hours of operation:

- Wheel nuts for tightness
- Front axle hub oil levels

IMPORTANT: Park the tractor on level ground and, where applicable, extend all cylinders before checking oil levels.

SAFETY PRECAUTIONS
Read and observe all safety precautions listed in "Servicing the Tractor" in the Introduction Section at the front of this manual.

NOTE: Dispose of used filters and fluids properly.

CAUTION: Do not check, lubricate, service or make adjustments to the tractor with the engine running.

PREVENTING SYSTEM CONTAMINATION
To prevent contamination when changing oils, filters, etc., always clean the area around filter caps, level plugs, drain plugs, dipsticks and filters prior to removal. Before connecting remote cylinders, ensure that oil contained within them is clean, has not degenerated due to long storage and is of the correct grade.

To prevent dirt entry during greasing, wipe dirt from the grease fittings before greasing. Wipe excess grease from the fitting after greasing.

1 Shorter sentences and paragraphs highlight critical content more effectively

2 Safety conditions: Warnings relating to potential loss of life must come before cautions and notes

3 Simplified language improves understanding

4 Bullets help streamline complex instructions, reducing the potential for error

With Principles

INTRODUCTION
This chapter describes the instructions for the maintenance of your tractor. The Lubrication and Maintenance Chart on page 7 shows the items for maintenance. Each item has a reference number.

DANGER: Always stop the engine before you service the tractor or apply lubrication.

WARNING: Always park the tractor on a flat, level surface. Before you check the oil levels, extend all hydraulic cylinders.

CAUTION: Always read, understand and follow the safety instructions as shown in the Introduction Section, "How to Service the Tractor."

NOTE: When you discard any engine oil, oil filters or hydraulic fluid, you must follow the instructions on page 40.

Maintenance for the Hydraulic System
Check these items every 10 hours, or each day during the first 50 hours of operation. Use the hourmeter to measure the hours of operation.

- Check the torque on the wheel nuts.
- Check the level of the oil in the hub for the front axle.

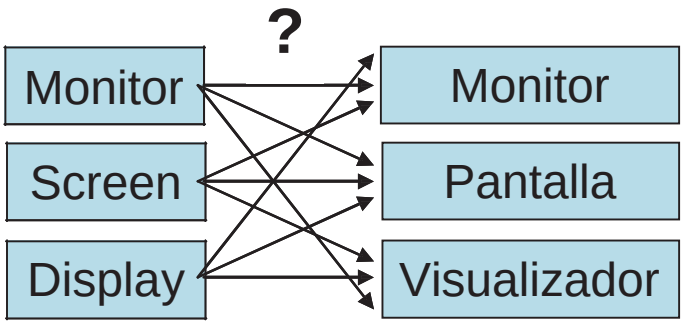
How to keep the hydraulic system clean

- Before you add oil or change any filters, clean the area around the filter caps, dipstick and drain plugs.
- Before you connect another hydraulic cylinder, check that the hydraulic fluid inside the hydraulic cylinder is clean. The hydraulic fluid must not contain dirt, metal or other particles.
- Clean the grease fitting before you apply grease. After you apply grease, clean the nipple on the grease fitting.

Consistent Terminology

Beyond sentence structure and "voice," an author's choice of words is as unique as his or her signature. Most languages are very accommodating in this area, offering your teams a multitude of ways to say the same thing, even in a technical environment. For instance, we look at the word "monitor" to describe that thing on which you view digital material. In some circles, this is a "monitor," in others it's a "screen," and for still others, a "display." For most of us, these are synonyms and in the right context, we have no trouble understanding their meaning. However, spread these same discrepancies across a user manual with interconnected steps and what is otherwise a quirk becomes a major annoyance.

Most firms have recognized this challenge and strive to control it either at the source or with diligent editing. These same firms are less focused, however, on how this issue can reemerge as part of the translation process. Taking the example above into the Spanish language, we see that those same three terms have a counterpart in Spanish and, as with English, they are interchangeable. However, as with English, having this trade off occur throughout an instruction manual is not acceptable to the end users. Companies must therefore strive to control not only the English source but the migration of that source as it moves through other languages.



Failing to control the English terminology will make global control impossible and failing to control the global terminology will lead to an explosion of redundant terms. Playing out the Spanish example above, we would have three words in English mirrored by three in Spanish. If the company translated into ten other languages to support their global sales, we could be attempting to control 96 different ways of saying the same word. By comparison, a globally developed and managed terminology would have just one approved version of the word for each language, eliminating the guesswork by the author or translator.

This geometric expansion of terms presents not only a customer satisfaction challenge but generates quantifiable additional cost. The ability to reuse content, both in English and translated editions, is a critical means of reducing document development costs; but the volume of content that can be sourced and reused is dependent on consistent application of terminology.

Global Authoring Technology

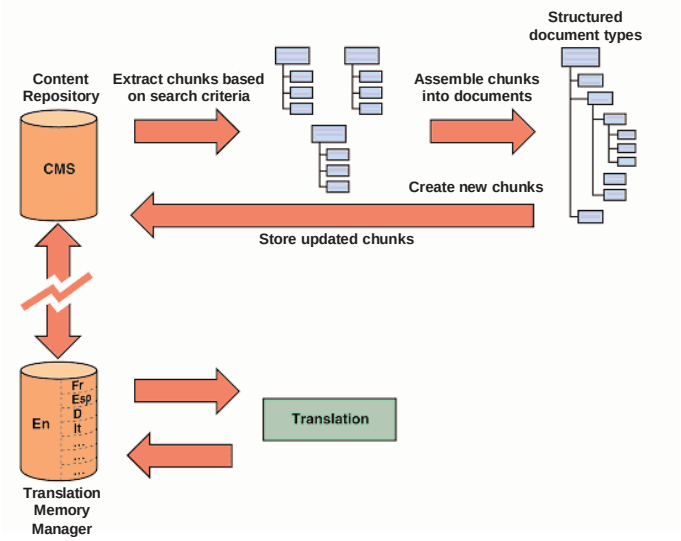
While many authoring teams are well versed in the latest content creation tools, they may not be aware that their selection of technology will have an impact on their ability to have content reused or translated. The biggest opportunity here lies with the use of emerging structured authoring tools based on the eXtensible Markup Language or XML, which enables parsing of content into very small, logical units such as sentences or groups of sentences. These units can then be tagged for easy sorting and accessed for reuse in future versions of the same document, other documents, or completely different media (i.e.. Web content). And the smaller the unit, the greater the chance it will be identified and reused. In this way, content is written once and published to a variety of formats, more commonly referred to as single sourcing. Single sourcing dramatically cuts down on the amount of human intervention required to take a document from concept to delivery.

Other issues created by an author's tool selection include basic language coverage. Though largely resolved, there are still applications in use today which are not capable of handling non-English languages, especially the double-byte Asian characters. Content authored in these systems must often be transcribed into an accommodating tool before translation into these languages can occur.

Another simple challenge involves file sizes, as larger files are more difficult to work with requiring extra effort to prepare them and route them to global translation teams to ensure no loss of data. On a more macro level, issues also may arise regarding the penetration of the software across the translator market. If translators, who are often freelancers, do not have access to your technology platform, they will be unable to work on your content. This limits the number of available resources you can engage, driving up your price and stalling your throughput.

Content Management and Translation Memory Systems

Though the earliest forms of these tools have been available for well over a decade, their penetration remains low and their leverage even lower. This may be due in part to the high up front installation and licensing costs, but as the early adopters begin to demonstrate the potential of these systems, they will rapidly become competitive necessities. A content management system (CMS), ideally coupled with a structured authoring system based on XML, is the lynchpin to many of the challenges and solutions outlined here. Advances in authoring style and terminology are substantial but can lose momentum over time as new authors and translators enter the team and the old disciplines become watered down. Utilizing a CMS and translation memory tools can extend the value of these lessons and investments indefinitely as each new team member is able to rely on and learn from the work of the prior.

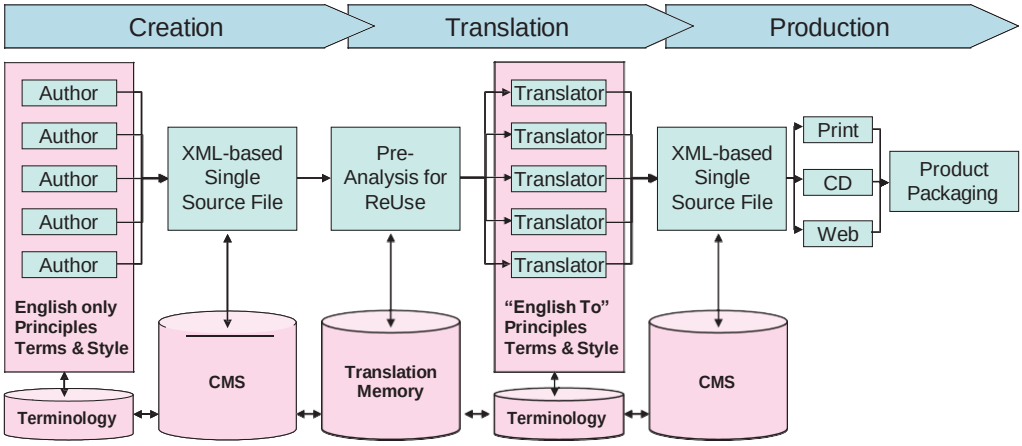


Failing to implement and leverage these systems means your authors and translators are effectively starting from scratch for each new effort, increasing the ramp up time and development time substantially. This also leads to downstream costs as the production teams must go through complete layout revisions and formatting efforts for each document since it is often unclear what has changed and what has stayed the same. Rather than performing a manual review, it is often seen as more cost effective to simply reset the whole effort.

Conclusion: From "Good" Documents to "Good" Documentation Programs

Putting It All Together

Mapping these five best practice considerations to the model we introduced before, we can see how a subtle shift in the focus and the strategic use of technology can unify an otherwise fragmented process:



By adhering to the five program design principles we outlined above, organizations can improve the impact and value of their documentation to consumers, while improved reuse and consistency can dramatically reduce development costs and cycle times.

As for Production, we stated earlier that the cost and time of Production is a derivative of the efforts expended in Creation and Translation, so if those are improved we must also assume Production has benefited as well. And it has. By utilizing a CMS and XML, layout time and costs are reduced as the content now lends itself easily to multiple formats. Conforming to strict authoring and translation guides has helped streamline the language used by the various creative resources, dramatically reducing the word and page count savings both on printing costs and shipping weight. And reliance on an integrated CMS eliminates redundant production efforts, saving time and cost.

Approach to Achievement

For most organizations, it would be impossible to rapidly and simultaneously change authoring behaviors, reengineer legacy processes, and adopt new technology across multiple areas of the enterprise. As a result, an evolutionary process must be employed, with each transformation progressing at its own pace. For instance, it would be an easy step to decide to author all new content in English versus the traditional domestic language. However, recruiting and reskilling the authoring team to complete this change may take six months or more.

So, where do you start? As with most cross-organizational efforts, the first step is to gain strategic alignment and buy-in from the various stakeholders. Leaders in each of the major phases, Creation, Translation, Production, must understand and respect the "Global View" model and contribute to the goals and plans to execute it. Once this shared vision is established, an audit must be conducted to identify gaps between your current programs and the "ideal" model outlined here. You may be surprised to learn that you have many of the raw elements already in place but have simply not made the necessary connections to achieve maximum leverage. This audit and gap analysis will help prioritize your transition effort and form the foundation for your overall migration plan.

From a tactical prioritization, we recommend starting at the source. Begin your work by determining "how" you intend author new content. Confirm your intent to author in English, determine the content design principles you will employ, and develop a single, standardized terminology base. Understanding "how" you intend to write documentation will enable you to recruit and retrain your creation teams with clear parameters and expectations.

As your authoring becomes more controlled, you will improve your ability to successfully deploy and utilize the specialized technology described here. As a result, we recommend you first structure your content and processes and then select and deploy the technology that best supports your coordinated behaviors. Once you are comfortable with the stability of your processes, look for systems which are built on an open architecture and offer the ability to integrate with other affiliated applications. Be wary of

systems purporting to be an all-in-one solution as these typically are deficient in one or more key areas. Instead, look for specialty solutions that can be connected and customized to conform to your unique creation program.

Finally, we recommend engaging some expert help at each stage of your transformation. As we've seen, for most enterprises, product documentation is not perceived as core to the business. As a result, investments in best practices benchmarking and leading edge support technology are rare. Working with one or more strategic partners, for whom the acts of content creation, translation and production are their primary business, can help accelerate your transformation by avoiding common pitfalls and recommending proven approaches for your particular situation.

About LT

L10N Technology (LT) is the leading provider of translation, localization, tech- nical writing and interpretation services that enable businesses to deliver locally rele- vant and culturally connected products, services and communications anywhere in the world. Companies throughout the world use our solutions to help grow their business- es in the Americas, Europe, Asia and Latin America.

Our scalable end-to-end solutions can help accelerate a company's time to market while improving the quality and consistency of the company's products and services. Our wide range of clients include leading businesses in information technology, automotive, e-learning, life sciences, entertainment, telecommunications, aerospace and power and utilities industries.

To learn more, contact us at mcgcompany@naver.com or find us on the web at www.liontech.co.kr.