MEMO

2011-09-19

To: Crimson clients and prospective clients

From: Marc H. Miller, President

Re: Medical Device Industry: Total Cost of Content

Summary

- Aging populations and developing economies drive growth and globalization in the medical device industry.
- An unwelcome side-effect of growth and globalization is a significant increase in industry's "Total Cost of Content" – the total expense necessary to create, verify, approve, update, manage, translate, and format content in the core functional areas of regulatory, marketing, and training.
- Based on verified industry estimates, Total Cost of Content for the U.S. medical device industry amounts to $1 billion/year.
- Based on an organized implementation of Globalization Management Systems and Component Content Management Systems (GMS and CCMS), total potential savings for U.S. industry is estimated at $400 million/year.
- System risk can be significantly reduced from current state by re-investing a portion of potential savings in targeted processes and resources.

Introduction

There are a number of wide-ranging trends that affect nearly every device manufacturer. Perhaps none is more important than the rapid aging of worldwide populations. According to an official UN report, worldwide aging is:

- **Unprecedented** in human history and accelerating
- **Pervasive**, part of a global phenomenon
- **Enduring**, once older, countries will not "grow young" again
- **Profound** in its serious structural implications for both society and industry

Aging populations are important for the medical device industry for one simple reason: Older populations spend more on healthcare of all types – including medical devices.

In fact, according to a report from Harvard University, healthcare spending increases over 500% as we approach life expectancy. Especially over the past decade, the growth and globalization of the device industry has been fueled, in large part, by this graying of worldwide populations.

Some 15 years ago, some experts in the device industry doubted the relative attractiveness of international markets – noting that the overhead of logistics, overseas operations, and regulatory compliance made them substantively less attractive than the domestic U.S. market. However, economic development in overseas economies has combined with aging populations to dispel this perspective. Now, international sales account for over 50% of total revenue at most large manufacturers… with developing economies representing their fastest-growing markets.

Red Sky at Morning

Even before the financial crisis of 2008-09 and Europe's current sovereign debt crisis, there was an acute awareness of rising national healthcare costs. Now, governments worldwide are more focused than ever on healthcare cost containment as an important means to tame runaway deficits – this is equally true, e.g., for EU countries, where healthcare costs constitute 8-9% of total GDP, as it is in the U.S., where healthcare costs constitute a whopping 16% of total GDP.

With worldwide healthcare budgets under scrutiny, reimbursement rates are generally declining and approvals are more challenging – increasingly based on data-driven proof of increased effectiveness and/or demonstrable cost-savings…so-called "Global Comparative Effectiveness Research," or "Global CER."

In an era of healthcare austerity, manufacturers have renewed their focus on cost savings as a means to increase bottom line profitability – recognizing that, dollar-for-dollar, cost savings have a larger impact on profitability than comparable revenue increases. And, in the current economic environment, they are often easier to achieve.

However, cost consciousness has also revealed a particularly unwelcome consequence of rapid globalization: an explosion in the volume of written content and information necessary to develop, test, register, train, and sell medical devices worldwide. Because, of course, along with an increased volume of content, has come a similar increase in the cost necessary to manage it.

Thus far, due to legacy processes and the sheer number of affected activities, tasks and functions, most manufacturers have demonstrated a fragmented approach to controlling content costs. However, research is now prompting manufacturers to reexamine their assumptions – this time with an appreciation for the cost-saving benefits of new strategies and technologies.

Total Cost of Content: A Conservative Estimate

For this memo, primary research and client interviews were used to estimate the "Total Cost of Content" for a typical, large device maker. These manufacturer estimates were verified by a device industry analyst at a major U.S. brokerage firm with direct industry experience. Secondary verification was provided by sample size. Manufacturer estimates took into account the cost to create, verify, approve, update, manage, translate, and format content in the core functional areas of regulatory, marketing, and training.

The method used to calculate the Total Cost of Content roughly follows the method laid out in a 2011 article by Michael Porter, noted professor of competitive strategy at Harvard Business School. In the Harvard Business Review article, *How to Solve the Cost Crisis in Health Care*, Porter observes, "Accurate cost measurement in health care is challenging, first because the complexity of health care delivery itself." The very same can be said of content creation and management within the typical medical device manufacturer. In fact, by some measures, content complexity has increased 300-400% over the past 15 years due to an increase in the number of contributors, markets, and output options.

Porter's method for managing this complexity is a "time-driven activity-based costing (TDABC) system to assign costs accurately and relatively easily to each process step along the path." Crimson used this same approach to identify device makers' staff involved in the various stages of content development, review, management, and approval, estimating the percentage of time that they were dedicated to content management activities, and multiplying that percentage by average salaries for specific roles.

example:

Content Contributor1; Avg. salary x Percentage of time dedicated to content responsibilities +

Content Contributor2; Avg. salary x Percentage of time dedicated to content responsibilities +

Content Contributor3; Avg. Salary x Percentage of time dedicated to content responsibilities +

(…)

It is important to note that, due to differences in overhead allocations per manufacturer, only unallocated "straight salaries" were used to produce this estimate. This has the net effect of understating actual totals. Following Porter's example, a fully costed per-hour rate (salary + benefits + allocated overhead) will yield a significantly higher, though more accurate total.

Added to the salary percentage total was a cost for translation/localization and formatting (not printing). The translation/localization cost was based on actual corporate spend and reflects the current industry standard practice of translating/formatting individual documents and files, using qualified resources, appropriate processes, and with the assistance of translation memory (TM) software (for leverage/cost savings).

Time to market expense was not considered for this exercise. However, in many cases, this is a key consideration for manufacturers. For example, by implementing certain content management strategies and technologies, the average translation/formatting turnaround for large documents may be reduced by over 30%. The value of this reduction is most appropriately determined on a per-company basis.

Other opportunity costs are also most appropriately determined on a per-company basis. For manufacturers operating with a traditional, document-based system, the opportunity costs of maintaining this approach can be significant – especially when considered in the context of labeling and translation risk management as well as upcoming eLabeling opportunities.

Based on the use of straight salaries and exclusion of time-to-market and other opportunity costs, we believe that the following estimated Total Cost of Content is generally understated and therefore conservatively accurate.

A Potential $400 Million Bottom-Line Boost

The vast majority of device manufacturers manage their content at a document level – creating, updating, and translating their content on an item-by-item basis. It is estimated that the cost associated with these activities amounts to 1% of manufacturers' revenue. For the U.S. industry as a whole, this amounts to **over $1 billion in annual Total Cost of Content**.

Based on content management lessons learned in the aerospace, consumer, and high-tech industries, it is further estimated that **the U.S. medical device industry could reduce this annual total by 40% ($400 million)**. Through a combination of Globalization Management System (GMS) software, content management strategies and

techniques and Component Content Management System (CCMS) software, manufacturers can restructure authoring processes for maximum efficiency, risk management, and reuse. Increasingly, web-based, software-as-a-service (SaaS) models are favored due to their low total cost of ownership, rapid implementation, reduced impact on IT, and continuous product improvement.

Of the potential $400 million total savings, 25% is due to GMS implementation and 75% is due to implementation of CCMS. Examples of leading SaaS-based systems include Translations.com's GlobalLink software suite (GMS) and Astoria Software (CCMS).

Risk Management

Based on internal and third-party audits conducted by Crimson, it is estimated that 35% of Serious Errors in translated labeling (may result in patient harm) are due to increased content complexity and inadequate publishing practices. According to a review of FDA data contained in *Packaging Postponement: Solving the Medical Device Ever-Changing Requirements* (unpublished Master's thesis by Harold Reisman), labeling-related recalls have constituted the majority of all recalls since 2006.

Through a planned implementation of GMS and CCMS systems, the root cause of many of these recalls (inadequate systems/processes to manage increasing content complexity) can be addressed. Also, by reinvesting a portion of the savings realized through GMS/CCMS in upstream quality enhancements, system risk can be further reduced – leading to fewer Serious Errors in, e.g., translated labeling.

Conclusions

The effort to convert from a traditional, document-based content management system to a GMS/CCMS-based system is non-trivial and requires senior management leadership and commitment. For this reason, many manufacturers have opted to preserve existing processes. However, the increase in content complexity due to a 300-400% increase in contributors, document types, and markets served has significantly elevated the Total Cost of Content for the medical device industry. New research estimates the Total Cost of Content for U.S. manufacturers at 1% of revenue ($1 billion). Potential savings from conversion to GMS/CCMS is estimated at $400 million. Given the current economic environment, this significant bottom-line benefit is driving manufacturers to reexamine their traditional labeling and documentation processes. Risk management benefits provide further impetus to content management reconsideration.

***

For more information on GMS/CCMS strategies and technologies, please contact:

Marc H. Miller, President
Crimson Life Sciences
www.crimsonlanguage.com

617.597.1984
mmiller@crimsonlanguage.com