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WHITEPAPER

How Structured Content Management (SCM) Is Revolutionizing the Life Sciences Industry

One can learn a lot about structured content management by playing with a pile of Lego® blocks for a few days. Available in a multitude of themes, any Lego set can be built as advertised using the blocks and directions included in the box. But that's not the true draw for this worldwide blockbuster of a toy– the real attraction is in the re-usability of the blocks that come in that box. Lego has built its success on enabling its end users to create an infinite number of structures from an almost infinite set of re-usable parts. The blocks from a set that started as a fire truck can be repurposed along with others to make a space ship; a Hawaiian island transforms into an airport and so on. Because the blocks are made to interconnect, users are limited only by their imaginations.

In a life sciences business context, if we think about the information that is created during the process of bringing a drug, biologic or medical device to market in terms of 'blocks' of re-usable information, an entirely different content creation and management paradigm can be realized. These blocks can still be used to meet regulatory needs (think about the blocks and directions for the fire truck purchased off the shelf), but it could also be used for other purposes such as information used by healthcare providers and patients (think spaceship transformation). By defining and storing information as independent components that can be connected and deployed in a fluid and flexible way, organizations can move beyond just creating documents that meet regulatory needs, and reach for the future of connecting research, technology and health care delivery.

The Office of the National Coordinator for Health Information Technology points out that it "has a critical responsibility to advance the connectivity of electronic health information and interoperability of health information technology (health IT)." One of the 9 guiding principles for achieving this vision is "Maintain modularity. Complex systems are more resilient to change when they are divided into independent components that can be connected together. Because medicine and technology will change over time, we must preserve systems' abilities to evolve and take advantage of the best of technology and health care delivery. Modularity creates flexibility that allows innovation and adoption of new, more efficient approaches over time without overhauling entire systems."

This principle can and should also guide those organizations that play a role in developing and delivering products to healthcare providers and ultimately the patients. By providing information modularly and in a structured fashion, these companies can ensure that the information being carried through the larger healthcare delivery environment arrives consistently, completely and efficiently.

Modularity within the Organization

Within a company's own walls, information such as research documentation, clinical study reports, brand labels, marketing materials, and thousands of other documents, are authored to meet regulatory and organizational needs. The process of creating these countless documents is highly labor-intensive and requires many authoring and approval cycles. In many cases, the information contained in these documents has previously been used in other materials, but there's just no easy way to repurpose it. Copying and pasting content from one document to another is both time-consuming and prone to error. The process grows even more complicated when you factor in multiple writers from various organizations all accessing the same information. As clinical studies progress and products move through to commercialization, information is updated at the source. Unfortunately, if copy-and-paste has been used, finding all the places that information now occurs will be like finding a needle in a haystack. Obviously, this can have dangerous health care and catastrophic legal and financial consequences.

Modularity across Organizations

External researchers, doctors, health delivery networks and even patients could also benefit from having access to more of the documentation than they currently do, but again, technology gets in the way. TransCelerate BioPharma is a nonprofit group that aims to collaborate across the global biopharmaceutical research and development community to identify, prioritize, design and facilitate implementation of solutions designed to drive the efficient, effective and high quality of new medicines. With leadership from the world's leading biopharmaceutical organizations, robust partnerships with leading industry organizations and collaboration and insight from Global Regulatory Authorities, the organization is developing key initiatives that facilitate the sharing of information. TransCelerate's growing portfolio of initiatives focuses on the shared vision of accelerating and enhancing the research and development of innovative new therapies. These initiatives develop practical solutions to overcome inefficiencies in clinical trials and are drawn from the combined expertise of our members and industry collaborators.

How will they achieve these goals? By creating industry standards that allow information to be more easily shared across all constituents. Initiatives such as:

- **Clinical Data Standards** to support the exchange and submission of clinical research and meta-data, while improving patient safety and outcomes;
- **Clinical Data Transparency** to develop a model approach for redacting privacy information found in clinical study reports and a model approach for the anonymization of patient-level data shared with the broader healthcare community;
- **Common Protocol Template** to work with industry stakeholders and regulators to create a model clinical trial protocol template containing a common structure and common language to improve accuracy in data recordation and speed study start up; and,
- **eLabels** to support TransCelerate Member Companies in establishing an innovative information channel: Electronic Labels (e-Labels). This initiative will work to enhance Label utility for patients.

All of these initiatives (and more) can benefit from organizing the information so that it can be logically used in a variety of ways by a number of resources. Consistent information available across organizations will give them the ability to improve the health of people around the world by accelerating and enhancing the research and development of innovative new therapies.

Given the critical need for accurate and consistent content and the high potential for human error, content authoring and management processes need to change. Modern solutions need to enable intelligent content re-use that can be shared as a single source of truth, all while promoting transparency across organizations. Enter Structured Content Management.

About Structured Content Management

Structured Content Management (SCM) is a foundation that maximizes content re-use by looking at information as identifiable components or topics. These topics are then pulled together into a published document with the use of a content map (think document outline). Maps can be developed for many standard requirements ensuring consistency and completeness of documentation. Further, when information is updated in the topic, all new publications utilizing that topic can also be updated, greatly reducing errors. By automating the process of assembling new documents from reusable topics, and requiring senior personnel to review and approve each topic only once, the process workload can also be drastically reduced and confidence regarding consistency greatly increased.

Just like in the building block example, one user can create a design (document) using one set of plans (map) with their blocks (topics) and another user can create a totally different design using many of the same blocks, but with a different set of plans.

SCM is especially attractive for highly regulated industries such as life sciences. In these industries, it's critical that information submitted to regulatory bodies be consistent. Inconsistent information can result in compliance concerns, audits, quality issues, warning letters, product recalls and fines. Thus, SCM can help organizations better adhere to compliance guidelines by allowing them to produce important information in a timely and consistent fashion.

The Benefits of SCM to Life Sciences Companies

Since life sciences companies churn out thousands of mission-critical documents, most of which must pass regulatory scrutiny, the benefits of SCM cannot be overstated. In short, SCM:

- Improves quality and consistency of regulated content
- Promotes greater efficiency
- Saves time and related costs
- Increases adaptability
- Reduces risk
- Speeds time-to-market
- Delivers greater peace of mind
- Helps provide patients with much-needed treatment options as quickly as possible
- Offers ease of use

To get a better sense of how SCM operates in the real world—and the benefits it delivers—let's look at an actual case study. **>>**

CASE STUDY
Sanofi: A Case Study Using SCM

Sanofi, a leading global pharmaceutical company, identified the need for more intelligent content re-use when it evaluated its clinical documentation capabilities and saw numerous gaps. A great deal of content was being re-used from one document to another. Yet the creation of this content was plagued with problems. If one person modified content in one document, there was no automated means of notifying all relevant stakeholders of the change. As a result, documentation was often inconsistent, which created issues with quality, efficiency, and perhaps most critically, compliance.

A think-tank at Sanofi began researching better solutions and learned of the success that other industries were having with SCM. In an effort to develop a prototype SCM tool for its own purposes, Sanofi partnered with DITA Exchange, an independent software vendor and Microsoft partner, as well as the ArborSys Group, a business consulting and technology integration services firm. The collaboration resulted in a prototype solution that incorporated Microsoft technology and was built on a SharePoint platform, which allowed users to work within an environment in which they were already familiar.

The solution focused on one part of the documentation compendium at Sanofi—the production of patient narratives. Patient narratives are the summaries of safety events for individual patients in a clinical study. These narratives typically pull data from at least three different sources and can be very time-consuming to create. A single patient narrative, for instance, can take anywhere from six to eight hours to manually write. Multiply this by the number of patients enrolled in a single study and it's easy to see how labor-intensive the creation of such documentation can be.

Incorporating SCM went on to deliver dramatic results for Sanofi, including:

- **A time savings of 70% to 80%.** The six hours required to manually write a single patient narrative was slashed to just 30 minutes. This means that for a study generating 4,000 patient narratives, the SCM approach would reduce the manpower hours from 24,000 to just 2,000 hours.
- **Significant cost savings.** The SCM solution reduced costs by approximately $275,000 for 1,000 patient narratives or $2 million for 7,500 narratives.
- **Faster time-to-market.** Creating clinical documentation manually involves redundant review processes. Using the SCM tool, Sanofi was able to re-use 65% of its patient narrative content. This allowed the company to review content and deliver high-quality documents in a much more streamlined way, making it possible to bring pharmaceutical products to market much faster.

Case Study Learnings

What broader learnings can be derived from the Sanofi success story?

According to Joan Affleck, Healthcare Business Executive at Sanofi, a key learning for life sciences companies is that they need to rethink clinical documentation. "Documents should no longer be regarded as stand-alone entities with a clear beginning, middle and end," says Affleck. "Clinical documentation is really a road map populated with content. Knowing that this content will be re-used over time, organizations need to back up that road map to the actual sources of content." This means thinking strategically during the early phases of clinical research about how to gather the right type of information. By beginning with the end in mind, it's possible to structure clinical trials in a way that generates data that can later be used to populate document maps.

Secondly, for content that will not and should not be altered, SCM offers the advantage of placing this information into "lockdown" mode. Locking key information into a content library allows for consistency of messaging, a unified voice, and a way to keep the same information from having to be reviewed time and time again.

Finally, the success of its SCM solution for patient narratives proved to Sanofi that SCM can be expanded to other departments. From preclinical research to clinical development to post-marketing, there are many opportunities for intelligent content re-use throughout the life of a product. Essentially, any application that involves documentation and reusable content is a candidate for SCM. Some common applications for pharmaceutical firms include:

- Labeling
- Clinical studies
- Patient narratives
- Standard operating procedures
- Technical documentation
- Training documentation

What About the Future?

Structured Content Management is already delivering meaningful change within the life sciences industry, and the potential exists for a true evolution—if not a revolution—in how information is created, reviewed, managed and shared in the future.

From a documentation creation perspective, SCM can open the door for greater collaboration and sharing of information. In the future, it may become commonplace for pharmaceutical companies, university research groups, biotech firms, and hospitals to share the same research information, albeit in an appropriate and secure way.

It's also possible that the regulatory review process might look very different in the future. If regulatory agencies have the certainty that specific content has not changed over time, or if they can view precisely how and when this content has been altered, there may be a reduced requirement for repetitive documentation. "If information is appropriately tagged," notes Sanofi's Joan Affleck, "a regulatory agency could theoretically hit a command on their computer to view that information in different formats, such as in a study protocol display or clinical study report template."

Ultimately, accelerating the process of new drug approval and improving the quality of this process offers a valuable benefit to patients. Being able to get a pharmaceutical product to market faster can mean offering a much-needed treatment option to patients sooner. At the end of the day, greater quality and efficiency in documentation may play an important role in optimizing patient care, opening the door to an entirely new way of bringing better healthcare to people faster.

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