ROCKLEY
PUBLISHING

Addressing the Challenges of Pharmaceutical Content

Prepared by: The Rockley Group, Inc.

moreinfo@rockley.com
905-939-9298
www.rockley.com
2015

Addressing the Challenges of Pharmaceutical Content

Part 2 in a 4-part series

As demographics change, and more and more new pharmaceutical and medical devices come to market, content plays an increasingly important role in regulatory requirements, and physician and patient knowledge and support. Yet content is still created and managed using manual methods requiring enormous amounts of time and human intervention.

The requirements for content in healthcare are increasing as well, with greater emphasis on helping patients to knowledgeably manage their conditions. Keeping up with the dramatic changes in guidelines and recommendations for patients, caregivers, and healthcare workers is very difficult and the increasing use of multiple devices is putting increasing pressure on the healthcare industry.

Dedicated and knowledgeable though our resources are, we can no longer rely on people to have an in-depth knowledge of our content and all its permutations to rapidly respond to changes and requirements. And we can no longer handcraft our content over and over again for multiple channels and devices. We don't have the resources or the time, and we can't afford the cost of this error-prone process.

Part 1: Challenges in Creating, Managing, and Delivering Pharmaceutical Content identified the challenges that Pharmaceutical organizations face. This second white paper looks at how intelligent content best practices can address these challenges.

Why is creating and managing pharmaceutical content so challenging?

Pharmaceutical organizations create a lot of content as:

- Molecules are discovered and formulated into deliverable forms
- Compounds/products are tested for safety and efficacy
- Applications for regulatory review and approval are created
- Labeling is developed
- Marketing, sales and training materials are created for approved products

To create multiple documents such as in Clinical:

- Investigational New Drug Applications (IND)
- New Drug Applications (NDA)
- Clinical Study Protocols (CSP)
- Clinical Study Reports (CSR)
- Common Technical Document (CTD)
- Formulary Dossier

In Labeling:

- Core Data Sheet
- United States Package Insert (USPI)
- Medication Guide
- Summary of Product Characteristics (SmPC)
- Patient Information Leaflet (PIL)
- Carton and package/container label

In Medical Communications:

- Medical letters

In Marketing:

- "Fair Balance Statement"
- Preparation and administration/Dosage and administration
- Sell Sheets
- Reimbursement guides
- Presentations
- In-Service Training

Too much content is created, recreated, and recreated for multiple uses. Content is created and managed in multiple areas within the organization, in multiple formats, and in multiple systems. Often, print-based materials are managed in layout products like Adobe InDesign and it is very difficult to make changes in a single document let alone across many related documents.

The methods used to create content are highly manual and error-prone. Content is written, copied, pasted, copied again, and on and on. Content is managed through people's due diligence and attentiveness to detail, but no matter how dedicated our people are, errors and mistakes happen.

Solution: Manufacture content, don't handcraft it

The way content is created today using multiple versions of the same content for different documents is unsustainable. Despite the fact that pharmaceutical content follows rigorous SOPs that define what needs to be included in a document, there are very few guidelines that identify how it should be written and created. It is as if we're back in the preindustrial age—handcrafting expensive artisanal products, only in this case they are handcrafted documents requiring huge amounts of labor. Different writers explain things in slightly different ways, and as content is reviewed and modified this causes a drift in the content. Each time this happens, it raises the level of complexity in the content and virtually guarantees an increase in translation and localization costs.

We have to move to a manufacturing model. We need to be able to build content products the same way we produce our products—using reliably created, consistently reused, and rigorously controlled content.

When a physical product is being designed, the individual components are considered a part of an interconnected whole, not just as small stand-alone pieces. The design is built around the fact that the components are reusable—you don't need to create new components to build new products. When you're manufacturing things, you can't be wasteful, rework is costly, and bottlenecks can kill productivity. We have to create content the same way: considering each component not only as an individual piece of information that has value, but also as a part of a larger content product, or ideally, part of more than one content product.

Manufacturers have been working on these ideas for years and we can learn from their efforts. We can learn from our own product manufacturing processes! Over the last 20 years, manufacturing has seen a number of techniques and methodologies come and go. But at the heart of the best of them lie two concepts that drive manufacturing toward making higher-quality products for less cost—lean manufacturing and agile manufacturing.

Lean manufacturing focuses on value: unless an action adds value to a product, it shouldn't be done. Agile focuses on speed. Together they concentrate on eliminating valueless work, errors, rework, and bottlenecks, and promote automation to allow people to work smarter, not harder.

It means that content creators will be able to concentrate on creating high-quality content that can then be reused in multiple content products. Think about it; each time you create a new product, you don't toss out everything you've learned from previous products and invent brand-new manufacturing processes. You use consistent product components and reuse best practice procedures to continuously produce quality products. That's what manufactured content is all about—designing modular, reusable content that can be efficiently "manufactured" into a variety of content products (documents).

Manufacturing content best practices

Manufactured content is supported by a methodology called Intelligent Content.

Intelligent content consists of three characteristics of content:

- Modular
- Structured
- Reusable

... supported by:

- Rigorous workflow
- Taxonomy (metadata)
- Structured content management system

Modular

Modular content is content that has been broken up into smaller chunks. Typically, a module consists of a section that begins with a title; however, you may find it appropriate to break the module down further into much smaller chunks. For example, dosage may exist as a module on its own.

Modular content enables you to:

- Change a single piece of content rather than a whole document
- Version and track each module individually
- Rapidly build new content assemblies from a selection of modules to meet new/changing needs
- Translate content based on only the modules that have changed, rather than the whole document

Structured

Structured content is content that follows a particular pattern. Content products have recognizable structures that are repeated each time the content product is created. Content products consist of components (topics) that also have structure within them. A content product can be a CSR, a PIL, a web page and so on.

Structured content:

- Makes it easier for authors to create content
- Ensures content is consistent and meets defined requirements
- Supports automated publishing

Reusable

Content reuse is the practice of using existing components of content to develop new materials. Reusable content is not content that is copied and pasted; rather you use the content in multiple locations by pointing to a single instance of the content (single source of truth). Reusable content reduces the time required to create, manage, and publish content, and it significantly reduces translation costs.

Reusable content enables you to:

- Write once, use many
- Write once, translate once, use many
- Change it once and automatically or selectively update the content everywhere it occurs (with no missed changes)
- Ensure content is consistent wherever it appears

Rigorous workflow

Workflow defines how people and tasks interact to create, update, manage, and deliver content. It's more than just the SOPs; it's a structured manner of linking the content, the SOPs, the Content Management System and your business requirements into a consistent flow of content. Workflow moves content from task to task, ensuring that the business rules specific to your organization are followed—for example, having sign-off occur at the appropriate levels.

Workflow ensures:

- Content adheres to the process as defined in corporate SOPs
- Content is reviewed at the right time, and by the right people
- Efforts aren't duplicated and content is consistent
- Work isn't held up at any given stage of the workflow
- Content is stored in the right place after it's written, reviewed, approved, and delivered.

Taxonomy (metadata)

Taxonomy is the discipline of organizing things, and metadata is "information about information." Put them together and we get a method for organizing and finding information. The information, of course, is your content.

We use taxonomy to structure your content into related categories (what type of content it is, where it might be used, what Health Authority affects it) and then use metadata to specifically identify it.

Some of the metadata is status related (what is the editorial status of this content, who wrote it, who reviewed it) other metadata is related to the taxonomic categories (what product does this content relate to, what country is it used in, who is the audience, what methods of measurement are used in a particular country).

By applying metadata to the content that answers these (and similar) questions, metadata enables:

- Effective retrieval
- Automatic reuse
- Automatic routing based on workflow status
- Tracking of status
- Reporting

Structured content management system

A structured content management system (SCMS) manages content at a granular (component) level, rather than at the page or document level. Each component represents a single topic, concept, or asset (such as an image or table). Components are assembled into multiple content assemblies (content products) and can be viewed as components or as traditional pages or documents. Each component has its own lifecycle (owner, version, approval, use) and can be tracked individually, or as part of an assembly.

A structured content management system enables you to:

- Manage (version control, access control) both components and documents
- Identify where content is reused
- Manage both components and documents through workflow
- Collaboratively review content
- Automate publishing

Addressing content challenges

Manufacturing content using intelligent content best practices addresses the challenges faced by pharmaceutical organizations. The following topics identify how the challenges can be addressed.

Managing change

In a typical environment, content is managed in the product that creates the content (e.g., Microsoft Word or Adobe InDesign). Structured content is created separate from format. Version control and workflow manage the structured components. Content cannot be published until it is approved.

Reusable content ensures that wherever the content appears, it is consistent and accurate. A change to the reusable content results in an automatic change everywhere that content appears. If you only want to update some instances of the reusable content, you can selectively choose which instances are updated and which are not.

Rather than reviewing content 'one after the other,' reviewers review content using collaborative review. Each reviewer can see changes and suggestions made by other reviewers, reducing confusion and fostering communication. Changes can be incorporated directly into the content, eliminating re-keying and reducing the need to continually proof the content.

Version control

Content is no longer attached to an email and sent out for review; content is reviewed and approved within the structured content management system. Every component, asset, and document is individually versioned. The most current approved version is automatically accessible, while previous versions can be retrieved if necessary.

When multiple concurrent versions of the same content are necessary to address multiple regulatory needs, each variant can be tracked and approved as necessary.

Managing content for multiple Health Authorities

Requirements for multiple Health Authorities (HA) can be addressed through structured master or core documents. The core document consists of all the modular content components that are common to all agencies and the components that are specific to one or another. Each component has metadata attached to it that identifies when the component is applicable. To generate a document for a specific HA, content is hidden or shown based on which components are required.

Content can be reordered as necessary, different terms substituted, and unique content added.

Globalization

In addition to configuring content for multiple Health Authorities, content must be configured and translated based on the region and country.

Translation is supported by structure and reuse. Structured content is more consistent content and is easier to create and translate. Each time content is reused, the cost of translation decreases because content that has already been translated does not need to be translated repeatedly.

Language Service Providers (LSPs) are typically responsible for making all the regional and country changes such as the units of measure. This is a very manual and time-consuming process. Content can be automatically configured at a more granular level such as within a component.

A variety of types of content can be configured to hide or show in different situations such as:

- Units of measure
- Thousands separator
- Date and time formats
- Use of symbols

In addition, structured content can be automatically published to page layout programs such as InDesign. The structured content is automatically "poured" into structured InDesign templates. Minimal or no tweaking is required to properly format the content. This significantly reduces the costs of laying out the translated content.

Supporting claims

Every claim must be backed up by references that support the claim. While the supporting references for the claims are not incorporated in the actual content, the references are required each time the content is reviewed. Claims are created as modular reusable components. Metadata is used to relate claims to references. Each time the claim is reused, the supporting claims are also reused; they never become separated from the claim. When a claim is revised, the claim is updated wherever it appears.

Conclusion

The methods used to create pharmaceutical content are highly manual and error-prone. Content is written, copied, pasted, copied again, and on and on. Content is managed through people's due diligence and attentiveness. Despite the fact that pharmaceutical content follows rigorous SOPs that define what needs to be included in a document, there are very few guidelines that identify how it should be written and created. It is as if we're back in the preindustrial age-handcrafting expensive artisanal products—only in this case they are handcrafted documents requiring huge amounts of labor.

We have to move to a manufacturing model. We need to be able to build content products the same way we produce our products—using reliably created, consistently reused, and rigorously controlled content. Manufactured content uses consistent content components and reuse best practice procedures to continuously produce quality products.

Manufactured content is supported by intelligent content. Intelligent content is modular, structured, and reusable and is supported by rigorous workflow, taxonomy (metadata), and a structured content management system.

Intelligent content addresses the challenges of pharmaceutical content.

The Rockley Group, Inc. (TRG) has been helping pharmaceutical, medical device, and healthcare providers create intelligent content strategies and adopt structured content management for more than 15 years. We help regulatory, labeling, and marketing content teams to meet the increasing demands of regulatory requirements, the complexities of globalization, and an increasing reliance on mobile devices. Our team of experienced analysts brings a wide variety of expertise to the table and can help you avoid expensive pitfalls.

The Rockley Group was established in 1995 to serve the information community. Our team has extensive experience at analyzing your content, your current workflow, identifying your pain points, and working with your goals and objectives to develop an intelligent content strategy that includes structured content models, reuse strategy, taxonomy, workflow, governance, multi-channel publishing, structured content management recommendations, and change management.

Our team of experienced analysts, content strategists, information architects, project managers, information technologists, and technology partners provide our clients with the skills necessary to create solutions that work.

Ann Rockley has helped pharmaceutical, medical device, and healthcare providers create structured reusable content strategies and adopt structured content management for more than 15 years. She has worked with clinical, regulatory, labeling, and marketing content teams—helping them to meet the increasing demands of regulatory requirements, the complexities of globalization, and an increasing reliance on mobile devices. Ann is known as the "mother of content strategy" for her ground-breaking work in analysis and content strategy and is the primary author of Managing Enterprise Content: A Unified Content Strategy (2nd Ed 2012). Ann has a MIS and is a Fellow of The Society for Technical Communication.

Charles Cooper is VP of The Rockley Group, Inc. He has been involved in creating and testing Life Sciences content for more than 20 years. Charles uses his prior experience in manufacturing and quality assurance to help companies understand their content and ensure that it can be intelligently created, managed, and published quickly and consistently. He develops workflow and taxonomy. He is co-author of Managing Enterprise Content: A Unified Content Strategy.