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Challenges in Creating, Managing, and Delivering Pharmaceutical Content

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Challenges in Creating, Managing, and Delivering Pharmaceutical Content

Part 1 in a series

As demographics change, and more and more new pharmaceutical products come to market, content plays an increasingly important role in regulatory requirements, as well as physician and patient knowledge and support. Yet content is still created and managed using manual methods requiring enormous amounts of time and human intervention. Keeping up with the dramatic changes in regulatory requirements and recommendations for patients, caregivers, and healthcare professionals is putting increasing pressure on the Pharmaceutical industry.

Dedicated and knowledgeable though our people are, we can no longer rely on them to have an encyclopedic knowledge of our content and all its permutations enabling them to rapidly respond to changes and requirements. And we can no longer hand-craft our content over and over again for multiple Health Authorities and audience needs. We don't have the resources or the time, and we can't afford the cost of this error-prone process.

Challenges in regulated content

A number of challenges face pharmaceutical companies in their creation and management of regulated content.

Managing change

In the early stages, Pharma content is typically written in Microsoft Word, but as the content moves closer to completion, content is moved into Adobe InDesign. InDesign is a good tool for developing attractively laid-out content, but it is not a good tool for managing content, let alone managing content that changes. It is difficult to identify where changes have occurred, but more importantly change which is required in multiple documents must be identified and manually changed in all the locations where it occurs. This is a very manual and error-prone task.

In addition, changes are typically marked on a PDF and have to be manually entered into the InDesign file. Errors can be introduced each time content is re-keyed so repeated review and validation are critical.

Every change often results in the requirement to 300% proof the content or to rely on comparison tools to confirm the accuracy of the change.

Version control

Content is typically attached to an email and sent out for review. It is very difficult to keep track of the most current version of content when it's buried in someone's In-box. As products go from approval back into revision as products change, it is often difficult to know which version of the content is the most recent version.

Once the content is finalized, it is typically stored on a shared drive or in a document management system with little attention to consistent naming conventions or metadata to clearly identify the date and status of the content. If a team is using a similar set of product content as a starting point for their material, they may accidentally select an older version to start from which doesn't have the latest version of a particular warning or other critical content. These situations can result in perpetuating old and incorrect content and could ultimately lead to costly errors in the field.

Producing content for multiple Health Authorities

Each Health Authority requires content to be provided in the form that meets their requirements. This may include a reordering of the content, removal of some content, modification of some content, or addition of other content. The preparation of content for multiple Health Authorities is a time-consuming task. Sometimes changes need to be reflected in multiple versions of the content. When this happens, each version must be changed manually.

Some companies use the Core Data Sheet (CDS) to manage local regulatory information, while others use it to manage multiple regional requirements. Moving from local to regional adds an additional level of complexity to the content, especially if it is managed in a Microsoft Word® document or Excel® spreadsheet. It becomes a matter of not only content complexity, but also a matter of technology limits as we try to manage multiple related threads of content for different Health Authorities in tools not designed for this activity.

Globalization

Content is not just local; it is global. Global distribution of content means that content must not only be translated, it must also be localized with the regional regulatory requirements. Changes and updates must be reflected in each language. Different product development teams may word the same content differently (e.g., a warning) resulting in the proliferation of multiple versions of translated content. Multiple versions of content increase the cost of translation significantly and they increase your management requirements to keep track of all the variations and update as required.

If content is managed in InDesign, this means copying and pasting changes into InDesign, increasing the probability of errors. If you have your Language Service Provider (LSP) provide the updated InDesign files, you incur yet another additional cost.

Supporting claims

Every claim must be backed up by references that support the claim. Claims are supported through clinical reports and other research. Before content is sent to regulatory, all the supporting documentation must be related to the relevant claims. Each time that claim is revised, updated or reused, the claim must be revalidated. When the relationship between claims and its supporting materials is done manually, it is a constant exercise to ensure that each and every time that claim is used, it is correct. Content can easily become separated from its associated supporting information resulting in a repeat of the claims validation process.

Marketing

Marketing content for Pharma products must also meet rigorous requirements for technical accuracy, claims, and regional requirements. These constraints can make it difficult to develop an effective content strategy. The law requires that ads and other marketing materials provide a "fair balance" of information about drug risks as compared with the information about drug benefits. This means that the risks must be fairly and accurately stated each and every time to ensure compliance.

In an effort to promote the benefits, the fair balance statement can get lost or modified so that it diverges from the standard when it is used in many different marketing vehicles.

Privacy issues also affect social interactions with customers making the task of social media more difficult.

Conclusion

There are many challenges facing pharmaceutical organizations in the creation, management and delivery of content. Current methods of management are time-consuming, error-prone, and unsustainable. Intelligent content best practices can help. Look for our second white paper in this series, "Intelligent Content for Pharma," coming in April that will identify how you can address these challenges.

The Rockley Group

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, complexities of globalization, and 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

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 has worked with Abbott, Bayer, Boston Scientific, Carestream, Edwards Lifesciences, Eli Lilly, Elekta, Johnson & Johnson, Lifescan, Merck, Medtronic, Roche, Siemens, Wyeth, and more.

She has developed the methodologies for industry best practices in intelligent content including structured content, content reuse, structured content management systems (SCMS), and globalization best practices, and has documented them in her book, "Managing Enterprise Content: A Unified Content Strategy," now in its second edition (2012). She is known as the "mother of content strategy" for her ground-breaking work in analysis and content strategy. Ann has a MIS and is a Fellow of The Society for Technical Communication.