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Medical Information

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Contents

Executive summary

The creation and management of the information supporting the development and marketing of pharmaceutical products has become a complex and costly process. Satisfying the need for information about a product in the post-launch phase has become particularly onerous.

As well as healthcare professionals, consumers and end-users now figure among those seeking information about the organization's products. At the same time, the channels through which they may be informed have multiplied and now include, in addition to traditional print documents and PDFs, web pages, mobile apps, social media and forums. As well as being increasingly globalized, the sector is also highly regulated.

Conventional document management systems have been slow to keep up with these developments. The document formats used in these systems (usually standard word-processing formats) make the retrieval and reuse of content in medical information processes difficult and prone to copying and versioning errors.

There is little provision for collaborative authoring and workflow controls to increase the productivity and accuracy of the editing processes, while the need to 'repurpose' information for multiple digital channels is labor-intensive and further penalizes productivity.

Recent advances in digital content management have addressed the above shortcomings. 'Structured authoring' systems based on XML create modular documents whose components can be held in a central 'pool' and used to generate information formats and responses through processes that are largely automatic. Documents and responses can be worked on in parallel by multiple users.

Permissions and checkpoints governing the workflow process ensure compliance with quality and regulatory requirements while reducing the need for manual supervision. The formatting of documents and responses for multiple digital and conventional channels is entirely automatic.

The result is to make the informing process faster and more efficient, while significantly improving the quality and compliance of response.
While the benefits of structured content management are particularly felt during the post-launch and marketing phases, all phases of the development cycle from discovery and clinical trials onward can be rendered more efficient and compliant through the use of this approach.

NOTE

The functionalities of the structured authoring approach described in this paper are those of the XML-based editorial platform *Méthode*, created by EidosMedia. *Méthode* has a worldwide user base that includes leading news media companies and financial institutions.

For more information see: www.eidosmedia.com or contact lifesciences@eidosmedia.com.

Medical information in the digital age

Introduction

Although documentation plays a fundamental role in the development of pharmaceutical products, conventional document management systems have been slow in keeping pace with the changing demands of the development process. At the same time they have been hesitant to take full advantage of the technological advances in digital content management that have emerged in recent years.

While the limitations of these systems manifest themselves at all stages of the development process, it is perhaps during the post-launch phase, when drug companies must deal with requests for information from healthcare professionals and other stakeholders, that their shortcomings become most apparent.

Maintaining an effective flow of information in this phase has become more complex and demanding due to both the multiplication of interlocutors, as well as the multiplication of channels and formats through which they may be informed. In addition to medical professionals, consumers and end-users now figure among the stakeholders with whom the company must communicate,[1] while web portals, chatlines and social media have all become possible channels of communication.

Regulatory requirements have also added to the challenge of informing effectively during this phase.[2] In many jurisdictions, all communications regarding a product's use and suitability must comply with standards of completeness, accuracy, etc., even when conveyed through more informal channels such as social media. This is particularly true concerning 'off-label' use of a product in a manner differing from that for which it has previously received approval. Careful control of the information conveyed to professionals and end-users is essential to mitigating compliance risk and associated penalties.[3]

This paper will look at the limitations of conventional document management systems in meeting the demands outlined above. It will then examine the ways in which a structured authoring approach based on XML may overcome such drawbacks, leading to greater flexibility, productivity and compliance in the informing process.

[1] Life Science CIOs Should Embrace the Digital Commercial Model (Gartner, 23 November 2016).
[2] The challenge of compliance in life sciences (Deloitte for Health Solutions, 2015).
[3] Navigating the year ahead Life sciences regulatory outlook 2017 (Deloitte, December 2016).

A new paradigm for the SRD

The ‘standard response document’ or SRD is a format favored by most companies to increase efficiency and uniformity in informing stakeholders. Bringing together all of the relevant information and data necessary to respond quickly and consistently to requests for information, this is usually an extremely heterogeneous document which may exist in several different editions to cover different geographical jurisdictions, as well as different language versions. Since the information relevant to the use of the product is continually evolving as a result of ongoing research and clinical practice, the SRD also requires regular updating and revision.

The use of an XML-based, structured authoring approach offers a number of significant advantages over conventional document handling for creating a validated, modular, single source of truth from which all communication channels can be served and updated.

This approach uses a dynamic, modular concept of the SRD. Rather than a single, monolithic compilation of information about a product, the idea is that of a ‘pool’ of validated resources that can be drawn upon to generate a range of documents and response formats, each tailored for a specific channel and recipient type.

Updates and corrections to any element in the pool automatically ripple through to all publications containing them, ensuring that all current communications are up-to-date and correct. (This ‘live’ content is entirely separate from past communications which are archived in a locked format that may be consulted, but not edited.)

Selection and formatting of the elements making up the response may be largely automatic, reducing response times and the need for manual intervention.

This approach overcomes many of the obstacles posed by conventional documentation systems.

The office app and its limitations

Most systems currently used for preparing and managing medical product documentation are based on conventional office word-processing and spreadsheet applications, often with the addition of basic document sharing and archiving functionalities.

Such systems are adequate for the preparation of simple reports, produced by one or two authors and destined for publication in a single edition in traditional print or PDF formats.

However, used for managing medical communications in a multi-channel, multi-interlocutor context, with frequent updating of source materials, they tend to be slow, labor-intensive, wasteful of human and technical resources and prone to errors and omissions.

The main shortcomings of these solutions are:

- **Storage of information in 'monolithic' documents**
  Standard word-processing documents pose obstacles to both the efficient retrieval of content and its reuse. Staff typically spend a large proportion of their time (50% according to a recent Gartner report) searching for existing content or recreating such content after failing to find it.

- **Duplication of resources and versioning problems**
  Once located, reuse of content brings additional problems: copying and pasting between documents creates multiple copies of an item. Subsequent updates or corrections must be made to all copies to ensure they remain synchronized. 'Version control' becomes onerous and errors become likely.

- **No parallel working**
  Conventional documents are 'locked' when being edited, preventing a document from being worked on in parallel by several authors. Splitting the document into sub-documents may help, but there is no provision for reviewing or previewing the whole document as it is developed.
  More evolved collaborative authoring applications such as Google Docs, provide access to multiple users, but lack the workflow controls needed for coordinated teamwork on critical content.

- **Limited workflow controls**
  Documents can be protected against erroneous editing by setting permissions, but these apply to the whole document. Effective workflow control requires differentiated permissions: some sections of a document freely editable, others only modifiable by a certain group of users, others 'locked' completely.

- **Manual repurposing for multi-channel delivery**
  Adapting conventional document content for dissemination through channels other than print or PDF (web portal pages, tablet or mobile apps, social media) is highly labor-intensive, requiring manual intervention and reformatting.

Another consequence of the limitations of conventional solutions is the recourse to ancillary systems to compensate for missing functionality. The result is often a constellation of applications of varying degrees of compatibility, difficult to maintain and update.

Although the addition of sharing and workflow functions may improve the performance of these systems to some extent, the fundamental unit of content in the system remains the document, limiting the flexibility and productivity of the solution.

The next section will look at how each of the above issues can be addressed by a suitable structured authoring system, with significant benefits in productivity, flexibility and accuracy.

Structured authoring

The role of XML

The power and flexibility of XML authoring systems derive from two main characteristics:

- **Granular representation**
  In an XML-based authoring environment content is represented at a more granular level than conventional document management systems. Each element of the document, from the smallest subtitle to an embedded video file, can be addressed and managed separately.

  This allows documents to be highly modular and consist of assemblies of subsections and media assets, each of which can be edited separately and may participate in other documents without copying or duplication.

- **Separation of content and presentation**
  The XML structure of a document is 'channel-neutral' i.e. agnostic to the communication channel - made up of pure content, totally separated from formatting. The appearance of each element is determined by elements called stylesheets and shape descriptors. For text elements the stylesheets specify typeface, font size, alignment, color etc. and for graphics they determine size, position, resolution etc.

  By applying different stylesheets to the same XML source, completely different formats and layouts can be generated. The same file that creates the printed package insert (patient information leaflet) for a product can also generate a web page or a mobile app version of the same content without manual intervention. Any update or correction to the file will immediately be visible in all rendered versions.

Multi-destination documents

The use of style information independent of content means that documents can be ready for multiple distribution channels from the moment of creation. Authors insert content into a template that is pre-formatted for multiple channels and already contains any fixed content such as disclaimers or disclosures. At any time, with a simple click, they can verify how the document will appear as a printed report, a web page, a mobile app version, etc.

As well as determining the appearance of the content, stylesheets can also determine the content to be included or excluded in each communication channel. In this way multiple editions can be created from the same file without duplicating or copying material.

This feature can be used, for example, to provide a brief version of a printed document for use on a web portal, with shorter headlines and some of the sections excluded or replaced by alternative text. At the time of publication the content is selected and formatted automatically for each destination channel. The document remains a single file for updating or archiving purposes.

Regional and language variants

The content of medical information responses may also vary between regions or regulatory jurisdictions. The modular nature of the XML document allows section variants to be included within the document file. The appropriate version of the section is selected automatically at the moment the response document is generated.

The same feature allows different language versions to reside in the same master file. Each language version is managed using the specific proofing tools and typographic rules for that language.

Parallel working

The modular nature of the document means that different users can work on different sections in parallel, improving overall productivity. Each user sees an up-to-date preview of the complete document as it develops, but may edit only the portions for which they have responsibility.

External content and boiler-plate

Documents may contain sections imported from libraries of fixed content (disclaimers and disclosures, for example). If such content is always included in a particular document type, it may be 'built-in' to the template so that it is always present when a new document is created.

Only users with the necessary permissions may modify this content – other authors may include it in their documents, but not edit it.

Like all material in the database, updates and corrections to the fixed content are immediately reflected in the documents containing it, ensuring that they are always up to date.

Permissions, QA and compliance

Each element of a document may have permissions assigned to it, specifying which users or groups may do what at each step in the workflow. These permissions are assigned automatically and change as items pass along the workflow sequence, ensuring that only authorized users may carry out permitted actions at each stage.

The modular structure of XML documents means that different permissions may be set for different parts of the document, preventing editing of fixed or critical sections, while allowing variable content to be modified by authorized users.

Other controls take the form of checkpoints, preventing certain operations from being carried out on a document until a particular validation or approval has been completed.

Permissions and controls are set up following a detailed analysis of the workflow sequences that users need to perform. Access and action privileges are assigned for each type of user across each content category and workflow sequence.

Once set up, the operation of permissions and controls is a largely automatic process, preventing erroneous editing or corruption, without intensive manual supervision.

These workflow controls significantly increase the speed with which documents can be created and edited. For example, by 'locking' imported material that has been previously approved, the permissions system makes further review of this content unnecessary.

At the same time the controls eliminate many sources of inaccuracy and compliance failure.

The content repository

The result of the XML authoring process is to create a content repository - a ‘pool’ of elements that can be combined to create documents and responses.

Some of these elements will be unique to a single product; others will be common elements, shared between different products or families – such as disclaimers, corporate information, regulatory statements etc. These common elements will be present in the database in only one copy; updates to that copy need only be made once and will show up in all product documentation it is linked to.

The structured response

The structured nature of the resources in a content repository created by this kind of authoring system allows faster, more accurate responses, especially in a multichannel, multi-interlocutor context.

Locating content

A repository of XML-based content can be interrogated very effectively using modern search technologies. The structured nature of the data means that, as well as entire documents, searches can return individual elements within the document structure.

Non-text content, such as images or media files, can be located using the metadata tags that the platform attaches to such content to facilitate its subsequent management and retrieval.

Fast, reliable retrieval of information resources cuts response times and improves staff productivity.

Re-using content

Any piece of content in the repository, from a dosage table to a video presentation, can be incorporated into other documents or responses. This is a simple drag & drop operation, creating a link to the single up-to-date copy within the database.

The linked item is automatically formatted by the template of the host document by applying the appropriate stylesheets and shape descriptors.

This mechanism allows rapid re-use of existing resources, ensuring that the linked item is up to date and correctly formatted.

Generating the response

Once the content repository has the necessary text and media elements, it can be used to produce information materials or responses to specific queries by populating pre-formatted templates.

The extreme flexibility of the XML structure means that information materials may be generated in an indefinite number of formats, from printed leaflets and PDF reports to web portal pages or brief summaries for mobile devices and social media posts.

Responses to specific inquiries may be produced semi-automatically, using a basic response framework with standard 'boilerplate' into which sections are inserted using drag & drop actions, according to the subject of the inquiry. These formats may range from a detailed reply to a health-care professional, to a short response to a request from a consumer via social media or a user forum.

Speed and accuracy

Documents and responses can be compiled quickly in this sort of system without compromising the quality and accuracy of the information. This is due to a number of key features of the approach:

- **One source.** The response is generated from a template in which all fixed content is completely up to date.
- **Automatic formatting**. All included text and graphics are automatically formatted correctly for the channel(s) used to deliver the response. All content presentations reflect the graphic identity of the organization.
- **Trusted content.** All information included in the response is approved and up-to-date because it is the only version and is generated from a single copy in the repository. No unauthorized users have accessed or edited the content.
- **Automatic compliance.** Many compliance features are 'built in' to the response 1) because it has been created according to the approval process described above and 2) because of configurable rules forcing the inclusion or exclusion of certain types of content according to the regulatory context.

These functions ensure that the response is both accurate and well-presented, while reducing the need for manual examination and verification.

Updating and maintenance

Periodically the information in the content repository will need to be revised and updated. New studies, both inside and outside the organization, may present new clinical data; there may be changes in regulatory requirements, off-label uses of the product may emerge. At the same time, some information may have passed its validity date and need to be retired or replaced.

XML-based systems can simplify and automate a lot of this maintenance work:

- The single-copy approach means that each content item in the repository need only be updated once in one place. All subsequent use will reflect the changes.
- The metadata tags that accompany each piece of content can contain a 'clock' that sends an alert to the person responsible when it reaches its retirement date; a similar mechanism may prevent the information from subsequently being used until it has been revised or replaced.

- Automatic alerts can also be set up to monitor external clinical databases to inform staff when a new publication mentions a product for which they are responsible.

These mechanisms significantly reduce the amount of manual inspection and intervention required to ensure the validity and completeness of the material in the repository. As well as increasing staff productivity, they also contribute to improving the quality and compliance of the information used in responses.

Cross-project potential

This paper has concentrated on the use of XML-based content management for the purpose of managing medical information during the distribution phase of the product life cycle. It should be clear, however, that the productivity and compliance benefits of the approach need not be limited to this phase.

In fact, the efficiencies and economies of a structured authoring approach can bring significant advantages at all stages of the development process, from initial discovery, through clinical trials, to manufacturing and marketing.

If used from the outset of the development project, a significant proportion of the content generated at each stage can be used to feed the content repository of the next phase, eliminating unnecessary duplication or rewriting. The savings in time, human resources and costs across the lifetime of the project may be considerable.

Standards and interoperability

Interfacing and integration

The XML format and the stylesheets used to specify appearance and layout are technical standards that make interfacing with other digital platforms straightforward using standard APIs and protocols such as REST.

This allows XML-based systems to form part of complex ecosystems, where the ability to exchange content with other platforms in the organization, from customer relationship management (CRM) systems to financial planning, adds considerable value to the solution.

At the same time, standard third-party tools like MS Excel™ and Adobe Photoshop™ can be integrated into the editing environment to provide specialized functionality without leaving the XML workspace.

Multi-system replacement

The versatility of XML-based platforms often allows them to replace the functionalities of several different systems:

- editorial planning
- editorial production
- page design
- digital asset management (DAM)
- web CMS
- video editing
- social media management
- mobile and tablet publishing
- business intelligence

Typical deployments replace up to dozen existing systems with a single platform.

Conclusion

Increasing globalization, fragmentation of communication channels and more stringent regulation have contributed to the cost and complexity of creating and disseminating medical information. At the same time, however, advances in content-management technology offer organizations the tools to meet these challenges.

By using a structured-content approach based on a channel-neutral format like XML, organizations can manage their information resources, as trusted pools of content from which informational formats and responses can be generated, specifically tailored for channels and recipients.

Automatic selection and formatting of content speeds creation and response, while workflow controls ensure quality and compliance, reducing the need for manual inspection and control.

These recent advances in content-management technology offer organizations the opportunity to manage their information resources in a way that is both sustainable and cost-effective.