THE ROCKLEY GROUP

Managing Life Sciences Content: A Unified Content Strategy

White Paper

Revised April 5, 2003

Table of contents

Introduction

Document management has been key in the management of successful life sciences content. As web information and e-commerce initiatives have grown, web content management has also become an important part of an effective content management strategy. However, life sciences content consists of much more than just web content and of much more than just documents. Content spans the entire enterprise; it is authored by multiple content creators and delivered to multi-channel information products for use by multiple users in multiple media.

- Content creators
  - Marketing/Communications
  - Clinical
  - Manufacturing
  - Regulatory
- Content users
  - Regulatory agencies
  - Physicians
  - Patients
  - Regulatory
  - Employees
- Multi-channel information products
  - Submissions
  - Labeling
  - Internet
  - Intranet
  - Enterprise portals
  - Marketing materials
  - Training
- Multiple media
  - Paper
  - Web
  - Wireless
  - PDA

The Content Silo Trap™

Too often, content is created by authors working in isolation from other authors within the organization. Walls are erected among content areas and even within content areas, which leads to content being created, and recreated, and recreated, often with changes or differences at each iteration. We call this The Content Silo Trap™.

A unified content strategy

A unified content strategy can help your organization to avoid The Content Silo Trap, reducing the costs of creating, managing, and distributing content, and ensuring that content effectively supports your organizational and customer needs. A unified content strategy is a repeatable method of identifying all content requirements up front, creating consistently structured content for reuse, managing that content in a definitive source, and assembling content on demand to meet your customers' needs.

Reuse plays a pivotal role in a unified content strategy. Most organizations already reuse content, though they copy and paste it. This works well until the content has to be updated everywhere it appears. Finding the content everywhere it has been revised can be time consuming. Not only is this time consuming, but it also causes errors if some occurrences of content are missed. Reuse as discussed throughout this whitepaper is the process of "linking" to an element of reusable content. The reusable content is displayed in the "document" you are working in, but does not actually reside in the document.

Benefits

A unified content strategy provides many benefits including:

- Faster time to market

   The time between regulatory approval and the time when a competitive product reaches market is shortening. This means that the opportunity to recoup costs of research and development and make a profit are decreasing. Many life sciences companies calculate their "lost opportunity cost" in millions of dollars for every day lost getting to market. It is imperative that they find ways of getting their product to market faster. While there are many aspects to the product development life cycle that must be improved to ensure faster-time-to market, the creation of content can play a significant role. Reduced content creation time is achieved through the following.

   - Less work to create content

      Content can be reused (written once and used many times). There are many opportunities for reuse in life sciences content:

      - Disclosures (reuse ensures disclosures are consistent wherever they appear)

      - Among labeling documents (Patient guides, Physician guides, Quick reference cards, Packaging labels, Package inserts)

      - Submissions (within a report and across the submission)

         At a recent DIA conference (Electronic Document Management Feb. 2002) Stephen Arlington, Head of European Pharmaceutical

Consulting, PriceWaterhouseCoopers stated that "re-using submission content was today's best practice."

- Less work to maintain content

  When content is written once and reused multiple times, it is less work to maintain the content as it can be changed once, resulting in changed content everywhere it is reused.

- Less time to review content

  Regulatory requirements mean that life sciences content must be reviewed numerous times and by numerous areas within the organization (e.g., regulatory, legal, engineering, clinical). This is a time consuming process and one that requires the reviewer to constantly check revised content with changes to the previous content.

  If content is written once and reused many times, everywhere that content appears you can guarantee that it is the same so reviewers only need to review it once. In addition, if the content changes, everywhere the content is reused the content will be changed so that no occurrences are missed.

  Once content has been reviewed by the regulatory agency and approved, a content management system can ensure that it is not changed without appropriate approval by your internal regulatory group.

- Improved quality and consistency

  If content is written once and used many times you can ensure that:

  - The message is the same across the organization

  - Content is the same wherever it appears

- Better use of resources

  If less content needs to be written (e.g., reused content reduces the amount of work), then fewer resources are required to create content. The same resources can be used to create more or better content.

- Repetitive processes are reduced

  The repetitive processes of writing, rewriting, reviewing, translating, and approving content is reduced through reuse.

- More value added work

  If resources are freed up from doing repetitive work, more value added work can be accomplished such as:

  - Improved quality of content

  - Content designed to more effectively meet the needs of the customer

  - Creative delivery of content

21 CFR Part 11

A unified content strategy combined with enterprise content management technology will help you to address the requirements of 21 CFR Part 11. 21 CFR Part 11 defines the regulations and criteria under which the FDA will accept electronic documents, electronic signatures, and handwritten signatures (applied to electronic records) as the equivalent to paper documents with signatures. The goal is to provide the maximum possible support to electronic technologies while still ensuring the validity of the submissions process.

The regulation defines:

- Validation
- Complete and accurate reproduction copies of documents
- Document archives
- Audit trails
- Control of systems documentation
- Controlled access (with competency)
- Electronic signatures

The reuse of content shares the requirements of 21CFR Part 11. Content, existing as physical or logical pieces, requires much more rigorous and systematic management than traditional documents. To be considered for submission as an electronic document, the document must have clear and traceable life cycle. Unlike in traditional documentation where content is copied and pasted and you cannot trace the history of reuse, you can clearly trace the history of a reusable object and ensure that it is the same object in a unified content strategy.

In addition, a unified content strategy requires that you be able to easily find, and clearly identify the content that you reuse. This is also a clear requirement for compliance with 21 CFR Part 11.

Quality initiatives

A number of life sciences organizations are adopting Six Sigma as a way to improve their customer service. A unified content strategy can help you to address your Six Sigma initiative:

- Content is product

  Content is a key component of every product. Content describes your product, its functionality, and its efficacy and safety for regulatory agencies. It helps your customers make the right purchase decision (marketing), how to use your product (physician and patient documentation and training) and supports your customer as they use the product (customer support).

- Content is manufactured

  Content is manufactured just like any product. It follows a specific repeatable life cycle process. The processes associated with the creation, management, and delivery of content can be significantly improved through a Six Sigma initiative.

You can address your DMAIC initiative by conducting a substantive audit (detailed analysis of your customers, content life cycle, content analysis) to:

- *Define* your customer content requirements through a audience analysis

- *Measure* the effectiveness of your current processes

- *Analyze* your current content life cycle process

Then develop your unified content strategy, define your vision, and determine your new processes to:

- *Improve* your content life cycle processes

- *Control* your processes through a clearly defined methodology or content management system and associated workflow

Analysis

Analysis is the first step in implementing an effective unified content strategy. It forms the foundation of your understanding of your content, processes, and technology requirements.

This section includes information on the following:

- Importance of analysis to a unified content strategy
- Benefits
- Customer analysis
- Information analysis
- Process analysis
- Skill set analysis
- Technology analysis

Importance of analysis to a unified content strategy

Analysis is critical to the successful implementation of your unified content strategy. It is important that the technology and processes support your corporate needs. Lack of a thorough analysis may result in an ineffective solution both for your employees and your customers.

Benefits

The results of analysis enable you to effectively:

- Create information models
- Design metadata
- Reuse content
- Develop templates
- Structure the information repository
- Design workflow
- Select appropriate tools

Business needs analysis

You need answers to the following types of questions:

- What are the goals of the organization?
- What are the challenges the organization faces?
- What are the needs of the customer?
- How can a unified content strategy address business needs?

Information analysis

Before you can build your unified content strategy you need to understand the content and structure of your information so that you can model it, develop authoring forms/templates, and determine how you can optimize the creation and management of content through content reuse. You need to look at this information closely to determine:

- Structure of the information
- Content of the information
- Potential areas of content reuse
- Potential areas for improvement

For example[1]:

This example is for a medical devices company that produces blood glucose monitoring meters. Because there are several versions of the meters, the company suspects there are may be similarities—or inconsistencies—in the information products produced for each version. Their audit focuses on comparing content across information products so they can figure out how to reuse information and ensure consistency.

The following table represents the top-level analysis of their materials.

	Information product						
Content	Owner's Guide	Quick Reference Card	Quick Start Guide	Web Site	Brochure	Product Package	Label (package insert)
Company logo	X	X	X	X	X	X	X
Contact information	X	X	X	X	X	X	X
Important (read the Owner's guide before...)	X	X	X	X		X	X
Product description	X			X	X	X	
Setting up the meter	X	X					X
Testing the meter	X						X
Sampling the blood	X		X				X
Inserting the test strip	X	X	X				X
Interpreting the results	X	X					X
Caring for your meter	X						
Solving problems	X	X					

The top-level analysis shows areas that warrant closer examination. For example, the company logo and contact information are used in every information product and the product description is used in all but three. In addition, a number of topics related to the setup and use of the product are repeated throughout.

---

1. This example is reused with permission from "Managing Enterprise Content: A Unified Content Strategy" New Riders Publishing, Oct. 2002

The results of the top-level analysis are used to drive the in-depth analysis. In this case, the top-level analysis shows similar information in the setup and use of the product. Further examination of the "Inserting the test strip" procedure shows the following:

Owner's Guide	Quick Reference Card	Quick Start Card
Step 1	**Step 1**	**Step 1**
Insert the test strip. Make sure the contact bars go in end first and facing up. The meter will turn on automatically. - - - will appear briefly on the display. *Note:* The bars must be all the way into the meter to avoid an inaccurate result.	Insert the test strip. Once inserted, meter turns on automatically.	Insert a test strip to turn on the meter.
Step 2	**Step 2**	**Step 2**
Apply the blood sample...	Apply the sample...	- - - will appear on the screen.
		Step 3
		Apply the blood sample...

There are subtle differences in the first two samples (Owner's Guide and Quick Reference Card), but the third sample (Quick Start Card) has a different second step. Are the differences necessary or will they confuse users? Quick Reference Cards provide concise information so the shorter steps are appropriate. The same holds true for the Quick Start Guide; however, the second step isn't really a step. The differences in the steps should be reconsidered.

Although this example shows just a small portion of content, it illustrates the seemingly insignificant, yet critical variations that can occur in content. In this case, the content would benefit from a unified strategy to ensure that each time the same information appears, it is consistent.

Process analysis   A unified content strategy facilitates the management and distribution of information through workflow. The workflow may replicate your current processes, or may change the processes. You need to analyze your existing processes to determine the content life cycle processes (create, review, manage, deliver) in your organization, and identify areas for change or improvement.

Skill set analysis   A unified content strategy introduces new tools, new processes, and new roles. You need to look closely at your authoring teams to determine their current skill sets. This analysis helps you to determine the impact unified content strategy will have on your organization.

Technology analysis   A unified content strategy brings new technology into the organization and must integrate with existing technology. You need to perform a thorough analysis of your existing technology base to determine what technology should be integrated and what should be replaced. Based on the results of

technology analysis, the other analyses, and your future requirements, you should develop criteria for the selection of specific tools and technology appropriate to your needs.

Designing information models

One of the most critical phases of a unified content strategy is building the information models on which the project is based. During the information modeling phase, you determine the elements required for each information product (or output) and how each information product will be designed for optimum usability and reuse. Once you decide which information products you need to develop and the information they should contain, you can develop the metadata, content standards, and templates to support them. Thus, the information models become the road map for your project.

This section describes:

- What is information modeling?

- Importance of information modeling

- Benefits

- Designing effective models

What is information modeling?

In a unified content strategy, you break information down to the element level (e.g., section, paragraph, sentence). Instead of writing documents, you write elements that are stored in a single source (often a content management system). Elements are then compiled into information products from that repository. The power of content reuse lies in effectively reusing information elements—whether they're paragraphs, procedures, or sentences—over and over again. Information models identify all the required elements and illustrate how to structure and reuse them.

The process of information modeling involves identifying all the information requirements for a particular project (or for an entire organization) up front, deciding which information belongs where, then building a model that illustrates how information elements will be compiled to form each information product. Authors refer to models to determine which elements are required for each information product and to determine which elements are reused.

Importance of information modeling

When you build information models that consider information requirements across an entire organization, you look beyond your own department to determine how other areas can use your information and how you can use theirs. An effective information model serves to identify all the knowledge within an organization, and to capture and reuse it effectively.

The information modeling process forces you to consider all information requirements and to assess what information is available to fulfill those requirements. You need to consider who produces the content, who uses the content, and how you can use the content in more than one place.

The information model becomes the "catalog" of all information products produced within an organization, and outlines the necessary information elements for each of them.

Benefits

Following an information model throughout an organization ensures that all information products are consistent, and that information is reused wherever it can be. Developing an information model not only provides you with an understanding of all the information within your organization and how it can be reused, it also ensures that authors develop information in the same way, so it can be reused effectively.

Designing effective models

Designing effective models requires that you start with solid audience and information analysis to understand who uses what information, and in what context. Information models depict all possible **uses** and **users** of your information, so you need to understand their needs. Thorough analysis of both use and users forms the basis for your information model.

Information product models vs. element models

Information product models identify how information will be compiled to create an entire information product (e.g., submission, manual). They contain information such as what elements are required, which are optional, and the order they appear in.

Information element models identify how each element in the information product model is structured. They identify such things as the semantic structure for each element, the metadata associated with each element, as well as any other elements nested within elements (e.g., overview, product description).

For example the model for the procedure shown earlier in the blood glucose materials would look like where the "X" indicates that the element would be reused in that information product:

Semantic	Owner's Guide	QRef Card	Quick Start Card
Step	X	X	X
Action	X	X	X
Detail	X		
Results	X	X	
Note	X		

Or the model for a component of a submission could look like:

- Objectives title
    - Study objectives
    - Main objectives
        - Main objective title
        - Objective
- Secondary objective
    - Secondary objective title
    - Objective

Metadata

As you have no doubt noticed, there is more information available than ever before, on the Web, your company Intranet, in your content management repository and elsewhere. This is both exciting and problematic, and extremely frustrating when you can't find what you're looking for.

More complex authoring processes and information delivery requirements need some way of classifying and identifying all of the information or content "bits" so that they can be retrieved and combined in meaningful ways for users.

What is missing is information about the information—that is, labelling, cataloguing and descriptive information—that allows the content elements to be properly processed and searched by a computer. This information about information is known as "metadata".

While metadata has been a buzzword in the information technology and data warehousing business for some time, it has recently emerged as an important concept for those who are developing search and retrieval strategies for information in reference databases or on the Web, for authors of structured content, and for developers of enterprise content management and Web publishing solutions.

This section includes information on the following:

- What is metadata?
- Importance of metadata
- Benefits
- Main uses of metadata
- Defining metadata and metadata categories

What is metadata?
Traditionally, metadata has been defined as "data about data". While this is true, metadata is actually much more. It is the encoded knowledge of your organization, described by David Marco as:

"… all physical data (contained in software and other media) and knowledge (contained in employees and various media) from inside and outside an organization, including information about the physical data, technical and business processes, rules and constraints of the data, and structures of the data used by a corporation."[1]

---

1. David Marco, *Building and Managing the Meta Data Repository: A Full Lifecycle Guide.* 2000, John Wiley & Sons, Inc., New York, NY

Importance of metadata	This definition is significant because it includes the often-overlooked idea that metadata can be used to describe the behavior, processes, rules and structure of the data, not just descriptive information. These elements are important when developing a sound metadata strategy for content search and retrieval, enterprise content management, and dynamic content delivery, because they determine not only what the content is, but who uses it, how it will be used, how it will be delivered, and when.

Metadata enables content to be retrieved, tracked, and assembled automatically, and makes content accessible. Metadata enables:

- Effective retrieval

- Automatic population of existing elements into placeholders for content reuse

- Automatic routing based on workflow status

- Tracking of status

- Reporting

Benefits	Using metadata for retrieval and content management enables content to be retrieved, tracked and assembled automatically, resulting in:

- Reduction of redundant content

- Improved workflow

- Standards that enable consolidation of hardware/software

- Lower maintenance efforts

- Reduced costs

When building a business case for a unified content strategy, try to include other related but less obvious benefits and cost savings due to metadata use, in the areas of information reuse, customer support, translation and localization.

Main uses of metadata	Although there are many uses for the content and data stored in your system, there are generally three main activities you perform in relation to the content:

- Reuse

- Retrieve

- Track

This section explains the usefulness of metadata to these three activities.

Metadata for reuse

Metadata for reuse can be particularly useful in a unified content strategy, eliminating content authoring redundancies. In this case, metadata is applied to each content element. Authors can search for elements before beginning to write, to see if they already exist somewhere in another document stored in the content management system.

Metadata for reuse could include:

- Content type
- Where the content should appear
- Creation date
- Content owner
- Keywords
- Links to where content is already used

Some metadata for reuse is applied automatically, based upon the document definition, (e.g., type of content), while other metadata is added by the author (e.g., keywords). Your system can use this metadata to find existing reusable elements, and, in more sophisticated systems, to populate placeholders in new materials in your authoring tool.

Metadata for retrieval

Metadata for retrieval enables content to be retrieved through searching, either in an authoring tool, or in your retrieval tool, such as your intranet or the Internet. Metadata for retrieval can include much of the same metadata you define for reuse, but is usually much more extensive. It can include metadata such as:

- Title
- Author
- Date (creation, completion, modification)
- Keywords
- Responsible party
- Security status
- Tracking (e.g., status)

Metadata for retrieval enables users to specifically define which content elements they want to view. This metadata can also be used to dynamically populate content for users, based on specific profiling information.

Metadata for tracking (status)

Metadata for tracking is particularly useful when you are implementing workflow as part of your unified content strategy. By assigning status metadata to each content element, you can determine which elements are active, control what can to be done to an element, and who can do it. Generally, status changes based on the metadata are controlled through workflow automation, not by end users. Status metadata can include:

- Draft (under development by the author)
- Draft for review
- Reviewed
- Approved
- Final
- Submitted

Defining metadata and metadata categories

Properly defining and categorizing the types of metadata you want to capture about your information is extremely important to the success of your metadata strategy. Improperly identified metadata, or missed categories of metadata, can cause problems ranging from misfiled and therefore inaccessible content, to more serious problems such as those encountered by the National Aeronautics and Space Administration's (NASA's) 1999 Mars Climate Orbiter mission, in which misidentified metadata resulted in the loss of the spacecraft, at a cost of $300 million![1]

First of all, you need to determine if you are defining metadata for retrieval, reuse, or tracking. Then, you need to understand what the end business result is that you are trying to achieve, and build your metadata backwards in order to achieve that result.

Properly defining the metadata you need helps to make sure that the right information is delivered to the right person, for the right reason, at the right time.

1. David Marco, *Building and Managing the Meta Data Repository: A Full Lifecycle Guide.* 2000, John Wiley & Sons, Inc., New York, NY

For example the model and related metadata for the procedure shown earlier in the blood glucose materials would look like:

Semantic label	Metadata
Step	All
Action	All
Detail	Owner's guide, Qref Card
Results	Owner's guide, Qref Card, Quick Start Card
Note	Owner's guide

Structuring content

When implementing a unified content strategy in your organization, content must be structured so that wherever it is reused, it "behaves" the same way. Regardless of who writes and stores a content element in your content management system, the element's structure must be the same, so that when an information product is assembled, all the elements fit together cohesively. Structured content also assists users in finding and comprehending information.

This section describes:

- What is structured content?

- Importance of structured content

- Benefits

- Principles of structured content

- Understanding content vs. format

What is structured content?

Information models tell you what you need to include in your information products. However, they don't tell you how to write the content effectively. Structured content principles provide these guidelines. Structured content principles are not as "rigid" as models, in that writers must make some informed decisions on what guideline to use in a particular situation. However, effective structured content guidelines used in conjunction with models produces clear, understandable, and very consistent materials.

Why structure?

Information can be structured such that each time someone views an information product (e.g., physicians guide, patient guide, package label), it always contains the same types of information, in the same order, with the same presentation style. Structured content guidelines help to govern how content is written. Guidelines are based on how the information is going to be used (e.g., in which information products) and what type of information it is (e.g., procedure).

Importance of structured content

A unified content strategy relies on all information elements adhering to content guidelines and can even enforce standards for each element of information stored in the system. Without effective content guidelines, you will not be able to reuse information effectively and will need to manually adjust the pieces to fit the information product you are compiling. This defeats the purpose of a unified content strategy, because you still have to "tweak" information to make it fit. Once you tweak the content, the source is no longer valid. All updates must be made at the source so that wherever the content is used, it is updated consistently. Structured content guidelines ensure that the content will be appropriate wherever it is required, so the manual adjustments are not required.

When establishing structured content guidelines, you look at each type of information your organization produces. In doing so, you are building a "catalogue" of all the information you produce, helping you to manage it more effectively.

Benefits

Within an enterprise, information often suffers from inconsistencies in presentation, structure, and organization. Standards for producing information may vary from department to department, and often one department will not know that another department is working on a similar information product or, that they could use information your department is producing.

Inconsistencies can cause frustration, lost time and money while users try to find and interpret information, as well as the costs from having to rewrite information for multiple uses. However, the majority of these issues can be addressed through the use of structured content. Structured content provides:

- Improved readability
- Improved usability
- Increased consistency
- Reduced maintenance costs
- Transparent reusability of information (e.g., across operating systems)

Following a method of structured writing also means that all contributors to the documents (both subject matter experts and writers) have a standard template (or outline) to follow when providing, writing, and editing information.

Principles of structured content

Structured content adheres to principles of cognitive psychology and is based on how people read and comprehend information. Structured writing also assumes that "not all information is created equally." In other words, information differs according to its type and should be consistently structured in a way best suited to its type. For example, a procedure is different than a process, or a concept, and should use a structure best suited to procedural information.

Defining structure

To define the structure of your content, you need to:

1. Identify content for different audiences/product lines/platforms.

2. Identify how content will be reused.

3. Decide how best the content should be structured, based on its type and potential audiences, based on principles of clear communication. Set guidelines for each information type.

4. Formalize and publish structured content guidelines for all authors to follow, showing how all the pieces fit together to form a complete information product.

Understanding content vs. format

Structured content relies on content standards rather than format standards. Content standards refer to the type of content in each element, and how it must be structured in order to be reused. Format standards refer to how the information must look, in the published outputs. While format is critical in helping users to read and comprehend information, it is addressed separately from content. This allows writers to focus on the content—ensuring the content is accurate and contains the necessary elements for comprehension and for reuse.

Format is addressed through information design, and is normally attached to content elements through stylesheets (e.g., XSL or cascading style sheets).

Changing processes and roles

Implementing a unified content strategy in your organization brings about many changes. Designing and writing structured content for reuse, together with the designated tools, requires changes to processes, as well as specific roles and skill sets.

In this section, we examine the following areas related to changing processes and roles:

- Collaborative authoring

- Re-engineering your content development processes

- Redefining roles in the organization

Collaborative authoring

Collaborative authoring is the combination of tools, processes and metadata that allow teams of two or more people to create content together. This can include authoring tools, content management systems and automated workflow.

Chances are, your authors are already creating documents in a somewhat collaborative fashion. Implementing a unified content strategy, however, requires even more cooperation and tighter integration of authoring processes in order to be successful.

Processes for collaborative authoring

There are specific changes you can make to your content development processes to make them more collaborative.

Most organizations create content for both paper and web. Content may be rewritten for one media or the other, or the content for one media is "massaged" to fit into the other media.

This process results in a high level of customization of the content depending on the context, and you end up with two different "instances" of the information. Changes to one may not be made in the other. Manual tracking, and duplication of the authoring and maintenance effort, is costly and time-consuming. As well, chances are your authoring groups work in "silos", or in relative isolation from one another, with little collaboration involved in either the content design or authoring process.

When you move to a unified content strategy, using collaborative authoring, you automate the tracking process, and eliminate redundancies in authoring and updating content elements. For this to work effectively, however, changes must occur to the way you design and write your content, both in structure, and in who does what. This can happen in several ways, for example:

- Specialized authoring

- Generalized authoring

Specialized authoring

Authors can become more specialized in a particular area of knowledge, and more generalized in the style of writing they produce. This requires a certain amount of flexibility on the part of authors, and an ability to see the "big" picture of the content set, understanding the overall information architecture and audience requirements. Because the information model is set up to accommodate all possible content outputs, the same author is responsible for writing both types of materials in one content element, according to the predefined model and structure, in such a way that both contexts are addressed.

Generalized authoring

An author from one group can remain responsible for the "parent" information set. Through automated workflow, authors downstream can access the completed content, and add context to it, according to the predefined model and structure. Because the content elements they are using reside in the CMS, they are automatically updated when the owner of the "parent" information set makes changes, eliminating the need to change the information in two places.

Importance of adherence to structure

In both cases, authors must work collaboratively to adhere to the predefined model and structure of the information. This is essential to the success of your unified content strategy. Depending on the tools you use, the structure can be enforced to a certain extent by the authoring tool. No tool, however, can ensure that the structure of individual content elements is consistent and properly written.

Authors need to be committed to the collaborative idea of authoring. Sharing reusable elements helps to ensure that collaboration occurs, because more than one author is involved in the process.

Re-engineering your content development processes

Collaborative authoring, will most likely require that you re-engineer your existing content development processes. Once you've conducted a thorough process analysis, re-examine your existing authoring and publishing processes with a view to improving efficiency, using the new tools.

Processes must be redesigned to match the way the authors work, and not make the authors work the way the system does.

Typically, process re-engineering is performed by business analysts in your organization who have an excellent understanding of the content creation cycle, and the issues and priorities of content creators.

Redefining roles in the organization	A new system and re-engineered content development processes mean that existing content development roles will change and others may be added. Some of the roles include:

- Information architects
- Authors
- Information technologists
- Enterprise project coordinators
- Content owners
- Editors
- Business administrators

Enterprise project coordinator (new role)

The traditional role of a product manager is to identify the project requirements, create a plan and schedule to meet these requirements, identify and manage resources, and manage the project from idea to implementation. Typically product managers work within one area of the organization, on one project. As such, they are responsible for and measured against the success of their project and their project alone and are therefore likely to veto anything that is not on their critical path. They have not had to take into account the requirements of other projects, nor has it been their responsibility to ensure the success of other projects. Instead, they stay focused on their own project to ensure its success.

In a unified content environment, you need an enterprise project coordinator to work with each of the product managers to ensure that the unified content strategy is being effectively addressed. In particular, the enterprise project coordinator needs to communicate the concepts and advantages of reuse on an ongoing basis to facilitate agreement among project teams.

The enterprise project coordinator must also be able to oversee many projects and determine the unified content strategy required to address both the needs of all the product owners and the needs of the content as a whole.

Information architects (new role)

Information architects play a key role in analyzing and designing content. They are responsible for building the information product models, element models, metadata, reuse strategies, and architectural models. They may also be responsible for designing the information retrieval for both authors and users. Accordingly, they should have a keen ability to design information for ease of use by content users and ease of reuse by authors.

Authors (modified role)

Creating materials in a unified content strategy separates the creation of the input (content) from the output (media or information type). This means that authors, as proficient communicators, will now rely less on the tools that are used to display the final information.

Authors no longer have to worry about applying styles or becoming involved in the formatting of the information; formatting is automatically handled by the authoring and delivery systems. Instead, writers can concentrate exclusively on the content they create and combine.

Authors identify the building blocks of information and how the blocks will fit together. They also identify opportunities for content reuse and write applicable content elements for reuse.

Content owners (modified role)

In a traditional authoring environment, writers own the content they create because they are also responsible for creating a specific information product. However, in a unified content strategy, content can be used in many different information products. The concept of the content owner needs to change to accommodate this.

In a unified content strategy, the person who authors the content still owns it; however, they may not own all the content that comes together to create an information product. There may be many authors, all of whom may not be responsible for creating an entire information product. Rather, they may be responsible for creating content about a certain subject that goes into many different information products.

In addition, there needs to be an owner of the unified content, someone who can oversee the creation of all the content related to a particular product, service, product family, or any other associated content set. The unified content owner facilitates the collaborative authoring process and ensures consistency and quality of the materials. This could be a team leader.

Editors (modified role)

Standards and consistency are important in creating seamless unified materials. In a unified content environment, it is particularly important that editors not just look at the words, but look at how the information is used to ensure it is written effectively for reuse.

Information technologists (new role)

In a traditional authoring system, many authors are responsible for creating the multiple media output for their content. In a unified content strategy, this is handled automatically by the system. An information technologist is required to handle the technology of the system.

An information technologist is skilled at implementing content models in the various tools, including programming and supporting style sheets to meet specifications provided by the information architect.

Information technologists should be well-versed in a wide variety of tools and technologies, including XML. Specifically, they should understand the tools and technologies you choose for your system.

Dynamic content

Until recently, content authors were limited to creating static content—content that is created in a specific way for a specific purpose, and that remains the same until the author deliberately changes it. As content reuse has made it possible to write information once and use it many times, authors can now create static customized content, which is designed to meet the specific needs of the user, the materials to be developed, and the delivery media. The content is customized for a particular requirement at a particular time but cannot be changed without being regenerated by the author.

Now, the ability to create dynamic content is changing the way companies envision, create, and distribute information.

This section includes information on the following:

- What is dynamic content?
- Importance of dynamic content
- Benefits
- Personalization

What is dynamic content?

Dynamic content is information that is assembled only when it is requested. It does not exist as a document; rather, it exists as a series of information objects that are assembled in response to the user's requests or requirements.

Note that while the majority of dynamic content is delivered dynamically through the web, you can also dynamically assemble a document that is then provided as a PDF where paper output is required (e.g., eCTD).

Importance of dynamic content

Dynamic content provides corporations with the ability to provide exactly the right information at the right time to their customers. It provides the ultimate flexibility in information reuse.

Benefits

Dynamic content provides the following benefits to corporations, enabling them to:

- Create multiple information products on demand
- Specifically address customer needs
- Reduce the cost of creation of multiple information products

Dynamic content provides the following benefits to customers:

- Reduces or eliminates the need to search for relevant information
- Provides customized content
- Provides "just-in-time" content
- Provides content which reflects their requirements or system configuration

| Personalization | Dynamic content draws on a technology known as personalization. Personalization means providing specific, relevant information to defined users or user groups. We are able to determine user requirements through the following: |

- Customer profiles

  Customers are assigned logins. Associated with each login is a customer profile that identifies the customer's role and information needs. When customers log in they see only information that is relevant to them.

- User selection

  Users can identify the type of information they want to view. They usually do this by selecting options on a form.

- Profiles, selection, and personalization

  Using a combination of user profiles and user selections, the system learns the user's information patterns and determines what additional information may be relevant. The system then "pushes" the information to the user or provides selectable links.

Profiling

Personalization is supported by profiling—the process of describing a customer's needs, requirements, and interests, based on a user profile. To create a customer profile, you must conduct a thorough audience and information analysis, develop information models, and assign metadata.

Automated workflow

Implementation of a unified content strategy brings about many changes to processes, roles and tools in your organization. Automated workflow can be an integral part of your solution, helping processes to run more smoothly, and enabling you to track development of your content.

In this section, we examine the following aspects of automated workflow:

- What is automated workflow?
- Importance of workflow
- Benefits
- Workflow tools
- Designing workflows
- Creating workflows

What is automated workflow?

Automated workflow can be defined as "... a system that is designed to control the movement of data from one processing to another, triggering appropriate actions and/or generating process control messages as required."[1] Workflow tasks typically have multiple steps, involve more than one person, and have a well-defined objective or end result.

As part of content development, automated workflow can help move content elements through the steps in the authoring and publishing processes, to be able to output content using the content management system.

A well-designed workflow solution combines automation, business rules, metadata and a willingness to change on the part of content producers, in order to be successful.

Importance of workflow

Content creation, management and delivery needs a flexible, smooth-flowing, well-managed, auditable process for the entire content development cycle, from creation to delivery.

A collaborative effort is required on the part of all involved, due to the diversity and amount of content involved. Chances are, at least part of your existing process is manual, so you know that trying to manage the content development cycle without workflow, and track all pieces of content involved in a project manually, increases the chances of errors and missed deadlines, as well as creates extra work for your content development team.

Workflow can assist the collaboration, automating much of the process and enabling you to effectively track the status of content any time.

---

1. *OII Guide to Workflow Management and Collaborative Authoring.* www.diffuse.org/oii/en/workflow.html

Benefits	One of the important benefits to be realized from the use of workflow tools is the automation of maintenance tasks for version archiving and audit trails. In industries where certain regulatory compliance is mandatory, automated workflow provides a practical solution to keep track of the types of details necessary for compliance.
	As well, effective workflows simplify processes and reduce the time taken to correctly route materials.
Workflow tools	Generally, workflow tools are part of a content management system, or a plug-in that works with the content management system to provide workflow functionality.
	Workflow tools should be scalable, flexible, and able to provide an enterprise-wide solution. They should support the following:
	• Collaborative work processes
	• Task assignment
	• Monitoring and notification
	• Routing and distribution
	• Approval
	• Auditing
	• Security
	In addition, workflow tools should provide an easy-to-use graphical interface for workflow creation.
Designing workflows	The first step in designing effective workflows is to re-engineer your authoring and publishing processes. Once you've done this, you need to let the content management system know how the work should be carried out. This is achieved by using workflow functionality in the workflow system.
	When you design workflows, you need to create flowcharts/diagrams to illustrate your re-engineered business processes, and to show how the workflow system needs to be configured to support them. There should be a separate workflow for each main content type you want to produce.
	Generally, business analysts perform this analysis and produce the workflow diagrams.
	Workflows should be defined independently of the system(s) used to help facilitate the tasks, to make sure that the system is designed to support people's work processes, not the other way around.
Creating workflows	Once the workflows have been designed, you use the workflow creation function to create the workflows.
	Typically, information technologists, systems engineers and/or systems integrators create the workflows.

The role of XML

XML is fast becoming the new Internet standard for information exchange. For complex content reuse, XML is the technology of choice.

This section describes:

- What is XML?
- Importance of XML
- Benefits
- XML and electronic initiatives
- XML and structured content
- Separation of content and format
- Built-in metadata
- Database orientation
- Use of XSL
- Virtual documents

What is XML?
XML is a standard for the development of markup languages for web-based information. If you are familiar with HTML, you are familiar with an instance of markup languages. But unlike HTML, which has a fixed set of tags, XML lets you define your own markup language.

Based on SGML, XML has been optimized for web-based delivery of all kinds of information. A family of standards, rather than a single standard, XML defines all aspects of information presentation, including markup, linking, style, structure, and metadata.

Importance of XML
You can develop a unified content strategy without XML, using certain traditional authoring tools, but you can do more with XML. XML supports the chunking of information into elements down to the paragraph or even sentence level. This chunking, along with efficient use of metadata, enables more efficient search and retrieval of content elements when used in conjunction with a content management system.

Benefits
Using XML has a number of benefits that directly support a unified content strategy, including:

- Reuse of existing content, reducing redundancy and costs
- Dynamic content delivery of personalized content
- Separation of content from presentation to allow multiple output formats
- Better-managed content, resulting in reduced costs
- Improved search and retrieval capabilities through the use of metadata

Electronic initiatives	The Electric Common Document eCTD is defined as "an interface for industry to Agency transfer of regulatory information while at the same time taking into consideration the facilitation of the creation, review, lifecycle management and archival of the electronic submission. The eCTD specification lists the criteria that will make an electronic submission technically valid."

An XML-based initiative, the eCTD standard describes the file structure, metadata requirements, and file formats that are acceptable for electronic submissions to regulatory agencies. It is intended to support a submission through its entire lifecycle of first submission, through updates annotations, to approval.

The eCTD includes an XML Document Type Definition (DTD) that represents an index of an eCTD. Every submission must include an XML file (sometimes called the backbone) based on the eCTD DTD. The backbone clearly identifies all of the files in the submission, with identification including file name, format, path, creation date, and even checksums to help ensure that documents are transferred intact.

Like 21 CFR Part 11, the eCTD does not directly relate to a unified content strategy. However, all of the information that you maintain about content in your content management system corresponds to the type of information you need for the eCTD backbone. Therefore, the information can be drawn from and managed by a content management system, helping to ensure that submissions will follow the standard. For some systems, the creation of the backbone can be automated.

If you are moving from one structure now to the eCTD, modular reusable content makes it easier to restructure your current materials to the eCTD structure and to any future structure.

XML and structured content	XML requires a DTD (Document Type Definition) to support the development and management of content. The DTD is like a structural template: it explicitly defines the structure of the content. This explicit structure ensures that authors can only enter content which follows the structure. That is, all of the required pieces of information are in place and in the correct order. There is no possibility of entering content which does not match the specified structure. This will assist authors in writing rapidly and eliminate validation errors.

Separation of content and format	Authors using products like MS Word are used to applying style tags that define the "look and feel" of the content. XML tags define the content. This means that any "look and feel" can be applied to the content, depending upon the desired output. For example, the content can look one way on paper, another in HTML, and many other ways if used in an article, presentation, or poster.

The "look and feel" is defined by the appropriate stylesheet selected in the final production process, or at any time in the authoring/review cycle.

Built-in metadata

In XML, you decide the tag names that you'll use in your documents. So you can create semantic tags (tags that have meaning), rather than generic tags. You apply tags that describe the content of the information, not the formatting. For example, typically in MS Word there is a tag labelled "Normal" that you would apply to information that you want to be formatted in a certain way. In XML, tags could be called "introduction", "title" or "objective". The semantic tags automatically provide metadata about the content they enclose, and can be interpreted for display in many ways.

For explicit metadata, XML can define attributes for the elements in a document. Similar in syntax to HTML attributes ("color='red'"), XML attributes are defined by you, to provide whatever additional information is required to identify the use of the information. Attributes can be used to identify information that is specific to format, product, user, or use.

Database orientation

XML was specifically designed to work well with databases. The first usage of XML has been application-oriented (e.g., e-Commerce), relying heavily on databases for fast access to information. This means that the XML-based content can easily be "chunked" for storage as elements rather than large sections and files, for fast access to individual elements of information.

Use of XSL

XSL (eXtensible Stylesheet Language) is the piece of the XML family of standards that defines formatting. But unlike a traditional stylesheet, which manages the look of a document, XSL is used to convert XML documents to other formats. These include HTML for web output, other markup languages like Wireless Markup Language (WML), and PDF. In addition, XSL stylesheets can be used to manipulate information, including sorting, filtering, moving and repeating information, and generating new information, such as tables of content and lists of figures.

You can create a stylesheet for each required output product and pass the same XML file through each, generating output that can differ in format and content.

Virtual documents

Through a variety of means—for example, extended linking, entities (include statements), and tools—XML enables you to build documents out of individual content files on the fly. Individual pieces can be assembled upon demand, in response to user requests or to meet the needs of a specific output format.

Enterprise content management technology

Tools and technologies available for content management have grown by leaps and bounds over the last few years, and indications are that they will continue to do so for some time to come. Understanding just what they do, and what kind of tools you need for your unified content strategy can be confusing. The tools can be expensive, and a wrong decision can be costly.

This section includes information on the following:

- Importance of the technology
- Authoring tools
- Content management tools
- Publishing tools
- Dynamic content engines

Note: The lists of tools below are not comprehensive, nor does this section specifically recommend any particular tool. Rather, it is provided to assist you in finding appropriate tools.

Importance of technology

Tools are a key component for the success of your unified content strategy. It is important that tools be selected that support your authoring, management, and customer requirements. Tools should not be selected until you have completed the analysis process and developed a selection criteria.

Authoring

Authoring tools enable you to create content. While you can create content and convert it to the format of choice, it is preferable to author in a tool that will minimize the amount of conversion that is required. There are four main types of authoring tools:

- Traditional WP/DTP
- XML aware
- Native XML editors
- Other

Traditional WP/DTP

Traditional word processing tools like MS Word or WordPerfect, and Desktop Publishing tools like Quark Express and PageMaker, can be used to produce content; however, they do not support the creation of structured documentation. MS Word can be paired with content management systems like JD Edwards Enterprise Content Manager, or XyEnterprise's Content@. It can also be used with an XML integrator like HyperVision WorX, or i4i S4/TEXT to create structured materials.

The other tools are limited to conversion to an appropriate format for document management (files), not content management—that is, management of elements of information. Conversion can be problematic because there is no

guarantee that authors adhered to the specified styles and structures. If an author chose to create content that does not adhere to the standard, it will not convert properly.

XML aware

XML-aware tools combine the ease of use of a traditional word processor or desktop publishing tool with the power of XML. They embed XML functions directly in the familiar authoring tool so the interface looks much like the one authors are used to, but provides XML as the output. XML-aware tools include:

- Adobe FrameMaker 7.0 (www.adobe.com)
- i4i S4/TEXT (www.i4i.com)
- HyperVision WorX SE (www.hvltd.com)

Native XML editors

The third method for authoring is native XML editors. A native XML editor provides a WYSIWYG environment for creating XML. These editors provide multiple authoring views (e.g., WYSIWYG, XML tags, visual representation of tags). The two most popular XML editors include:

- Arbortext Epic (www.arbortext.com)
- Corel XMetal (www.corel.com)

Other

There are other tools that support enterprise content management and structured writing. These tools have traditionally been used for technical publications, but are becoming more common for content reuse in the enterprise. These tools are not XML based. A example of one of these tools is:

- AuthorIT Software Corporation, AuthorIT (www.author-it.com)[1]

Content management

There are many different types of content management systems:

- Web content management systems (WCMS) assist an organization in automating various aspects of web content creation, content management and delivery. Delivery to the web is its primary format, but many WCM systems also deliver to wireless devices.
- Transactional content management systems (TCMS) assist an organization to manage e-commerce transactions.
- Integrated document management systems (IDMS) assist an organization in managing enterprise documents and content.
- Publication oriented content management systems (PDMS) assist an organization in managing the publications (manuals, books, help) content life cycle.
- Learning content management systems (LCMS) assist an organization in managing the web-based learning content life cycle.

---

1. AuthorIT is an integrated authoring, content management, publishing tool.

- Enterprise content management systems (ECM) vary in their functionality. Some support both the web and publications content life cycle, while others support the web content life cycle and either transactional content or customer relationship management content.

Content management systems that will support enterprise content management include:

- Author IT [proprietary] (www.author-it.com)

- ContextMedia Interchange Suite [many formats including XML] (www.contextmedia.com)

- Documentum [Many formats including XML] (www.documentum.com)

- Enigma [SGML/XML] (www.enigma.com)

- JD Edwards Enterprise Content Manager [Word] (www.jdedwards.com)

- Lightspeed Astoria/iEngine [SGML/XML] (www.lspeed.com)

- Oracle iFS [XML] (www.oracle.com)

- Panagon Filenet [XML, other formats] (www.filenet.com)

- Progressive Information Technologies Vasont [Any structured format including XML] (www.vasont.com)

- Stellent Content Management [Many formats] (www.stellent.com)

- Siberlogic SiberSafe XML [XML] (www.siberlogic.com)

- XyEnterprise Content@ [XML, Word, FrameMaker], (www.xyenterprise.com)

Delivery

Delivering enterprise materials requires the ability to publish not only to traditional outputs (e.g., paper and HTML), but also the publishing of XML, PDF, and to WAP devices (e.g., PDAs and cell phones).

These tools include:

- Documentum [All] (www.documentum.com)

- Arbortext E3[1] (All] (www.arbortext.com)

- XyEnterprise XML Personal Publisher [PDF, HTML, XML] (www.xyenterprise.com)

---

1. E3 is more than just a publishing tool, it is also a dynamic content engine.

Dynamic content engines

Dynamic content engines read and interpret the customer profiling, access the database (i.e., the content management system), assemble the "document," dynamically serve the pages to a portal, and publish the content in the required media.

These tools include:

- Arbortext E3 (www.arbortext.com)
- Documentum (www.documentum.com)
- Interwoven (www.interwoven.com)
- Lightspeed Interactive iENGINE, Eclipse (www.lspeed.com)
- Vignette (www.vignette.com)

Summary

Managing life sciences content is more than just managing content or producing reusable content. Life sciences content management requires a unified content strategy. A unified content strategy is the creation, capture, delivery, customization, and management of content across your organization. It's the encapsulation of your intellectual capital...it's the transformation of your information into power.

Elements of an effective strategy

However, an effective unified content strategy is only as good as the work you put into it. It involves:

- Thorough analysis of information, audiences, and processes

- A consistent approach to structuring information, based on the information's type and the audiences' needs

- Information models that form the road map for your project, telling you what each information element should contain and where it can be reused

- A sound metadata strategy, allowing you to classify, identify, retrieve, and track all the information "bits" within your content management system

- Potentially, a strategy to produce dynamic content so you can provide exactly the right information at the right time to the right audience

- New roles and processes to support a new way of looking at and producing information

- Automated workflows so the new processes run smoothly and you can track the development and reuse of your content

- The right technology to support your goals

For more information

Please contact us for further information about your enterprise content management needs, or to share stories about how you've implemented successful information strategies within your organization. You can reach us at more-info@rockley.com.

Look for our book "Managing Enterprise Content: A Unified Content Strategy" from New Riders Publishing, October 2002, ISBN 0735713065.

Appendix A: Company Profile

The Rockley Group was established in 1995 to serve the information creation community. Founding president Ann Rockley has an international reputation, with more than 20 years' experience in online documentation, web design, instructional design, content management and, content reuse.

Right from the beginning, The Rockley Group has been a pioneer and innovator in their field. Most recently, the company has focused on ground-breaking work on unifying content, providing much-needed services and solutions to organizations throughout North America.

The Rockley Group is passionately committed to discovering innovations in the field of content design and management. This commitment is evident in their belief in education as part of their responsibility to the information creation community. Senior members of The Rockley Group team regularly teach university courses and seminars, speak at industry conferences, publish articles, and present workshops and papers around the world related to XML, content management, e-learning and content reuse.

From a solid business base providing online documentation and instructional design solutions, The Rockley Group has responded to client needs by expanding service offerings into the area of enterprise content management (ECM) and unified content. Innovative work in these areas has established The Rockley Group as one of North America's leading providers of enterprise content management methodologies and the only providers of a unified content strategy.

The Rockley Group Team is made up of experienced analysts, instructional and new media designers, information architects, project managers, editors and writers who bring a wide variety and depth of skill and expertise to the company.

.

Appendix B: Table of contents for Managing Enterprise Content

This is the table of contents for *Managing Enterprise Content: A Unified Content Strategy,* New Riders Publishing, October 2002, ISBN 0735713065.

Appendix A   Unified Content Strategy Checklist

Appendix B   Writing for Multiple Media

Appendix C   Vendors

Appendix D   Tools Checklist

Appendix E   Content Relationships

Appendix C: Customer List

Financial

- Bank of Canada
- Bank of Montreal
- Bank of Nova Scotia
- Canadian Imperial Bank of Commerce
- CGU Group Canada Ltd.
- Citibank Canada
- Coopers & Lybrand
- Deloitte & Touche
- The Investment Funds Institute of Canada
- The Dominion of Canada General Insurance Company
- Manulife Financial
- Norwest Services
- Ontario Municipal Employees Retirement System (OMERS)
- OPSEU Pension Trust
- Sun Life of Canada

Life sciences

- Guidant
- IDX Systems Corporation
- ISG Technologies
- Major North American Pharmaceutical
- Medtronic
- MDS Sciex
- Nellcore, Puritan, Bennett, Mallencrodt
- Visible Genetics

High tech

- Bell Sygma
- Brain North America Inc.
- Cisco Systems
- Compaq

- Delano
- Digital Cement
- Hewlett-Packard
- Hummingbird Communications
- Intel
- Lexmark
- Nortel
- Ontario Systems Corporation
- Promis Systems Corporation
- Sasktel Mobility
- Texas Instruments
- Watchfire

Other

- Canadian Standards Association
- Citizenship Immigration Canada
- Dofasco Inc.
- Dynegy
- Environment Canada
- GO Transit
- Hudson's Bay Company
- Inco Ltd.
- Purolator Courier
- Sears Canada Inc.
- Schlumberger