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# *The Shortcut Guide<sup>™</sup> To*



# Using e-Documents for Collaboration

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## Chapter 2: The Top Four Considerations in Improving Document Creation and Collaboration

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Controlling costs is a fundamental concern to any business. In today's economic climate, no business process, including collaboration and information exchange, can be overlooked when trying to improve the efficiency of operations. Uncovering inefficient information exchanges can be difficult because information flows can be ad hoc, nebulous, and outside the scope of formal management procedures. For example,

- Product development is delayed because business partners lack confidence in Internet security and will not share confidential design documents over the network
- Poor document management practices result in leaks of private information leading to regulation violations and fines
- Employees waste time converting between document types because they use different tools or different versions of tools

Information exchanges are so pervasive that they involve virtually every process in an organization; because of that, business drivers are shaping how we collaborate. In this chapter, we will examine the diverse array of factors affecting content creation and collaboration, consider the domain-specific requirements from several industries and governments, and conclude with a discussion of key tools and methods for optimizing information exchange.

### Business Considerations in Content Creation and Collaboration

In spite of the wide uses of collaboration, there are common business considerations with regard to how we create and share content. These include:

- Cost efficiency
- Timeliness and ability to deliver content
- Compliance and security concerns
- Optimizing business processes

There is some overlap between these factors and, as we shall see, how we address one factor can have an impact on the others.

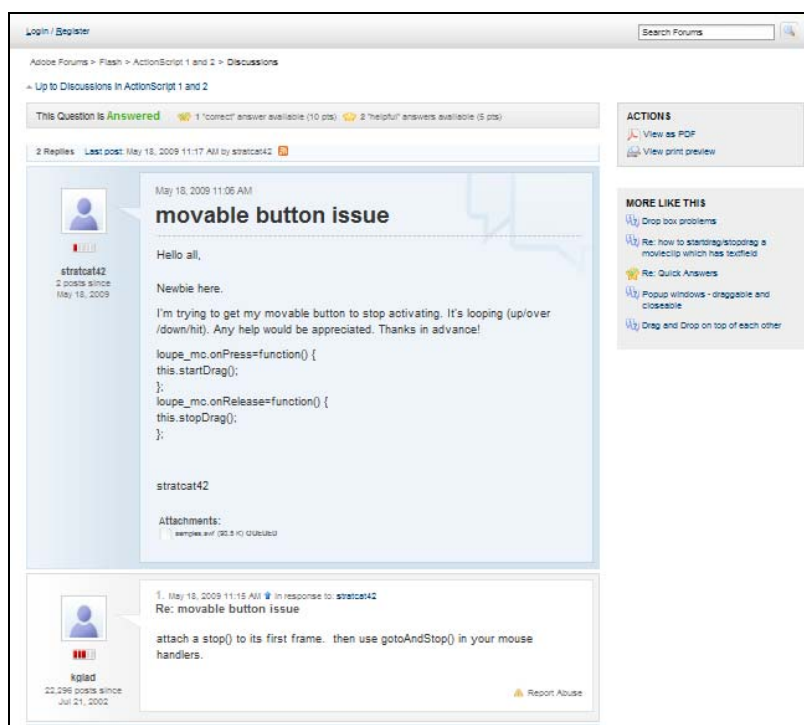
## Cost Efficiency

The cost of content and collaboration includes the cost of creating, distributing, and disposing of content. The cost of each of these, in turn, is shaped by various factors.

## Three Types of Content, Three Cost Structures

Consider three types of content: an informal posting in a corporate wiki, a project plan, and a service contract. The formality, breadth of distribution, and dependencies created by each type of content are fundamentally different.

Postings in a corporate wiki may include meeting minutes, rough notes on market research, or ways to work around a technical glitch in a commonly used application. Wikis are relatively informal and postings do not follow a set format. Forums are similarly informal, conversational structures.



**Figure 2.1: Informal collaboration in business is common with the increasing use of wikis and forums. (Source: Adobe Support Forums, <http://forums.adobe.com/message/1971270#1971270>).**

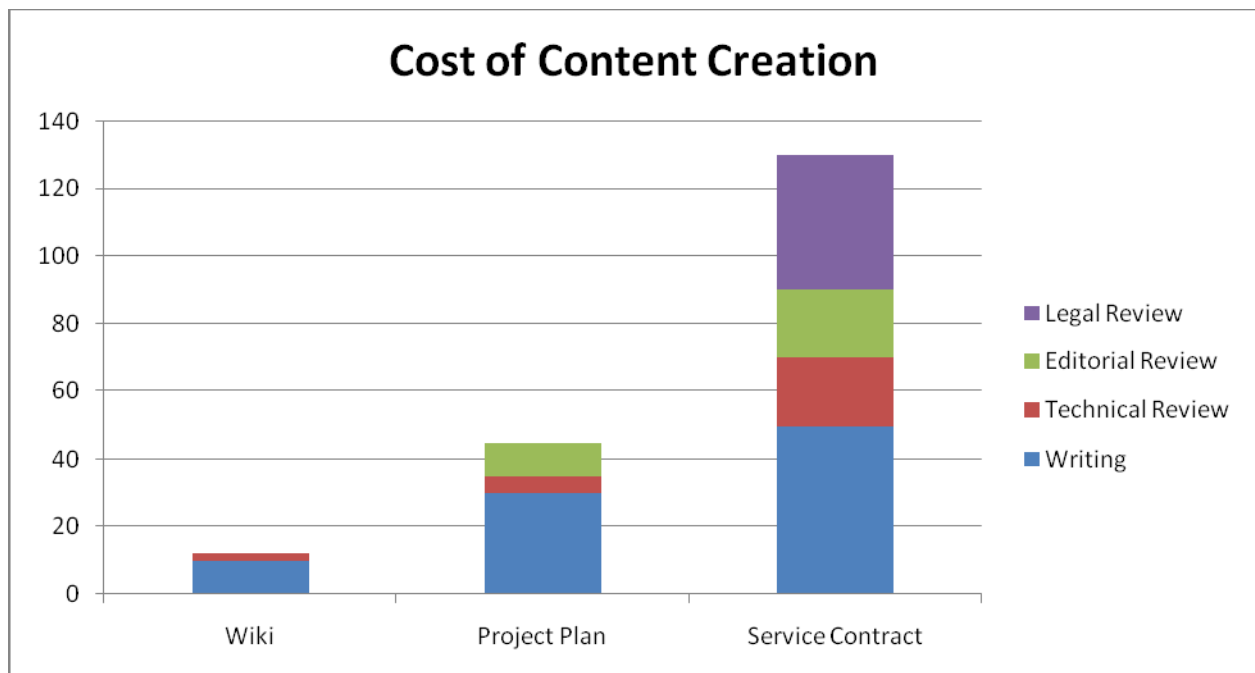
The writers may use colloquial terms, make reference to events or objects not mentioned in the document, or include an unorganized list of links to related material. Readers will likely be peers of the author. The cost and value of creating this kind of content is low because it requires minimal effort on the part of the writer and there is no formal editing and review process. Wiki collaborations are suitable for informal, internal collaboration where the need to quickly and easily share information is more important than maintaining formal business-writing standards.

A project plan may also be primarily for internal consumption but requires more attention to detail and formality. The document is capturing information that will guide a substantial amount of work, so language is clear and precise. The document is written for the appropriate audience, which may include technical staff, managers, and executives. The contents are written by multiple collaborating authors and checked for accuracy and completeness by several reviewers. Documents such as project plans require more attention to detail and form than informal wiki pages.

A service contract is a legally-binding agreement between parties and therefore requires the most attention of the three examples under consideration. In addition to the collaboration of multiple authors and several reviewers needed for formal internal documents, these documents require legal review, which can entail several iterations before the proper content is established.

### Controlling Constituent Costs of Content Creation

Cost of creating content depends on the formality of the content, its purpose, the audience, and the legal consequences of the content exposure. Controlling costs is not simply a matter of cutting steps in the process; eliminating legal review of a contract would save in the short run while costing much more in the long term. Instead, controlling costs should focus on reducing the time and effort required to accomplish individual steps in the content creation process.



**Figure 2.2: The cost of creating content is made up of several factors, which vary by the type of content created. Improving cost efficiencies should focus on improving the efficiency of these individual factors, not in eliminating them.**

One of the ways to control content creation costs is to streamline the creation process, especially as content moves through its various stages of writing, review, and revision. Improvements in these processes can also directly impact the timeliness of content generation and delivery.

### **Timeliness and Ability to Deliver Content**

Journalists are not the only writers on deadlines. In business, the value of content is sometimes dependent on when it is available. Proposals need to be in clients' hands when they are ready to read them. Status reports need to be in by due dates. Documentation has to be ready to ship with a product. These kinds of constraints may force a business or government agency to re-design their content workflows. This is especially true in cases where organizations are reducing staff while continuing to maintain prior levels of service.

When we discussed cost efficiency, we focused on the different steps in the content creation process. With timeliness, we shift our attention to the way in which those steps are carried out. For example, the need to improve timeliness can lead to adopting procedures for:

- Reducing review time by using automated workflows to forward documents to reviewers and notify them that material is ready for their review.
- Reducing content generation time with the use of templates and boilerplate content. Project plans typically have a common structure detailing tasks and milestones. A typical business contract has clauses about notices, assignment, and choice of law and forum.
- Tracking all changes and comments as document metadata enables reviewers to understand the development of a piece of content and reduces the likelihood of revisiting an issue multiple times.

Fortunately, these measures also support compliance and security concerns.

### **Compliance and Security Concerns**

The need to maintain regulatory compliance and to protect the integrity and confidentiality of information are two additional business drivers that shape the way we develop and manage content.

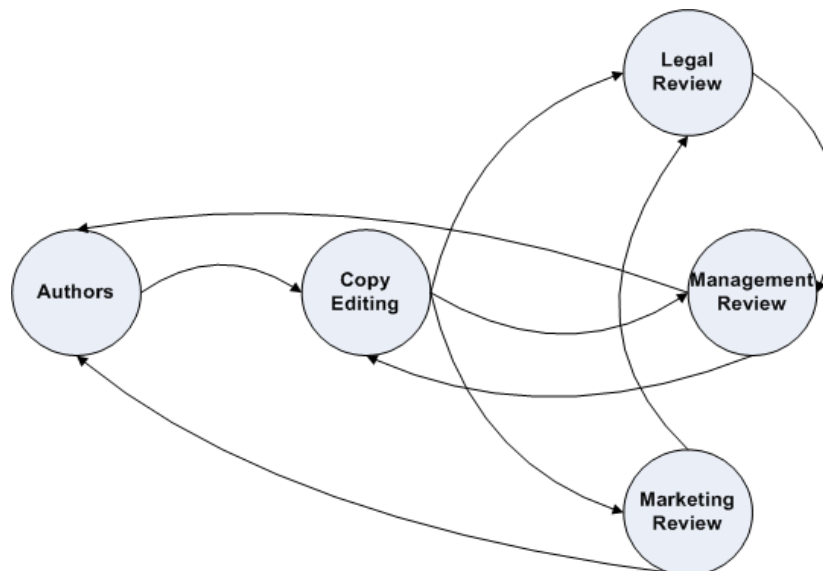
Some regulations, such as the Sarbanes-Oxley Act (SOX), define requirements for governance and are designed to ensure the integrity of corporate information; others, such as the Health Insurance Portability and Accountability Act (HIPAA), establish protections for private healthcare information. The common implication of both types of regulations is the need for controls over the sharing of information, including documents and other forms of unstructured content found outside of databases. Such controls include:

- Limiting access to those who can read and revise protected content
- Limiting the distribution of protected content
- Demonstrating the effectiveness of controls in maintaining compliance with regulations

Other business drivers are internally motivated.

### Optimizing Business Processes

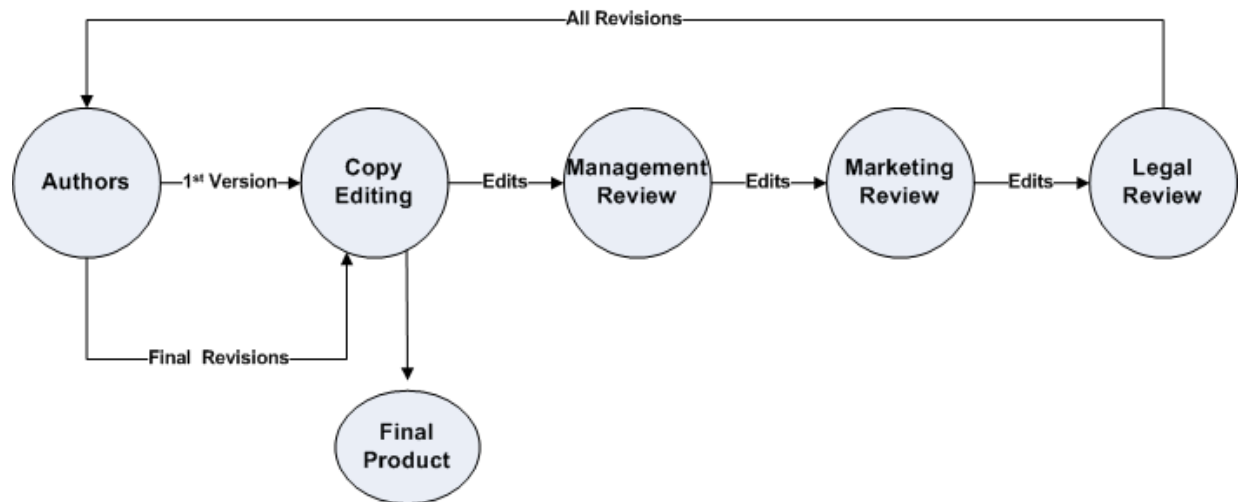
As noted earlier, part of the cost of generating content stems from the number and types of review required before content is complete. Similarly, the cost of executing business processes is in part based on the way content is created, shared, and managed as part of the business process. Inefficiencies can creep into a business process, for example, when email is used to distribute content to a wider audience than needed, leading to more revisions and discussion than necessary at a particular step in the process.



**Figure 2.3: Ad hoc business processes, including those with significant content generation and revision, can be difficult to manage and be inefficient.**



A more efficient alternative is to establish a standard procedure for review, revision, and publication that controls for inefficient and sometimes counterproductive multiple iterations of review. As Figure 2.4 depicts, a structured workflow can capture essential steps in a business process and control the sequence of execution. Formal workflows such as these are general enough to include other operations besides content management, allowing for optimization of broad business operations.



**Figure 2.4: Structured workflows have well-defined sequence of events and structured outputs. Each step can be monitored and the process optimized over time as business gains experience with the workflows.**

The diverse array of factors affecting content creation and collaboration include the need for cost-efficient operations, timeliness and the ability to deliver content, compliance and security concerns, and the general drive to optimize business processes. Managing all these drivers is something of a balancing act. Cost efficiency argues for fewer steps and minimal oversight while compliance and security demand documented control processes.

The key to achieving an efficient content-centric business processes while meeting other needs is to use tools and best practices that are designed to support all these objectives. In the chapters that follow, we will discuss these tools and practices, but first we will examine examples of industry-specific challenges and the role of efficient information exchange in addressing those challenges. The following sections draw from:

- Life sciences and pharmaceuticals
- Financial services
- Manufacturing
- Government

Although these are industries and public sector organizations server widely different purposes, they all face pressures that require attention to content creation and information exchange.

## Life Sciences and the Need for Efficient Flow of Information

Life sciences and pharmaceutical industries bring healthcare innovation with the development of diagnostics, drugs, medical devices, and other biologics, such as vaccines. The industry is facing an unusual combination of market pressures that could substantially change the way it plans, develops, and markets products. These pressures include:

- Industry-wide contraction and consolidation, exacerbated by the global economic downturn
- Weakness in drug development pipelines that leave fewer prospects for “blockbuster” drugs and the need to adapt to more niche-oriented product strategies
- Shifting emphasis on healthcare public policy to broaden availability while reducing costs

These macro-level pressures may set the stage for substantial changes in the way businesses in this industry operate. Life sciences and pharmaceuticals have long had strict documentation requirements as governments around the world seek to ensure that drugs, medical devices, and related products are both safe and effective. For example, in the US, the public code known as 21 CFR Part 11 governs the use of electronic record and electronic signatures when they are used to meet US Food and Drug Administration (FDA) regulations. In addition to these regulations, businesses are confronting market pressures that lead to more efficient business operations. These efficiencies can come in several forms:

- Efficient flow of information
- Electronic records and compliance with 21 CFR Part 11
- Support of innovative business processes

As we shall now see, these efficiencies are closely linked to the nature of life science business operations.

### Efficient Flow of Information

Pharmaceutical companies can employ tens of thousands of employees working in research and development, clinical trials, and marketing, legal, and sales areas. Information may have to flow from any point in the organization to another: A clinical trial application may require data from researchers, marketing and sales departments may exchange information on physician education programs for new products, and attorneys in the legal department may have to conduct discovery for litigation involving all those departments.

Some of the characteristics of information flow in such a complex industry include:

- Content and information created and managed for one purpose may be leveraged for uses unanticipated at the time of creation
- Business processes, such as new drug development, can go on for years and require long-term information management strategies
- Large volumes of information can lead to information-retrieval problems unless content is sufficiently augmented with metadata, indexed for search, and categorized and classified along multiple dimensions
- No single content repository will likely meet all needs, however, the use of common document formats, metadata structures, and workflow systems can contribute efficient, distributed, and interoperable information management systems

These information flow characteristics are further specialized by industry regulations.

### Electronic Records and Compliance with 21 CFR Part 11

21 CFR Part 11 defines regulations for the use of electronic records, which replace paper records used to demonstrate compliance with FDA rules. It includes definitions of records and validation of computer systems for records management, audit trails, and record retention. Security provisions in 21 CFR Part 11 includes provisions for:

- Access controls to protect electronic records
- Use of authorization controls
- Ensuring developers are sufficiently trained to develop electronics records software
- Policies governing the use of electronic signatures

These regulations apply to the later stages of drug and device development, including clinical trials, as well as earlier development phases. Although government regulations such as these may be the primary driver to maintain detailed, trustworthy records from early stages through clinical trials, the records themselves may be raw material for innovative business processes.

## Supporting Innovative Business Processes

Detailed electronic records are useful for ensuring proper practices are followed in product development. They can also support investigations into failed product developments. The cost of new drug development ranges from \$500 million to \$2 billion. Many potential drugs fail to make it all the way through the drug approval process and the sooner a failed drug is identified, the greater the cost savings. Comprehensive documentation of the drug development process, as required by regulation, along with internal research and publically available data can provide a starting point for detecting potential failures. Roughly speaking, an early failure detection process could be established by:

- Collecting detailed data on various stages of both successful and failed drug development efforts
- Grouping the data according to the types of failures; for example, failures may be due to toxicity or ineffectiveness
- For each type of failure, use a combination of data mining and text mining techniques to identify common patterns in failed products
- Monitoring new content as it is generated to look for patterns in new drug development efforts and triggering scientific review of documentation and data when such patterns are discovered

Ideally, this type of early warning system would find patterns indicative of failure early in the process. In practice, myriad variables in drug development, limited knowledge on the mechanism of action in drugs, and difficulties consolidating information present significant challenges to realizing such an idealized system. Nonetheless, standardizing on records management procedures, using standardized file formats, data entry forms, and data collection and consolidation procedures, can improve an organization's ability to analyze a vast array of information already collected for other reasons.

The life sciences and pharmaceutical industries require complex content and information sharing systems that support multi-year initiatives and span large groups of collaborators. The industries are highly regulated with regard to product safety and efficiency; the same data and systems created to comply with those regulations also provide the potential analytic systems that could improve the efficiency of product development.

## Financial Services and Complex Documentation

The financial services industry has proven to be as innovative and adaptive as any other segment of the economy. Much of the innovation in finance has come from the ways we use documents to track assets, debts, and obligations. It started with bank notes in 7<sup>th</sup> century China, evolved into bills of exchange in the Middle Ages, and ultimately led to the complex investment instruments of the global economy.

Investors have a wide array of investment instruments to choose from. Many of these are derived from or structured around traditional investment instruments, such as securities and mortgages. Financial services firms today may issue mortgages, bundle them together as an asset, and then sell shares in that asset to investors. This kind of securitization can occur with mortgages, car loans, credit card debt, commercial paper, and other revenue-generating assets. Keeping track of what assets are in a securitized bundle and who owns how much of those assets is no trivial task.

### Complex Documentation

Some industries deal with tangible assets, such as automobiles, medical equipment, and refrigerators; in financial services, documentation is as close as we get to a tangible asset. For example:

- A mortgage documents an agreement between a borrower and a lender for the purchase of a real estate asset
- Equity shares represent ownership in a company
- Annuities are contracts obligating the issuer to make payments to the holder at specified times
- A basket option is a derived instrument with a value based on underlying assets, such as a set of foreign currencies

These are highly varied instruments but they share common characteristics. In each of these examples, there is an agreement between at least two parties that is documented in some type of contract. The rights and responsibilities of each party are spelled out in these documents. How well a company manages such documentation can have a significant impact on the bottom line, and this is a key business driver for the need for formal workflows.

### Need for Formal Workflows

Formal workflows are well-defined processes for generating, reviewing, auditing, and archiving documents. These are especially important in financial services because the documents produced in these procedures can commit the business to significant obligations. Automated workflows can help ensure consistent processing of operations and enable standardized tracking and auditing of document generation.

A mortgage application workflow, for example, might include:

- Collecting personal information about the applicant, including credit reports
- Documenting income and assets
- Performing employment history checks
- Initiating an appraisal process

Each step in the workflow provides an opportunity to assess the need to continue the process. For example, a poor credit history could be detected early in the workflow, allowing the bank to terminate the process without committing time and resources to unnecessary steps. Workflow steps can also act as gatekeepers, suspending processing until all prerequisites for a step are met; for example, the mortgage cannot be scheduled to close until the appraisal documentation is complete. Details about each step in the process can be automatically logged as part of an audit trail, providing raw data for management reporting as well a compliance reporting. A final step could include archiving documents in a secure, reliable repository that allows for efficient retrieval when needed.

These workflows not only provide the means to implement an efficient and consistent business process but also can help avoid costly errors.

### Cost of Errors

A range of document management errors can prove costly to a financial services firm. In the simplest case, inordinate amounts of staff time may be required to track lost or mis-categorized documents. In addition to unnecessary staff time wasted tracking documents, there may be opportunity costs for poorly managing content. For example, when there are peaks in the mortgage refinancing arena, banks may have to compete to retain customers; if the refinance process is delayed because of inefficient document management processes, customer may move on to another lender.

At the other end of the cost spectrum is the potential for costly litigation because of the inability to produce documents or to manage them efficiently. Document review constitutes 30 to 50 percent of the cost of litigation, and hourly rates for manual document review and computer forensics can run \$250 to \$500 per hour (Source: Charles Skamser, "The Cost of e-Discovery" at <http://ediscoveryconsulting.blogspot.com/2008/09/cost-of-ediscovery.html> September 10, 2008). These costs could be dwarfed by sanctions imposed by courts if a litigant is unable to produce electronic documents as required by the courts. In an early e-discovery case, a defendant was unable to produce required electronic evidence and a jury awarded \$29.3 million in damages, including \$20.2 million in punitive damages (Source: Thomas J. Smith and Michael J. Crossey, Jr. "E-Discovery Sanctions: A Continuing Trend" at [http://www.klgates.com/files/upload/eDAT\\_2007\\_04\\_E\\_Discovery\\_Alert.pdf](http://www.klgates.com/files/upload/eDAT_2007_04_E_Discovery_Alert.pdf) April 2007).

Of course, these costs of errors extend well beyond financial services to other industries. These are virtually universal business drivers for improving content and document management.

## Manufacturing and Efficient Collaboration

Manufacturing is becoming more distributed as designers, engineers, suppliers, and manufacturers in different parts of the world work together to drive the most efficient manufacturing processes possible. One of the reasons businesses can use global manufacturing resources efficiently is that information technology provides the means to communicate and collaborate efficiently. For example, engineers and product developers can collaborate on design issues by exchanging documents, conducting online meetings, and using asynchronous collaboration tools, such as emails, forums and wikis. In other cases, manufacturers can use state of the art collaboration and information sharing systems to communicate with partners. These help to enable efficient manufacturing practices, such as just-in-time delivery.

As we have seen with examples from financial services and life sciences, there is a wide array of documentation that must be managed in a manufacturing environment:

- Design documents and engineering drawings
- Customer-specific formulations, configurations, and specifications
- Orders, contracts, invoices, and other order-fulfillment documentation
- Safety information, such as training documents and material safety data sheets

As in other industries, inefficiencies in managing these documents can lead to higher operational costs and potential compliance issues.

The need for efficient content management and information exchange is not limited to commercial ventures. Governments face similar and sometimes idiosyncratic pressures as well.

## Governments and the Public: Extreme Collaboration

Governments are responsible for creating, publishing and archiving some of the largest catalogs of documents and other forms of content. Just consider the breadth of topics in the U.S. federal governments list of publications which includes: environment law, patents, confirmation hearings, space and technology, and historical records. The U.S. Government Printing Office (something of a misnomer since the office is also responsible for electronic publications) describes itself as the “primary centralized resource for gathering, cataloging, producing, providing, authenticating, and preserving published information in all its forms.” (Source: [http://www.gpo.gov/about/faq.htm#GPO\\_do](http://www.gpo.gov/about/faq.htm#GPO_do)).

When it comes to publishing and content sharing, governments are distinguished by the breadth of topics, the time frames in which they operate, and the openness with which they share information. In particular, governments tend to face more demanding constraints with regards to:

- **Accessibility**—All citizens should have reasonable access to information about government operations, excluding reasonable limits for privacy and security concerns.
- **Archiving**—Government publications are historical records that require perpetual preservation.
- **Efficiency**—Governments at all levels—national, state, and local—are under constant public pressure to do more with less; businesses face similar pressure but generally with less public scrutiny.
- **Openness**—Legislatures and regulatory agencies may have elaborate procedures for soliciting the input of interested parties, documenting those findings, and publishing results.
- **Accuracy**—The need for accuracy and precision is especially important when documents establish policies and rules that others will follow; this can lead to comprehensive review and approval processes.
- **Speed**—Government agencies may find themselves having to rapidly release information in response to a public event or immediate concern, such as when the Center for Disease Control (CDC) released information on the H1N1 (“swine flu”) virus after it emerged in April 2009 and quickly generated concerns of a pandemic.

These requirements and the volumes of information governments have to manage demonstrate the extreme demands that some organizations have to address and the importance of efficient business processes for meeting those needs.

## **Optimizing Content Sharing Operations Across Businesses, Industries, and Governments**

Content sharing and information exchange is fundamental to modern organizations, as is the need to perform these operations efficiently. One way to approach optimization is to start by focusing on distinct sub-operations:

- Forms creation
- Data collection
- Document retention and archival
- Security



Forms creation should not be a barrier to more efficient content sharing. Creating online forms should ideally be as easy as creating paper forms; fortunately, forms creation no longer requires programming or HTML skills. A potential drawback of easy forms creation is that anyone with access to tools can create and revise forms, potentially creating confusion about proper versions. Formal policies about creating and revising forms should be in place to control this risk. Organizations should also consider using workflows for creating and revising documents to ensure policies are enforced.

Forms can and should be linked to databases or other content repositories for efficient data collection. Data quality checks should be performed when data is collected and before it is stored to reduce the chance of errors in the database. Typical checks include making sure all required fields are provided, the format of data is suitable for the field (for example, an email address should have an '@'), and separate data items in the form are consistent (for example, start dates may not be later than end dates).

Once forms are created, data is collected, and documents are stored, they need to be managed according to document retention and archiving policies. As noted earlier, the cost of errors in document retention can be severe, especially when litigation and e-discovery are involved. Again, organizations should consider developing formal policies and enforcing those policies through workflows to ensure consistency and the ability to report on the status of retention and archiving operations.

Security is not so much a sub-operation of content management and information sharing as it is a set of considerations about how we perform those operations. Government regulations and public expectations for privacy and confidentiality are well known; data leaks are costly in many ways, from fines to brand damage to lost customer loyalty. We should avoid confusing data leaks with just breaches of transaction processing databases, point of sales systems, and similar-structured data applications. Leaks of forms and data on forms can be as damaging as leaks from relational databases.

Organizations are in a position to optimize content sharing and information exchange when tools are in place to enable efficient forms creation, collect data without cumbersome manual intervention, store and retrieve content as needed, and do all of these tasks with sufficient security measures in place.

## Summary

Several business considerations are common to content creation, regardless of industry: cost efficiency, timeliness and the ability to deliver content, compliance and security concerns, and the ability to optimize business processes. These drivers are found in widely different environments, from life sciences and financial services to manufacturing and government organizations. In each of these distinct areas, we see that the particular needs of those types of organizations can be met by a combination of efficient use of content creation and management tools, established policies for governing content sharing and information exchange, and formalized workflows for enforcing those policies.

In the next chapter, we turn our attention to technologies that provide the foundation for implementing the practices advocated here.

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