IBM Healthcare and Life Sciences
May 2005

Beyond enterprise content management: A compliance-centric architecture

ibm.com/industries/lifesciences

Contents

Introduction

The last ten years have seen a significant evolution of solutions to support compliance in the biopharmaceutical industry. Specifically, document and content management technologies have undergone a remarkable transformation that has taken them from vertical document management systems with departmental installations to cross-department solutions with publishing, electronic signatures and document workflow capabilities to knowledge management solutions that have improved both the capture and accessibility of knowledge assets.

Today, change continues in this space, as new compliance requirements combined with shifts in market focus and evolving technologies, such as business process management and application integration tools, are compelling organizations to re-evaluate their process, technology and compliance-related strategies. The outcome of such evaluations is shaping the next-generation of solutions for compliance and the means by which industry will respond and adapt to emerging compliance and market demands.

In this increasingly complex environment, effective management of regulated information is critical to reducing regulatory risk, improving submissions and increasing the speed of development and manufacturing cycles. To address these needs, IBM has developed IBM SCORE: Solution for Compliance in a Regulated Environment, a product that supports the next generation of enterprise content management capabilities by uniting document and data management with compliance-centric business process management, application integration and collaboration tools.

Industry Challenges

Changing market dynamics, product evolution and new compliance requirements are driving change

Several factors are driving change in the way that biopharmaceutical organizations will need to approach the next generation of enterprise content management systems. One such factor is the need to adapt to a continually changing compliance landscape. Requirements for compliance have evolved significantly over the last ten years and the industry's understanding of the impact of these requirements has grown respectively. As compliance requirements, such as 21 CFR Part 11, HIPAA, SOX and others continue to change, the technologies that support these requirements will also need to support rapid adoption of such changes will require increased visibility of documents and business processes.

Additionally, factors such as changing market dynamics and increased competition, as well as product evolution, such as the evolution towards targeted treatment solutions, will continue to impact the requirements for content management across the enterprise. Specifically, the capability to effectively collaborate, both within organizations and with external partners, suppliers and vendors, will become more and more important. Additionally, the ability to effectively manage and control the greater volume of information anticipated as a result of regulatory and product evolutions will become an ever more important area of focus. Finally, increased

competition in the marketplace will mean that organizations must find new ways of increasing process efficiency and productivity, as well as new ways of harnessing the value of existing information assets. These and other challenges will drive the requirements for a new generation of enterprise content management system; a next generation that is driven by an underlying compliance-centric architecture and is able to rapidly adapt to changing business, product and compliance environments.

Enterprise Content Management (ECM): Where Do We Go Now?

ECM needs to be reassessed across the enterprise and across the globe to ensure it is ready to comply with changing regulations and adapt to changing science

Based on 2003 industry figures, IBM estimates that new regulatory requirements referred to earlier place significant revenues at risk for the industry. And to compound the issue, existing assets and processes in development and the supply chain are fundamentally incapable of supporting the quality and operational requirements of emerging regulatory requirements and targeted treatment solution business models. Non-compliant companies risk spending millions of dollars in fines or worse, having operations shut down entirely. And those companies who fail to respond to the changing market demands and continue to invest solely in elusive blockbuster drugs may find themselves out-marketed by more innovative companies that have replaced single blockbusters with many targeted treatment solutions. Enterprise Content Management (ECM) needs to be reassessed across the enterprise and the globe to ensure it is ready to comply with changing regulations and adapt to changing science.

The remaining sections of this paper will focus on describing the requirements for and benefits of a new generation of technology architectures, with a strong emphasis on the transformation of ECM technologies. Specifically, the next-generation ECM architecture will focus on supporting:

- Emerging compliance requirements
- New product evolution
- Changing market dynamics

The Next-Generation Architecture: Beyond the Bounds of ECM

A majority of systems today focus on the documents instead of the underlying process they enable.

ECM technology for regulated processes has come a long way since the early 1990s. Document Management Systems (DMS) Solutions have grown in complexity to address the needs of multiple areas of the enterprise, such as submission management and SOP management. However, the majority of systems today focus on the documents themselves instead of the underlying process that they enable. Even those systems that are specifically architected to support business processes usually stop at a discreet division of work within the organization. A majority of systems today focus on the documents instead of the underlying process they enable. So, while individual silos of data and applications have become quite sophisticated in addressing individual needs within the value chain, their architecture lacks the fundamental capabilities required to support the view of the document within the business process context and integration of the document processes between different value chain segments.

A new environment must be forged across the value chain addressing both specific functional area requirements and interfaces between groups

Requirements for a Next-Generation Architecture

In order to respond to the regulatory, product and market challenges outlined in the sections above, a new environment must be forged across the value chain addressing both specific functional area requirements and interfaces between groups, such as regulatory, manufacturing and sales & marketing. Information must appear seamless and be presented in a way that provides access to role/job-function specific information at appropriate points in time. Additionally, from an information systems perspective, information must be allowed to flow freely from system to system without the need to be re-entered or re-created— reducing the risk of transaction errors and increasing the value and accuracy of information across the lifetime of the information component. Finally, from a business process perspective, the next-generation environment must break the bounds of traditional "pocket" or single function workflows, extending the automation of functions beyond typical single piece "review" and "approval" workflows.

To address these new environmental requirements, the architecture should be broken into layers that allow organizations to fully leverage multiple components as needed in their unique environments.

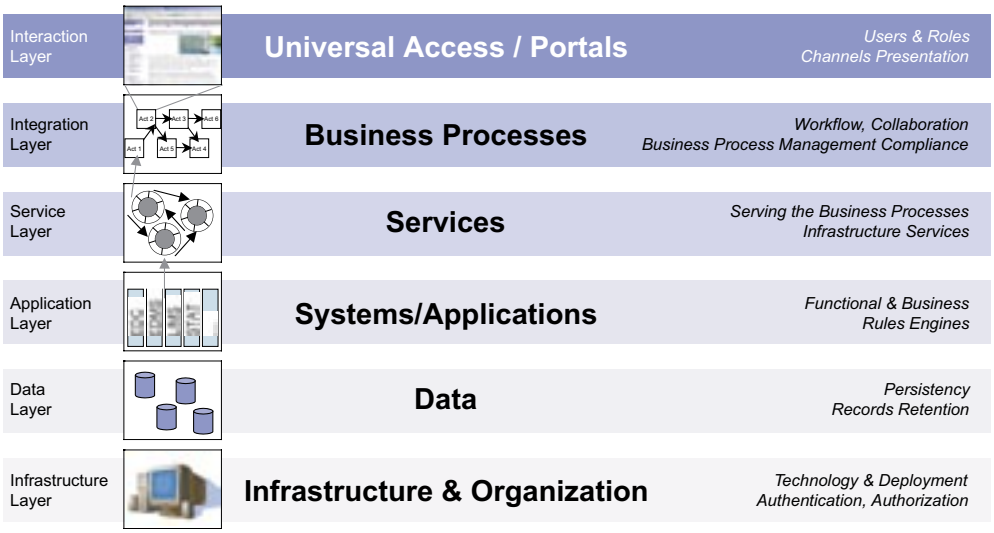


Figure 1 — Next-Generation Architecture for Compliance

For example, the interaction layer may provide user interfaces specific to functional roles within an organization (e.g., Quality Assurance). The data layer may allow data storage in various repositories (e.g., Content Manager, Documentum) to interact with the application layer through repository abstraction. And the integration layer may allow a DMS to interact with ERP, LIMS and MES systems. Such an infrastructure, built on open standards, allows each organization to enhance the capabilities of each layer, while providing consistency of design and implementation.

Universal Access/Portals

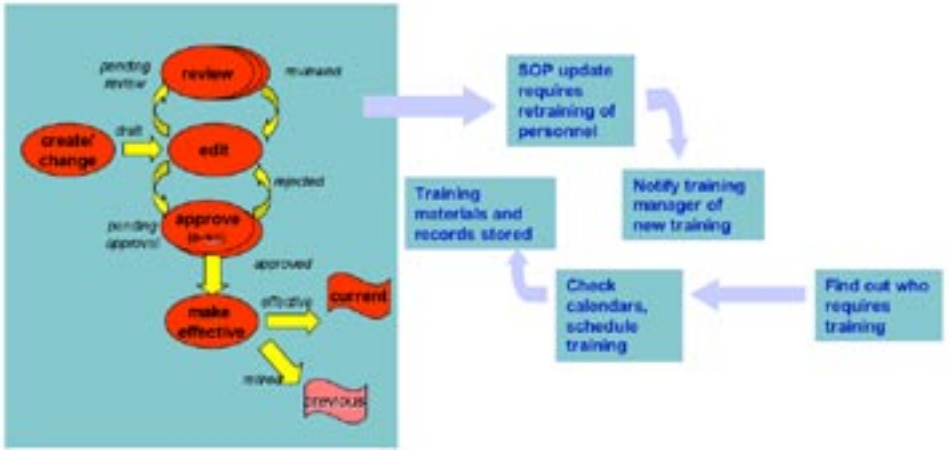
One-size does not fit all when it comes to the user experience. Our next-generation architecture's user experience delivers interfaces that are unique to each role in an organization. A medical writer needs to view complex documents, such as clinical study reports and CTDs. Shop-floor workers require limited and timely access to only the most recently approved SOPs in read-only format. And sales representatives need the proper collateral based on the doctors (and the indications they treat) they are visiting on any given day. Useful and relevant content varies significantly from role to role, and technology must be able to deliver interfaces that are intuitive and deliver the content each individual needs. This can improve the usability of the system and ultimately lead to wider acceptance and propagated use throughout the organization.

Companies with disparate compliance systems have disparate user interfaces to purchase and maintain. Portal technology has evolved to provide user interfaces as varied as the employees doing the work. With portals, a small fixed investment allows companies to create multiple interfaces at a lower variable cost.

Business Process Management and Collaboration

Perhaps one of the most powerful advancements in technology is the ability to separate the business process from the technology. Abstracting this layer allows the overall solution to adapt to changes in business requirements and processes without affecting the overall system architecture. In addition, it places the business process at the heart of the system, promoting the concept that the business should drive the technology, not vice versa.

If we look, for example, at ECM-related process, the old model is very document-centric: "Here is a document, now update it." Updates would follow a traditional workflow approach of review-edit-approve. Unlike the traditional workflow, our next-generation architecture supports the ability to move beyond the boundaries of content-centric workflows to enable the full business process segment as defined by the business community, not the technology. For example, a department needs to create and issue a new SOP. The SOP document itself is created and managed in a traditional document workflow, but the process of identifying resources requiring training, completing the SOP training and maintaining the training records is a business process that requires a process workflow.



Current model is document-centric: "Here is the document— what do we do with it now?"

New model is process-centric: "We need to train these people as per the new SOP"

Figure 2 — Document--Centric and *Process-Centric Workflow*

In the next-generation architecture, the business process drives the architecture of the technology. The business process defines the data that is created and maintained (SOP, training records), how to share that data across the value chain, initiate training when a new SOP has been approved and how to put structure around otherwise unstructured data. In order to achieve the new vision in the scenario described above, integration between the DMS and training system is required. Collaboration between organizational functions is required. A view into the entire process is also necessary to manage the complete flow of information. We can begin to see the separation of the underlying technology and the business process above it that drives its behavior which, in turn, is driven by compliance requirements.

Application Integration

Systems need to be leveraged and accessed across the enterprise. Research uncovered during drug discovery needs to be accessed to create a submission. Packaging and labeling information is created initially for a new filing but updated many times over a drug's life as it is manufactured and marketed. Study-related information is expanded with additional safety information after the drug is marketed.

The systems that typically support the many enterprise processes (DMS, LIMS, ERP, etc.) need to be able to share data in a manner that is automated and invisible to the end user.

Integrated Data and Document Management – Services, Systems and Applications

In addition to the user interface, business process management and application integration layers described above, our next-generation architecture needs to support access to services across multiple applications. In this way, the ECM functions that have traditionally been accessed for business process segments supported by point

solutions become available across the larger business process. For example, the new architecture ECM features for regulatory submissions systems must support:

- Interactions between documents, dossiers and other business systems
- Structured and unstructured data information
- Active and inactive states of the information

The following diagram illustrates an example of the integration of services, systems and applications across an organization's business process with a focus on the management of both documents and data within the overall architecture.

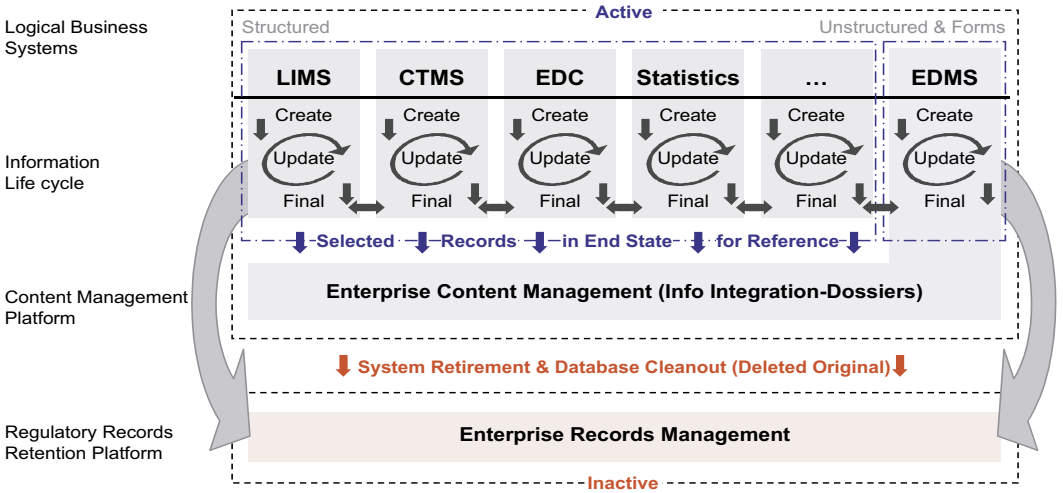


Figure 3 — Integration Across the Process Lifecycle

Benefits of the Next-Generation Architecture

The next-generation architecture helps mitigate the risks associated with non-compliance and, at the same time, introduces efficiencies that lead to multiple, tangible business benefits

The benefits that the next-generation architecture can bring are two-fold: it can help mitigate the risk associated with non-compliance and it can introduce efficiencies that ultimately lead to cost savings, speed to market and greater volumes of quality output. Both of these areas are discussed in more detail in the following section.

Reducing Regulatory Risk

As discussed earlier, existing regulations, as well as anticipated changes in the compliance environment are driving significant change in the methods and tools used to address compliance. The next-generation architecture supports existing and emerging compliance and quality requirements by providing greater visibility and access to information across business process segments supporting a more science-based approach to compliance and providing secure, role-based access to the right information at the right point in time, while restricting access in accordance with regulatory and business requirements.

Quality and compliance benefits achieved through the next-generation architecture include:

- Satisfaction of requirements while minimizing the cost of compliance
- Improved quality of data
- Integration with other areas of the value chain
- Improved usability
- Promotion of business processes not content-centric processes

Examples of key regulations and guidances supported by the next-generation architecture are:

- 21 CFR 11
- Sarbanes-Oxley
- HIPAA
- eCTD

Improving Operational Efficiency

Technology cannot simply address the issues surrounding compliance. It must provide users with a benefit not otherwise obtained through manual processes or legacy systems. Technology should improve performance, be flexible to address various business processes and adapt to changing internal and external requirements—and be intuitive and easy-to-use.

Reduction in Effort Spent on Development and Validation

Every organization has a different set of operating procedures with different document lifecycles, workflows, authorizations, document formats, document types and templates. Solutions must be configurable to satisfy an organization's individual requirements while at the same time providing standard configurations for items that vary little from company to company. These configurations can be used as the starting point for implementing the solution across different industry segments such as manufacturing or sales & marketing. They must also be portable and reusable so that organizations can setup the configuration of system once and then easily move it between systems, such as a development and a production system.

Configurable systems also lesson the burden of validation be allowing configuration changes to be addressed through change control rather than development or custom coding. Because requirements change often—either due to external factors or changes in internal processes—customized systems involve coding changes, which bring with them development, documentation and significant system and regression testing. Changes to a configured system, however, can generally be accommodated through a change-control process that requires significantly less time and effort.

Increased Access to Information

In addition to reducing the amount of time and effort associated with systems development and validation, the next-generation architecture also provides increased access to information, thereby reducing the time required to locate critical information assets. Specifically, access to information is facilitated through integrated search and retrieval mechanisms, as well as role-based access to appropriate information at appropriate points through a portal-based user interface.

Reduced Time to Create, Manage and Distribute Content

The business process management and application integration layers of the next-generation architecture will also aid in reducing the time required to create, manage and distribute content. By supporting process flows beyond the content-centric workflows that exist today and by facilitating collaboration both within and external

to the organization, the processes to create, manage and distribute content are no longer limited to a specific set of information, process segment or user group.

Reduced Operational Costs of Document and Data Management

The next-generation architecture also reduces the operational costs traditionally associated with document and data management. By providing integrated search, support for management of electronic records in both active and inactive states and support for movement of information between business process segments and line of business applications, the costs associated with legal discovery, for example, across multiple media, systems and locations is greatly reduced. Additionally, because information is more easily located and transmitted, costs associated with re-creating information or re-entering information are also reduced.

IBM SCORE: Bringing the Next-Generation Architecture to Life

IBM SCORE is a portal-based, strategic solution developed to address architectural requirements indicated by the emerging compliance, product and market challenges in the biopharmaceutical industry. This system combines the power of the IBM WebSphere® family of products and the strength of best-of-breed document and content management products to provide functionality in four key areas:

- Application integration
- Business process management
- Collaboration
- Document and data management

As a next-generation solution for the biopharmaceutical industry, IBM SCORE addresses requirements across the value chain from discovery to manufacturing to sales and marketing.

As a next-generation solution for the biopharmaceutical industry, IBM SCORE addresses requirements across the value chain from discovery to manufacturing to sales and marketing. While document and data management functions reside at the heart of the IBM SCORE solution, SCORE also provides additional functionality for business process management, collaboration and application integration to respond to the challenges posed in *Pharma 2010* and emerging compliance requirements.

Key IBM SCORE features include:

- Support for critical industry regulations and processes, such as GXP and 21 CFR Part 11 compliance
- A portal-based, role-based user interface that provides a richer and more intuitive interface
- A repository neutral architecture
- Extensive configuration capabilities
- Open standards (e.g., J2EE, XML, Web Services Architecture)
- Component-based approach to support interoperability and flexibility
- Assets to assist with the implementation, migration and validation of the system

IBM SCORE Solution Component Overview

A high-level view of the IBM SCORE architecture is illustrated below. At its heart, IBM SCORE provides compliance driven document management capabilities, including

integrated document lifecycles and workflows, 21 CFR Part 11 compliant electronic signature and auditing, controlled printing and controlled access to documents based on user roles. Additionally, IBM SCORE includes a set of industry-specific accelerators that decrease the time required to configure, implement and validate an ECM system. Additionally, IBM SCORE provides a means of accessing collaboration functions and also provides an integration layer that will allow clients to readily link to other business critical systems, such as ERP or training systems.

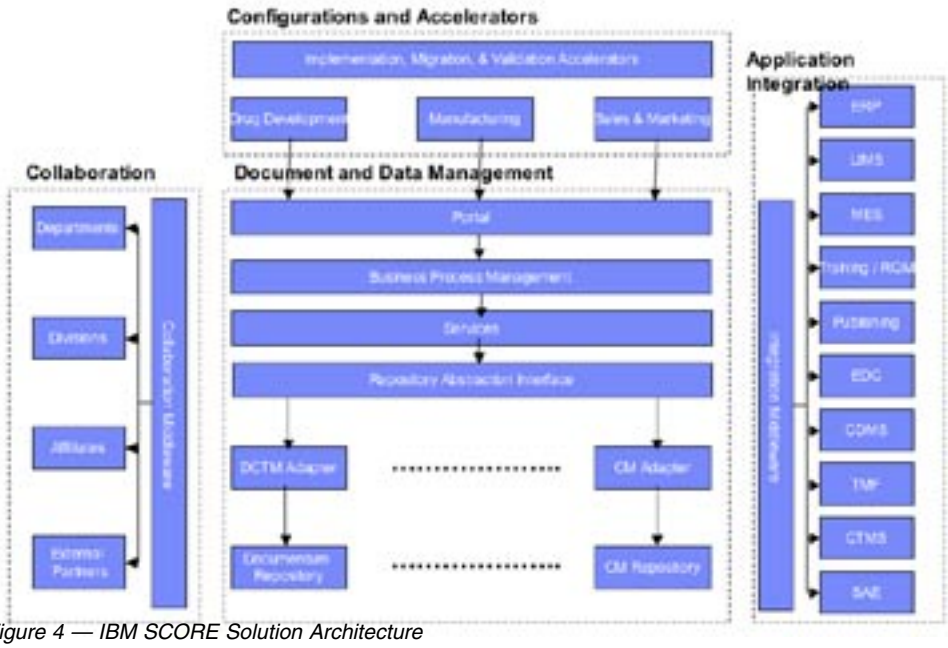


Figure 4 — IBM SCORE Solution Architecture

The following sections describe the technical components of the IBM SCORE solution, as well as the implementation accelerators and configuration tools provided as part of the solution set.

Portal-based User Interface

The IBM SCORE User Interface (UI) is a portal-based interface, providing a thin-client interface made up of any number of portlets. A user accesses the application via a Web browser. The benefit of using portlets is based on three simple factors. Different solutions across the life sciences value chain will require common user tasks such as searching and information presentation. By implementing portlets for these functions, IBM SCORE supports multiple solutions with a common framework. In addition, the use of portlets within the SCORE portal allow pre-defined, role-based configurations to be created. This type of role-based user interface allows users to view information relevant to the role they perform within the organization. For example, the portal view for a medical writer would be different than that of a packaging engineer or a clinical trials manager. A third factor is that solutions need to interoperate. By implementing portlets with a common look and feel, IBM SCORE users can more readily appreciate that the solutions form an integrated set.

Business Process Management

IBM SCORE contains a business process management (BPM) component within the application server that is considered a pure-play business process management tool. It can be used for the choreography of all types of business processes or flows. The business processes implemented in an enterprise typically require a mixture of human and IT resources. The types of business processes can vary greatly, ranging from Web services navigation to business transaction support. Business processes can be automatic, recoverable processes or processes that require human interaction. With the IBM SCORE BPM component, you can combine business process technology with any other service offered by the open J2EE architecture.

Services Component

The Services component contains IBM SCORE application logic, which applies the configuration to facilitate processing and working with the documents in the system. Interactions with the document management system happen through the IBM SCORE application component. Based on the configuration, the component is responsible for updating users' and groups' rights to documents, managing documents through their lifecycle, notifications and interacting with the workflow engine. The application layer also uses the configuration to drive the user interface.

Listed below are some of the features of IBM SCORE.

Document Classes:
- Simple documents
- Compound documents

Document Lifecycles – with Auto Promotion of Lifecycle Status:
- GXP Controlled
- Approval
- Regulated
- Finalized
- Change request
- Import
- Templates

Workflows with Target Recipients List:
- Serial
- Parallel
- Phased

Task Actions:
- Due dates
- Delegate
- Add
- Reassign

Role Assignment/Reassignment:
- Change coordinator
- Change business owner
- Manage viewers
- Manage notification recipients
- Manage printers

Integrated Change Control Management:
- Configurable lifecycles for change requests
- Supports document change control
- Supports changes to products, GMP systems, technology, and other non-document subjects

Configurable Attributes:
- Supports the enforcement of business rules during data entry

Document Actions:
- Send for authoring
- Send for review
- Send for approval
- Issue document
- Make document effective
- Create new draft version
- Send for periodic review
- Send for obsolete approval
- Withdraw
- Print controlled and reference copies
- Import and export
- Manage relationships
- Document history/audit report (21 CFR Part 11)

PDF Manipulation Services:
- Electronic signature manifestation (21 CFR Part 11)
- Controlled viewing with overlays and watermarking
- Controlled printing with auditing
- Annotations

Reporting:
- Configurable reports
- 20+ pre-configured management reports for document, task, security and auditing tracking

Searches:
- Configurable search screens
- Pre-configured searches
- User-specific saved searches

IBM SCORE Configuration Model

One of the strengths of IBM SCORE is that it maintains a separation between the configuration, which shapes the way the solution is implemented, and the core technology itself. IBM SCORE configuration tool controls all the configuration parameters that are managed within the system as controlled documents. This enables configuration management of the system as well as the rapid and repeatable configuration of each additional instance. This is an imperative within a validated environment. Some of the benefits of this configuration model include:

- Incremental implementation of configuration design
- Incremental developments and enhancements to live system configuration
- Reliable roll back to previous configuration versions
- Reliable replication of configuration between environments
- Auditing of configuration changes
- Complete configuration management

IBM SCORE Accelerators

IBM SCORE is comprised of software with implementation, migration and validation accelerators. Together with the configuration features of the product, these accelerators enable the rapid development and deployment of a GXP and 21 CFR Part 11 compliant electronic document management system and reduce the overall cost associated with implementation.

Validation		Migration
• Validation approach	• Site validation report	• Migration plan
• Test strategy	• System test report	• Migration approach
• Qualification scripts and templates	• User acceptance test report	• Migration options - workshop set
• Validation plan	• Project review SOP	• Migration questionnaire
• System test plan	• Project documentation standards SOP	• Migration checklists
• User acceptance test plan	• Periodic review SOP	
• Test process training	• Test Execution SOP	
• Validation report	• Test error handling SOP	

Implementation		
• SCORE project plan (document template)	• Project charter	• User management SOP
• High-level GDPM (milestone plan)	• Pre-training brief	• Startup and shutdown SOP
• Risk management template	• Communications strategy and plan template	• Disaster recovery SOP
• SCORE project schedule	• Document overlay definitions	• Training strategy template
• Implementation approach overviews	• Performance and capacity requirements analysis workshop materials	• Training approach overview
• Business case methodology and tools	• Physical and logical security SOP	• Training SOP
• Stream roles and responsibilities identifiers	• Backup and restore SOP	• Training needs analysis
		• Training course assessment form
		• Training course tracking spreadsheet

Table 1 — SCORE Accelerators

The Benefits of IBM SCORE

IBM SCORE aids organizations in enabling compliance, reducing costs and accelerating revenue by providing an architecture that addresses the functions required to support data and document management, business process management, application integration and collaboration components. Specifically, SCORE delivers business benefits in four key areas:

- Compliance and quality
- Efficiency/cost reduction
- Revenue acceleration
- IT maintenance and validation

Compliance and Quality

Healthcare, biopharmaceutical and other regulated life sciences companies must capture, record and securely store documents, data and events as part of their business to ensure certain processes are being followed. IBM SCORE supports these controls by performing authorization checks prior to executing operations on controlled documents, and generating audit trail entries on completion of operations. Additionally, IBM SCORE provides a highly-configurable role-based security model that helps to ensure that the right people are provided with the right content at the right time. Finally, IBM SCORE provides a number of pre-configured reports that allow organizations to track and organize system-, process- and document-related information. These features, in conjunction with a robust set of accelerators for systems validation, help organizations support compliance across the value chain. Additional quality and compliance benefits of IBM SCORE can be realized across the biopharmaceutical value chain.

Research & Development	Manufacturing	Sales & Marketing
• Integrates the business process thereby reducing the complexity of information transfer points and supporting tracking across multiple business areas. – Discovery → Preclinical → Clinical → Regulatory • Integrates with other systems to allow for automated transfer of information, reducing the risk associated with re-entering information • Enforces standards across the enterprise – Reduces the likelihood of incorrect doc types – Boiler-plate and protected templates minimize user liberties • Supports 21 CFR Part 11 compliance by enabling a full audit trail, electronic signature and electronic signature manifestation	Information auditing across component manufacturing processes • Availability of information—access to most current SOPs, validation documents, training materials • Periodic review notifications • Controlled viewing and printing • Automated and controlled Change Request procedures • Support for integration with ERP, LIMS, MES and other systems to allow for the automatic transfer of manufacturing information • Process-centric workflow extends process automation and tracking beyond current document workflows • Configuration capabilities support creation and integration with product and other data dictionaries	• Review assembled documents as a unit to avoid asynchronous material • Visibility to document status to avoid non-compliance risks/unsupported claims • Support for integration with SFA systems to capture on-line orders associated with each piece of collateral • Support for integration with call center application to allow for tracking of consumer and provider communications content • Only approved product information is distributed • Real-time collaboration • Reduces burden of version control

Table 2 — Compliance and Quality

Increases Efficiency and Reduces Costs

IBM SCORE increases efficiency and reduces costs by supporting the automation of processes to decrease process cycle times, and by supporting the reduction of manual information transfer points. Additionally, IBM SCORE's meta-data architecture and search and retrieval functions help to reduce the time and cost associated with locating information. Finally, IBM SCORE's compliance features, such as audit trail, authentication and granular security support the reduction of costs associated with legal discovery activities. Additional efficiency and cost reduction benefits include:

Research & Development	Manufacturing	Sales & Marketing
• Shortens development cycle for submissions • Facilitates re-use of information across markets • Reduces duplicative effort • Shortens review/approval cycles • Flexible and dynamic workflow • Secure portal enables exchange with third parties and agencies	• Information changes can be updated once and propagated to multiple outputs/documents • Role-based, portal UI—right information to the right people at the right time • Automation of information hand-off points - e.g., packaging specification information to MRP system	• Shortens review/approval cycles for product content – Flexible and dynamic workflow – Secure portal grants third parties access (ad agencies, reg. agencies) • Support for integration with CRM promotes efficient distribution of materials to sales force, providers and consumers • Integration of controlled content with other LOB systems support reuse rather than recreation of information • Product content stored in one location

Table 3— Efficiency and Decreased Cost

Revenue Acceleration

In addition to reducing costs and increasing efficiency, IBM SCORE's business process management and application integration capabilities can also help organizations accelerate revenue by reducing the time and complexity associated with key bring-to-market milestones. IBM SCORE's collaboration functions also support interactions with all members of the value chain, including partners, suppliers and vendors, increasing the value of these interactions by decreasing the time and effort necessary to support such collaborations.

Research & Development	Manufacturing	Sales & Marketing
• Support for greater submissions volume, as well as multiple submissions types – eCTD – INDs – Rolling submissions • Decreased submissions timelines – Faster submission – Faster approval – Faster revenue recognition	• Technology transfer from R&D to manufacturing is streamlined through collaboration between internal departments and integration of LOB applications • Higher manufacturing output by providing the latest document to the right person at the right time • Facilitates contract manufacturing collaborations increasing opportunities since information can be more easily shared while manufacturing • Product updates get propagated and marketed faster	• Increase sales force effectiveness – The right collateral to the right reps to the right customers – Updated collateral distributed faster – New indication collateral distributed faster

Table 4 — Revenue Acceleration

IT maintenance and validation

Every organization has a different set of operating procedures with different document lifecycles and workflows, authorizations, document formats, types and templates. IBM SCORE is configurable enough to be able to fit into a organization's unique environment while still providing out-of-the-box default configurations that can be used as a core configuration. Configurations are portable and reusable so that organizations can setup the configuration of system once and then easily move it between systems, such as development and production.

These configurations include:

- Research and development
- Manufacturing
- Sales and marketing

Additionally, because the business process is separated, the process can change without the cascading data and system validation impacts typically seen in today's EDMS systems. As industry guidances and regulations change and are updated, organizations can update their IBM SCORE configurations without the need to create or update customizations and without the need to wait for new versions of supporting software. Instead, organizations can often update configurations and/or business processes and validate changes through change control, as opposed to a full systems validation. This not only reduces the validation burden on IT resources, but also allows IT to support changing business requirements much more efficiently.

Conclusion

In order to not only meet the requirements indicated by such changes, but to turn these requirements into business advantages, organizations will need to fundamentally change the way they approach compliance-centric enterprise content management architectures.

The biopharmaceutical industry is experiencing significant change propelled by shifting market dynamics, the evolution of products toward targeted treatment solutions and a compliance landscape that is moving toward more scientific, risk-based approaches. In order to not only meet the requirements indicated by such changes, but to turn these requirements into business advantages, organizations will need to fundamentally change the way in which they approach compliance-centric enterprise content management architectures. Specifically, organizations will need to move away from the siloed, document management point solutions of today to more integrated systems that support views across multiple repositories, as well as the ability to integrate across multiple applications. Additionally, architectures will need to shift from document or content-centric workflows to broader business process management flows that support interactions between multiple business areas and across multiple application domains. Finally, the next-generation enterprise content management architecture will need to support a collaboration environment that allows for increased interactions both within organizations—between departments and functional areas—and external to organizations—with suppliers, vendors and partners.

IBM SCORE is a solution that supports the emerging requirements of the biopharmaceutical compliance space. As a solution for compliance in a regulatory environment, IBM SCORE provides support for the following key areas:

- Application integration
- Business process management
- Collaboration
- Document and data management

Additionally, SCORE provides organizations with business-area specific document and data management configurations (R&D, manufacturing, sales & marketing), as well as a set of implementation, validation and migration accelerators that serve to speed time to implementation, as well as reduce overall system implementation effort. Finally, SCORE provides an architecture to support benefits across the business process value chain, including increased quality and compliance, increased process efficiency and reduction of costs and acceleration of revenue.

IBM Corporation
Route 100
Somers, NY 10589
U.S.A.

Printed in the United States of America
5-05

Printed in the United States on recycled paper containing 10% recovered post-consumer fiber.