IBM Global Business Services

IBM Institute for Business Value

The new biopharmaceutical blueprint

Aligning business and IT with service-oriented architecture

Life Sciences and Pharmaceuticals

IBM Institute for Business Value

IBM Global Business Services, through the IBM Institute for Business Value, develops fact-based strategic insights around critical industry and cross-industry issues relevant to senior business executives. This executive brief is based on an in-depth study by the Institute's research team. It is part of an ongoing commitment by IBM Global Business Services to provide analysis and viewpoints that can help companies realize greater business value. You may contact the authors or send an e-mail to iibv@us.ibm.com.

The new biopharmaceutical blueprint

Aligning business and IT with service-oriented architecture

By Pieter Deurinck, Kathleen Martin and Jay DiMare

Bringing a pharmaceutical or biologic product to market takes more than just good science. It takes an agile business to respond to the changing market dynamics. Research and development (R&D) is under pressure to bring new treatments to market faster and extend its reach in global markets. Likewise, manufacturing needs to incorporate more efficient, quality-centric processes that scale across regions and partners. At the same time, sales and marketing need to address regulatory demands by re-evaluating how they manage the increasing number of channels and partners. The challenges of integrating technologies can hamper all of these efforts. Service-oriented architecture (SOA) can serve as the new blueprint for aligning business and IT. This paper is intended for business executives and explores how SOA can help enterprises effectively achieve business flexibility within a compliant environment.

The new biopharmaceutical blueprint

Aligning business and IT with service-oriented architecture

The importance of flexible technology integration increases in the context of collaborating in a global marketplace.

Introduction

Biotech and pharmaceutical companies (BioPharma) are challenged today by cost pressures, the availability of more complex scientific information and the need to make faster, better business decisions -- all in the context of a global marketplace and a new economic environment. Many are actively collaborating and partnering to augment their core competencies and extend business beyond organizational and geographic boundaries. With this in mind, companies have invested in many forms of technology to improve business processes, integrate their organization and drive innovation.

Businesses seek flexibility within a compliant environment – their processes are not static – and performance improvement is an ongoing effort. While IT solutions are required to support business flexibility, current integration approaches cannot support the level of responsiveness needed to sustain continuous improvements. Service-oriented architecture (SOA) has the potential to dramatically address this challenge and provide benefits when:

- Business users must exchange information across multiple systems.
- Business processes span several applications across partner organizations.
- Businesses are transitioning to newly merged or acquired owners.
- Business users need information in near real time.
- Point-to-point solutions prevail, with fixed interfaces that are costly to maintain.

But what is SOA, and how can this approach provide an organization with the levels of efficiency and responsiveness it needs to effectively compete in today's changing market?

The power behind SOA is the ability to share services through system-to-system interactions that can help improve efforts to adapt end-to-end processes. SOA helps automate

What is service-oriented architecture (SOA)?

Service-oriented architecture (SOA) is a style of developing and integrating software. It involves breaking down an application into common, repeatable "services" that can be used by other applications, both internal and external, in an organization – independent of the applications and computing platforms on which the business and its partners rely. Using this approach, enterprises can assemble and reassemble these open, standards-based services to extend and improve integration among existing applications, support collaboration, build new capabilities and drive innovation at every point in the value chain.

process steps; remove redundancy; use messaging and alerts to trigger essential people-powered workflow, and enable new capabilities. When a company adds new applications and retires old ones, SOA can help facilitate the transition and migration. Over time, services may be modified, shared and recombined to streamline activities across yet more applications. This approach allows companies to more efficiently automate regulated and compliance-driven activities – freeing people to perform higher-level activities, and providing an integrated business view to authorized staff throughout departments and organizations. This in turn can support continuous improvements through the monitoring and redesigning of processes linked to technology services.

Service-oriented architecture offers an integrated, collaborative approach to aligning business and IT services and supporting evolving business needs. However, the business must be actively involved – identifying the processes that must be managed on an ongoing basis. Current IT integration methods can continue to exist because SOA preserves legacy systems through the use of services. Furthermore, SOA can be applied using a small, step-wise approach that can expand as companies add more processes and applications. Like a stone creates a ripple in a lake, initiating SOA can help create benefits that quickly ripple through many other areas of the organization and its partners.

SOA is easier to understand through real-life examples. Here, we will take a look at three critical, industry-specific issues to show how SOA can be applied to resolve these problems and add more business value to an organization. We have identified three scenarios in the BioPharma industry:

- *Research and development (R&D)*, where SOA systems integration techniques can be applied to manage clinical trials more efficiently
- *Manufacturing*, an area where SOA approaches can support enhanced information-sharing for internal systems, and tighter integration with manufacturing partners
- *Sales and marketing*, where SOA services can help improve regulatory compliance reporting when coupled with rules-based technology and everyday tools that can help extract, transform and load data (ETL tools).

Research and development: Managing clinical trials more efficiently

Clinical processes must be highly responsive to the networked nature of running today's clinical trials and the increasingly fluid quality of healthcare information. BioPharma companies are thus turning to external partners

–including clinical research organizations– to expand their skills and capabilities and extend their portfolios. At the same time, having multiple partners involved in clinical trials introduces more variability and challenges to manage trials more efficiently.

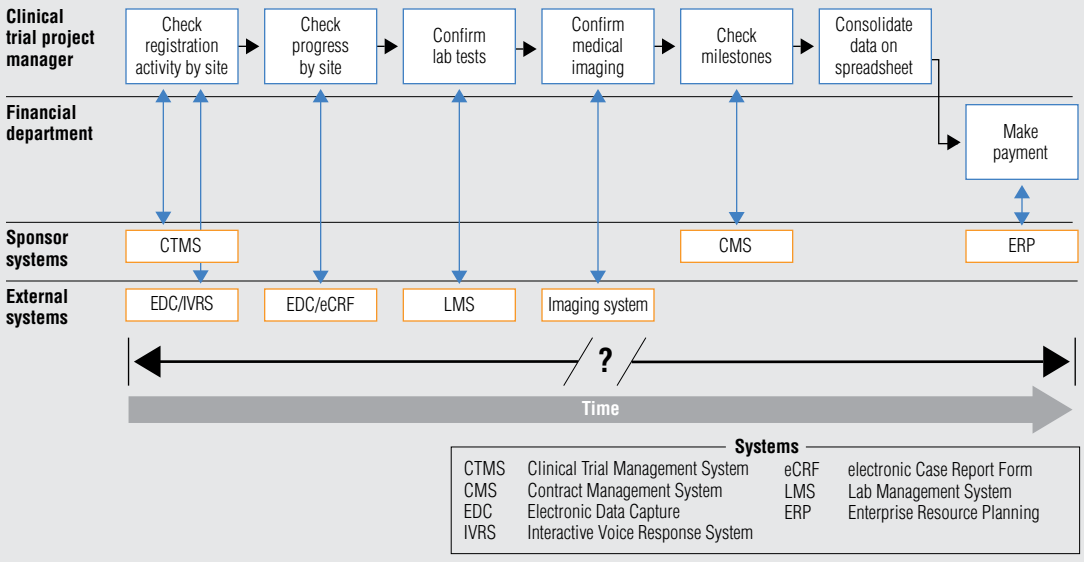
Integrating clinical systems often involves point-to-point solutions that are "hard-wired" and costly to modify when accommodating new business needs or connecting to new partners. Inefficient connections can limit visibility to the timely information needed to make important decisions. This makes it more challenging to reuse information stored in various systems, which can be difficult to manage and maintain. Too often, clinical study staff must manually extract information stored in several systems, and aggregate it each time they need to generate the same summaries, using tools such as Microsoft® Excel. Data may also exist outside the control of the company that ultimately needs the data. These situations can make it difficult to consistently enforce regulations, and can compromise compliance and data quality.

How clinical trials are managed today

Today, clinical development must work hard to effectively manage investigator relationships and clinical trials across disparate applications. For example, members of the clinical staff, such as study managers, often spend more time on administrative tasks than value-added activities. Figure 1 shows the manual steps a study manager must take to check patient enrollment status and evaluate if payment is due to an investigator.

In this scenario, the manager was unaware of the site's enrollment status and that the investigator was due a payment. The site manager

Figure 1.
A sample process to check patient enrollment and evaluate investigator payment.



had to call the study manager to initiate the process where she accessed six separate systems before she had a full view of the critical information she needed. She then had to determine whether or not the investigator had registered patients according to plan. She also had to confirm that patient data submitted met study milestones, such as those involving initial laboratory and imaging tests. Actual enrollment was close to forecasted and all criteria were completed. By the time the financial department was ready to mail the payment, two weeks had passed. The check came four weeks after it should have been received. *How long does this process take in your company?*

These processes are challenging enough to manage on a small scale. Imagine the time and resources they consume on a global scale. Study managers must repeat this process each time they want to check ongoing study progress – often learning about issues like enrollment delays *after* costs have been incurred. They gain little insight into the reasons for slow study enrollment unless they call the investigator site. They are unable to effectively reuse information for investigator sites that are active in multiple studies. Investigator information can exist in many locations with conflicting data – obliging staff to contact sites for the same information several times. This can hamper efficient interactions among study staff and make it harder to build long-term relationships with investigators, who are critical to successful trials.

To add to this already complex picture, BioPharma companies rely on new study designs that require real-time data visibility and new sources of information to help identify patient subgroups likely to benefit from treatment. New types of information can include genomics, proteomics, new imaging technology, and advanced modeling and simulation, which can be integrated with traditional study data to generate new insights. This calls for sophisticated data management, and new methods for connecting information.

Again we pose the question: With these new and complex variables in the equation, how long would our sample process take in *your* company? Can your business systems support changes to this process? While systems collaboration can help address these questions, the issue is how best to do it.

An integrated approach to clinical trial management

Rather than having the study management team take responsibility for checking a myriad of different systems, consider what it would be like if those systems communicated among themselves so that the study manager only had to check *one* system? This goal is understood, but quite a challenge to implement – until now. With SOA, companies can build such a solution while considering all

With service-oriented architecture, access to data across both internal and external clinical trial applications is improved and accelerated.

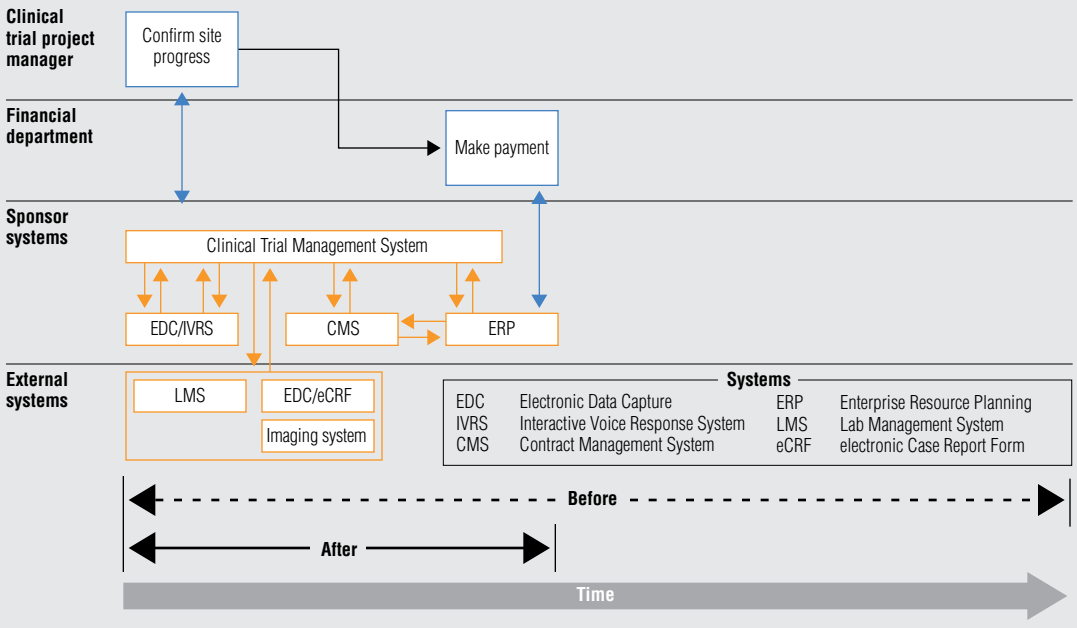
the issues and obstacles described earlier. Figure 2 shows how an SOA-built approach can reach across internal (sponsor) and external (investigator, partner and vendor) applications.

Continuing our example, staff members are no longer forced to seek out critical information from disparate sources; they can collect the information they need through a *single system*—dramatically improving the business process. In this case, the Clinical Trial Management System (CTMS) collects the required information. This level of change is possible using SOA services, which involve additional programming or application code that acts like a phone line between the systems that need to talk. Figure 3 on page 8 shows how SOA services can help orchestrate system-to-system communication across organizational boundaries and provide enrollment information in real time—enabling other decisions.

In Figure 3, SOA services support the exchange of information between the sponsor's CTMS for investigator information and:

- The external partner's EDC (Electronic Data Capture)/IVRS (Interactive Voice Response System) that holds patient enrollment progress and visit data. In our example, the CTMS would use the SOA service "Get trial status" from an EDC system to learn the status of the trial being managed by that particular EDC system.
- The sponsor's EDC that holds data from other sites that monitor themselves, using the same service as described earlier for obtaining the trial status.

Figure 2.
A single integrated access point can help accelerate and improve access to data across systems—for partner and sponsor.

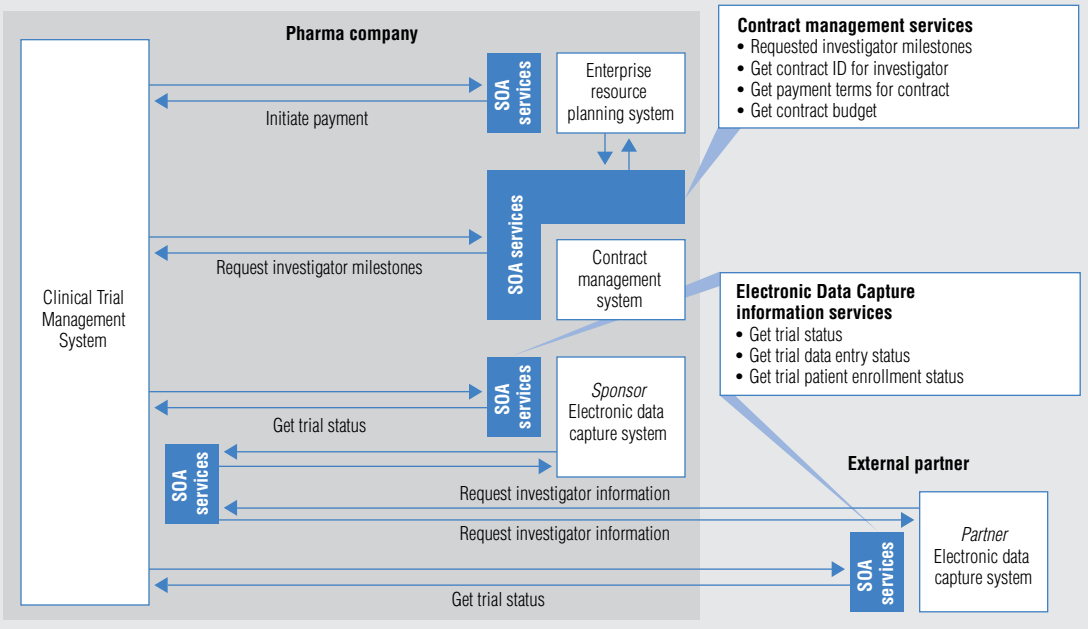


- The Contract Management System that contains documents and contractual milestones for each site. Here, the CTMS may need to compare investigator milestones in a contract with current progress and status contained in the CTMS system. The CTMS would use the SOA service "Request investigator milestones" from the Contract Management System to obtain this information.

Integrated in this fashion, the CTMS introduces a new level of efficiency that allows a comparison to be made across systems to determine if a milestone has been reached. If so, the sponsor can pay the investigator in a timely fashion. These SOA services can also be reused internally to help integrate the CTMS and the Contract Management System with their ERP system. These same services can be used externally to integrate their internal EDC system with their partner's EDC.

As companies extend their borders into emerging markets like China, India, South Korea, Eastern Europe and Latin America, SOA can assist in overcoming the complexity of expanding studies to access new pools of patients with external partners. SOA can help manage clinical studies by simplifying how data is shared – all in a controlled, secure fashion that also helps protect intellectual property. This approach can enhance partnering with contract research organizations (CROs), improve co-developing with partners by enforcing partner contracts and agreements, and provide more control over processes that extend outside the organization.

Figure 3.
An example of SOA use: a Clinical Trial Management System (CTMS) using SOA services to connect to other systems.



SOA can help build in efficiency and compliance across the organization allowing companies to manage and scale their clinical trials.

The value of the SOA approach

The SOA integration approach allows many systems to continue to operate as they do today. They maintain ownership of the data they manage and support their existing business processes. At the same time, SOA services allow the Clinical Trial Management System to access specific data in real time, without requiring additional human interaction with the system. SOA helps integrate systems in a non-intrusive manner – allowing the CTMS to operate as usual. Contracts can continue to function in the contract management system, with the systems sharing information. The study manager can evaluate study progress in real time, resolve an issue and perform only the essential steps to make timely investigator payments. All of this helps to nurture productive relationships with the investigators. It also helps build in efficiency in a number of ways by enabling:

- *Real-time access to study progress.* SOA has the potential to allow systems to exchange information in real time across their studies. Information is accurate and up-to-date – exchanged at the point in time it is needed.
- *Preservation of existing IT investments.* Services can communicate business tasks concerning specific data recognized among existing systems and applications helping to extend their longevity regardless of geography, number of sites, or trials[1]
- *Reuse of SOA Services.* As shown in our example, SOA services can be used by systems like EDC for clinical studies, and by all EDC systems used by partners. SOA services that support access to CTMS data can be built once, and used by any internal or external system. As you integrate SOA into your business, you and your partners can find other ways to reuse data using services across your applications.
- *Enforcement of compliance.* As processes are properly governed and updated, SOA, in turn, can help enforce sponsor-level compliance and consistency across applications through system collaboration.
- *Facilitation of business process change.* SOA services help make it easier to change and scale the business processes required for clinical trials. Because SOA makes system functionality more granular, the processes that use them can be easily accessed and applied to other systems.
- *Expansion beyond organizational borders.* SOA services offer a standards-based approach to systems integration. Services may be exposed locally or globally with select partners such as IT providers, logistics services, randomization providers and other vendor services important to managing studies.

In today's pharma manufacturing environment, the product release process is hampered by paper generated by most supporting application systems.

Having an efficient integration approach such as SOA enables business processes to span the organization. Equally important is how SOA permits a company to manage and scale its clinical trials as it addresses market pressures and looks to collaboration with external partners.

Manufacturing: Improving the product release process

Today's regulatory agenda demands "quality by design"–a proactive approach that addresses compliance issues *before* they occur. Customers and regulators want nothing less than continuous supply, reliable product safety controls and the ability to track issues efficiently. In manufacturing, more parties are involved to produce more complex products requiring more communication. This exposes the industry to risk from local variations and monitoring procedures managed by global partners. We will focus our discussion on a real-life scenario: getting manufactured products released into the market.

BioPharma manufacturing is striving to create tighter integration among all the players: suppliers, technical development, manufacturing facilities, co-marketing, logistics and markets. At the same time, manufacturing is an inherently changing environment. We will look at one part of the release process and examine the many systems supporting it. Companies often experience integration challenges when there is:

- One enterprise resource planning (ERP) application with many instances–internally or externally–across manufacturing sites
- Many ERP instances with many best-of-breed applications
- Different systems for each department discipline involved in the manufacturing process
- A reliance on paper generated from these various systems, with the legal requirement to retain the paper and show an audit trail for the released batch
- Loosely enforced global IT standards within the organization or with partners.

Managing the product release process today

The release process is complex involving massive amounts of information from numerous sources. All compliance-based processes must come together at this point before a batch is released to the market. Staff is involved across the organization and outside the company including quality control, in-house or third-party manufacturing, engineering, quality assurance and supply chain operations. Figure 4 shows how a typical release process occurs today.

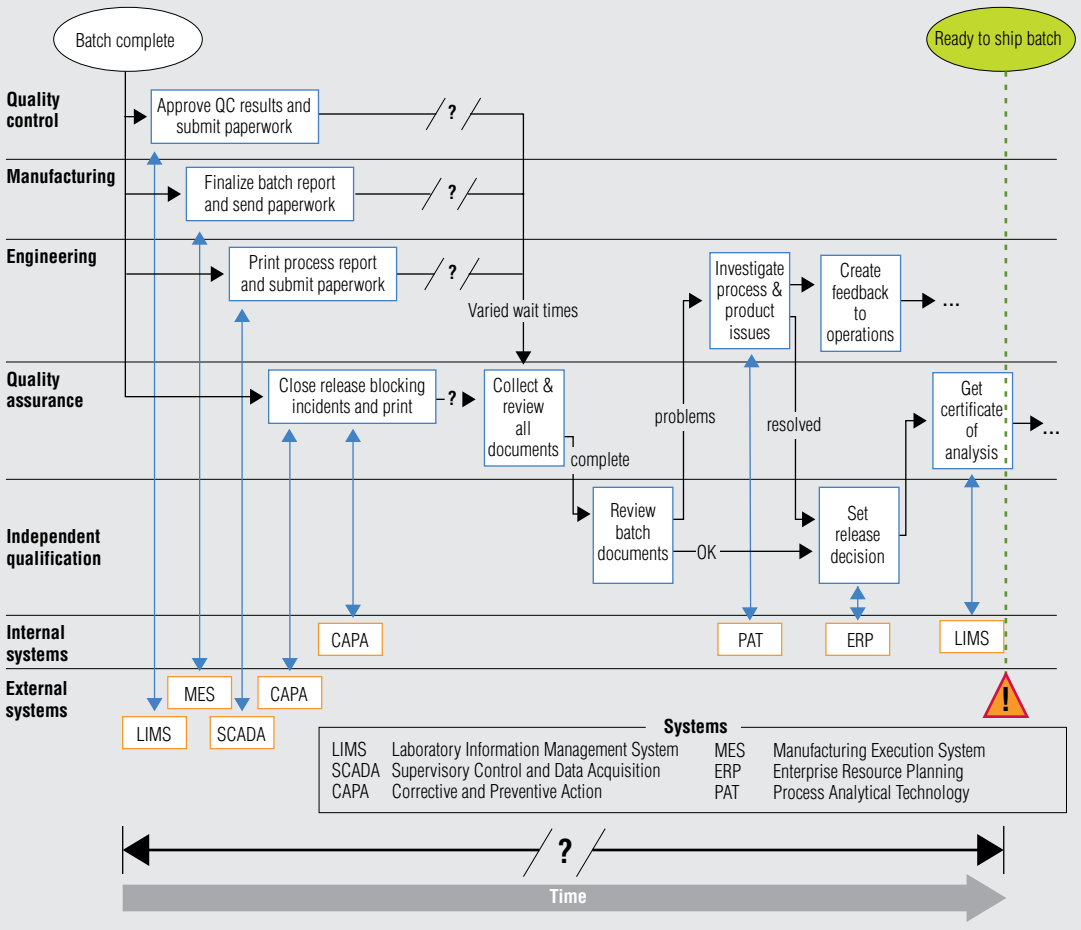
This process is triggered when a batch is completed. Today, the process is slow and inefficient because it is still largely paper-based and with many applications. It relies on people to push the paper to its next step

or to transfer the information manually from one system to the next. Documents can get lost and be difficult to trace during critical stages. Standalone applications may only have partial information, and the manual entry of information into multiple systems can lead to redundant or even conflicting data. Each discipline has its own reports to document the manufacturing of the batch. It is the collective set of documents from all activities and departments that provides the basis for knowing whether or not the batch should be released. There are many issues that can occur as documents are collected. Iterative document generation and collection loops can prolong the process without triggers to alert staff about existing issues or ongoing corrective actions, making it difficult to measure and manage.

Streamlining the product release process

To support Good Manufacturing Practices (GMPs) of global regulators like the FDA in the U.S. and EMEA in Europe, staff and

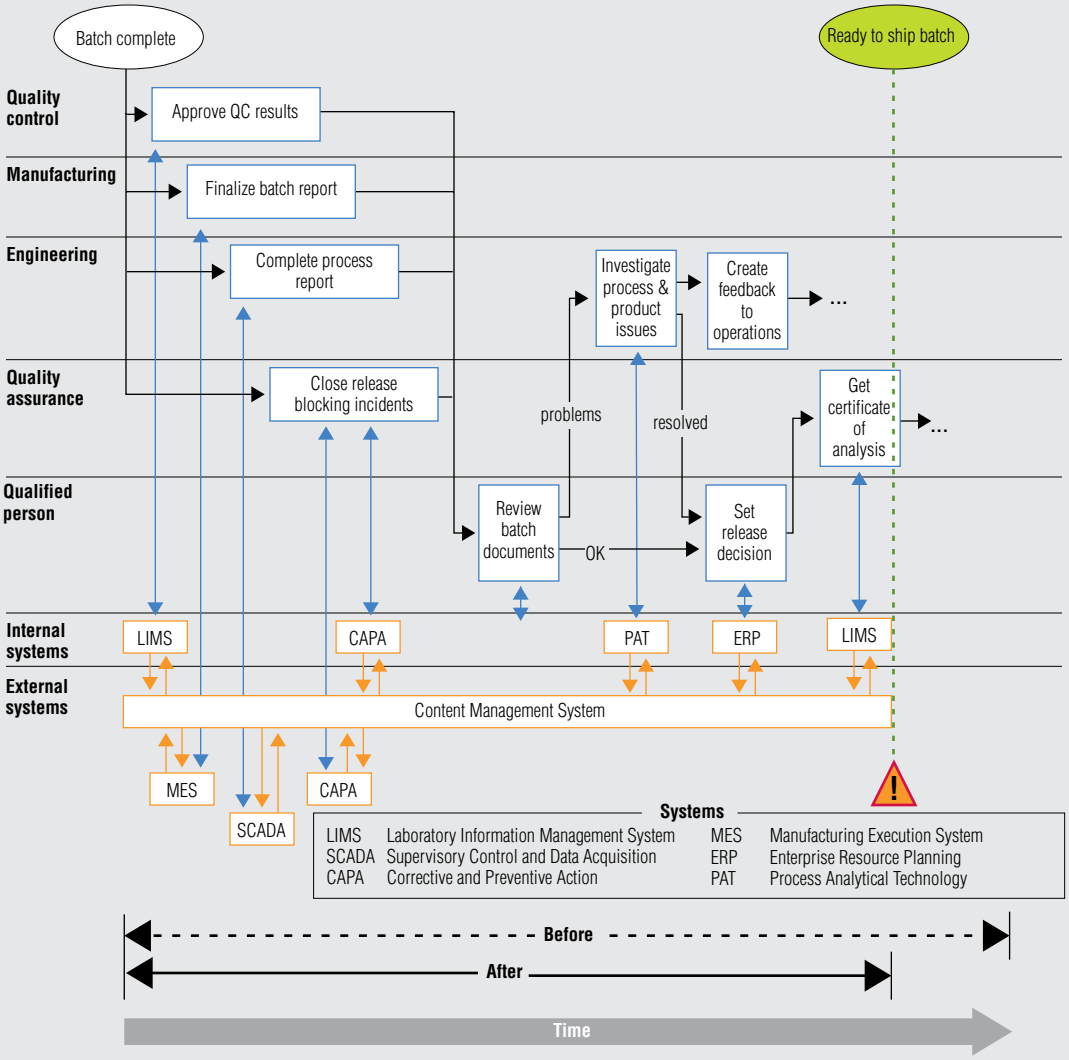
Figure 4.
Today's release process involves many manual, iterative processes.



equipment must be in compliance at all times. Compliance is often supported through business processes like those presented in Figure 4. In many cases, to improve this process, companies need to eliminate paper and employ systems that can store and share required reports and documents in a logical manner – from system to system. Hopefully, this level of integration would not require custom programming of the systems actually generating the reports. Figure 5 shows how the process might improve with an SOA-enabled Enterprise Content Management System (ECMS) that manages data stored in a database (structured data) and documents stored in a document store or repository (unstructured data).

Integrated systems as shown in Figure 5 offer a number of advantages:

Figure 5.
A revised batch release process.

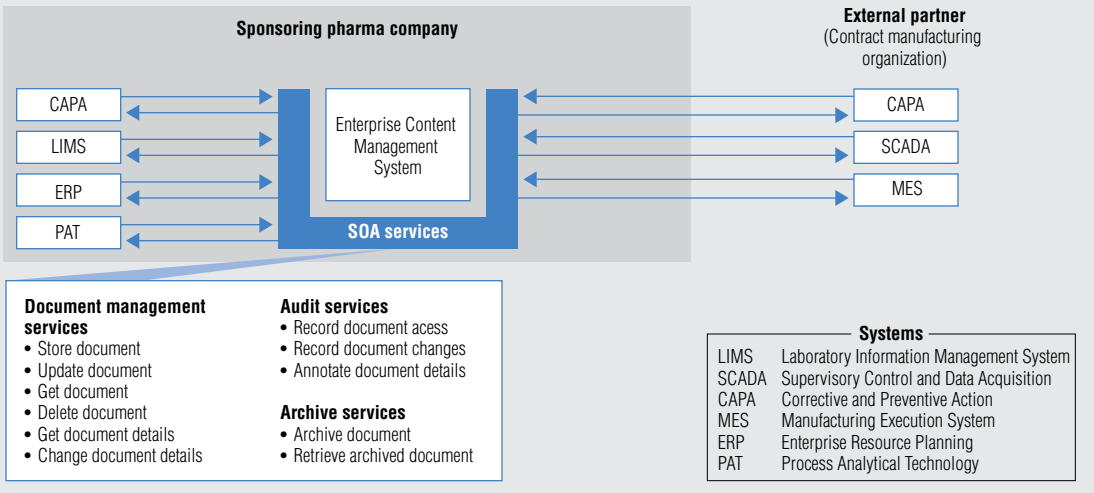


An SOA-enabled Enterprise Content Management System can be integrated with both internal and external systems.

- The departments supporting the batch release process continue to use their existing systems – with a new efficiency that allows staff to focus on value-added activity. These systems communicate to an SOA-enabled content management system to store any required reports.
- Paper generation and movement can be eliminated – removing the uncertainty and reducing overall cycle time.
- The system can help manage the process; for example, only allowing the process to continue when all of the proper documents have been generated, collected and stored appropriately.
- The qualified person who is responsible for releasing the batch can more easily see if there are open deviations in the documentation collected.
- The development of a more efficient and effective process platform is made possible by using SOA to integrate the supporting systems. In the past, this often required custom, point-to-point programming dependent upon proprietary platforms and programming interfaces provided by the software vendor. This has been notoriously difficult – complicated by the nature of storing documents and reports from various sources, in a variety of formats. The complexity is only increased when the process requires the integration of multiple business partners around the globe.

There are many software solutions for enterprise content management. If the enterprise content management solution provides SOA services, we can offer the level of integration shown earlier with a compelling integration approach – for both the sponsor's and the business partner's IT departments. Figure 6 shows how this level of systems integration can be achieved using SOA.

Figure 6.
A closer look at an Enterprise Content Management System providing SOA services.



Using Figure 6 and continuing with our example:

- If the person who handles Quality Assurance had closed the release-blocking incidents and wanted to publish an incident status report, they would use the Corrective and Preventive Action (CAPA) system, as normally done. The CAPA system would generate the report, and use the SOA service from the content management system, "Store document," to store the report associated with the batch.
- When the qualified person reviewed all of the documents in the content management system and decided to set the release decision, this would be done in the ERP system, as it is today. However, when the production order was ready to be published, the ERP system would complete that task – using the SOA service from the content management system, "Store document," to store the report associated with the batch.
- If Quality Control was releasing the batch and wanted to generate the Certificate of Analysis, they would do so in the LIMS system, as usual. The LIMS system would use the SOA service from the content management system, "Store document," to store the report associated with the batch.

The SOA-enabled ECMS provides a standards-based approach that allows other systems to deposit reports and documents, and maintain those documents over time. This involves defining SOA services for distinct document-management functions, like depositing or retrieving a document or report. In our example, not only can the initial batch of documents be stored; downstream documents that must be retained, such as the certificate of analysis (CoA) and electronic batch records (eBR), can also be stored collectively by any system participating in the process. This can help simplify the generation of regulated documents. It also allows staff to quickly resolve issues that are tracked in the CAPA system, rather than having to chase after supporting documents.

The value of SOA: Tighter integration among all players

The SOA-enabled ECMS solution is just one example of how SOA can impact the manufacturing environment. SOA brings value to the overall organization through:

- *Reusable data/repeatable processes*. SOA establishes an environment that helps support the evolution to quality by design, as well as continuous, "real-time" quality assurance to help build in efficiency within the organization and with global partners. Using a service-driven approach like SOA enables processes that permit departments, manufacturing sites and organizations to adapt to changes in their environment.

Successful sales and marketing relies on getting the right message to the right people at the right time while complying with changing regulations globally.

- *Reuse of SOA services.* These SOA services can be reused by *any* application producing documentation. This common activity permeates not only manufacturing processes, but many other processes within the industry. Consider how valuable SOA services could be for other central or key applications like ERP.
- *Facilitation of business process change.* SOA services help make it easier to adapt to changes in manufacturing business processes. SOA makes system functionality more granular – allowing processes that use them to be easily accessed and applied to other systems. As SOA services are reused, IT systems become more flexible – helping to reduce development time.
- *Improved risk management.* An SOA framework can also help monitor the execution of a process. The same SOA services that connect two business applications can also support any of the monitoring applications.
- *Support for automated processes across applications.* SOA allows process-management or workflow systems to "talk" to relevant applications. This helps reduce administrative burdens, increase compliance and extend processes into new areas of the organizations and to external partners.
- *More efficient partnerships.* Business partners can be integrated with the BioPharma company in a non-intrusive manner, using industry-standard interfaces. SOA offers a way to integrate without wholesale change to existing applications for companies or their partners.
- *New business strategies.* SOA offers connectivity options for new partners while allowing companies to explore new product capabilities. New support systems can be built more easily using portal technology and SOA services.

Sales and marketing: Improving compliance reporting through enhanced analytical environments

Successful sales and marketing efforts rely on accurate and timely information – getting the right message to the right people at the right time. In the past, sales and marketing relied on communicating with stakeholders face-to-face. Today, the industry can no longer depend solely on this method. Channels have broadened to include phone calls, e-mails, conferences and meetings, which must be managed and integrated effectively. Restricted budgets and government policies are limiting marketing and sales activities. At the same time, the pressures on the healthcare market are strengthening the roles of other stakeholders – providers, payers and patients, for example – who must now be targeted through a combination of channels. In addition, the message concerning innovative products, such as targeted treatments, is becoming increasingly complex with more information needed on product safety and cost.

Complying with regulations in today's changing environment

While BioPharma sales and marketing teams must rely on more channels and more partners, they must also remain compliant with regulations across the globe. Some of these policies limit how often sales and marketing can contact a prescriber, or how much they can spend on these interactions.

In Europe, for example, government controls much of the healthcare spending. Requirements vary across European countries restricting how often pharmaceutical companies can contact a physician, as well as the methods they can use, by brand or product. For example, if a marketing manager in the U.K. is assigned to physicians, she may discover she only has one more opportunity to e-mail a doctor because someone on another team has already used this channel near its limit earlier in the year. Having better visibility is critical to anticipate these limits and avoid fines and violations. SOA can accommodate the myriad country-specific requirements in a highly complex environment where multiple affiliates are supported by central processes and/or solutions.

In the United States, state spend laws restrict BioPharma companies' spending on medical professionals who prescribe, dispense or purchase prescription drugs in that state.[2] Currently, a total of five states have passed these laws. Each state sets different requirements – making it difficult for companies to collect and report the data on a country-wide basis. As more states consider this legislation, channel interactions become increasingly difficult to track. The challenge is how to anticipate when companies are approaching or exceeding a spend limit when other teams are pursuing the same influencers.

Tracking and coordinating these interactions is further complicated by systems that are not currently integrated or are connected through point-to-point solutions with fixed interfaces. Often, they have no overarching architecture or governance to enforce regulations. Information about physician interactions within a channel is often hosted by marketing agencies outside of the BioPharma company, or housed in independent databases. Relying on independent data sources like these makes it difficult to synthesize and evaluate the volumes of information available to determine the optimal combinations of channels.

Analysis and reports can help address these issues with information that can be updated in the application within the respective businesses. It is not evident that issues exist and compliance actions are needed until the reports are generated. But these reports are not available until the analytical environments are set up or refreshed. Once a compliance action is identified, a request is routed back to someone who can update the system controlling the requirement. As time passes, the

company can move farther and farther out of compliance. As a result, many BioPharma companies are unable to provide access to clean, reliable information in a flexible, reusable manner.

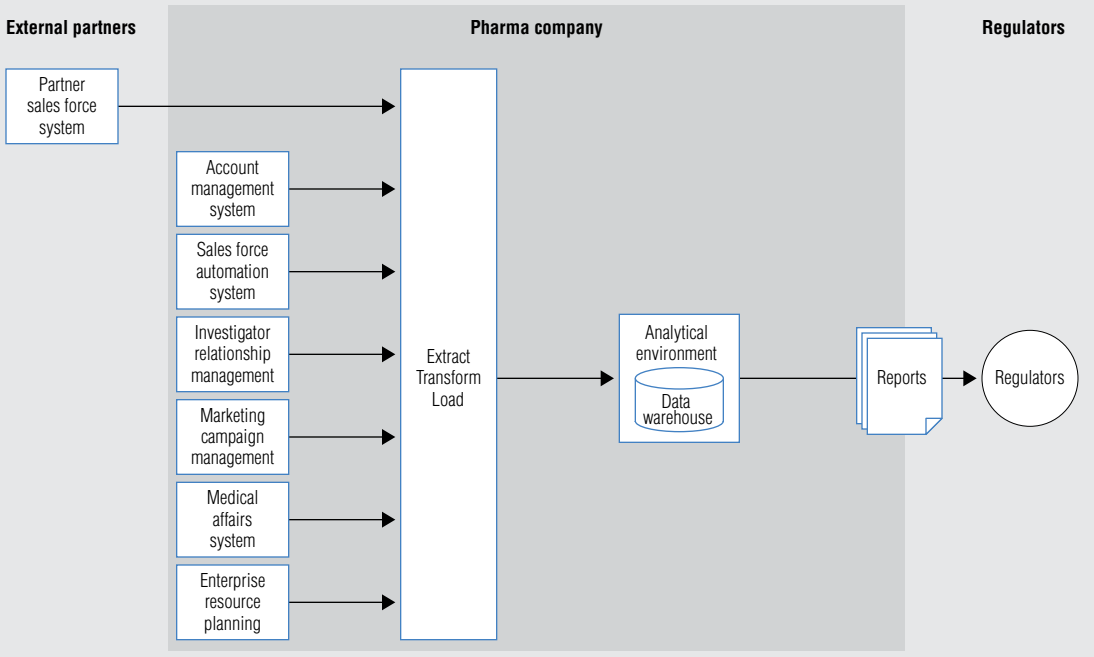
Many BioPharma companies build an analytical environment to create these reports. This usually includes a data warehouse and data marts, or online analytical processing that exists independently from the transaction-based processing used to support day-to-day business processes. Figure 7 denotes "business as usual" for many IT departments and shows a few typical sales and marketing systems that would feed into the reporting systems. These systems need to respond to compliance issues and constraints. It is usually a one-way, overnight or background activity.

How can we take advantage of the knowledge that starts to surface as these data sources come together? Is there a way to exploit the analytical environment to meet the needs of daily operations?

An SOA-enabled approach to addressing restrictions on promotional activity

Many of the challenges described in this scenario can be addressed with business rules technology, which uses a rules engine. This type of software allows the execution and management of business rules, which can then be used by multiple applications. Rules can be executed during the periodic build or update of the analytical environment. The challenge is, once you know a rule has been satisfied, how do you systematically and efficiently go back and change the appropri-

Figure 7.
A standard approach for building an analytical environment with internal and external data sources.



ate application? Figure 8 shows how SOA services can be used to exploit the processing effort that creates the analytical environment beyond its current capabilities, using a standards-based, non-intrusive approach.

In Figure 8, notice that the analytical environment is still built the same way. There is no change or disruption to the approach. However, during the process, the ETL tools will use a rules engine to apply simple rules such as checking for spending limits. If it is time to turn off spending in an area, the rules engine will use SOA services to go back to the responsible system and set that control at that point in time. For example, while marketing managers input their forecasts, it can trigger alerts in the Sales Force Automation (SFA) system telling users they are approaching a specific threshold. Business rules could then block them from carrying out their plan. Building in requirements, such as these, help staff avoid compliance issues and allow them to consider other options.

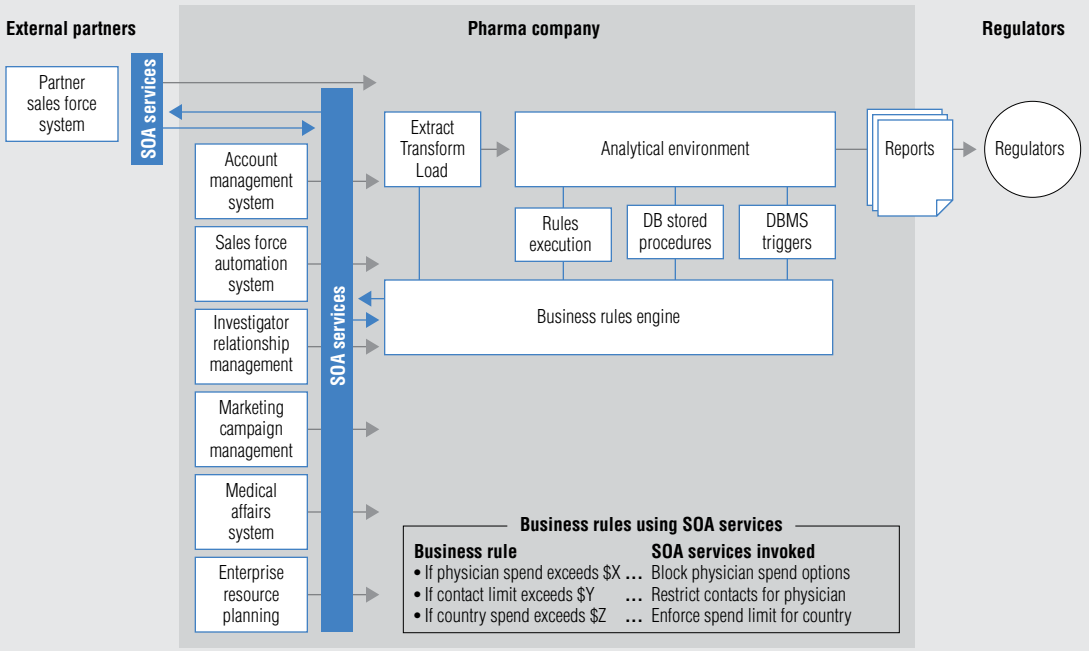
By using a standards-based approach and SOA services, the current analytical environment is enhanced to enable real time compliance actions when the information is first available – not after it is read in a report.

Some rules will require the analysis environment to be completely set up. As such, rules can be collected and executed in a batch or package. Likewise, other rules can be invoked as the data warehouse or data store is created, using database technologies such as stored procedures or database triggers. A single set of rules can be created and reused by many different processes – "calling" or requesting SOA services from the rules engines.

The value of SOA

SOA services enable analyses that can improve decision making across many parts of the organization:

Figure 8.
A revised approach for building an analytical environment using a rules engine and SOA services.



- *Reuse data/repeatable processes.* Services can use business rules that can be validated and reused – without revalidation – to adapt to and enforce changing regulations. These, in turn, enable analytics that can provide insights for decision making when users are approaching thresholds.
- *Increased flexibility.* A rules engine having access to SOA services allows business rules to be isolated from the services. SOA services provide granular access to specific functionality in a business application, such as setting a restriction on a spending level. The business rules can be as simple or as complex as needed that can be applied across many different situations.
- *Reduced errors.* Systems are updated by other systems. If a compliance report shows an activity that needs to be restricted, this can be done without having to re-key information or rely on manual approaches that can introduce human error.
- *More efficient partnering.* Sponsors that rely on partner-acquired data can have easier access to reports and data sources as they evaluate information to make decisions more efficiently. This visibility can also be used to gauge how well a partner meets the milestones and obligations outlined in contractual agreements.
- *Support new business strategies.* SOA services permit a broader view of interactions with influencers enabling them to reduce repetitive contacts, build on previous discussions and coordinate interactions. Ultimately, this can help heighten efficiencies, foster credibility and potentially reduce spending. As organizational leaders develop a broader view of their internal landscape, they develop a better understanding of the combinations of channels that can help them plan their strategies domestically, as well as in new markets.

Conclusion

Although the BioPharma industry is actively addressing its challenges, many current environments are not scalable or responsive enough to meet future demands or to efficiently compete on a global scale. SOA enables companies to simplify the complex nature of today's BioPharma business to facilitate "smart" system interactions and "built in" compliance. We have presented three examples of how SOA can address these challenges: managing clinical trials, efficiently improving the product release process, and enhancing analytical environments to improve compliance reporting.

SOA should be applied with a sense of vision and purpose, and a strategy that:

- Focuses on a business problem and uses SOA to solve it.
- Directs attention on revenue-generating capabilities or areas where inefficiencies affect overall costs.
- Thinks long-term. Once a company makes its initial investment in an SOA architecture, additions or changes can become much less expensive (and faster) to integrate. The return and benefits on this investment can be dramatic.
- Addresses governance, which is an enterprise approach to managing services inside and outside the organization.

SOA allows a step-wise approach to preserving internal investments and aligning the business with the technology that supports it. Once companies begin using SOA services to manage a small portion of their environment, they can extend this efficiency through reusable information and repeatable processes that span departments and partners. They can then proactively respond to today's changing regulatory environment and competitive landscape.

The collaborative nature of SOA can support a new level of partnering, and accommodate the global reach that is necessary to stay competitive in an evolving BioPharma industry. We expect that BioPharma leaders will make SOA a critical part of their organizational strategies to help them reach out to other companies and bring the intended benefits to society on a worldwide scale.

About the authors

Pieter Deurinck is a Managing Consultant and Global Solutions Architect within the IBM Global Business Services Life Sciences/Pharmaceuticals team. With nine years of business consulting he has developed deep industry insights into multiple functional areas within the global Life Sciences industry. Pieter has solid business experience with transformational business strategy, business process design and project management. He has also acquired IT architecture and IT management experience in multiple industries including financial services, pharmaceuticals, medical devices and government. This experience involved business requirements analysis, solution design and implementation, user training, and IT operations. Throughout his career in consulting, Pieter has supported market research and has significantly contributed to the development of the IBM vision for the pharmaceutical industry. He holds a Masters in Marketing and a Masters Degree in Applied Economics. Pieter can be reached at *pieter.deurinck@be.ibm.com*.

Kathleen Martin is a Managing Consultant in the IBM Institute for Business Value, Life Sciences/Pharmaceuticals team. She has 10 years' experience in business consulting and five years' experience in clinical consulting. She has also worked in the pharmaceutical and healthcare industries, where she specialized in oncology and women's health.

Kathleen's consulting expertise includes project management, business strategy, change management and process improvement. She has extensive experience in addressing the business aspects of technical implementations with pharmaceutical clients and the U.S. government. Kathleen has an MPH in Epidemiology and has published in the areas of medical malpractice, corporate learning and clinical development. She can be reached at *kathleen.martin@us.ibm.com*.

Jay DiMare is an Associate Partner within IBM Global Business Services. He has more than 25 years' experience in the development of large-scale, complex, cross-organization applications in the financial markets, banking and insurance industries. He is currently the global leader for the Application Innovation Services team at the IBM Institute for Business Value. His recently published paper, "Service-oriented architecture: A practical guide to measuring return on that investment," presents a framework for measuring the business value of SOA investments. He holds a patent for software algorithms applicable to document management applications, and has developed IBM software products in partnership with clients. Jay is an IBM Certified IT Architect and a certified Master IT Architect with The Open Group, as well as a member of the IBM IT Architect Certification Board. Jay can be contacted at *jdimare@us.ibm.com*.

Contributors

We wish to thank Guy Lefever, George Pohle and Heather Fraser for their overall guidance and support. Thanks are also due to the subject matter experts who helped develop each of the three scenarios:

R&D: Stuart Henderson, Guido Roumans, Wim Huybrechts, Mark Hammond

Manufacturing: Michael Ricci, Herbert Vander Elst, Rik Van Mol

Sales and marketing: Gary Ryan, Kari New, Nathan Beaver, Chad Downey

The Right Partner for a Changing World

At IBM Global Business Services, we collaborate with our clients, bringing together business insight, advanced research and technology to give them a distinct advantage in today's rapidly changing environment. Through our integrated approach to business design and execution, we help turn strategies into action. And with expertise in 17 industries and global capabilities that span 170 countries, we can help clients anticipate change and profit from new opportunities.

References

[1] IBM Institute for Business Value report: "Changing the way industries work: The impacts of service-oriented architecture." October, 2006. Available at http://www-935.ibm.com/services/us/gbs/bus/pdf/g510-6319-01-soa-changing.pdf.

[2] 2007 Prescription Drug State Legislation http://www.ncsl.org/programs/health/drugbill07.htm

IBM Global Services
Route 100
Somers, NY 10589
U.S.A.

Produced in the United States of America
March 2009

GBE03194-USEN-01