Research Spotlight

Collaboration in 2015: Creating a Single Version of Truth in Life Sciences

Every life sciences organization faces a similar set of challenges around improving quality, meeting regulatory compliance, and reducing costs. What makes management's job exponentially more difficult is the task of juggling these challenges with continual pressures to accelerate innovation, exceed both public and private health and safety expectations, and improve efficiency across the drug development lifecycle. The truth is it is neither feasible nor cost-effective for most companies to do this alone, which is why—according to a recent Contract Pharma study—47% of life sciences companies expect to spend more on outsourced relationships in 2014.

Building collaborative relationships with contract manufacturers and other partners is a critical component in the success equation for life sciences organizations today. These relationships can bridge the gaps many face with capacity, expertise, and other factors; however, they present a number of challenges as well. Collaborating with external parties in such a regulated industry requires a single and coherent view of quality and compliance beyond the enterprise. Unfortunately, many life sciences organizations face disconnects in key areas—culture and leadership, business processes, and supporting technology—which preclude the ability to fully leverage external relationships.

As outsourced business models continue to pick up steam, updating strategies and technologies for managing quality and compliance is essential. This Research Spotlight provides insight into emerging best practices. Specifically, it covers the following areas:

- The Opportunities and Challenges with Collaboration in Life Sciences Today
- How Disconnected IT Environments Hinder Outsourcing
- Next-Generation Quality and Compliance Solutions
- Actionable Recommendations

As an outsourced business model only continues to pick up steam, life sciences organizations will require updated strategies and technologies for managing quality and compliance.

The Opportunities and Challenges with Collaboration in Life Sciences Today

Opportunities

Building collaborative supplier and partner relationships is a strategy many organizations employ to improve performance. However, the motives behind those relationships may vary between organizations and even by the department within an organization. For instance, manufacturing may outsource to take advantage of lower labor costs whereas those responsible for drug development may need to leverage external expertise. Below is a list of the top reasons companies are outsourcing in 2014:

- Improving time-to-market
- Combating shrinking operating margins
- Focusing on its own core business
- Leveraging external expertise
- Sharing and/or reducing risk exposure
- Increasing capacity
- Gaining access to new markets

Successful outsourcing can bring many advantages while reducing risks and costs. To remain competitive, companies must evolve transactional relationships to true collaborative partnerships.

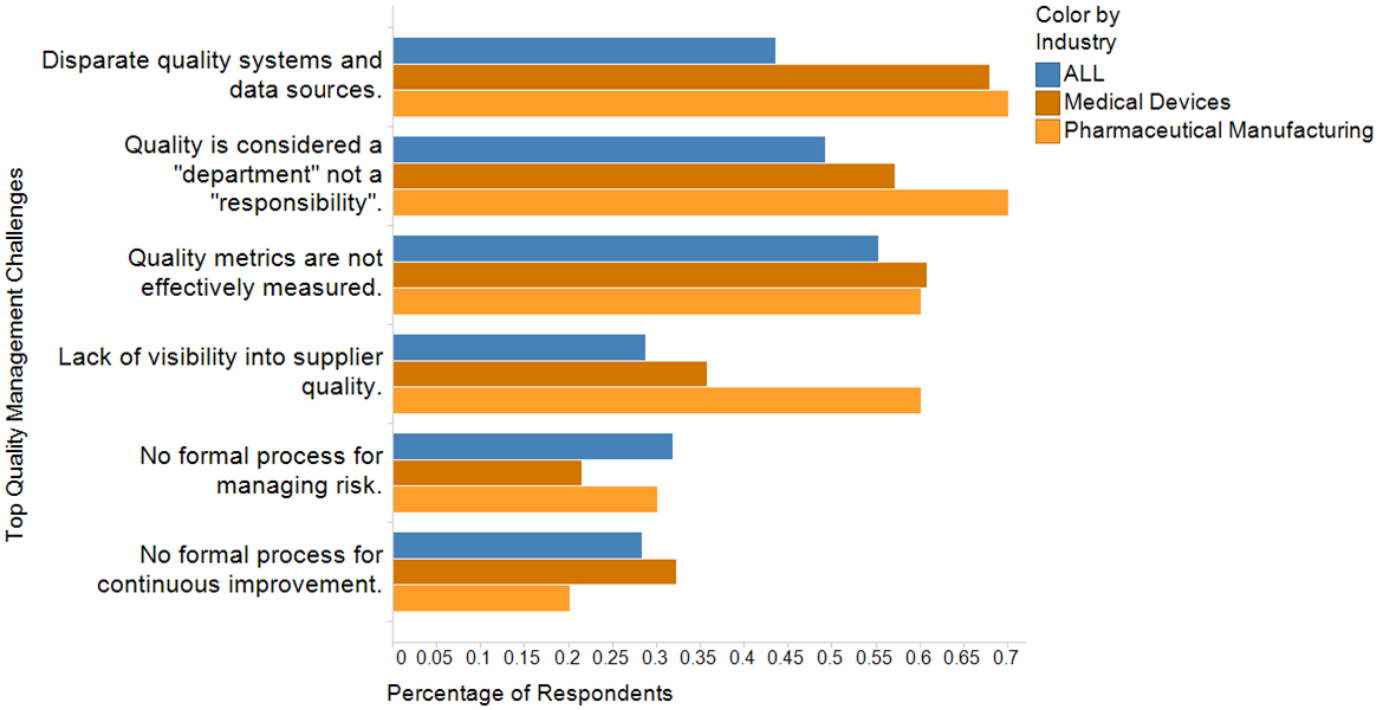
LNS Research's executive interviews and survey data have shown that in many cases the ambition behind investment decisions and their execution are often limited to a specific department or facility, not taking into account the impact to the broader enterprise or operational model.

Challenges

Many life sciences organizations are making considerable investments and organizational changes to improve the effectiveness of internal collaboration and the ability to meet compliance. However, LNS Research's executive interviews and survey data (presented below) show that in many cases the ambition behind these decisions and their execution are often limited to a specific department or facility, and do not take into account the impact to the broader enterprise or operational model. Quality, risk, and compliance issues are magnified when leveraging contract manufacturers, suppliers, and other partners.

More than 750 executives were asked a variety of questions about their top quality management challenges, objectives, current and planned technology adoptions, and annual performance improvements. The chart below shows the top quality management challenges from the survey (participants were asked to select three), drilling down into those reported by medical devices and pharmaceutical manufacturing executives versus executives from all industries.

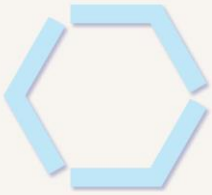
Figure 1: Benchmark Data on Quality Management Challenges



As shown in the survey results, the life sciences organizations revealed challenges that aligned with the top challenges of the broader set of organizations. For life sciences, however, most of these challenges were far more magnified. A vast majority reported a challenge of having too many disparate quality systems and data sources, with a close second split between organizational and performance metrics issues. Pharmaceutical manufacturing organizations also reported a top challenge with lack of visibility into supplier quality.

Although these challenges span people, processes, technology, and metrics, they can primarily be sourced back to the numerous shortsighted and quick-fix IT-related decisions made over the years, as well as past limitations of the software solutions available at the time of implementation. Below looks into the implications of these decisions and discusses why they are becoming increasingly unsustainable in today's competitive life sciences environment:

- **Information silos are no longer acceptable:** The study highlights difficulties organizations are facing with disparate IT and information silos. Departments and facilities need the ability to easily communicate and collaborate with one another. However, having numerous systems in place to do so can cause confusion and frustration, often resulting in process inefficiencies and non-compliant workarounds. It is not uncommon for quality, scientific, and manufacturing professionals to use different versions of the content, introducing compliance risk and impacting productivity.



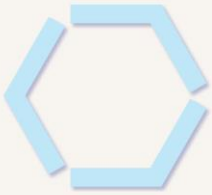
- **Requirements for digital systems are increasing:** New federal documentation and security requirements are driving the shift away from paper and spreadsheet-based methods for managing documents and information. For instance, the FDA Safety & Innovation Act of 2012 was created to, among other things, enhance safety in the drug supply chain, making it significantly more important to be able to track and trace materials as well as improve record keeping capabilities. Similarly, the FDA's Electronic Common Technical Document (eCTD) dictates the standard format for regulatory submissions. As a result, organizations face increased pressures to manage and control documents and validate and ensure security of content and data. Life sciences-specific respondents from LNS Research's Quality Management survey reported an 18% adoption of automated document management capabilities, while respondents from all other industries reported adoption rates of the technology closer to 10%.
- **Homegrown solutions are costly, less scalable, and unsustainable:** Inevitably, homegrown solutions eventually need to accommodate more users or meet new requirements. Relying on internal IT expertise and bandwidth to maintain and upgrade these systems is extremely costly. For life sciences, with its dynamic regulatory environment, custom solutions quickly fall short. In response, more organizations are moving to the cloud and taking advantage of flexible software-as-a-service (SaaS) pricing and delivery. With the benefits of cost savings, agility, and responsiveness to regulatory change, this low-maintenance model is providing life sciences organizations incentive to move past the confines of the disconnected IT environment. In LNS Research's Manufacturing Operations Management (MOM) survey, 7% of companies had a cloud-based software deployment in place, while 17% were in the planning stages.

With the disconnected IT environment, accurate oversight to ensure responsibilities are being met or suppliers as well as their suppliers are following compliance becomes nearly impossible.

The Disconnected IT Environment and Outsourcing

Technology investments are typically made to better support people and processes. However, it is arguable that numerous disconnected IT investments made over the years have actually put organizations at a disadvantage today, particularly with outsourcing. These internal inefficiencies and security risks can easily be compounded when extended out to contract manufacturers and partners. In particular there can be:

- **Lack of data security/Risk of intellectual property loss:** Without the proper technology, life sciences organizations are typically collaborating via email and other workarounds not built for highly regulated environments. Duplication of content from IT silos also makes it difficult to track sensitive data. Someone with malicious intent could potentially access data and acquire critical IP from multiple entry points. A recent string of high-profile



data breaches in other industries has only increased focus on the risk of IP loss in life sciences.

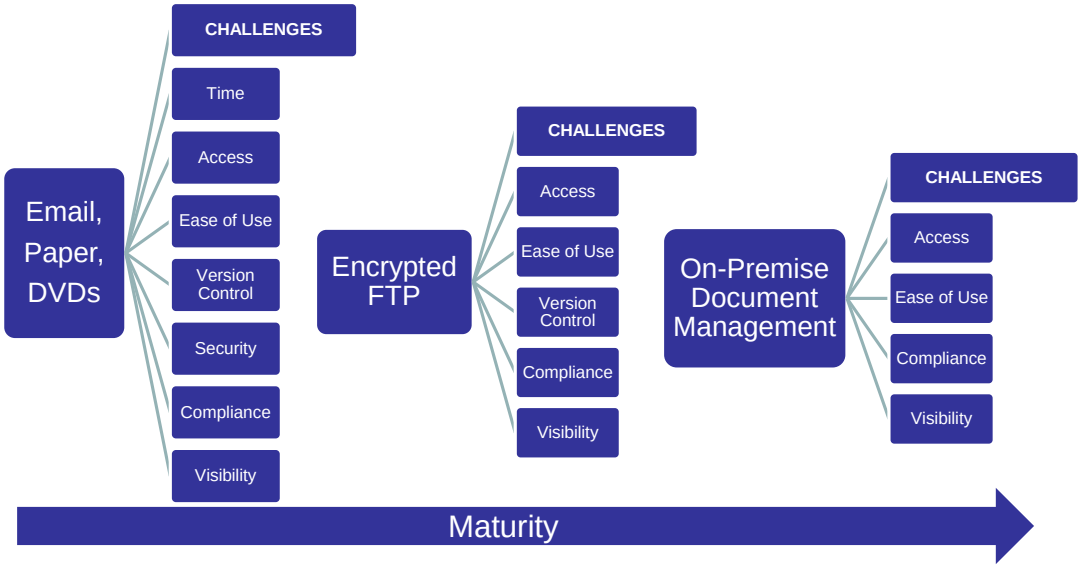
- **Cultural differences:** Without a single version of the truth for quality and compliance, cultural differences—whether organizational, geographic, or other forms—can have a major impact on the ability to collaborate and drive innovation. Just as effective technology can be an enabler of collaboration and innovation, insufficient technology can have the opposite impact.
- **Lack of formalized processes:** Formalized processes for communicating and collaborating with external parties are a sign of organizational maturity. They can show visibility into progress of a contract or facilitate compliant transfers of information. With a disconnected IT environment, however, this can be a challenge as each system has its own methods, forms, and workflows used for meeting regulatory requirements.
- **Lack of visibility into supplier/partner performance:** Many organizations require some form of visibility into supplier performance. Again, this is a challenge without a single version of the truth. Accurate oversight of partner activities becomes nearly impossible with siloed IT environments, inhibiting companies from monitoring supplier performance and compliance.

Information Sharing Gaps and Collaboration Challenges

As is the case with most business challenges, professionals are quick to turn to technology they understand and readily have access to for solutions. For outsourcing challenges the most immediate solution tends to be email. Email delivers short-term benefits, but is still a rudimentary form of communication and collaboration. In conjunction with email, many organizations develop ad-hoc solutions with encrypted File Transfer Protocol (FTP). FTP is a more secure way for sharing data and sending large files, but it creates additional challenges around accessibility and version control.

For life sciences with its stringent requirements the email-encrypted FTP combination often falls short. Collaboration challenges are exacerbated for growing organizations and many have turned to traditional content management solutions or, more recently, cloud file sharing applications. Traditional content management solutions provide versioning and security, but are not easily extended to partners. Although cloud file-shares on the other hand are easy to access, they lack workflows and robust version control. As organizations mature they eventually use a combination of all three to address the limitations of each solution—but still face significant challenges, especially when communicating with external parties.

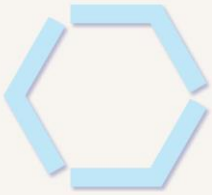
The graphic below maps this progression, from email, to FTP, to document management software.



Many life sciences organizations are still dealing with a complex web of data sources and systems, which do not relieve burdens on costs, help to overcome cultural barriers, or improve visibility into external activities.

- **Email, Paper, and DVDs:** Life sciences companies, at the most rudimentary levels, are able to execute many activities such as outsourced research or collaboration with contract manufacturers via email, paper, and DVDs. However, this is neither a compliant nor secure strategy, often creating more communication challenges and outweighing the benefits with outsourced relationships.
- **Encrypted FTP:** Encrypted FTP adds an additional layer of security and can be helpful for transferring large files or data sets. However, similar to the email, paper, and DVDs approach, encrypted FTP lacks any modern capabilities such as version control or role-based access, and is not generally built with life sciences compliance and collaboration requirements as the foundation.
- **On-Premise Document Management:** Many companies have made the leap to an on-premise document management solution, often making it the foundation of a particular department's ability to share create, share, and store content. In many cases, this is executed with Enterprise Content Management software, where the solution is made to securely handle documents, but typically lacks life sciences specific functionality and the ability to extend document management capabilities out to suppliers and partners.

Burdened by a complex web of systems, and solutions not designed for collaboration in a highly regulated environment, organizations are adopting industry-specific, next-generation solutions.

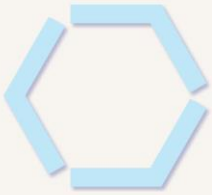


The Need for Next-Generation Systems to Address Challenges

Many organizations are making the move to next-generation document management software, which is architected with quality and compliance as the focal point. Often deployed as an enterprise-wide solution, this platform approach enables organizations to communicate and collaborate with the assurance that activities are compliant, efficient, and secure. Because it is typically delivered via the cloud, the benefits to compliance, efficiency, and security are experienced within the organization but can also easily be extended to external parties.

In particular, the following functionality separates next-generation solutions from traditional solutions:

- **Reporting and Visibility:** One of the most important aspects of this type of solution is the reporting and visibility capabilities. In-house teams can monitor the performance of partners by easily viewing reports and metrics, and even use that information to rate and rank them for the future.
- **Compliance:** Above all, these solutions deliver considerable compliance benefits, as they are developed with both current and emerging regulations in mind. Today's next-generation document management solutions meet or support electronic documentation and e-submission requirements from the FDA Safety & Innovation Amendment of 2012, FDA Electronic Technical Document (eCTD) of 2015, 21CFR Part 11, Annex 11, and more.
- **Workflow:** Providing the ability to visualize and contextualize how documents move from one location to another, workflows enable organizations to streamline and monitor the health of collaboration processes.
- **Access:** Unlike on-premise document management software, next-generation solutions provide the capability for role-based access, so only assigned parties can see particular pieces of secure information.
- **Control:** When multiple partners use files simultaneously, different versions can become confusing and time consuming. Next-generation document management solutions provide version control so all changes to records internally and externally are tracked by date, time, location, and user, and recorded to audit trails as well.
- **Web-Based:** The cloud is becoming requisite for remaining competitive today, and Web-based solutions are driving transformation in the life sciences industry. These solutions provide organizations with an easy way to extend the same in-house capabilities out to partners.



- **Built-In Best Practices:** Solutions are generally architected with industry best practices in mind, which can extend beyond regulation related enhancements. Rather, they are often also based on expertise and experience of the solution provider's product team, and can extend out to contract management, oversight, performance metrics, and more.
- **Ease of Use:** Today's solutions are made to mirror major consumer applications such as Amazon or Google, requiring little to no training. Users can intuitively understand functionality such as version control, search, changing security access, and more.

The Importance of a Single Version of the Truth

Next-generation document management software is also becoming increasingly recognized as the foundation for additional quality management and R&D capabilities. Many leading solution providers have partnerships with Enterprise Quality Management Software (EQMS) and Product Lifecycle Management (PLM) vendors, where the document management solution is used concurrently with other EQMS or PLM functionalities. This is critical for creating closed-loop processes: the concept of sharing critical quality data and process information between different functional units.

LNS Research's Quality Management survey highlights this move toward a centralized, single source of truth. Of the executives surveyed, 20% of companies currently had an EQMS platform deployed, while 27% were in the planning stages of a deployment. With nearly half of executives reporting a current or planned EQMS deployment, LNS Research sees this as a rising focus on holistically managing quality and compliance.

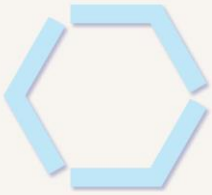
As more organizations rely on the supplier and partner network to remain competitive, compliance and security must be ensured. The disparate nature of these relationships makes an investment in a Web-based solution one of the foremost thoughts on most executives' minds.

Actionable Recommendations

An investment in next-generation document management software is on the horizon for many life sciences organizations. This solution creates a single version of the truth that is requisite for in-house communication and collaboration, but also increasingly necessary for external communication and collaboration as well. As more organizations rely on the supplier and partner network to remain competitive, compliance and security must be ensured. The disparate nature of these relationships makes an investment in a Web-based solution one of the foremost thoughts on most executives' minds.

Executives interested in harmonizing the disconnected and often inefficient systems for managing quality and compliance can take the following steps:

- **Evaluate solution providers with next-generation document management solutions built for life sciences:** Keep in mind that not all document management solutions are built for life sciences. More general,



enterprise content management systems tend to lack next-generation capabilities and the depth in life sciences-specific expertise and functionality.

- **Evaluate solution providers that support a cloud-based SaaS model:** With outsourced relationships only rising, evaluate solution providers with the capability for delivering the solution via the cloud. This helps to ensure compliance and mitigate risk while interacting with suppliers and partners.
- **Select and deploy a next-generation solution that fills communication and collaboration gaps:** Choose a solution that meets immediate communication and collaboration needs, and also supports the long-term vision for closed-loop quality and compliance.

LNS Research provides advisory and benchmarking services to help Line-of-Business, IT, and Industrial Automation executives make critical business and operational decisions. LNS research focuses on providing insights into the key business processes, metrics, and technologies adopted in industrial operations.

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