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White Paper:

How to Successfully Manage
Your Suppliers and Ensure
Product Safety and Compliance

Creating a Paperless Process Using MasterControl



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Introduction

The more advanced manufacturing has become, the more streamlined it has gotten. Parts come from various suppliers throughout the world; certain functions or entire processes are outsourced. Companies achieve efficiency and reduce operating costs this way, but they sometimes risk product safety and regulatory compliance when they fail to properly manage suppliers, contract research organizations (CROs), and contract manufacturing organizations (CMOs).

In the pharmaceutical industry, the vulnerability of sponsors has come to light recently when contaminated heparin from a Chinese supplier caused patient deaths. Outside of the life sciences sector, the auto industry has seen numerous problems with faulty parts coming from foreign suppliers.

In the past, manufacturers were primarily concerned about cost savings when outsourcing functions or contracting with vendors. Now they must also be vigilant about managing these external parties to ensure compliance and product safety. If your company uses the services of suppliers, CMOs, and CROs, this white paper will show you how the MasterControl[™] GxP process and document management software solution can help you manage these external parties more effectively to minimize supply chain risks, ensure compliance, and optimize your outsourcing investments.

Third-Party Activities under Scrutiny

While it has become the norm for manufacturers to use third-party expertise and services, the practice has never come under heavier scrutiny than it has today. Public attention was largely precipitated by the “heparin scare” in the pharmaceutical industry in 2008, which came about after the U.S. Food and Drug Administration (FDA) traced the deaths of 81 patients to contaminated heparin, the active pharmaceutical ingredient (API) that enables blood thinners to prevent blood clots. The contaminated batches came from Changzhou SPL Co., a Chinese supplier to Wisconsin-based Scientific Protein Laboratories, which sold heparin to Baxter International and other companies.

In the medical device industry, Guidant was plagued by supplier problems. A 2005 recall of its implantable cardioverter defibrillators and pacemakers was blamed on a faulty magnetic switch from a supplier.

In another example in the auto industry, the National Highway Traffic Safety Administration is investigating complaints about tires that leak because of defective valve stems in Ford vehicles. The faulty valve stems came from a Chinese supplier, and the investigation involves one million Ford vehicles.

These are just a few examples that drive home the importance of vigilance when dealing with the supply chain and third-party providers. However, many companies are at a loss as to how and where to begin when it comes to managing external parties. It is best to start with a clear understanding of existing regulations and international standards that affect your company and your outsourcing activities. For the majority of regulated companies, FDA regulations and ISO standards are the most critical.

FDA Expectations

There is a general understanding that when pharmaceutical companies, medical device firms, and other life science companies transfer a function to a CRO or a CMO, these organizations become subject to the same regulatory action as their clients. Successful CROs and CMOs take pride in their own FDA compliance, which in turn enables them to obtain more business in a highly competitive market. However, it must be noted that while the FDA accepts the fact that companies may outsource almost anything to stay competitive, the agency believes there is one thing that must not be outsourced—responsibility. In other words, the FDA places most if not all of the regulatory burden on sponsoring firms, and any failure to monitor and control the supply chain or third-party provider activities are likely to result in a Form FDA-483, or worse, a Warning Letter.

This FDA expectation is articulated in 21 CFR Part 820, a key regulation that applies to medical device firms, which provides for “purchasing controls” (Section 820.50) that require each manufacturer to “establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements.”

For the drug industry, the FDA's "Q10 Pharmaceutical Quality System" draft guidance states that quality system responsibilities extend to the oversight and review of outsourced activities. It states that "the contract giver should be responsible for assessing the suitability and competence of the contract acceptor to carry out the work required," and that "the responsibilities for quality-related activities of the contract giver and contract acceptor should be specified in a written agreement."

ISO 9001:2000 Expectations

ISO 9000, a group of quality standards developed by the International Organization for Standardization, is commonly used across industries throughout the world. Some countries require ISO certification, but for the most part, adherence to ISO standards is voluntary. ISO certification is considered a hallmark of quality, and it is widely sought by companies for their own standards, as well as in those of their suppliers and service providers.

ISO 9001:2000, the most popular standard in the ISO 9000 family, is straightforward in terms of what is expected of companies that use contractors. Clause 4.1 says: "Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such outsourced processes. Control of such outsourced processes shall be identified within the quality management system."

Top Five Problems in Managing Suppliers

A recent study conducted by the Center for Strategic Supply Research and A.T. Kearney among 165 companies in 24 industries shows that 80 percent of survey participants said they outsourced activities to reduce their operating costs and to focus on their core competencies. The emphasis on the bottom line is well and good, as long as companies don't lose control over quality and compliance. For many companies, the issues below concerning supplier management may signal quality and compliance problems that ultimately defeat their purpose in engaging the services of third-party providers.

- 1. Lack of centralized platform and structure for managing multiple suppliers.** Outsourcing can be function-specific or full-service. Many companies engage in both types simultaneously, which means they must deal with multiple contractors at any given time. For example, a pharmaceutical company may contract with a number of vendors while running several studies on the same compound. For non-life science companies such as aerospace manufacturers, 70 percent or more of their product's parts are outsourced. Without a centralized platform and structure for gathering or receiving information, the company will have to look for data from each vendor in different places. Information stored in electronic servers may have to be printed and routed manually, making any document-based process inefficient.
- 2. Inability to monitor and track input from suppliers and other providers.** A company's inability to monitor and track input from suppliers and other providers is a sign of a lack of control on the project, function, or process involved. In a regulated environment, where supplier control is critical, this can be a major problem. For example, the FDA's Quality System Regulation requires medical device firms to "maintain data that clearly describe or reference the specified requirements, including quality requirements, for purchased or otherwise received products and services." Monitoring and tracking supplier input is essential in maintaining such data.
- 3. Inability to report problems involving suppliers quickly and effectively.** Each activity that involves suppliers, CROs or CMOs must follow well-defined processes and good standards. Each activity (including delivery of parts or ingredients or services and the quality of what you are receiving) needs to be documented and assessed. This becomes particularly critical when problems arise. Kim Trautman, a consumer safety officer for the FDA's Center for Devices and Radiological Health, told *The Silver Sheet* that more and more medical device firms are reporting supplier problems as the root cause of the failure in their devices. For medical device and other regulated companies, it is critical to have an effective system for reporting and correcting supplier problems before they result in recalls.
- 4. Lack of oversight of suppliers.** In 2008, the FDA issued a Warning Letter to Ohio-based X-spine Systems, a spinal implant developer and distributor, for violations of current Good Manufacturing Practice (cGMP) requirements. A couple of violations pertained to lack of supplier oversight. The Warning Letter cited the company's "failure to clearly

define the type and extent of control to be exercised over suppliers.” It said that while X-spine System’s supplier approval procedure provides for ongoing monitoring, it “does not define the frequency and type of monitoring for these suppliers.” The lesson from this Warning Letter is that companies must establish a reliable system for conducting oversight on all essential third-party providers.

- 5. Poor communication between contracting company and contractor.** The success of any contractual relationship ultimately depends on successful communication between the parties involved. The contracting company must know who is doing what, and when. In a regulated environment, it is imperative that this kind of information is documented. In addition, FDA-regulated companies are expected to specify quality-related responsibilities in their contract agreements.

MasterControl Solution

In any outsourced activity, the goal is not to “beat” suppliers, CROs and CMOs into submission, but to collaborate with them successfully. Early on, you must define your own quality standards, to which your contractors must adhere. The MasterControl software solution provides you with a framework to manage your suppliers and contractors successfully, as well as the tools to make it easier for them to collaborate with you.

Here is how MasterControl addresses the top five problems discussed above:

- 1. Provides centralized platform and structure for managing multiple suppliers.**

- **Electronic AVL** – If your company is like most manufacturers, you need an Approved Vendor List (AVL) to make sure that the parts you are paying for meet required specifications and quality standards. MasterControl Supplier[™] provides a user-friendly AVL that is easy to maintain and a centralized electronic repository for all documents pertaining to suppliers, their status, and their quality-related information. The AVL not only manages approved suppliers, but also the specific good and services they are authorized to supply. Adding new suppliers or removing inactive ones, viewing lists of suppliers, and importing or updating supplier information are all automated, greatly increasing efficiency. With this solution, you will no longer need cumbersome spreadsheets and disparate notes and files for your AVL.
 - **Internet-Based Platform** – If you have CROs, CMOs and other contractors that need to be part of a review, approval or revision process, MasterControl Documents[™] provides a platform for storing, routing, escalating, revising and approving documents regardless of the software used to create them. MasterControl’s Internet-based platform gives your internal and external users in different locations or time zones access online, making cross-functional review and other documents-based and forms-based collaboration possible from virtually anywhere. MasterControl’s Organizer, similar to Windows Explorer, allows each team to maintain its documents, and at the same time allows documents to reside in multiple Organizers. You can create Organizers for CROs, CMOs and other external collaborators to help them find all the documents that need their input faster.
- 2. Provides capability to monitor and track input from suppliers and other providers.**
- **Automatic Tracking** – Monitoring information such as supplier audit results and supplier non-conformances is an ongoing process. When you use a manual process—by relying on paper documents and disparate electronic files—to monitor supplier information, it is inherently difficult to repeat the process on a regular basis. With MasterControl Supplier[™], tracking supplier information is automatic, and therefore, continuous. All critical information will reside in a centralized location and can be compiled easily for supplier quality ratings. The system also provides a powerful workflow capability for approving suppliers. It tracks new parts or goods from suppliers by linking them. If a part is linked to a supplier that has not been approved, the link will simply be disabled until the supplier’s status has changed.
 - **Best-Practice Forms** – If you work with external parties in forms-based processes, MasterControl Process[™] provides electronic forms with best-practice features that prompt users with select data, making it easier to gather, monitor, and track their input. If tracked by status, a form will show either as “in process” or “complete.” If tracked by revision or approval history, it will identify the people who have reviewed it and when.



3. Provides capability to report problems involving suppliers quickly and effectively.

- **Robust Reporting Capability** – In addition to supplier audits, companies need other tools for spotting potential problems with external parties that could jeopardize product safety or compliance. MasterControl Supplier[™] provides powerful reporting capability that allows you to trend and track suppliers' quality events such as deviations and CAPAs.
- **Effective CAPA Management** – If your company has a proactive CAPA and risk management policy, you may use MasterControl Supplier[™] in conjunction with MasterControl CAPA[™], an ideal solution for effective management and implementation of the corrective and preventive action process. The system allows inclusion of suppliers and other authorized external parties to report product issues, customer complaints, and other problems that could lead to a CAPA as well as proposed action to resolve the CAPA. It provides an “8D” process to guide the quality team through every step of CAPA implementation.

4. Provides tools for conducting oversight on suppliers.

- **Choice of Tools and Solutions** – The term “supplier oversight” is almost always associated with diligent audits, which are indeed important. However, over the long haul, “diligent monitoring” may prove to be more effective in terms of conducting oversight on suppliers and contractors. Whether you are contracting out or are getting supply from external parties, you must have the right information to understand what may adversely impact your product. MasterControl Business Process Library, a subscription-based service that allows you to choose solutions, provides you with the tools you need for managing external parties. The service provides access to all MasterControl solution packages (including MasterControl Audit, MasterControl NCMR and MasterControl CAPA) for a 12-month period, plus implementation assistance and ongoing technical support. It provides you with the flexibility to start with one solution and the option to add other applications without spending more on software during the 12-month period.

5. Provides tools for better communication with suppliers and contractors.

- **Compliant System for Communication** – In a regulated environment, “communication” means more than just using the telephone, e-mail, and fax machine to exchange information with your contractors. To be compliant, you must have a system for communicating with and receiving information from them that is well-documented and can be tracked. The robust features of MasterControl Supplier[™] and MasterControl Documents[™], as discussed above, could serve as your foundation for communicating important information with external parties and documenting all important aspects of the parts, materials, and services that they provide for you.
- **Communication via a Virtual Workspace** – MasterControl Collaboration[™] automates and simplifies documents-based collaboration between your internal and external users by providing a virtual workspace for them to work together without being physically present in the same room. This module automates tasks pertaining to collaborative projects, including routing, follow-up, escalation, revision, and approval.

Conclusion

One of the biggest lessons that companies in general can learn from the recent heparin scare is this: They must take responsibility for the quality of their products and the integrity of their suppliers, CROs, CMOs, and other contractors. While outsourcing/contracting is a fact of modern manufacturing, it is not an excuse for poor quality.

If you intend to work with external parties, you need utmost care in the selection of providers. Once they start working with you, or if they already are a part of your operations, you must be vigilant in managing them. You need to collaborate with them successfully. Moreover, you need to help prevent them from jeopardizing the safety of your product. Using the MasterControl solution as part of your overall strategy in managing your suppliers and contractors will help improve the quality of your relationship with them, which in turn, will help increase your long-term success.



About MasterControl

MasterControl Inc. is a global provider of GxP process, quality audit, and document management software solutions for life science companies. MasterControlTM products are easy to use, easy to deploy, easy to validate, and easy to maintain. They incorporate industry best practices for automating and connecting every stage of the product development cycle, while facilitating regulatory compliance. By combining an integrated platform with a continuum of risk-based software validation products and services, MasterControl drives down the total cost of ownership and enables customers to extend their investment across the enterprise. Hundreds of companies, including 50 percent of the top 20 pharmaceutical enterprises, currently use MasterControl solutions for easier compliance, faster validation, and better process management. For more information about MasterControl, visit www.mastercontrol.com, or call 800-825-9117 (U.S.) or +44 (0) 1256 325 949 (Europe).



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