Quality Management in the Third-Party Supply Chain

New age capabilities and solutions for effectively integrating third-party CMOs with GMP manufacturing quality systems and operations.

May 2016

Many pharmaceutical, medical device, dietary supplement and other regulated-products manufacturers make extensive use of third-parties in their manufacturing supply chain. In recent years, that supply chain has expanded greatly to include packaging components, raw materials, outsourced manufacturing and packaging, and laboratory testing services. And no wonder companies are doing this – externally sourced manufacturing service capabilities provide firms with a ton of flexibility, scalability, and agility in getting their products to market, and in managing shifts in product portfolios and demand. Need to introduce a new product or line extension while continuing to supply your popular legacy products, while scaling back on less popular brands? Not a problem. The companies who utilize external manufacturing and testing service providers are also able to limit their capital investments associated with building out manufacturing and testing capabilities to support new product launches, while at the same time increasing their speed to market.

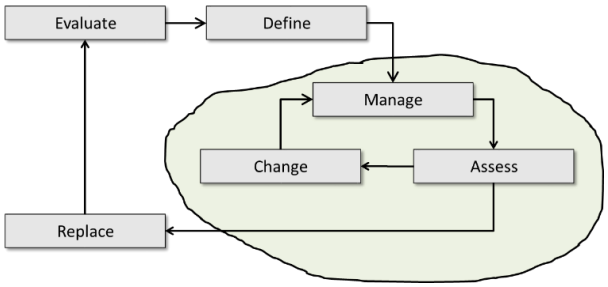
The case for networked manufacturing service capabilities seems clear. ***But wait a second. What about quality?***

Even for regulated manufacturing companies, quality is all too often an afterthought as companies enter agreements with external service providers. Purchasing people who are focused on price and volume often lob in language regarding the quality agreement at the end of the negotiation, and it rarely receives much attention by those involved. **Frequently, quality agreements are poorly written, poorly understood, or sometimes completely out of alignment with what should be key requirements in the service provider relationship.** Quality organizations subsequently suffer when trying to do their job in managing their responsibilities with external service providers because these providers don't know what quality standards they are supposed to apply, and when they are supposed to apply them.

What makes matters worse is that quality organizations are typically inconsistent between one supplier and the next. Teams of quality professionals are frequently tasked with managing the quality aspects of the third-party relationships, but the processes, standards, and tools with which they are provided are out of alignment, or are more geared towards

managing internal manufacturing operations rather than the unique challenges of managing the quality of external service providers. Communication of standards and requirements is inconsistent, and is frequently managed by multiple emails and phone calls. Companies have not established the right solutions to get to sustainable, reliable, and repeatable outcomes with respect to service quality from their providers.

The Basic Outsource Model

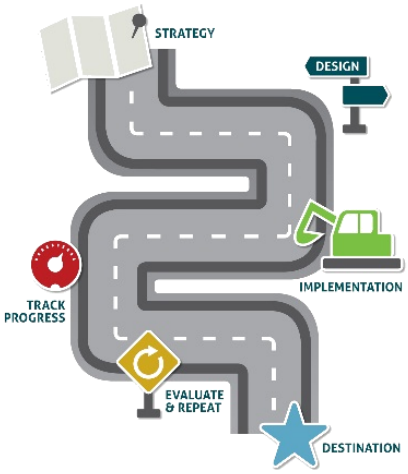


The Problem

The problem is that the companies who use external service providers are still responsible for product quality. While the work can be outsourced, the responsibility for quality products and services cannot. The cost of managing external manufacturing quality can actually get quite high, to a point where the benefits of flexibility, scalability, and cost begin to erode. The answer is, all too often, throwing more people at the problem – including temporary employees, contractors, and consultants – generally leading to higher cost, but not necessarily better or sustainable outcomes. The danger is that the scope and rigor of the quality oversight function may be compromised in order to satisfy budgetary pressures. And the larger the company, and the larger the network of external service providers that need to be managed, the greater the complexity and size of the problem.

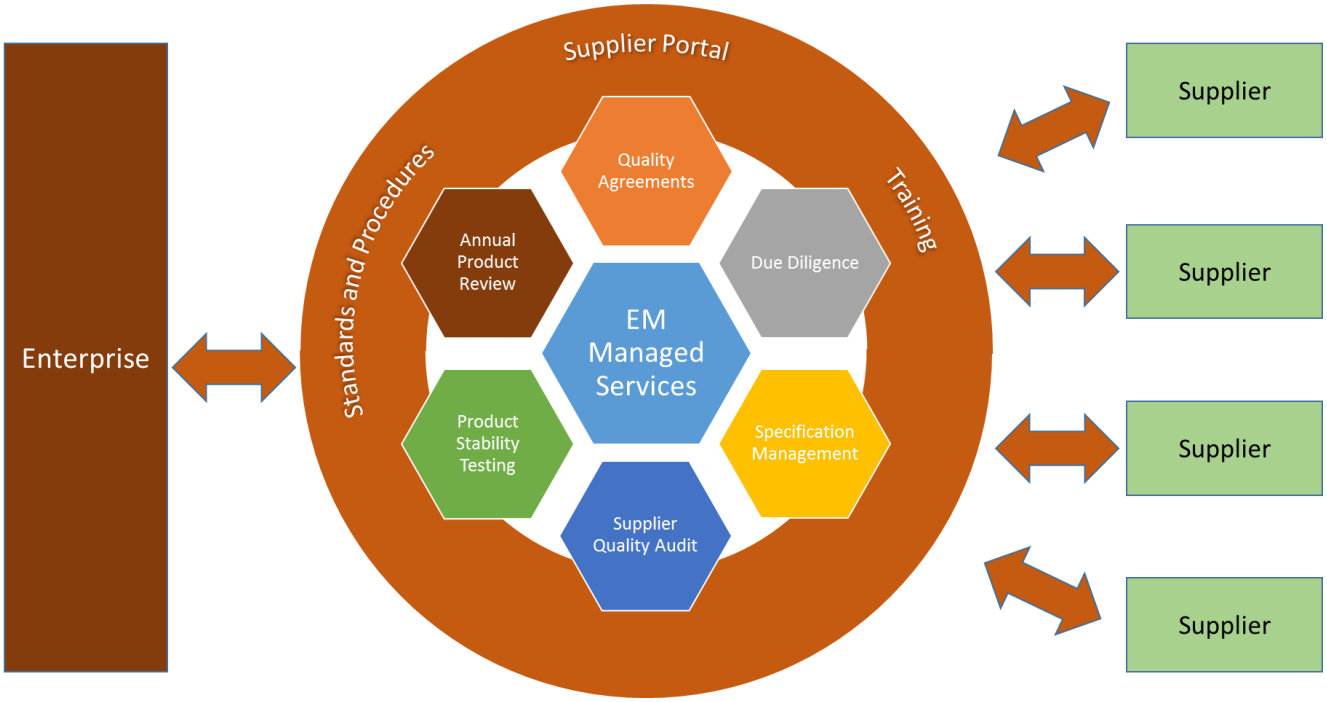
Changing the Game

The answer lies in *thinking differently* about the solution. Collaboration-based solutions make it possible to define and manage the quality relationships with external suppliers through **a centralized hub** that includes agreements, standards and procedures, services, training, and real-time collaboration capability. Communications, submissions of reports and information, management of schedules, due dates, and expectations for various activities are all driven though a common solution.



Companies who have been successful with such solutions recognize that they entail more than just an implementation of technology. There are people elements, process elements, and procedural elements that need to be factored into the build and deployment plans. In fact, it usually makes sense to start with the process and procedural elements before figuring out how to use technology as an enabler. A key first step is in defining **a solution roadmap**, so that you know how you intend to get from Point A to Point B to Point C, and how quickly. Does the company simply want to improve the structure and utility of its quality agreements? Does it want to improve the rigor and oversight of supplier quality audits? Does the consistency and timeless of APRs need to be addressed? Perhaps the solution needs to address all of these elements and others, but how fast and in what order?

The technology component of such solutions does not need to cost an arm and a leg. While there are proprietary, high-end software products that offer fairly rich features and functions, much of what most companies need is available through configurations of their existing, off-the-shelf SharePoint instance. Companies may choose to implement services through iterative pilots and deployments versus doing a large scale development and implementation project.



More good news: there are firms, like Compliance Architects® that have already taken companies through the journey. Compliance Architects® is well equipped to help companies across the spectrum of FDA-regulated industry plan, build, deploy – and operate – these solutions.

Making it happen

So how does this work? Let's step through some of the more detailed aspects of how a comprehensive collaboration model would work with suppliers and external service providers.

Standards, Procedures, and Training: These documents are the foundation for success for any people-process-technology solution. They provide the "glue" that ties the three elements together in an integrated solution. From an enabling perspective, supplier portals can provide a library of applicable standards and procedures that suppliers need to follow, and that tie to company standards and other requirements. Links to the enterprise training management system

can be provided, or training management capabilities can be built directly into the portal. Frequently asked questions and/or supplier discussion forums can also be provided, if desired. Collaboration capabilities can help suppliers become more of a true extension of the company -- something that just isn't possible with traditional phone, fax and email.

Quality Agreements: Sometimes the people responsible for managing quality in the manufacturing service provider relationship have never even seen the quality agreement! And if they have seen it, the agreement is often tucked away in the supplier's files somewhere, making it hard to use and reference.

"A collaboration portal can completely transform the utility of a quality agreement."

The terms and conditions of quality agreements can be electronically reviewed and accepted, and remain electronically available to the people within the enterprise and with the supplier responsible for quality management. Applicable standards, specifications, and the audit frequency schedule from the agreement can be clearly called out, and can interface to some of the other management capabilities within the portal. The quality agreement can br transformed into a dynamic, responsive set of requirements that can be reviewed in real-time, on a regular basis. We call this "operationalizing the quality agreement" – something that we believe is essential to modern, effective third-party supply chain management.

Due Diligence: The level and rigor of due diligence required in each supplier relationship will vary, depending on the criticality and risk profile of the supplier. Supplier collaboration portals can provider a risk assessment checklist to drive due diligence requirements. Some due diligence information can be submitted by the supplier through the portal, and other due diligence information can be collected, input, and stored. It is even possible to implement a repository of information assets that need to be held in escrow, for business critical supplier arrangements that involve licensing of strategic / proprietary technology.

Specification Management: Do you know the status of all of the specifications for all of your products at your suppliers and service providers? Can you electronically deliver updated specifications to your suppliers as the Bill of Specifications changes? Do you have confirmation from your suppliers that they have received specification updates, and that they have integrated updated specifications into their manufacturing operations for your products? Unfortunately, these questions are problematic for most enterprises that rely on external manufacturing partners. Collaboration portals can be designed to provide closed loop systems for specification distribution and management. Bill of Specification information and specification changes can be interfaced to Annual Product Review for pharmaceutical or combination products.

Supplier Quality Audit: Supplier collaboration portals can manage audit schedules, resource assignments, and logistics; audit results, including observations and supplier status; and audit remediation commitments and plans. Remote / virtual audit capabilities can be set up for lower risk suppliers or as a periodic check between

on-site audits. Input to the audit schedule can be interfaced from the electronic quality agreements. Dashboards can highlight past due audits, remediation commitments, and high risk suppliers and outstanding issues. Significant issues and observations can be interfaced to both internal audit systems and Annual Product Review processes.

Product Stability Testing: Stability testing protocol development and approval can be facilitated through portal workflow capabilities, and the schedule of time point submissions for Certificates of Analysis for each product can be managed through the portal. Out of specification / out of tolerance (OOS / OOT) results can be logged and addressed, and stability summary information can be interfaced to Annual Product Review systems.

Annual Product Review (APR): The schedule of all the APRs for pharmaceutical / combination products that need to be completed each month is maintained in the portal, as well as when the associated inputs from manufacturing partners, stability testing, and pharmacovigilance / product safety need to be provided. Secure submissions of reports and data can be made through collaboration portals, rather than relying on email or paper. Various levels of APR review and approval can be facilitated through portals, and dashboards for completed and past dues reports and activities can be provided. Electronic repositories of final, approved reports can be maintained.

Getting Started

Customers who have proceeded down the path of establishing quality collaboration portals with their manufacturing partners and suppliers have seen the benefits of such solutions. It's easy to take a stepwise approach to getting started – you don't need to do everything at once – and there is value to be gained with implementing subsets of the functionality described above. If you are interested in learning more about how such capabilities can help your enterprise, please contact us to set up a meeting.

Interested in learning more? Contact us to set up a meeting: 888.734.9778

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