Blueprint for Optimizing Supply Chain Control within the Life Science Industry

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Life & Health

A Blueprint for Optimizing Supply Chain Control within the Life Science Industry

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One of the most significant growth challenges facing Life Science manufacturers is improving Supply Chain Control.

This struggle spans across QA/RA, production and product development teams. For operations, today's volatile demand chain is forcing companies to gain additional visibility into supplier qualification, supplier selection and supplier communication. This visibility would enable companies to quickly react to any number of unanticipated activities that could disrupt the demand chain.

For the supplier quality team, the US FDA has increased its inspection focus on purchasing controls. And worldwide, many global regulators require companies to control supply chain procurement, surveillance, manufacturing and product distribution. Beyond the regulatory challenges are other factors which are making the supply chain more complex, such as supplier diversity.

In this paper, we discuss three elements that Medical Device manufacturers are including in their supply chain operations to optimize control:

- Supplier Oversight: The On-Site Imperative
- Supplier Analysis and Selection
- Supplier Collaboration

These approaches take advantage of third party supplier auditing services and the latest technologies to streamline deployment and reduced costs.

Increased Global Regulatory Vigilance

Within the Medical Device segment of the Life Science industry, there is heightened awareness on the supply chain. From 2010 to 2014, there was a 25% increase in the number of 483s that the US FDA has issued for deficiencies against CFR 820.50. With this increase, the number of 483s issued relative to the overall supply chain represented 13% of the total 483s issued during this period.[1]

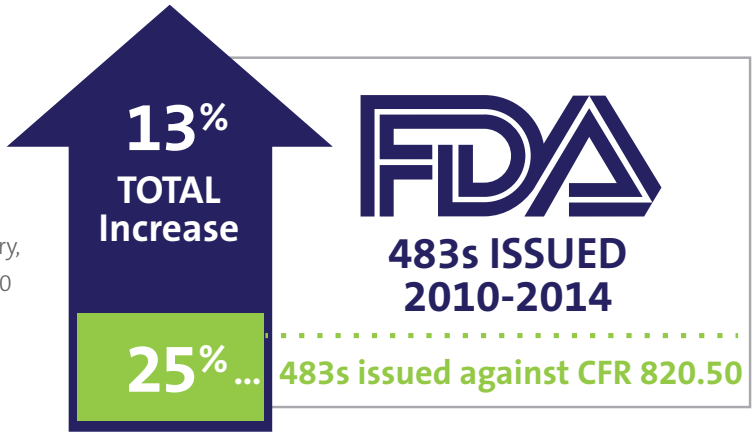
The 820.50 regulation states that "each manufacturer shall establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements."

The intent of 820.50 is to ensure that device manufacturers select only those suppliers, contractors, and consultants who have the capability to provide quality product and services. FDA's ongoing mantra with finished devices has always been that quality cannot be inspected or tested into products or services.

At the 2015 MedCon panel session, FDA officials emphasized the need for companies to identify those processes necessary to manufacture supplied parts, such as:

- Ensuring suppliers have performed adequate/appropriate validation studies.
- Inspecting CTQ attributes – the FDA investigators suggested that manufacturers shouldn't assume that all specifications are tested and/or inspected by their suppliers.
- Methods for documenting oversight, such as scorecards.

This third point requires further discussion, as a supplier scorecard demands a commitment to collect consistent and reliable data on all critical suppliers. With the proliferation of regulatory requirements specifically relating to supply chains and the increasing globalization of supply chains, Medical Device companies need real-time data, not results from self-assessments conducted months earlier.



Increased Supply Chain Complexity

Beyond the regulatory complexities, the Life Science manufacturing supply chain is also burdened with a large volume of product SKUs, the varied long and short lifecycles, security issues, sustainability issues, and others.

A Blueprint to Optimize Supplier Controls

To address these regulatory and production-related complexities, Life Science companies must seek proven processes to control their supply chains, while also focusing on the costs, speed and quality of their operations. What is required is a focused effort to transform traditional supplier relationships into a more unified supplier network, in which evaluations, qualifications, communications, and continuous improvement are managed within a single platform.

For this paper, we have identified three elements that make up the "optimized supplier network." Each element builds on one another to strengthen the manufacturer/supplier relationship, resulting in improved product quality and output:

- **Supplier Oversight – The On-Site Imperative:** this involves the use of in-person audits, conducted by qualified auditors, and re-evaluation process.
- **Supplier Analysis and Selection:** using supplier data for selection, using detailed qualification rankings and product filtering tools.
- **Supplier Collaboration:** leveraging supplier network portals to share and capture two-way change management information and policy revisions.

1. FDA Inspections http://www.fda.gov/ICECI/Inspections/ucm250720.htm

Element #1:

Supplier Oversight – The On-Site Imperative

Just as the FDA has relied on "Accredited Persons" to conduct third party audits for products regulated by the agency, so have Life Science manufacturers embraced the idea that using third party auditors can reduce compliance risks while also reducing costs. These on-site audits must be built from a solid team, structured processes and consistent definitions, which utilize tools and data analysis. An on-site audit program built in this fashion and leveraging the right tools will help the organization keep up with the ever evolving supply base.

All Life Science companies have procedures related to supplier qualification. These quality agreements and procedures include the control measures necessary to ensure high quality and compliance. Inspections and approval of the materials are a step in the supplier oversight, but many companies are challenged on whether or not to conduct on-site audits and assessments on all high-risk suppliers.

For example, many UL clients have categorized their suppliers into risk-based tiers. Adding the Human Element approach to all "Tier 1" suppliers ensures that all suppliers are visited by a qualified auditor, whether that individual be a company auditor or a qualified third-party auditor who can conduct the evaluation, and do so more cost effectively. In this way, the first-hand visual inspection determines that the supplier has met the specified requirements. And equally important, the audit data is captured properly for analysis, as we will discuss in the next section.

For Tier 2 and Tier 3 suppliers, a consistent mechanism to collect self-assessments must be in place. This often involves an electronic self-assessment that retrieves all supplier responses and merges this data into a single repository. These mechanisms allow for the entire supply chain to be considered, compared, evaluated and improved through a common set of controls, metrics and analytics.

Element #2:

Supplier Analysis and Selection

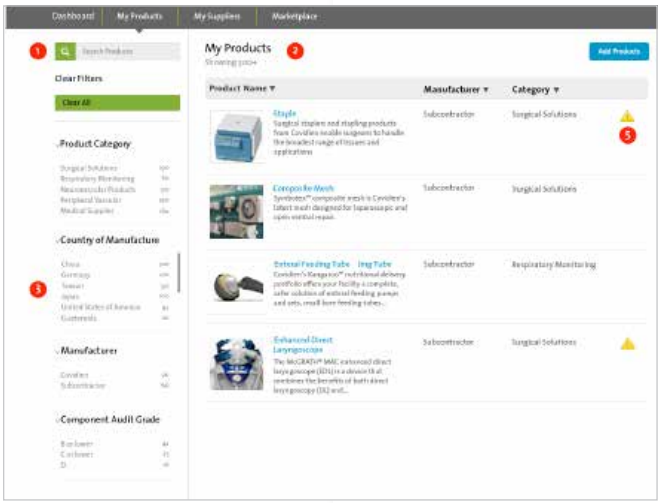
Audit reports contain critical data about the supplier, and the aggregate audit data can benefit product teams, operations and quality assurance teams.

The key is combining data into a single repository. For example, gathering on-site audit report data and the supplier's demographic information (region, products, etc.) into a single "Supplier Knowledge Management" system can optimize supplier analysis and the supplier selection process.

Medical Device companies should take advantage of advances made with data analytic and storage technologies, combined with the proliferation of data acquisition mechanisms and huge volume of data points, to make supplier selection more reliable and less time-intensive.

When the data is gathered and presented as supplier analytics, supplier quality teams can ensure that the right measures are being applied to the right supplier, and generate scorecards that are accessible by product development teams in the organization.

What's more, the scorecards can draw data from ERP or Supply Chain Management systems, to help supplier relationship teams assess supplier return on investment (ROI) goals, and help supplier quality teams focus on continuous targets.



Element #3:

Supplier Collaboration

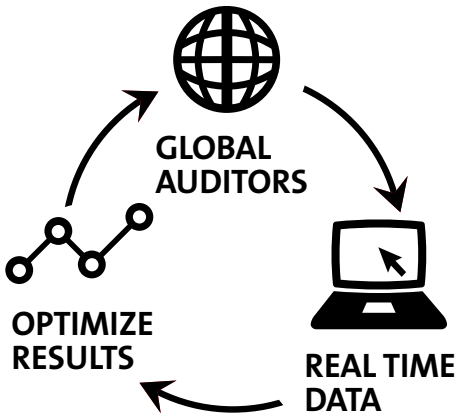
Data that's consistently captured on each supplier can help inform the decision-making process and incentivize suppliers to improve. The data can additionally enable a more collaborative experience and help develop more proactive supplier relationships.

In fact, the supplier data collected from audits serves as the basis for meaningful supplier visibility – working to the suppliers' advantage as well. When manufacturers provide data to suppliers, the suppliers also are able to anticipate the manufacturers' needs and expectations, and be able to react to any unexpected changes within the supply chain. Armed with their clients' expectations, suppliers can also make meaningful suggestions to improve existing processes.

It is the manufacturer's responsibility to establish the performance metrics and assure that information is clearly communicated. These measures need to be established in a two-way fashion, which encourages equal participation and fosters the "right" behaviors from the supplier. The manufacturer must have in place the necessary tools to support this two-way dialogue, which includes tools that both push out communication and educational activities that can be tracked and analyzed.

The result is a streamlined "supplier network" that facilitates two-way communication and fosters a culture of collaboration and continuous improvement. From a secure portal, suppliers can efficiently complete self-evaluations, and also notify manufacturers of complaints, or changes to processes or materials. This same supplier network portal can be used to review quality agreements, procedures, CAPA reports and ongoing product and regulatory training. This approach works hand-in-hand with the concept of building a robust supply chain that limits redundancy and mitigates risk.

Conclusion



One of the toughest challenges for the Life Science industry today is effective supply chain control and management. Organizations need to keep pace with evolving supply chain best practices and focus on the optimized supplier network. This network utilizes the three elements of on-site audits, supplier analytics and ongoing supplier collaboration, which can lead to smarter supply chain decisions.

The optimized supplier network enables companies to learn more about suppliers and anticipate the challenges facing suppliers, thus helping to mitigate risks and take corrective action. Manufacturers gain the visibility needed to identify, and improve, troubled suppliers. Similarly, manufacturers also learn when it's time to cut suppliers that are redundant, or whose risks of retention outweigh the supplier's value.

Adding the these three elements requires dedication. Through that dedication and commitment you can realize a supply chain which is agile, optimized and proactively able to deal with potential risks. Additionally, when manufacturers execute the blueprint discussed in this paper, they can achieve these results:

- Share supplier information across all areas of the product development lifecycle, such as product design, clinical management, inventory management and others.
- Incorporate risk management through ongoing monitoring of suppliers and partners enabling informed decisions on which suppliers to use for production.
- Elevate the supplier relationship by building a more formal information sharing model, in which both manufacturers gain increased visibility and collaboration with all supply chain partners.
- Reduce the financial and regulatory risks associated with non-conforming product, shortage of materials, inadequate supplier education, and more.

Advantages to Using UL:

Improve Your Control – Increase your ability to monitor your supply chain by outsourcing to local UL staff.

Reduce Your Risks – Fix non-compliance issues in your supply chain quickly. Monitor high-risk situations closely and flexibly.

Reduce Your Costs – We have local staff in all corners of the world. Don't fly there, when our auditors can drive there.

For assistance with supplier identification, audits, or monitoring & control, contact UL to discuss our Supply Chain Services:

E: medicalinquiry@ul.com | W: www.ul.com/contactus

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UL Health Sciences provides comprehensive services to support medical and IVD companies with global regulatory approvals.

Our local services include integrated systems registrations for ISO 13485, Canada CMDCAS, European Notified Body, J-PAL, Brazil – INMETRO and Risk Management ISO 14971.

Our experienced engineers provide safety assessments to IEC 60601, IEC 61010, Home-Healthcare and CB Scheme.

Our Human Factors Engineering experts provide validation testing.

Our team can also support your Regulatory and Learning Management Systems through ComplianceWire®, online and in person training.

UL also conducts non-clinical tests including sterility, shelf-life, transport and packaging validation and biocompatibility testing. UL experts are on the leading edge of supporting customers with global regulatory submissions documentation, clinical evaluation and testing services for eHealth mobile medical applications, and interoperability.

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