Optimizing the Medical Supply Chain for Product Stewardship, Sustainability and Compliance

The Medical EPP Imperative: Sustainability, Environmental Compliance, and Environmentally Preferred Purchasing

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Medical Companies Face Risks to Revenue, Brand and Market Share

Medical companies have begun to see a rapid increase in the number of requests to provide material and chemical content data for their products. These requests are coming from such customers as group purchasing organizations (GPOs), integrated delivery networks (IDNs), hospitals and other healthcare providers, in addition to international entities and other OEMs. Just two recent examples:

First, in April, healthcare supply contracting company Novation invited its more than 500 suppliers to incorporate sustainability into their company practices, including by disclosing all information regarding the chemical and material composition of products and by reducing the use of "materials of concern." Through its affiliations with VHA, University HealthSystem Consortium (UHC) and Provista, Novation represents the largest purchasing volume in the industry, with $37.8 billion in annual purchases. (See www.sdcexec.com/12308 for more information.)

Then, in May, managed healthcare provider Kaiser Permanente announced that it will require suppliers to provide environmental data for $1 billion worth of medical equipment and products used in its hospitals, medical offices and other facilities. Kaiser Permanente's new Sustainability Scorecard is intended to allow it to evaluate the sustainability of each medical item it purchases while also encouraging suppliers across the industry to provide greener products for the healthcare sector. It is expect that by September 2010, when Kaiser Permanente's key supply chain partner, Broadlane, adopts the tool, the scorecard could influence $10 billion in medical purchasing. (www.sdcexec.com/12348)

The two most prevalent requests are for material disclosure documents and certificates of compliance to support regulatory compliance initiatives, and requests for proposals (RFP) to support environmentally preferred products or purchasing (EPP). In a growing number of instances, customers no longer will accept bids without detailed material content disclosures. That fact is that manufacturers' brand and reputation are now at stake based on their ability to deliver upon lesser or reduced effect on human health and the environment when compared to other products and services that serve the same purpose, and the manufacturers must compete for the attention of patients, healthcare employees and the broader general population. As a result, these requests are having an increasingly significant impact on top-line revenue, customer satisfaction and subsequent market share for the medical products manufacturers.

This trend is a byproduct of the rising tide of legislation aimed at regulating the chemical and material content of products, the overall toxicity of products, and the impact of products on the environment and human health. The list of these regulations is long and growing, including EU REACH, EU RoHS/WEEE, the EU Medical Device Directives, US FDA (e.g., Title 21 of the CFR), China RoHS and Health Canada. (See **Figure 1**.) These regulatory initiatives stem, in turn, from increasing

public concerns about the use and effects of various substances – substances like DEHP, a plasticizer that found in everything from drainage bags and tubing to catheters. DEHP is just one of seven substances targeted for prohibition in the European Union by 2012 as a Substance of Very High Concern (SVHC) under EU REACH. As of March 2010, it is also one of 29 SVHCs on the "candidate list" that triggers an obligation on manufacturers to provide information about products that contain it. The European Commission has recently agreed upon on a roadmap to include 106 priority SVHC substances by 2012. These regulations, and the potential for non-compliance, are creating unprecedented risks to medical products manufacturers' brands that also threaten top-line revenue and market share.

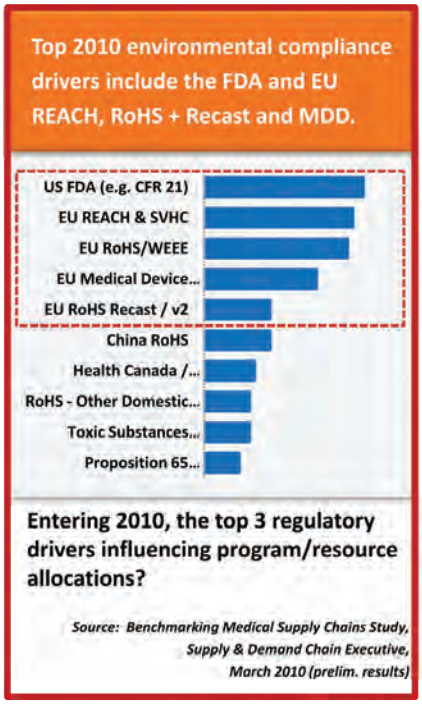

Figure 1.

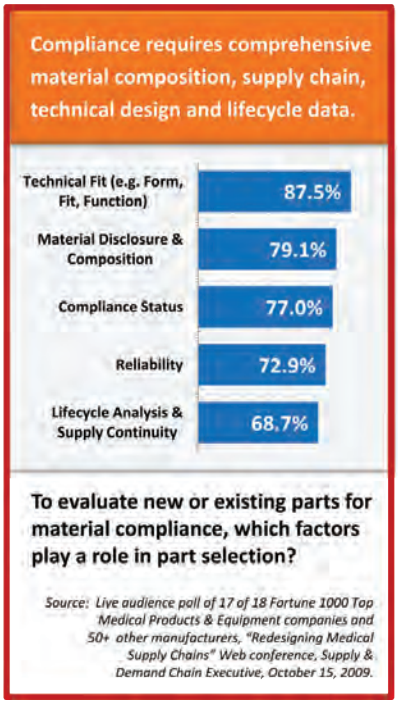

Figure 2.

Medical Manufacturers & Suppliers Are Behind the Eight Ball

In the face of OEM customer requirements and government regulations, companies in the medical supply chain have no choice but to act – and act now. Revenue, market share, recalls, company brand – and even executive jail time – are all at stake. It's no wonder, then, that C-level executives have begun to raise sustainability and compliance to the level of a corporate imperative. Yet several characteristics of the industry have mitigated against immediate action and left medical manufacturers behind the eight ball in the move to meet the urgent challenge of compliance, including:

Extensive M&A: Frequent mergers and acquisitions mean that companies in the industry typically include multiple business units operating with disparate systems and distinct processes. Parts lists are fragmented between units, and few companies have undertaken comprehensive, ongoing efforts to rationalize and optimize systems and parts lists across BU boundaries.

Expiring Exemptions: While the medical industry has enjoyed exemptions to regulations such as EU RoHS, those exclusions are now being phased out. And while the deadline for compliance with RoHS is often cited as "2014," in fact the deadline is December 31, 2013 for medical products manufacturers to complete design and certification of products in order to meet the requirements for "medical devices ... which are placed on the market from 1st January 014."

Expanding Regulations: Medical manufacturers must look beyond RoHS 6/6 compliance to recast RoHS (September 2009 revision), which places four additional substances on the list for assessment (HBCDD, DEHP, BBP and DBP) to harmonize RoHS with REACH, and which provides for exemptions "up to" four years, versus four years, and for a grace period for exemptions of only up to 18 months.

Extended Compliance Cycles: The time required to extract part and material information from fragmented databases and drawing, identify non-compliant and at-risk or obsolete materials, redesign products, and complete quality assurance, certification, labeling and shipping can extend beyond three years for the typical medical manufacturer. (See **Figure 2**.)

These factors, taken together, mean that a manufacturer that is not actively engaged in product redesign for compliance is already behind and must act now to avoid the consequences of non-compliance.

Compliance as the Key to Competitive Advantage in the Medical Supply Chain

Of course, compliance has frequently been viewed as a tactical-level issue not linked to C-suite and shareholder concerns, as well as a net cost to the enterprise, resulting in a lack of senior-level sponsorship, underfunding and non-alignment with sustainability objectives. Increasingly, however, business leaders at the C-level are recognizing compliance

as a strategic opportunity to optimize the supply chain. These first-movers are taking their cue from leaders in other industries – e.g., high tech and electronics – that have moved forward with leveraging a comprehensive compliance strategy to deliver supply chain benefits to the enterprise. These leaders are being recognized for enabling competitive advantage through increased efficiencies and reduced total costs, accelerated time to market and lower supply chain risks:

Increased Efficiencies/Reduced Total Costs: A comprehensive compliance strategy provides for the aggregation of item-level data across the enterprise as a preliminary step toward either verifying compliance or redesigning parts and products for compliance. This step also serves as the foundation for material and part rationalization, as well as supplier rationalization, yielding:

Reduced Administrative Costs: Industry estimates are that it costs at least $1,500-$6,000+ to create and maintain a part over its lifecycle. The elimination of parts duplicates (as much as 50 percent or greater at many companies) can result in significant savings.

Improved Commodity Management: Increased spend visibility allows companies to better leverage their total spend with suppliers by aggregating demand across fewer suppliers for fewer items/SKUs.

Improved Spend Compliance: The creation of approved vendor lists (AVLs) and preferred parts lists (PPLs) helps to limit maverick, off-contract spending or the use of non-preferred suppliers.

Reduced Supply Chain Costs: Supplier rationalization lowers the total cost of ownership of the supply chain by reducing logistics and inventory carrying costs, as well as the costs of integrating and interacting with suppliers.

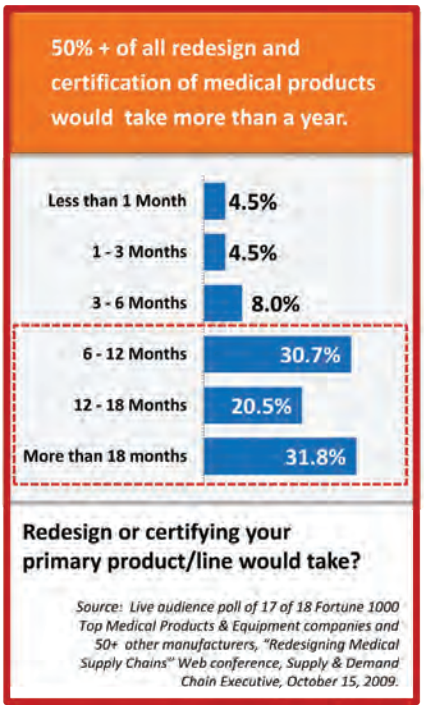

Figure 3.

Accelerated Time to Market: Moving to a smaller number of approved vendors and preferred, qualified parts can accelerate time to market by allowing engineers to focus on design issues rather than searching for parts. In fact, tech industry estimates are that engineers in enterprises without PPLs can spend as much as one-quarter or more their time searching for parts during design/redesign. The improved information flows and availability associated with an optimized, compliant supply chain also increases supply chain speed. All these incremental benefits can add up to a significant impact on the bottom line benefit, with one tech sector OEM estimating that improving time to market by one month can increase profits by greater than 10 percent.

Lower Supply Chain Risks: A manufacturer that gains comprehensive visibility into its parts lists and leverages that visibility to create AVLs and PPLs can see higher material availability and reduced supply chain risk. Complete parts visibility means that obsolete, end-of-lifed, last-time/lifetime-buy and non-compliant parts and materials can be avoided and/or designed out as necessary. This ensures that parts will be available when and where required for production, minimizing plant downtime, and, at the same time, reduces supplier lead times – not to mention overall supply chain complexity. In addition, product recalls due to non-compliant materials can be minimized. (See **Figure 3**.)

Improved Supplier Performance, Innovation, and Collaboration: By virtue of gaining parts visibility and increasing communications with suppliers and partners around compliance issues, manufacturers have the opportunity to increase their overall level of supply chain collaboration, thereby helping to total reduce risk in the supply chain (e.g., through improved information flow and tighter OEM-supplier alignment), achieve greater adherence to supplier scorecards and performance criteria (e.g., through heightened supplier sensitivity to requirements), and expand opportunities to innovate and improve responsiveness (e.g., through stronger linkages to supplier product development teams).

The Road Forward to Compliance

With the benefits of approaching compliance as a supply chain optimization clear, it is no wonder that business leaders are coming to view compliance as a unique opportunity to gain a competitive advantage. So how to get started?

A compliance strategy can deliver benefits similar to those of an enterprise strategic sourcing and supplier management exercise, and the steps to move toward compliance are similar as well:

■ Consolidate parts data across business units to gain full visibility

across the enterprise.

- Cleanse data to identify duplicates.
- Identify at risk parts, including:
- Parts that that are non-compliant, obsolete or sole-sourced;
- Parts that have a shorter lifecycle than the anticipated lifespan of the end product (plus redesign time);
- Parts from suppliers that are out of business or that are risk of failure.

What is most critical, however, is for the company to recognize the opportunity and make the commitment to leveraging rationalized project data to achieve the initial benefits, and then to build or upgrade processes in order to capture future benefits. The process of creating AVLs and PPLs provides benefit on its own regardless of compliance. But the benefits of this process can make compliance initiatives "self-funding," so that projects in response to regulatory mandates or customer requests can be viewed or positioned as a net value-add rather than purely as a "cost of doing business."

5 Steps to Focusing on the Value Drivers

The key, then, to ensuring lasting corporate benefit is not only crafting an effective compliance strategy but extending that strategy across the enterprise. Building support for a comprehensive compliance strategy across the enterprise requires five essential steps linking the initiative to value drivers that are important to specific stakeholders and constituencies within the company as a whole and within the individual business units/functions. These steps are depicted in Figure 4 and described below:

Step 1. Identify Regulations

Document the key regulatory drivers behind compliance as it applies to your company's markets and products, and then link those regulations to the potential penalties (including fines and jail time) and other impacts (including possible recalls) that could result from non-compliance. As part of this step, it is important to understand the timeline for compliance with individual regulations.

Figure 4.

Step 2. Identify Key Customers, RFPs/Requests for EPP, Markets

Understand the incoming requirements from key customers, including those contained within current requests for proposal and requests for environmentally preferred products, and then calculate the revenue and market share at risk from non-compliance – or to be gained by ensuring compliance.

Step 3. Identify Organizations/Stakeholder Impacted

Both supplier- and customer-facing organizations must be engaged and collaborating with one another on an ongoing basis as part of a compliance process. Product, sourcing and supply chain stakeholders must be engaged to work with suppliers in assessing materials compliance and responding to customer and regulatory impacts. But sales, marketing and support teams also must also be brought into the process to understand and manage customer requirements and to assess market/sales opportunities based on compliance. Legal and finance also must be involved to understand the company's risk and revenue exposure in the event of non-compliance events.

Step 4. Identify Redesign Implications and Risks of Product & Material Exposure

An understanding of compliance deadlines and customer requirements provides a foundation for identifying redesign implications, including which products and materials are at risk. Working backwards based on those cut-off dates, you can "reverse engineer" a timeline for redesign broken down by product or product line, based on the lifecycle of each given product, and then link these to supply risk, revenue at risk and legal risk. Compliance cycles that extend beyond compliance deadlines, of course, are clearly a risk. But compliance cycles that are targeted for completion in advance of deadlines offer opportunities to iterate product designs with new materials, collaborate with new suppliers, and redesign processes, potentially leading to new innovations.

Step 5. Identify Opportunities for Rationalization

Enterprises today face a proliferation of systems for the management of parts and materials, bills of materials, standards and suppliers. This is particularly true for companies that have grown through multiple acquisitions. Consolidating those systems across the enterprise can form that basis for the supply chain optimization benefits described earlier. Consolidation also can yield direct savings of as much as 25 percent or more of the costs of maintaining multiple systems. And moving to a consolidated process for managing information around standards as part of the compliance strategy can produce six-figure savings for a Global 2000 OEM. These kinds of savings can provide "seed funding" for the compliance initiative from the systems standpoint.

Outputs

At the end of this five-step process described here, you will be armed with these "deliverables":

- List of key regulations, chemicals of top concern, impact and ramifications.
- Documentation of dollar, market share, competitive or relationship/customer satisfaction risks and opportunities.
- Organizational stakeholder impact map or "pain chain" showing resource/performance burdens, who benefits from compliance funding, and efficiencies/processes at risk.
- Design cycle time plotted against compliance milestones to produce an Unscheduled Redesign Scenario Plan with a "balance sheet" of current risk exposure and impact.
- Documentation of supply chain benefits and opportunities to fund compliance project.

Navigating the Organizational Realities

As with any similar initiative in the enterprise, a comprehensive compliance strategy must take into account the organization's culture (the people) as well as the processes and technology that form the environment in which change will take place.

Managing the People Change: The medical industry has a long history of continuous mergers and acquisition, and many companies in the sector today are the result of multiple M&A deals, comprising eight, nine, ten or more business units or product lines that have been merged together. This reality inevitably complicates any proposed enterprise-wide initiative, including the move toward a comprehensive compliance strategy, which involves standing up and optimizing systems and parts lists across the business. The challenges involved in overcoming organizational resistance clearly cannot be minimized. However, executives who build the business case as outlined in this paper will be prepared to educate key stakeholders across the BUs and product lines on the opportunity and benefits of the compliance process. Rolling out an initiative within a single division, business unit or product line, if necessary, also offers the opportunity to achieve benefits and demonstrate value to entire other BUs to join the program later.

Managing the Process and Technology Change: The evolving nature of medical device manufacturers has also left its mark on the IT systems and technologies used within those organizations. This shows up most prominently in the often archaic and heterogeneous landscapes of multiple product data management (PDM), product lifecycle management (PLM) and other product information management systems and approaches running within these companies. Generally enterprises will maintain product and division lists, but parts lists are sparse and harder to come by, while the idea of a preferred parts list is rare.

Bottom line: One has to keep an "eye on the prize." And that "prize" is the material compliance and composition information that customers and regulatory authorities are increasingly demanding. Much of the information on parts and materials can be found in drawings or locked in product data, enterprise resource planning or other software packages, but another "black box" software application or database is not the solution to compliance. (See Figure 5.)

Rather, the key is the content itself, the information on parts and materials that will form the basis of decisions regarding opportunities for supply chain optimization. Those business leaders who quickly recognize, and can convey to internal stakeholders, that material content enables decisions around supply chain optimization, which in turn deliver real value to the enterprise, will gain from appropriately funded projects and executive engagement. And these leaders' companies stand to gain the most in adopting a comprehensive compliance strategy.

Where Leaders Lead – Getting Ahead of the Eight Ball

Customer requirements and regulatory mandates are pushing compliance to the top of the business agenda, even as increased shareholder and social pressure have raised executive awareness of the need to pursue compliance-related initiatives. Unfortunately, due to its history of M&A, previous exemptions to regulations and its extended product development/redesign cycles, the medical industry now finds itself behind the eight ball in terms of enabling and ensuring compliance.

Emerging from behind the ball will require that medical manufacturers look beyond tactical compliance "projects" and a "cost of doing business" approach. Instead, leaders will look at compliance as a strategy that focuses on optimizing the supply chain and adding value to the business. These first-movers and fast-followers are recognizing that compliance represents not only a requirement but also an opportunity to create tremendous enterprise value. Given that companies have no choice but to enable compliance, thought-leaders are moving to get ahead of the eight ball – and ahead of the competition – by enabling a comprehensive compliance strategy now. ■

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