

DESIGNING MEDICAL PRODUCTS FOR RoHS, REACH AND GLOBAL HAZARDOUS SUBSTANCE REGULATIONS

Retooling legacy products and information systems to eliminate toxic substances while maintaining product quality and supply chain continuity

BY ERIK SWAIN



Thanks to new environmental regulations, medical device manufacturers are going to have to understand their supply chains to a degree they have never had to before. Concerns about hazardous substances are mounting daily. Medical product manufacturers are familiar with regulatory compliance, but they are much less accustomed to the growing number of environmental regulations restricting

the use of hazardous materials introduced into their supply chains. Medical product manufacturers are now going to have to anticipate and adapt to even the smallest changes in materials and substances, even if they occur at the very beginning of the supply chain. Legacy products and information systems are not equipped to respond to the swift pace of regulatory changes and growing pressures from government authorities, healthcare purchasing organizations, shareholders, and consumers.

The consequences for not being on top of these issues will be considerable. Yet, understanding their scope and managing them will take a significant amount of time, effort, and resources. A tremendous amount of information and insight — about the relevant regulations and standards and about the materials and substances in the supply chain — has to be collected



and analyzed. It is very likely that outsourcing some of these functions will be a more efficient and less costly way to meet these challenges than trying to perform them in-house. What is certain is that whatever decision a company makes on tackling these issues is going to have major implications. If they haven't already, engineering and procurement personnel will have to raise these issues at the corporate level.

"Medical market segments are very familiar with regulatory compliance, but they are not as familiar with environmental regulatory compliance," says Scott Wilson, content solution strategist for IHS, which provides data, analysis, market intelligence, and other information to the medical device industry and others. "And now they are going to have to be."

What follows is a discussion of the new regulations, how they will transform supply-chain

management in the medical device industry, and how outsourcing may be the best way to keep medical device companies compliant and ready to adapt without breaking the bank.

REGULATIONS BRINGING CHANGE

There are hundreds of thousands of chemical substances used to make materials and products worldwide. Some are known to be toxic; some are known to be harmless. But for most — as many as 75 percent — little is known about their impact on the environment or human health.

The European Union is determined to change that. In December 2006, it enacted Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18 December 2006, or REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals). This regulation covers all materials and substances made in or imported into the EU, as well as all articles made of substances. Obligations for chemical manufacturers and importers under REACH started in December 2008, while notification requirements started Oct. 28, 2008, for manufacturers that use Substances of Very High Concern (SVHC).

The goal of REACH is to protect human health and the environment by understanding the risks associated with chemicals and how users can use them safely. Some substances will be deemed too hazardous to use safely and will be restricted or eliminated. The process of determining which hazardous substances to consider for restriction begins with identifying the most problematic ones and labeling them as SVHC. These substances are "candidates" for restriction, and the list of SVHC is called the "candidate list." When a substance is identified for restriction it goes on the "authorization list" — where the substance can only be used with authorization from the European Chemical



Agency (ECHA). Once the substance is put on the authorization list, a timeline is published for its sun-setting, after which it cannot be used.

The core principle of REACH is “no data, no market.” One of the implications of this is manufacturers must understand what is in their products and know what SVHC are there.

“Knowing about the presence of a SVHC in purchased parts, materials, and preparations is important,” Wilson says. “It carries the requirement of notifying downstream partners of their presence and responding to inquires on their presence from consumers. In some cases where use is high, it means notifying the ECHA. Once on the authorization list (Annex XIV), it’s an even bigger deal. It means companies must have specific authorization to use the substance, and companies understand that will drive obsolescence issues.”

THE CORE PRINCIPLE OF REACH IS “NO DATA, NO MARKET.”

Seven substances are currently designated as “priority SVHCs” (see figure 1). The EU has called on manufacturers to phase them out of their supply chains, and it expects to enact an outright ban or restrict them to specific uses in the future. Most significant on that list for medical device manufacturers is Bis(2-ethylhexyl) phthalate, commonly known as DEHP. It is used in a number of extrusion and molding processes. Medical products that contain DEHP include blood and IV bags and tubing, ECMO circuits, drainage bags, enteral feeding tubes, examination gloves, catheters, and dialysis equipment.

But that is not where the scope of REACH ends (see figure 2). Another 15 substances have been identified as candidates for inclusion on the SVHC list, and starting in December, 2009, more will be added every six months.

Information about how to safely use these

figure 1

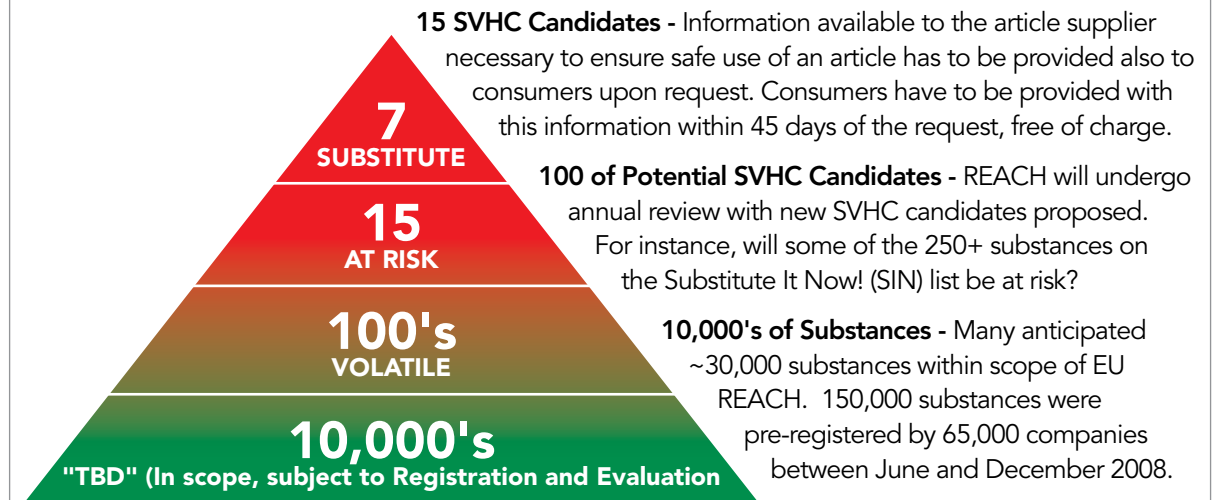
REACH SVHC PRIORITIES: FIRST ANNEX XIV PROPOSAL	
Calls for progressive substitution; Targets prohibition by Dec 2012	
SUBSTANCE	USE
5-tert-butyl-2,4,6-trinitro-m-xylene (Musk xylene)	Fragrance enhancer in household products and cosmetics. Imported from China.
4,4'-Diaminodiphenylmethane (MDA)	Feedstock for urethane and epoxy resins and other high-performance polymers.
Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins - SCCPs)	Sealants, paints, textile backcoating, and rubber products.
Hexabromocyclododecane (HBCDD), and all major diastereoisomers	Flame retardant in styrenic polymers and foams. Polymer dispersions used in textiles.
Bis(2-ethylhexyl) phthalate (DEHP)	Production of adhesives, sealants, and inks. Polymer calendaring, extrusion, and molding.
Benzyl butyl phthalate (BBP)	Plasticizer in PVC flooring, leather, and textile.
Dibutyl phthalate (DBP)	Plasticizer in PVC, fiberglass, and rubber.
These seven substances have been targeted for phase-out by 2012 in the European Union. Of particular importance to the medical device industry is DEHP.	

figure 2

SUPPLY VOLATILITY REPRESENTS GREAT RISK

No industry is “exempt” from changing supply

7 SVHC Prioritized - ECHA recommends they not be used without specific authorization. Authorization process seeks to ensure that the risks from substances of very high concern are properly controlled and that the substances are progressively replaced.



Only a handful of substances have been flagged under REACH so far, but processes are in place to identify many more.

substances and the products containing them must be provided upon request. Downstream “customers” must be notified after publication of new SVHC and have 45 days to respond to inquires from “consumers,” which might include NGOs that are already taking an active role in finding products that contain SVHC.

Those administering REACH will conduct a review every six months to determine which other substances should be included on or considered for the SVHC list, meaning hundreds of substances could be added during the next several years. A group of non-governmental organizations have designated a “Substitute It Now!” (SIN) list of materials believed to be harmful, using the criteria for SVHC as established in REACH. About 250 substances are currently on the SIN list, and many are likely to be added to the SVHC list

because of their hazardous characteristics.

Research will be performed to determine the hazards and risks associated with the hundreds of thousands of substances for which little or nothing is known. More than 150,000 substances were pre-registered by the Dec. 1, 2008, deadline that allows a phased-in registration period. The most hazardous and largest-volume substances must be registered by December 2010; other phased-in deadlines are December 2013 and December 2018. (All “new” chemicals must be registered immediately and prior to use.)

It would not be surprising if REACH eventually becomes the basis for a global standard. Health Canada has adopted similar regulations, meaning the use of certain substances is already restricted in Canada, and other nations are working on related efforts.



It is also important to note that the EU's Restriction of Hazardous Substances Directive (RoHS) will begin applying to medical devices in 2014 under a proposed recast. RoHS restricts the use of six categories of substances: lead, mercury, cadmium, hexavalent chromium, polybromated biphenyls (PBB), and polybromated diphenyl ether (PBDE). Medical devices were not part of the directive's scope when it was first enacted.

"Many companies felt like they dodged a bullet the first time it came out," Wilson says. "Some larger companies spent time learning about it, but most of the industry did not. They're behind on their tracking of RoHS compliance and the reliability issues associated with compliant (lead-free) parts. Now, they

have to do a lot of research on things like lead-free soldering."

The recast of RoHS would also make the CE Marking process more complex than it used to be, Wilson adds. And RoHS is worded more vaguely than REACH. While REACH identifies specific substances, RoHS mostly identifies classes of substances, Wilson says.

It is a good idea for medical device companies to coordinate compliance activities. Instead of going after REACH and RoHS, many companies are including other regulations such as the Stockholm Convention on Persistent Organic Pollutants (POPs), an international treaty that banned nine substances and restricted four others. "It's best to put them all together and figure out what overlaps," Wilson says. "Many substances of concern are common to multiple lists, but it's difficult to see this without investigation."

SUPPLY CHAIN RISK

REACH has tremendous implications for the medical device industry. All companies that supply products to the EU must comply, and significant penalties may result for firms that do not. (Each member-nation determines its own penalties.) There are no exemptions for medical products, as has been the case for some previous environmental regulations such as RoHS. Now that the medical device sector has become a global industry, with a global supply chain, the regulation will impact almost every device company.

Compliance is not as simple as making sure that your products no longer contain DEHP. Any number of substances could be added to the SVHC list in the coming years. Device firms must prepare themselves for the possibility that any substance currently used in their products could be eventually eliminated. They must also prepare their suppliers, and their suppliers' suppliers — going all the way back

to raw materials — to change the composition of their products because of what gets added to the SVHC list, or even because of what is anticipated to be added.

"The ripple effect from REACH creates an entire supply chain risk," says Rory King, senior manager at IHS. "It impacts the raw materials supplier, the component manufacturer, the intermediate manufacturer, the brand owner, and the downstream user. All have a regulatory obligation, especially the brand owner. You have to know what is in your products."

Generally, medical device manufacturers primarily deal with their immediate suppliers and immediate customers. REACH changes this dynamic. Now, device firms must know what substances and materials are used by everyone along the entire supply chain. They traditionally have little interaction with their suppliers' suppliers; now that must change. (The only experience many device companies have had with this was when latex allergies

"THE RIPPLE EFFECT FROM REACH CREATES AN ENTIRE SUPPLY CHAIN RISK,"

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SENIOR MANAGER
AT IHS

forced them to determine the latex content in their products, Wilson notes.)

In addition, some hospital systems, healthcare purchasing organizations, and other customers have begun to specify that products from their suppliers — the medical OEMs — identify the presence of hazardous materials or comply with REACH and related regulations.

This dynamic must change quickly. "Many industries have a head start on medical manufacturing, having spent years allocating significant resources to comply with RoHS and redesign products to accommodate lead-free, compliant materials," King says. This includes critical time and experiences dealing with the implicit consequences of regulations, issues like fundamental changes to component reliability, which have an impact on design integrity and product quality. "Most medical products were initially exempt from RoHS, and companies are now playing catch-up while dealing with current pressures like REACH," he points out. "Our more mature

customers 'get it' fairly quickly." Rather, they view REACH and SVHC each as part of an integrated approach to supply management, which accounts for substance regulations horizontally across international concerns such as EU directives and the United Nations, as well as national interests like the FDA, Norway PoHS, and Canada's Chemical Management Plan. They also include NGO pressures like the Chemsec SIN List.



figure 3

MEDICAL INDUSTRY HAS INHERENT RISK: Challenges from marketplace behavior and dynamics	
MARKETPLACE DYNAMIC	BUSINESS RISK IMPLICATION
Life Critical Application (Quality & Reliability)	New, different materials pose risk if not transitioned properly (new = different) ▶ Longer lead time to redesign and certify products than other market segments (additional cost, additional time, additional resources).
Product Life Cycle (Continuity of Supply & Integrity Throughout Service Life)	Component & Material Obsolescence Management Standards and Regulations Management ▶ Already a challenge, but the stakes increase with volatility imposed by abrupt material transitions.
Competitive Marketplace (Reluctance to Collaboration, Information, and Standards)	Custom Components/Devices Buried in Systems/Drawings ▶ Extremely challenging to identify materials to even understand risk, redesign, supplier issues.
Globalization & Growth (Complexity & Exposure)	Supply Network & End Markets = Borders/Regions Regulations, Workforce, Intellectual Property, Security... ▶ Supply Shortage Exposure, Counterfeit Exposure.
Failure to comply with REACH and other environmental regulations will expose every manufacturer to product viability and marketability risks.	

But many others are lagging, according to King. "This global transition is not just a trend or a fad or a market opportunity," he notes. "If you fail to get on board, you could be left behind." What this means is that very granular information on substances used in your products is absolutely critical to supply chain continuity and product integrity, and it requires new data. "Just to arrive at a list of your products is a difficult activity," King says. "Then you have to collect the substances that go into all of them. You have to work with your suppliers to produce the information. REACH is really an

MANY COMPANIES ARE ASKING THEIR SUPPLIERS FOR FULL MATERIAL DISCLOSURE OF ALL SUBSTANCES USED IN PRODUCTS.

indicator of your IT health. The communications required up and down the supply chain should be considered as a process that builds a competitive advantage."

Many companies are asking their suppliers for full material disclosure of all substances used in products. However, it is resource-intensive and is being met with reluctance to divulge intellectual property and fears over the subsequent production of competitive or counterfeit products.

It is also impractical in some cases, as many manufacturers don't have systems in place to readily provide the necessary information, Wilson

notes. Device companies and suppliers can work around those issues, though. "We're starting to see manufacturers fall into two camps: those that are willing to provide full material disclosure on their products and those that won't," Wilson says. "Manufacturers providing full material disclosure won't have to provide information to their customers every time a new chemical is added to the SVHC list. Manufacturers not providing it will need to rapidly notify downstream users of the presence or absence of chemicals newly added to the SVHC list. Either way, many manufacturer systems need to be enhanced to deal with full material disclosure, at least internally, and push this new type of information downstream."

A number of risks are involved if this information is kept hidden (see figure 3). If REACH causes a device manufacturer's suppliers to change the substances in their products, that may impact the life cycle of the device OEMs' existing products and their lead time in developing new products. It will have to spend extra, money, time, and resources to certify that products are compliant and redesign products that are not. Some device manufacturers will receive the unpleasant news that a product is non-compliant, meaning it will have a shorter life cycle than expected. The commercial electronics industry is already experiencing this.

This new volatility in materials and substances will put more pressure on device companies to better manage component and material obsolescence, and to better manage compliance

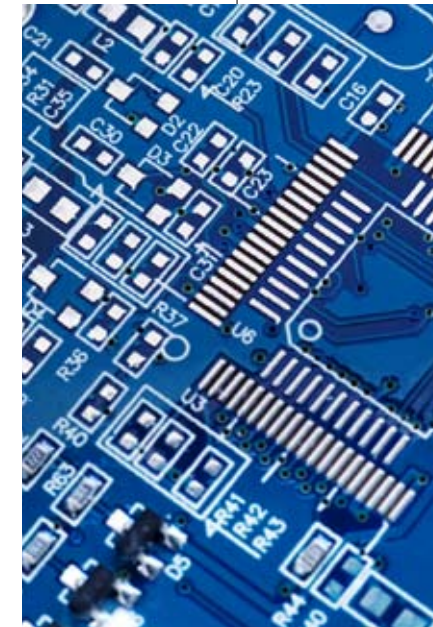
with standards and regulations. "Changes of standards, regulations, materials, and components are all interrelated," King says.

Even identifying materials in order to understand what changes might have to be made could be difficult, especially for custom products. And changes in how suppliers behave could lead to material shortages and increased risk of counterfeiting. "It will probably take about 10 years for supply and demand to balance out," King says. "And counterfeiting exposure can happen because of obsolescence. If you go on a wild goose chase for an alternative, the secondary source might be a counterfeiter. So you have to plan for obsolescence and the end of your product's life.

"It is essential for companies to get their arms around this," he adds. "REACH is in force but the market is unprepared. Companies can't wait three or four years for the market to get its act together. They must respond to customer and regulatory demands today. They must re-evaluate and redesign products in order to comply, and know what is in those products. Environmental issues, intellectual property, and managing supply chain risk must all be part of a risk management strategy."

Indeed, managing the REACH compliance process can dovetail nicely with product design procedures (see figure 4).

REACH forces medical device companies to do what they should be doing anyway: obtaining new information about a product, analyzing it, managing the risks it presents, communicating among departments about



these risks, and designing the next version of the product based on the information, analysis, and collaborative assessment. "You have to understand what's different," King says. "You have to look at the potential of a material supply going away entirely. And this is a particularly tough challenge for the medical device industry because it has fewer standard components than most industries."

The process should begin with assessing and interpreting regulations, standards, and the changes made to them. A system must be in place that immediately notifies relevant personnel as soon as a crucial change is made. This is essential to keep up with REACH, which will evolve over time, but it also comes in handy for staying on top of any number of important regulations and standards.

Companies will require a list of all products and all components, materials, and substances used in each product, as well as all suppliers and customers affected by them. "You can't address any problems if you don't know what is in your products," King says. "You have to get very specific information about your supply chain. You have to be able to acquire data sheets and related information."

OUTSOURCING CAN HELP

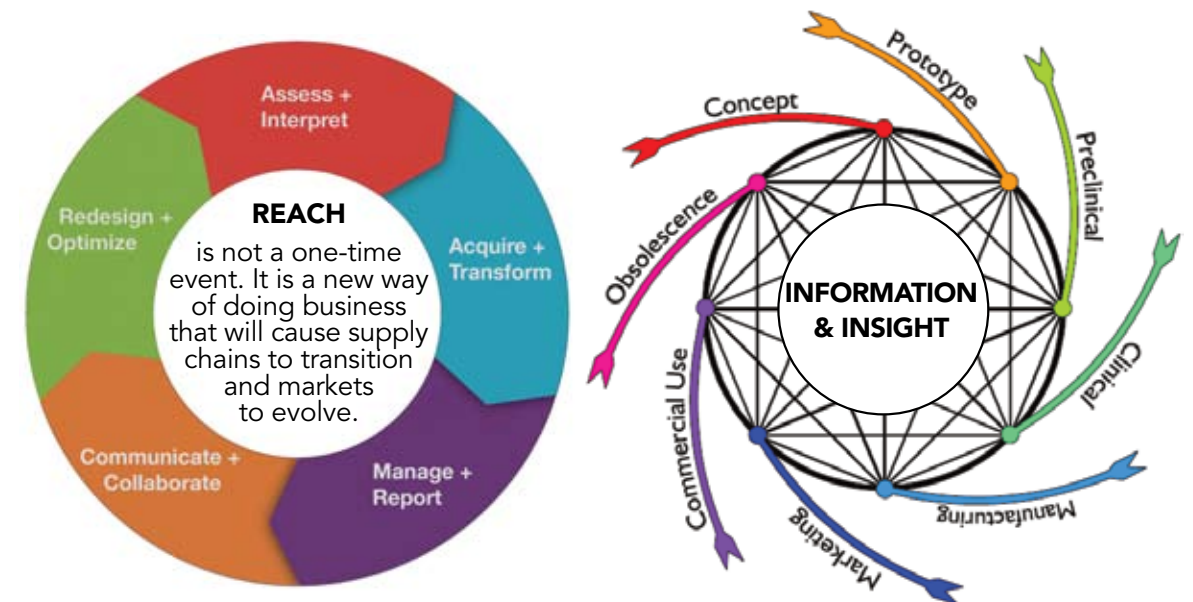
This is an enormous task. Figuring out what materials and substances each vendor along the entire supply chain uses, and determining which ones may be flagged by REACH or other standards and regulations would eat up an incredible amount of time, money, and labor if a firm had to start from scratch. The information is not well-known, and a lot of digging is required to get it.

It may pay to outsource this sort of extensive information gathering to a vendor that already has databases with information covering much of this ground.

"The first thing about half of our customers did was subscribe to a commercially available component database with information on tens of millions of parts," says Tom Keyserlingk, director of compliance services for IHS. "While many parts are in the database, many do not have all the detailed data required for REACH as SVHC composition information has only been available since November 2008. Without the composition data for their specific parts, it cannot help." A database can only bring so much value. "Our experience shows that of 40,000 parts used by a typical medical OEM,

figure 4

AN INFORMATION & INSIGHT COMPETENCE is critical to enabling medical marketplace performance



Managing the REACH compliance process dovetails with the product development process.

approximately 50 percent are commercial-off-the-shelf (COTS) electronic components," Keyserlingk points out. "Databases only pro-

vide data on COTS electronic parts. With an 80-percent match rate, 16,000 parts may be in a COTS database. Relevant REACH material

GETTING STARTED ON SUPPLY CHAIN RESTRUCTURING

Here is a quick guide to the first steps medical device companies should take when revamping a supply chain and the information systems that feed into it.

Assessment

- ▶ Learn which regulations impact your markets and which substances have been flagged by regulations such as REACH and RoHS, treaties such as the Stockholm Convention, and treaties such as the SIN list.
- ▶ Learn which regulations and standards govern the use and processing of these substances and substitution options.

- ▶ Identify all your products, components, materials, and substances and the compliance and reporting requirements for every market (with an enterprise view if possible, not product line or division).
- ▶ Identify opportunities to standardize components and suppliers, as well as hazardous material substitution options.

Planning

- ▶ Define the specific component, supplier, and substance data elements required for compliance for every product, market, and duration of the product's life cycle.
- ▶ Establish supply chain data exchange and communication process requirements.

Implementation

- ▶ Contact your suppliers, going back as far as raw-material providers where required, to review banned substance lists in current and pending regulations.

- ▶ Acquire substance data. Perform regular updates for changes in composition, alternate components or substances, and newly banned substances.
- ▶ Review and update product plans and compliance deadlines to determine what needs to be discontinued or redesigned.
- ▶ Repeat all of the above as necessary to maintain compliance or introduce products in new markets.

composition data is typically available for 10 percent to 25 percent of these — about 1,600 to 4,000 parts out of 40,000. Not to mention the non-electronic parts and the fact that additional substances may be added to lists every six months.”

Developing a relevant compliance database is not a one-time purchase or data-collecting endeavor. It is imperative to “get data on all kinds of parts, chemicals, preparations, custom materials, off-the-shelf products, and mechanical products,” Keyserlingk says. It is also crucial to have current information about standards and regulations. Firms may have to build an electronic version of their parts list from legacy drawings, standards, and related items in order to have a data management asset.

And they must keep abreast of which substances are on various restricted or banned lists throughout the world, to avoid surprises later, Wilson points out. An outsourcing partner can help with all of these functions.

Once this data is collected, it must be analyzed not only for compliance with environmental regulations but also as part of an

overall evaluation of supply chain efficiency. This analysis can also help firms get a better sense of the reliability of their various parts and suppliers. Keyserlingk says that many device companies do not have standard materials specification and purchasing practices across business units. This lack of standardization leads to waste, inefficiency, and sometimes noncompliance with regulations. Once firms have access to materials data, they can identify outdated materials and procedures and streamline inefficient purchasing practices. Outdated or restricted materials are subject to supply shortages, which increase costs.

“We worked with one device company that had never worked up its parts list,” Keyserlingk says. “We found a significant overlap in products and components used across four business units. We worked with another that had DEHP in all its cables but had no idea. This kind of data management not only helps with compliance but also assists with numerous other operations.”

Another aspect to coherent data management is an improved ability to manage the end

of a product’s life. Some companies find they are making legacy products that cost more to produce than what they can be sold for because they are using outdated materials or processes, Keyserlingk notes. “In one case, a device that sold for \$1,500 was costing \$5,000 to build,” he says. “For the first time in years, they were able to make informed decisions about which products are at the end of their life and which are not. All because they had the data and could do analytics.” The data helps firms make choices about which products should be discontinued. It is easy to decide to discontinue a low-selling product that contains non-compliant materials. The choice gets much tougher when it comes to high-selling products.

So having the full data helps firms decide which high-selling products need to be, and can feasibly be, redesigned for compliance. “You have to look at each part, assess its life cycle impact, assess its liability potential, and then go and find alternative parts and suppliers if you need to,” Keyserlingk says. “You have to determine exposure, awareness, and cost. In many cases, companies are trying to do this by the end of 2009, so they can market redesigned products by 2014 when RoHS will be enforced for medical devices. So you need to invest in systems that will help you answer these questions.”

Device companies could design and manage such systems themselves, but the task is complicated and costly. “Aggregating data on parts is not their forte,” Keyserlingk says. “More important for them is doing the work required once they get the data back. That impacts design, supply chain, and materials issues, such as obsolete parts; use of hazardous or restricted

materials; responsiveness, or lack thereof, of suppliers; and the risk of having a sole source for a material. We can perform data collection for typically a 25 percent to 40 percent lower cost than what they could do themselves, and for better quality, because it is not their core competency. But it is ours.”

When corporate-level executives find out the true cost of what it would take to perform data aggregation and analysis in-house, their jaws often drop, Keyserlingk says. The number of products, parts, and materials that have to be catalogued is astounding, but device firms usually don’t have personnel with the skill sets required to find and interpret

the data. Firms that don’t use outside experts will often use temporary employees, but the risks and business implications are too great to rely on them. Millions of dollars could be lost if the firm goes about the process the wrong way. Sometimes, firms will rely on sample testing instead of data aggregation, but testing can be 10 times as expensive and is no more reliable.

For maximum efficiency, this work must not only be embraced at the corporate level, it must be funded there, too. “All but one medical device company that we deal with has no funding at the corporate level to do this work,” Keyserlingk says. “All the funding is at the business unit level, so it gets decentralized. We’re trying to drive them toward standardization. It’s hard for companies to get in sync at higher levels. But this is forcing them to make critical decisions that they haven’t made before. They are slowly getting it.”

One company found that its business units were using mostly the same materials, whether for high-end premium products or low-end

DEVELOPING A RELEVANT COMPLIANCE DATABASE IS NOT A ONE-TIME PURCHASE OR DATA-COLLECTING ENDEAVOR.



commodities, Keyserlingk says. IHS was able to show how many duplicate parts were being purchased across business units, and even how many duplicate orders there were for different products within the same business unit. This was detected before the firm launched product redesigns to comply with RoHS in 2014. Because of that, Keyserlingk says, the firm ended up saving hundreds of thousands of dollars. Eventually, savings for REACH-related compliance will be even greater because the scope of REACH is larger.

Once the data is collected and analyzed, and it is determined which products must be redesigned, firms should not look at each product in isolation, Keyserlingk says. "You need to look at your entire list of parts, as well as alternative parts," he says. If a unit decides to use parts or materials that the firm has never used before, it can take 90 days or more to dig up the necessary data. That extends design time, and the longer the design process lasts, the costlier it gets. Instead, if all products, parts, and materi-



als are considered at once, the firm can make informed decisions about how to best leverage its material and supplier choices. And the right decisions can lead to substantial savings.

"You have to be able to rate suppliers and understand the risk matrix," Keyserlingk says. "Who gets it right the first time? Whose products actually contain what they say they do? IBM reduced its supply chain costs by 25 percent by parsing compliance data and rating suppliers on it. There is a huge opportunity for medical device companies to do the same thing. At the corporate level, you have to revisit all your materials and suppliers, evaluate for risk, redesign the supply chain for risk and cost, and rationalize the parts, materials, and suppliers in use. If you do this, you not only accomplish compliance, but five or six other improvements, as well.

STAYING ON TOP OF REGULATIONS

Crucial to adapting your supply chain to changes in the marketplace is the ability to stay on top of changes in regulations and standards. This is an arduous task that can be costly in terms of the time required to acquire, review, and maintain, as well as risky if critical notifications or updates are missed. But it is essential. If you don't know which materials and procedures are no longer in favor, you risk non-compliance and materials shortages. (see figure 5).

"Standards promote efficiency and economy in business, they affect interchangeability and interoperability in business, and they provide companies access to global markets," says Cathy Wyatt, senior product manager of Standards/Regulatory for IHS.

Because of copyright laws, most standards cannot be photocopied for distribution throughout a firm. "They're governed like textbooks, and you don't want to buy one and pass it around," Wyatt says. That means single copies of stan-

figure 5

PRODUCT ENVIRONMENTAL ISSUES	
ACTIVITIES	ISSUES
<ul style="list-style-type: none"> ▶ Product Design ▶ Product Content/ Constituents ▶ Sales and Distribution ▶ Product Packaging & Labelling ▶ Product Use/End-of-Life 	<ul style="list-style-type: none"> ▶ "Design For Environment" ▶ Chemical, Material Restrictions ▶ End-of-Life Product/Packaging Take-Back/Recycling ▶ Product Environmental Impacts ▶ Eco-Labels ▶ Green Purchasing/Procurement

dards are ordered multiple times by different departments of the same company, and even by different individuals in the same department. Without a managed resource, a lot of money can be spent on duplicate information, and, even more critical, different departments can possess different versions of the same standard. This is a poor compliance and business strategy because there is no assurance that everyone is acting on the latest information. Minimizing compliance risks requires active management of regulations and standards to understand requirements and make the best decisions.

So collecting and managing relevant regulations and standards is another area where medical equipment firms may be able to attain greater efficiencies by outsourcing. For example, companies can monitor all FDA, OSHA, and EPA regulations, and the standards cited within, Wyatt says. They can use a number of tools, including a tracking system to highlight recent changes and distinguish between different versions of the same document, a cross-referencing system, an e-mail alert system that notifies personnel instantly about changes to crucial documents, and search and collaboration capabilities.

Where European regulations and standards related to electrical and electronic equipment are a

concern, collections that compile pending and final relevant regulations from 50 countries, link directly to their full texts, and provide summaries in English can greatly improve compliance practices. A system can also provide e-mail alerts on changes regarding an export market, detailed analyses of new developments, and enable people within a firm to share notes and steps they will take to address issues.

"There are other unseen risks of managing a hardcopy library," Wyatt says. "These include lost productivity, missed deadlines, quality risks, liability risks, and rework." Additionally, when maintaining hardcopy libraries, companies must also consider the costs to research and locate the required standards, to issue a purchase order, to manage and distribute documents, to track changes, and to deal with copyright compliance. If those are accounted for, the savings of an online resource becomes even more

substantial. In one case, a medical equipment manufacturer needed AAMI's standards; the device-related standards of ASTM, ISO, and IEC; and the standards cited in EU directives. An enterprise-wide electronic system provided savings of 80 percent when compared with the purchase of hardcopies.

As with product and material information, enterprise-wide access

"YOU HAVE TO BE ABLE TO RATE SUPPLIERS AND UNDERSTAND THE RISK MATRIX,"

**TOM KEYSERLINGK,
DIRECTOR OF COMPLIANCE SERVICES FOR IHS**



to standards and regulations is the key to making the best decisions – from design, quality, sourcing and manufacturing to long-term product support. Charles Sidebottom, Director of Corporate Standards for Medtronic, Inc., said "We use the electronic system's watch-list capability as a way of alerting people to changes in relevant standards, whether it be new publications, new editions, or something else. People get notified when those changes happen, and we have found that to be much more efficient than a "pull system" where you go investigate the environment to find out when things have changed. Our watch list adds up to about 4,000 documents. About 1,000 are regulatory standards. The rest are engineering documents and things of that nature. It gets very expensive to try to keep up with all that on our own."

"We think it's saved the company considerable time and effort," he says. "I'm firmly convinced it's a much more efficient way to approach the problem of keeping up with standards than having individuals spend time to do that on their own. And it is much more cost-effective than having individuals managing documents themselves."

**AS WITH
PRODUCT AND
MATERIAL
INFORMATION,
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AND REGULATIONS
IS THE KEY TO
MAKING THE BEST
DECISIONS.**

Wyatt says an actively managed standards and regulations resource can play a valuable role in supply chain optimization by improving the ability to identify current compliance issues, understanding data exchange and reporting obligations, and developing efficient communications processes.

CONCLUSION

The onset of REACH, RoHS, and other environmental regulations will transform how medical device companies manage their supply chains. They will need access to more information and better processes to analyze, manage, and communicate that information across the entire firm.

It cannot be stressed enough that these issues must be dealt with at senior levels of management.

Otherwise, a comprehensive solution that will deliver the maximum return on investment (ROI) is unlikely to be attained.

"REACH and RoHS have not gotten high enough visibility," Wilson says. "Procurement, component engineering, and maybe

QA personnel had to deal with

them, and they are the ones that understand that this is a high-risk area. In some cases, they are having difficulty getting the message to a high level in the organization. This needs to go up to at least the vice president of global sourcing. The process can be so much more efficient if it is tackled collectively across the entire corporate entity."

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