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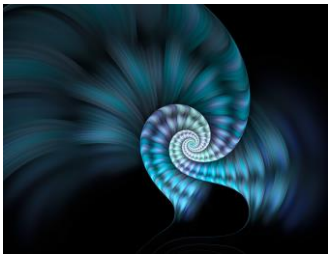

Traceability as Opportunity

Medical Device manufacturers must proactively re-frame compliance needs

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by Julie Fraser, Iyno Advisors

Can medical device makers re-frame shifting regulatory compliance needs to create business improvement? Yes. Some are already doing it. It's essential other companies join them or risk falling behind.

Medical device manufacturers regularly groan about the cost and burden of regulatory compliance. With regulations changing every day around the world, paper-based or disjointed information systems cannot keep up. That is what most companies have, and they will struggle to comply without a hit to profits.

However, this need not be the reality. Companies can, rather than simply viewing traceability requirements as a necessary evil, re-frame traceability to find the opportunities it offers the business. (See box below.)

In fact, medical device companies can and must re-frame to survive. Given that some have seen the opportunity in end-to-end data flows and are thriving, you might think it's obvious.

Yet companies and executives in this industry have a long history of simply complaining about the burden. Maintaining the status quo and applying a "bandage" approach does not offer sustainable growth.

By viewing the situation from a new perspective, companies may find an array of business processes that could be improved, accelerated or implemented with coherent traceability data. While much of the required data comes from suppliers and manufacturing operations, the opportunities for improvement radiate throughout the company.

This delivers excellent opportunities for a multi-disciplinary approach to finding the opportunities and making a sound business case. By envisioning the future together, leads from each discipline can contribute to a plan for new information flows.

The software for electronic device history records (eDHR), universal device identifier (UDI), and other track, trace and product genealogy needs exists, though many have not fully implemented or integrated it. There are special characteristics the software needs to have in order to deliver not only compliance but also better decision support across the enterprise.

For those bold enough to shake off the fear of regulators in favor of the vision of new frontiers, growth and new opportunities abound. The business case for traceability information flows can look quite compelling. Fortunately, compliance can be a by-product of these efforts.

Opportunities from traceability

- Quality, cost and efficiency of manufacturing and operations
- Analyzing products for low-cost country expansion timing
- Fact-based supplier negotiations and supplier quality boosts
- Quality process enforcement
- Enterprise-wide decision support from complete, timely sources
- Improved customer and/or patient service & support
- Lower cost of compliance

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Burdens & opportunities

Medical device manufacturers face myriad challenges that require them to both be agile and innovative while also complying with regulations. New products and variants of products come out regularly. Each product must be made to comply with the regulations for each market in which the company plans to sell it. Through all of that, quality must be outstanding to protect patient safety.

Making this even more complex, regulations for each region change constantly. This means separate documentation and "variants" for every version of a product in each market. Some of the more common regulatory requirements revolve around product records, labeling and traceability.

For example, the device history record (DHR) is increasingly expected to be electronic (eDHR). The US FDA also now requires manufacturers to submit universal device identifier (UDI) information and make it available from the product's label or marking.

You can't change the regulations and are only likely to have more products selling in more markets. So does this mean the burden will simply grow?

If the company is focused only on compliance, each new regulation will just appear to create a greater burden of compliance. The burden can seem massive, as a DHR includes quite a bit of information.

However, the entire concept that regulatory compliance must be a burden is not necessarily true. Admittedly, this is counter-intuitive for most participants in the medical device industry today.

Can you see opportunity in the challenge or in the regulation? Of course you can.

Even if you can't control the situation, you can control how you see it and how you respond to it. So as a business, you must re-frame regulatory compliance requirements. Focus on what the business needs to improve, then explore how each new regulation might enable you to do that.

A fundamental re-framing of regulatory compliance is required for medical device companies to continue skyrocketing growth and profitability as margins are squeezed and regulations inevitably continue to change.

This is also called re-framing. A fundamental re-framing of regulatory compliance is essential for medical device companies to continue their skyrocketing growth and profitability as margins are squeezed and regulations inevitably change. Companies that continue to focus on compliance as an added burden without fully exploring the potential benefits to the business will not be able to compete with those who succeed with this re-framing and opportunity to change.

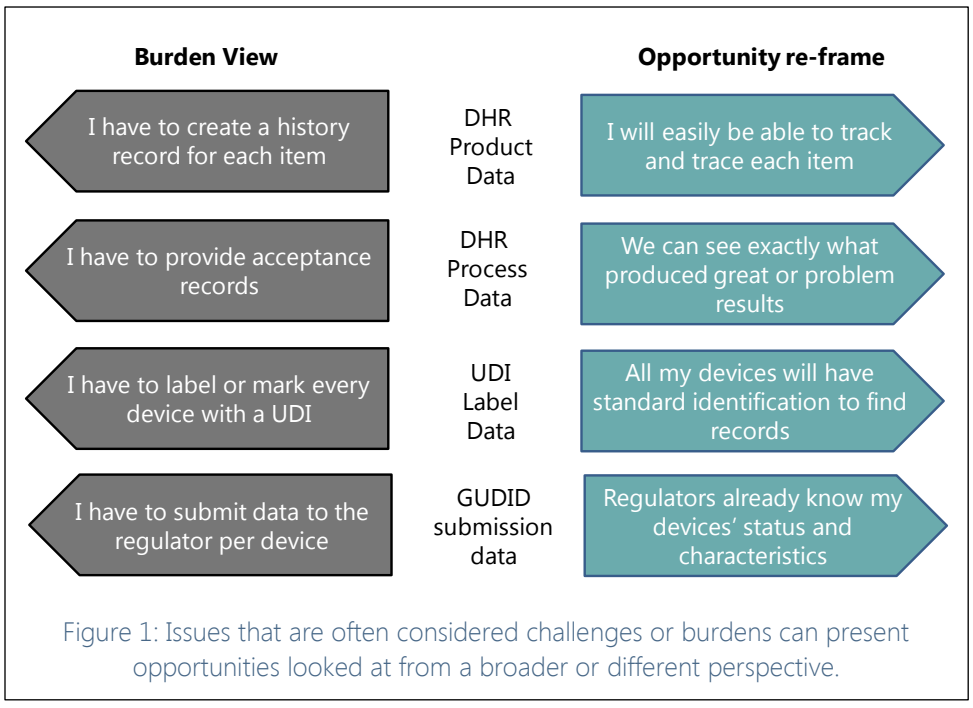

Figure 1: Issues that are often considered challenges or burdens can present opportunities looked at from a broader or different perspective.

Re-framing the requirements

The key to establishing momentum is re-framing traceability to see opportunities rather than just regulatory burdens. Taking eDHR as the example:

What is the *opportunity* for a medical device company in having immediate electronic access to a complete set of data about all of its products, plus the materials and processes that went into it, aggregated into a system like eDHR? What is the added benefit of having it in an industry-standard format for each device to be clearly marked and identified with UDI? The answer is: it's an enormous potential benefit.

At heart, implementing comprehensive traceability measures can radically improve the quality, cost and efficiency of production and regulatory operations. It can also point the way to more effective supplier relationships.

In fact, some companies are already finding that implementing an eDHR system is delivering a path to business improvement. They are finding that UDI and traceability for compliance can be a side-effect of a sound eDHR and quality system supported by complete and appropriate software.

For example, one medical technology company implemented eDHR and gained significant operational and business improvements. See Figure 2 for specific areas, but benefits accrued in manufacturing, R&D, quality, customer service, and regulatory. When so many disciplines stand to benefit, such a project might logically gain momentum.

Here is an idea for how to do start to re-frame:

1. Envision how the company could have greater success (may be in a strategic plan)
2. Identify which processes currently lack coherence or use a stop-gap approach that is not sustainable
3. Focus on processes where having quick access to comprehensive product information would matter
4. Form a multi-disciplinary team to further flesh out the processes you need to improve and likely benefits of doing so
5. Build your business case and present it to get the resources you need to succeed

Some companies are already finding that implementing an eDHR system results in UDI and traceability for compliance as a side-effect.

The core elements of full traceability include genealogy, product trace back and track forward, process traceability, UDI labeling and marking, and a supply-chain wide enforcement process. This is no mean feat.[1]

Most medical device companies, create a true paperless eDHR by implementing manufacturing operations management (MOM). This delivers additional benefits.

When a complete record of what happened to each batch or lot is combined into a set of applications to support employees and dashboards to enable rapid decision-making, you can imagine – and get - amazing results.

Figure 2: Results from an eDHR implementation show benefits far beyond regulatory compliance in all aspects of the operation.

[1] *Will You Let UDI Destroy Your Margins? Five Keys to Cost-effective Traceability and Compliance* © 2014 Iyno Advisors Inc.

Processes to improve

The processes that would benefit greatly from gaining full traceability are likely to span the company. As a result, it's critical that every discipline be involved in envisioning where they might use quicker and more effective access to the information in a DHR.

To start your thinking on processes that might benefit from integrated information for production data management and analysis, here is a list of just one idea from each of several different domains:

Design: Leveraging on-line complete DHRs for each product and variant, designers working on new variants and product designs could complete risk analysis far more confidently and efficiently

Marketing: Knowing manufacturing and supply issues with various products might suggest which to take into emerging price-sensitive markets first and which might need to mature further to keep a reasonable margin.

Procurement: Clearly if quality issues caused by a material supplier are immediately apparent, this provides solid facts for discussions on improvement needs and a basis for contract negotiations.

Planning: Seeing the details of how long various products take to make is the foundation for effective production and materials planning.

Manufacturing: MOM is truly a comprehensive system for the managers and employees in production. They can understand the impact of changes in SOPs, CAPAs, equipment, operators, training, settings or materials. Best of all, it's immediate feedback while the product is still in process. This speed is the key to keeping production on track.

Quality: Any quality system is only as effective as its enforcement, and with MOM you can ensure that operators use the SOPs by preventing processing out of order or without sign-offs

Deliver: If the logistics team knows exactly which products were produced when in which facility and how long they have been waiting to ship, they can improve perfect order performance. This means customers get orders on-time, with correct products as they expect them.

Finance: Preparing appropriate warranty reserves for the financial plan and public financial records could benefit from analysis of products' past quality histories.

Maintain: Companies with products that have a long lifecycle can leverage instant product histories to see where problems are likely to arise. For example, a technician might bring spare parts stock based on rework history during manufacturing.

Regulatory: Assembling data for regulatory reporting, submission and filing needs, audit preparation, and proving compliance are all streamlined radically with electronic history records.

Regulatory affairs for eDHR and manufacturing as main user of MOM the obvious winners. This shows that every department might stand to gain. Further, the company could streamline many critical inter-disciplinary processes. Examples include: new product introductions (NPI), entry into new markets, containment and response to adverse events, and regulatory submissions. The key to all of this is having software that allows in-context information to flow freely to the departments executing these processes and making decisions.

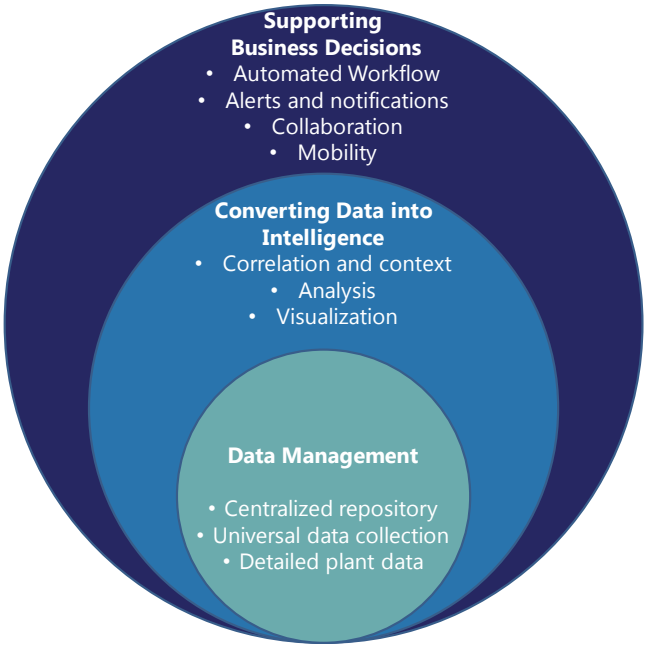

Figure 3: Software to support effective eDHR, UDI and the full enterprise set of traceability needs in medical device must have certain key characteristics.

Software support

Fortunately modern software can assist companies in streamlining these processes. MOM in an integrated solution set can help to move beyond lowering the cost of compliance and into seizing these opportunities to improve. Figure 3 summarizes those needed characteristics.

Centralized data repository platform

A single system for eDHR data means people no longer need to spend time searching out appropriate files from different systems, locations and partners. A study a few years ago showed that companies that improve profitability as they grow are much more likely to have integration between critical information systems. [2]

Agnostic data collection

No company has all of the data required for UDI in a single system. So the capability to receive or extract data from any source into a single, global repository using a standard format saves effort and time.

Detailed data from the plants

Much of the data in a DHR and for UDI comes from the production process. Most software applications cannot handle the quantity and type of data entailed in manufacturing for every unit from every facility, owned and partner-owned. Detailed product and process data for complete records that ensure auditable compliance is usually based in MOM.

Data correlation and context

Having all of the data about a unit together means more than typical genealogy that shows product, lot or batch, materials and location. You must also link to data about the process, quality, events, personnel, conditions, and issues. The key is to have intelligence that can handle all of that manufacturing data effectively, which traditional business intelligence is not intended to do.

Analysis

To turn correlated data into actionable insights for decision-makers, you need to analyze it.[3] This includes identifying root causes and examining the relevance of correlations among products. Analyzed data is where other disciplines often start to use manufacturing data effectively. Figure 4 shows a concept of moving from data to information to intelligence and insights.

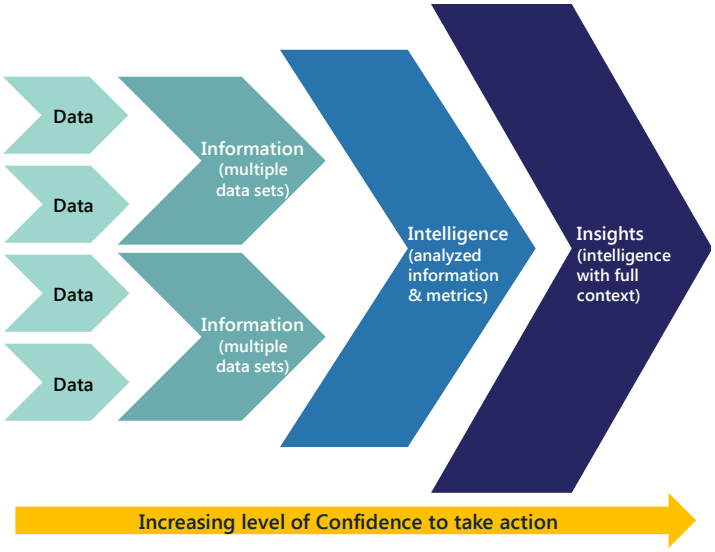

Figure 4: Taking action that can change company outcomes rather than just allow regulatory compliance requires insights, not just data.

Visualization

Having easy ways to see genealogy and trace information speeds all of these processes even further. Research shows that humans simply process visual data rapidly.

Automated workflow

To enforce traceability, modern systems automate workflows to support governance processes. When work is routed through each step of the process, with defined expectations, critical SOPs, traceability and containment processes are far more likely to move quickly.

Alerts and notifications

Managing by exception means people only work on what needs their attention. Alerts tell them right away when they must act. Distributing alerts not only within the production plant but also across locations and out to supply chain partners can save many hidden costs.

Collaboration

Enabling multiple locations and partners to work together effectively can improve improvement efforts, deliver supply chain visibility and speed the resolution of issues. With broad business processes, this is critical to effective decision-making.

Mobility

Employees and partners can be effective participants in the process even when they are not at their desk if systems play on mobile devices. This is how information workers stay involved and keep the process moving.

Fortunately, such systems exist today. Some are specifically designed with templates and built-in workflows that reflect the traceability processes required for medical device industry compliance and success. Some also can handle the vast quantities of detailed data to track every product end-to-end in a complex supply chain.

[2] *Beyond Trade-offs: How Medical Device Manufacturers can Balance Innovation, Quality and Compliance while Improving Profit*, © 2012 Cambashi Inc. and UBM Canon – pp 15 & 16 sponsor link here: http://bit.ly/1h2wCUi

[3] *How Global Manufacturers Leverage Intelligence to Sustain Market Leadership: 10 ways to engage in better decision-making* © 2013 Iyno Advisors Inc.

Beyond the mandates

Successful medical device manufacturers are very innovative. Many companies are also looking to penetrate markets in new customer segments and emerging economies. Many seek to develop uses for additional conditions and populations. And some are developing products that simply are more efficacious or safer or easier to use correctly.

These are the opportunities companies want most to execute against successfully. To capture these opportunities as product lines grow and regulations change, companies must have complete product data in an instantaneous format.

Each of these elements adds new dimensions to an already complex decision landscape for the people central to executing management strategies.

These people are in every department, as Figure 5 and the preceding section indicate. If all of these people have the information they need to gain insights and make good decisions, the company can better fulfill its mission. These people can innovate, produce, deliver and ensure high quality, regulatory compliance and new value for patients and healthcare providers.

Figure 5: Every department stands to gain from information systems that create consistency and easy, timely data access to product, process and device data.

Will your company be a leader and re-frame the compliance requirements into ways to seize new opportunities?

Some of the medical device manufacturers who have developed new business models or strategies are flourishing. For example those that have developed custom medical devices for each patient based on x-rays from the doctor's office. Others are delivering added services, and collaborating with other companies to improve customer value and patient success.

In every case, the opportunity can be served more effectively with complete product records in electronic format. Whether you think of this as an eDHR system, a way to comply cost-effectively with UDI, or simply a paperless manufacturing or MOM implementation, this is a path that is risky not to take.

All of this requires some outside-the-regulatory-compliance box thinking.

Will your company be a leader and re-frame the compliance requirements into ways to seize new opportunities? The business case can be compelling.

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