Impact of the new 510(k)/PMA process on companies for quality management

The entire medical device community is waiting patiently to see how the U.S. Food and Drug Administration changes the 510(k) clearance process. In January 2011, the Agency announced a plan containing 25 actions it intends to implement during the year to improve the most common path to market for medical devices.

According to a press release, the FDA's key actions include:

- Streamlining the "de novo" review process for certain innovative, lower-risk medical devices,
- Clarifying when clinical data should be submitted in a premarket submission, guidance that will increase the efficiency and transparency of the review process,
- Establishing a new Center Science Council of senior FDA experts to assure timely and consistent science-based decision making.

As it stands right now, manufacturers must register new products with the FDA prior to going on the market. The submission, known as 510(k), must show that the proposed product is "substantially equivalent" to a legally marketed medical device.

In other words, forget innovation if you want a "quick" approval of your new medical device. Instead, think about how your product is "just the same as" another on the market. For many, this doesn't sit too well, especially when the product their approval is based upon has its clearance rescinded.

Many medical device companies argue that the program doesn't allow for an increasing complexity of technology. Plus, what was designed as a process to reduce time to market, medical device manufacturers say takes even longer. Although a response is required within 90 days, in almost all cases, that is when the manufacturer receives additional questions, further drawing out the process.

Consumers and health care experts doubt the process, citing that patient safety is at risk. The alternative is the Premarket Approval process, which takes at least 180 days and requires formal clinical data and laboratory studies. It's more costly for all involved – manufacturer, FDA and the ultimate end user – but some argue that the deadliest recalls involve those that did NOT go through the PMA process.

A Task Force was created to make recommendations on how to incorporate new science into the process to encourage medical device innovation while improving patient safety. The FDA promises us a "smarter medical device program." All we can do is continue to work on and document our processes for quality management in anticipation of what the FDA will require from quality professionals. Ultimately, whatever the FDA requires, it is the responsibility of the quality management department to evaluate risks and ensure that products are safe.

The More Things Change… The More They Stay the Same: Best practices in Change Control

Take a trip down the grocery store aisle and you'll quickly see packages and cans boasting "New and Improved Formula" for everything from soup to soap. It seems that manufacturers are constantly improving their products. But improving is a marketing word. The reality is, they are changing their products. It doesn't necessarily mean it's a change for the better; it could be that a vital ingredient is no longer readily available or is suddenly more expensive. It could be that the competition harped about something in their product that they claimed was unsafe/unhealthy, etc. It could be the marketing department's idea to make news.

Regardless, changes mean work in the Quality Management department. Change Control is a vital part of the quality manager's job. The FDA has certain expectations of companies and, like it or not, documenting change is one of them. Unfortunately, documenting change isn't just jotting down "changed from paper to plastic" in a notebook somewhere. Rather, the FDA has a laundry list of things the Quality department must address including: facilities and equipment, materials, production, packaging, labeling, laboratory controls, design controls, components, aseptic/controlled process, viral inactivation/removal, validation, computer systems and preapproval. All must be classified in one of three categories: *major*, *moderate* or *minor* change.

Change Control is a formal process. The challenge for Quality managers is to develop an enterprise-wide system to manage change so that no one is caught off guard when any change is requested. Quality is typically the last department to approve changes, and before doing so, they should review the change for any potential effect on employees or the environment.

But not all changes are planned events. Sometimes, deviations occur because of a host of unexpected factors such as safety hazards, equipment damage, human error, etc. A good quality plan will have an SOP for handling deviations. We all know, stuff happens. It will also plan for corrective and preventive procedures, using trend analysis.

As surely as the sun will rise, eventually an FDA inspector will pay a visit to your Quality department. After exchanging a few niceties and small talk about the weather, you'll inevitably be asked for your recent Change Control log. What he'll be looking for is the number of change requests pending, those changes performed without quality department's approval, and a system to ensure a formal system is in place to monitor and evaluate change as well as routinely check trends.

You can prepare yourself for such a visit by following some industry-standard best practices for Change Control and by implementing solution automation to support the collection, tracking, management and reporting for enterprise change control.
A good Change Control system should:

- Identify the needed change
- Justify the change
- Document the change

- Get the appropriate approvals
- Communicate and train
- Implement and evaluate

You should also hold regular Change Control meetings with Quality professionals and other departments that are involved. Discuss issues regarding proposed changes, regulatory requirements, and evaluate trends. Assign responsibility for tracking and monitoring changes, and even enlist a senior manager to this team. Keep everyone in the loop on outstanding requests and stay on top of your system.

The biggest mistake a company can make is to underestimate the value of a Change Control system. It should be a strong aspect of the Quality department, helping to address problems you know about and detect problems early enou

Perfect harmony across your global organization

When you think of harmony, you're more likely to think of a group of people singing in perfect key together than a global organization working in total agreement. Just like in singing, not all people are singing the same notes, but the notes that they do sing are in perfect alignment and compatibility with the others. That's what global harmonization is – alignment of business processes and data for global standardization and enforcement. It's not performing identically, but in a way that complements performances of others.

The Benefits of Global Harmonization are many, including:

- Global consistency
- Business process improvement
- More operational control
- Leverage best-practices for success
- Enterprise visibility
- IT cost-savings

Harmonization avoids a one-size-fits-all approach. It makes the trade-off between too many and too few process standards and avoids inconsistencies between standards. Like a well-orchestrated performance, this doesn't happen by accident, but rather by commitment. First of all, senior management must have buy-in and governance. The process standardization and harmonization must be explicitly stated as objectives. Without buy-in from management, it's impossible to execute dramatic cultural change.

There must be clear rules for standardization and harmonization. The criteria for such should include when process variants should NOT be standardized. You will need to understand what should be standard and what should be allowed for variance or local adaptation. You must also take into account the global needs and strategy of company as well as its local requirements and resources.

There should also be a rule for selecting the best standard based on process performance and process cost. Your standardization and harmonization efforts need to be well organized and clearly defined, developing the roles and responsibilities for the team. Investing in training and developing a "train the trainer" program helps expand knowledge, reduce resistance, and produce skill and capacity for long-term improvements.

Set measurable goals and establish key performance indicators. Focus on eliminating waste and showing impact within and beyond the boundaries of the enterprise. As for change management, dig into the root problems of both people and processes to re-engineer the business before relying on technology to enhance the value. Doing so, you'll achieve more successful implementations and better overall results.

How to get started: Involve right individuals in the “planning stages” to get the right input. Create teams for oversight, implementation, execution and trial/testing. These teams should be a combination of local process owners, management, end-user representatives and IT. Although teams are a good idea, someone needs to make final decisions and therefore, you need to assign the “lead” decision maker for consensus to be achieved.

Set up communication plan for knowledge and new idea sharing. By doing so, people will be more willing to participate if they know they are being heard. Recognize the differences between different business processes that are likely to exist across lines of business, sites, and even within a site. Remember, we’re not dealing with all tenors or sopranos in this harmonization effort! Not all processes have to be identical.

Take into account the environment, culture and terminology. Where are the plant sites, outsourcing, and partners? What are the specific equipment needs for facilities and product lines? What are the specific needs for product manufacturing that may require some variances? What are the language and culture differences, from language and date/time formats for each locale, user interface language for easier user adoption, and terminology use across the organization.

Don’t try to change the world overnight. Start small. Select one or two key processes to map and harmonize first. Develop models that offer space for local adaptation, and then perform trials. Users at successful pilot sites will help the rest of the end-user community adopt the new processes. Explain the reason for change throughout the process. Help users recognize how new processes/requirements may be required to support and align to future state business process.

Finally, make sure everybody understands the key requirements and aligns with final business processes. Without consensus on the process and key requirements, a second major project will more than likely be needed to correct deficiencies in the first release.

A global harmonization implementation plan is never easy. It stretches a company and its employees professionally, personally, and at all levels. However, the resulting performance can bring beautiful music to the organization!

Monitoring Supplier Performance throughout the Product Life Cycle

Knowing your suppliers is as important as knowing the resources themselves. If you have a product defect, it doesn't matter if it was a supplier's fault or your own – the only thing the public will see and react to is your product and brand. Ouch. It pays to keep a tight control on supplier management.

The first step in understanding suppliers is through an evaluation and acceptance process. What are their business systems? Are they financially stable? What does Dunn & Bradstreet have to say about them? What percent of their sales is the product or resource you need? If it's not substantial, will that affect the quality?

What is the capacity of the supplier's operations? What technology do they use? Do they have a good reputation in the industry? Are their product costs and distribution costs in line with competition and your budget? Physically, where are they located, and who are your points of contact?

Suppliers come in many flavors, such as:

- OEM (original equipment manufacturer) –design control
- Contract manufacturer –process control
- Critical service provider –data control
- Critical material supplier –material control
- Catalog/off the shelf material supplier
- Routine or low-risk service provider
- Distributors
- Sister plant –depends on patient safety impact of service or material

You need to ask yourself a set of questions to determine your risk with this supplier, and assign a value to your response such as "adequate, deficient, unsatisfactory," or a numerical value that can be calculated to equal a total score. Include questions about the market and classification of the device. Consider regulatory requirements and any past or risk of exposure due to product recalls. As far as the manufacturing capability and supply chain, consider how many suppliers, the number of sources, and supplier manufacturing location. What is their technical capability and how does that match with yours? Finally, for quality purposes, are they certified to ISO 19001, ISO13485, etc?

Assigning a risk criticality level to your suppliers will help determine how to control and monitor the supplier relationship: high risk or level 3, medium risk or level 2, or low risk, level 1. Based on this ranking, you can then determine the frequency and type of supplier audits commensurate with risk (bi-annual, annual, third party, etc.). You can determine the frequency and type of inspections, from dock to stock, sampling, first article to 100% inspection. You can determine the quality metrics (SCAR response time, thresholds, PPM's, etc.).

As for performance monitoring, there are many factors you can look at, such as:

- Parts Per Million (PPM's)
- Nonconformance's (NC's) – "trend"
- Supplier Corrective actions (SCAR's)
- Key Performance Indicators (KPI's):
- On-time, Inventory Turns, COPQ, Rejections, etc
- Scorecards: quality, cost, service, delivery, compliance
- Risk
- Technical data trends

Find the metrics that are right for your product or process and supplier relationship, from scorecards and global supplier ratings to approved supplier list (ASL) and SCARS-Feedback and more. Update your supplier risk profile and analyze it to monitor the "health" of the supplier in real time. Monitoring the performance of your suppliers throughout the product life cycle can help you identify problems and rectify them before they become a potential brand disaster.

The Impact of SOX on Quality

The Sarbanes Oxley Act (SOX) was passed in 2002 after many high profile corporate scandals, such as Enron. The law's main goal was to improve the quality of financial reporting and increase investor confidence. Several aspects of SOX are similar to quality compliance in FDA, such as QSR and GMP. Boiled down to its basic elements, SOX shares a goal similar to that of quality management: continuous improvement of an organization.

SOX includes several articles concerning management responsibilities, and in particular, internal control. Implementing SOX involves (1) declaring management responsibility for establishing Internal controls which guarantee that accurate financial information is generated and communicated to executive management; (2) evaluation of the effectiveness of the internal controls and reporting their conclusions as to their efficacy within 90 days of issuance of financial reports; and (3) disclose to the company's auditors and the audit committee of the board of directors all significant deficiencies in the design or operation of internal controls, and any fraud, whether or not material, that involves employees with a significant role in the internal controls.

Even though SOX is not required of private companies, SOX represents the "best practice" for avoiding fraud. Manufacturing companies are used to dealing with extensive regulatory requirements as part of daily operations. However, accounting departments have traditionally been under less scrutiny, especially with regard to FDA regulations. Recent experience with Part 11 provides a good base of understanding for SOX compliance issues. Rather than introducing a regulatory corporate culture from scratch, companies can build on existing regulatory structures. Many companies already seeking to centralize all compliance issues (FDA, HIPAA, OSHA) within a single interface should incorporate SOX into this framework.

For many regulated companies, keeping finance and operations under control while meeting SOX internal control requirements in a rapid growth and competitive environment can prove to be a challenge. SOX compliance increases administrative time and costs. There is an increase in the cost of IT support, both in terms of capital equipment and resources. Plus, with required auditor reviews of the effectiveness of internal control as required in Section 404, the company may incur additional auditing fees.

Is there a way to alleviate these issues and implement SOX as well as manage regulations and quality compliance? If you consider automating the SOX processes to address internal controls using the same quality compliance system, the answer is *yes*.

To be successful, the focus must be on the process -- NOT the project -- and procedures: creating, documenting, controlling/tracking, training others, communicating. The role of internal control over financial reporting is to support the integrity and reliability of the company's external financial reporting processes.

ISO 9001:2000 Quality System has a lot of similarities to SOX requirements. Many companies consider this to be a "Quality Initiative" impacting the "Financial Organization". The COSO Framework, the most popular framework adopted by most companies to tackle SOX requirements, is based on ISO 9001:2000. The steps are similar to setting up a quality plan:

- Identify staffing (internal/outsource/3rd party)
- Identify framework/methodology for evaluation such as COSO (i.e., guidelines like QSR, GMP)
- Define objectives/risks (goals)
- Record process narratives (requirements)
- Perform risk assessment (severity/probability)
- Identify controls (functional areas/systems)
- Document, Approve, Train

The real opportunity for the quality managers is in showing how the quality management system can help meet the key objectives of SOX, which is to improve corporate management and governance so financial statements represent a true state of the corporation. Aligning quality management with that of SOX requirements not only eases the burden of compliance, but also provides an organization with a model for continuous improvement.

Is the FDA Keeping the U.S. from Innovation?

This past January, the Food and Drug Administration's (FDA's) Center for Devices and Radiological Health (CDRH) announced its plan of action for implementation of its 510(k) and science recommendations. Under section 510(k) of the Act, announced in August 2010, a person who intends to introduce a device into commercial distribution is required to submit a premarket notification, or 510(k), to FDA at least 90 days before commercial distribution is to begin. While safety is at the core of this regulation, is it also limiting the possibilities for innovation and delivering products to market?

According to a study by PricewaterhouseCoopers, developing companies have made significant gains in the last five years in medical technology innovation, edging closer to the US who still has the lead.

The report states, "emerging-market countries such as China, India and Brazil, despite comparatively weak healthcare system infrastructure, are quickly taking the lead in developing lean, frugal and reverse innovation. This type of innovation simplifies devices and processes, retaining essential functions while applying newer technologies that are more mobile, customized to consumers' needs and less costly. Such innovation will enable these nations to leapfrog developed countries in innovative healthcare delivery." Stricter regulations also hurt the smaller companies from bringing devices to market faster. The extra time and costs associated with the stricter guidelines prohibit smaller companies from competing with larger firms, that are also gleaning the support of investors seeking quicker return. Are we hurting ourselves or protecting ourselves with the regulations like 510(k)?

Recently, the FDA announced its plan of action for implementing 510(k) and is scaling back on some of the extensive recommendations the agency originally issued in August 2010. The Director of CDRH, Dr. Jeffrey Shuren, emphasized the agency's concern with facilitating innovation to promote the public health, which it intends to achieve by increasing predictability and reducing uncertainty in the premarket review of Class II medical devices. Called "the New Paradigm" it presents device manufacturers with two new optional approaches for obtaining marketing clearance for devices subject to 510(k) requirements: the "Special 510(k): Device Modification" option, which utilizes certain aspects of the Quality System Regulation, and the "Abbreviated 510(k)" option, which relies on the use of guidance documents, special controls, and recognized standards to facilitate 510(k) review.

The FDA believes that the New 510(k) Paradigm will provide considerable flexibility for the medical device industry in demonstrating substantial equivalence in 510(k) submissions. Over the next several months, the FDA will continue to review and analyze the procedures and promise to improve the 510(k) process. The medical device industry needs to stay aware and assist the FDA with its requirements so we can, first of all, improve our processes and ensure patient safety, while not stifling innovation which can provide patient benefit and not delaying its time to market. The U.S. is a leader in medical device technology and while the FDA is a necessary component of our success,

working with the agency to help improve its regulations will benefit the industry as a whole.

Managing Quality, Compliance and Risk in a Global Economy

Time to market is one of the major reasons we look to the global economy. Acquisitions and mergers can take us across international borders to quickly gain the intellectual property we need. International supplier sourcing can get products more quickly to our manufacturing sites and our customers, or broaden our foot print in a country quicker and faster.

While the global economy can help us realize productivity gains, we need to carefully manage it so operational excellence across the value chain can be realized. As manufacturers, we got really good at managing our domestic raw material suppliers and our own factories who were supplying our local customers…but remember, it took us years to get this down and develop systems.

The strategies that we have to embrace has our organizations focusing on reducing risk from the highest enterprise-level risk down to managing supply chain risk. There is expanding quality focus as we grow our customer base and enter new markets. We will have to stay compliant as the regulatory/quality requirements are constantly evolving, putting an increase on internal global procurement policies and tighter controls and practices on supply chain management.

As we build these complex value chains we have different types of relationships:

- Suppliers & Customers in any country
- Private Label Manufacturers
- Contract Manufacturing Operations (CMOs)
- Local and International Distributors
- Outsourced Development (R&D)
- Outsourced Services: sterilization, distribution, packaging, Regulatory Services, etc.
- New Technologies & Acquisitions

Each of the different suppliers determines different types of communication and responsibilities that have to be sorted through to ensure the appropriate control of the interactions of the relationships.

Some of the supply chain problems we have with our global suppliers are the same as what we had 20 years ago with local suppliers. They do not have the technology nor the business processes in place to quickly manage the needs the OEM has to put on them, to find and manage information. We need to think of sharing information with customers and suppliers and we need to make that process more efficient.

With paper-based solutions, the increase of suppliers and monitoring quality, performance with supplier systems becomes even more challenging. Minimizing the risk of liabilities, manufacturers need to have global visibility into their supplier

performance across the entire organization and all their product lines to ensure consistency, quality control and compliance.

Based on your supplier relationship, you should develop a Supplier Contract so you can define your expectations of each customer and supplier throughout your value-chain. This will detail what you are both going to do and when you will do it when that "event" occurs. Because you know it will – it's just a matter of when it will.

So what's needed to help you manage the business processes that you are going to have to "control" and to ensure "compliance" between both your suppliers and your customers? A top-down architectural approach to compliance and quality for any business process that you need to "integrate" between your customer or your supplier, so that it is flexible enough to allow for continuous improvement. Plan – Do – Check – Act.

A flexible approach can help enforce compliant process performance and control; monitor information accurately and in a timely manner for decision support; support change management throughout the value chain; be supported by metrics to mold culture and behavior; sense and respond to nonconformances as they occur; have procedures to correct problems that result; and, have the tools and processes to prevent the problem from recurring by improving design or process. In doing so, it can provide a framework for continuous "real time" assurance of quality, compliance and continuous improvement to help achieve operational excellence.

We need to maintain close relationships with our suppliers' Quality systems because ultimately, we are responsible for the entire product quality. Look across your supply chain and see what technology your suppliers are using, and then look to see where you can automate your business processes and integrate so that you can get access to real-time information. And finally, leverage a business intelligence tool so that you can pull information from various data sources to get the types of metrics and analytics that you need to make the right decisions at the right time.

LITTLE THINGS MEAN A LOT

Skinny jeans, 100-calorie snacks, smart cars – everyone is focused on smaller and leaner. So why not manufacturing? Research has shown that almost all activities in manufacturing fail to add value to a product. Nielsen Research reports that a minute of downtime can cost a manufacturer more than $20,000! A MINUTE! Success lies in efficiencies. It's about being lean.

Lean principles have been with us for a while in quality and manufacturing. You're probably familiar with Six Sigma, TQM, Kaizan, etc. Lean is about getting the right things in the right place at the right time and always looking for continuous improvement. It can apply to processes throughout the value chain.

It's simple to see why the focus is on lean. Our current economy is unstable. Mergers and acquisitions, layoffs, increases in the cost of doing business and on resources makes a focus on doing more with less while maintaining high quality products a must. It sounds so simple, just like if you want to lose weight, eat less, right? How many go on the "crash" or "fad" diet to achieve the desired results? The focus needs to be on the big, long-term, big picture -- continuous process improvement, not metrics and projects.

Re-engineering processes will allow you to get rid of all the waste and inefficiency in your systems. Lean, simple and intuitive procedures and robust process architecture can result in quick navigation, each to use and focus on problem solving, not navigating the maze. Implementing a lean program requires that you meet all applicable regulatory requirements, have an effective Quality Management System, know your products (specifications, batch records, etc.), identify and monitor your predictable processes, consider risk management, and measure the results in terms of cycle time, complaints, recalls, etc.

So what can go wrong? Way too much! First of all, over-documentation without understanding the whole system can obstruct the whole process. Adding resources without understanding whether the existing resources are being utilized correctly can also be a pitfall. If you make the system dependent on people, it won't survive long-term. If you're always being reactive instead of preventive and think technology will be the magic wand that solves it all, you will never achieve lean.

Enter Automation. The benefits of automation include data improvement, with automated systems and reports, and less reliance on memory and experts, and reduced human error. It also can create reproducible data and information so trends are easily evaluated. With real time data, reports can be generated when needed and knowledge can be shared more quickly. It also allows for accountability from across multiple locations.

Automation can also improve processes, by reducing process cycle time through automated workflows, and increase productivity through easier collaboration of automated notifications and discussion threads. Automation makes it possible to handle multi-tasks, create standardization and enforcement from policies not perception or interpretation, and eliminates guessing who owns what across departments.

For success, focus on the fundamentals:

- Learn to associate **efficiency with effectiveness**
- **Foster a culture** of business excellence, quality and productivity into fabric of the organization
- **Empower an effective workforce** with the right skills, knowledge and decision-making capabilities
- Deploy capability to measure performance and calculate the **value through the "right" metrics**
- **Leverage technology automation** to enable effectiveness, efficiency, and closed-loop processes that complement your overall investments
- Finally, understand what controls can be put in place to **sustain the gain**

Going lean is solving the problem, not addressing the symptoms. Match the right skill sets to do it right the first time. The benefits of lean systems are an efficient use of resources, rapid cycles, higher quality at a lower cost, greater flexibility and sustainable processes. Remember, less is more!

A New Focus on Information Security

According to the FCC, American small businesses lose billions to cyber attacks annually, and 74 percent of small and medium businesses reported being affected by cyber attacks in the past 12 months. The average cost of these attacks for business, per incident, was $188,242. The most important step your company can take is securing your data. This is not only a good idea financially, but also from a legal and regulatory standpoint.

No information system is without vulnerabilities. Hackers, terrorists, viruses, spam, fraud, data theft, system failures, power outages and more can have a significant impact on an organization's profitability and sustainability.

The need to "secure" the organization in the face of increasing complexity, uncertainty, and interconnection is brought about by reliance on technology to accomplish the mission. Threats put information security risk management at a crossroads, which might ultimately result in redefinition of function within the next 5 years (Gartner).

Consider this: an organization that successfully approaches security as an investment may increase its overall value in the marketplace, and may even be able to capture this value as "goodwill" on their balance sheet. They will also keep core assets and processes in service in the face of an attack, accident, or failure and actually improve their ability to adapt to future events.

The evolution of a risk-based paradigm for security has made it clear that a secure organization does not result from securing technical infrastructure alone. A security approach that is mission-centric (i.e., based on strategic drivers) strives to secure the organization's critical assets and processes regardless of where they "live." Many organizations are adopting a risk-based approach to security. The move to a risk-based paradigm is a catalyst for moving security from a technical specialty to an organizational competency. Applying a risk perspective to security is a logical progression—risk management is a basic business function, and whether it is done implicitly or explicitly, it must be performed at an organizational level to be purposeful.

An Information Security Management System (ISMS) is a well-defined, documented management system that takes an inventory of information assets and assesses the risks associated with them. It identifies the processes, policies and procedures to take to protect the assets. A good ISMS is one that is reviewed, audited and checked as well as continually improved.

The standard ISO 27001 is designed to help organizations identify, manage, and quantify their information security risks by ensuring the selection of adequate and proportionate security controls. The international standard, ISO 27001—"Information technology. Security techniques. Information security management systems. — is the result of defining what should be in the ISMS, not how it should work.

The objective of the standard is to "provide a model for establishing, implementing, operating, monitoring, reviewing, maintaining, and improving an Information Security Management System".

The benefits of ISO 27000 certification include:

- Reduction of information security risks
- Reduction of probability and impacts of information security incidents
- Certification to an international standard
- Marketing advantages
- Structured, coherent approach
- Comprehensive risk assessment
- Focuses information security spend to greatest advantage
- Demonstrable governance

Plus, ISO 27000 will satisfy requests to partners/suppliers to substantiate information security controls and provides a rational and independent information security standard against which to assess quality of controls at partners/suppliers. Having ISO 27000 certification can also be a marketing advantage, whereas reluctance to demonstrate compliance could be taken as a sign of vulnerability. Finally, certification helps assure stakeholders, auditors, industry regulators, *etc*., that organization is actively minimizing information security risks by demonstrating organizational commitment to information security (corporate governance or due diligence issue) given the potential for information security exposures.

In order to achieve certification, an integrated, enterprise-wide management system can significantly improve your chances of achieving certification in a timely manner.

An integrated management system will help you to document and manage the process (planning and scoping, inventory, assessments, risk treatment, policies & procedures, training, etc.) in such a way that an audit will be seamless and corrective actions will be clearly documented. By doing so, you will provide a more global view of systemic weakness and deficiencies occurring in information systems across the organization. It will also provide an opportunity to develop organization-wide solutions to information security problems, and increase the organization's knowledge base regarding threats, vulnerabilities and strategies, for more cost-effective solutions to common information security problems.

There's no question that information security will increasingly continue to be a threat for any company. Having an ISMS in place, and obtaining certification is one way to address, manage and improve policies and procedures that can keep data secure. Companies that invest in security can, at a minimum, preserve an organization's bottom line, if not improve it.

Compliance

Moving Into the New Generation of 21 CFR Part II

In 1997, it wasn't uncommon to hear "You've got mail!" when you used your telephone to log onto the Internet. This is the same year that the Food and Drug Administration (FDA) issued 21 CFR Part 11, electronic records. Six years later, in 2003, you were probably using broadband and going directly to the Internet. In this year, the FDA issued a Guidance for Industry of Part 11, Electronic Records; Electronic Signatures. It shouldn't be any surprise that seven years later, the FDA is piping up about Part 11 again. This time, it is in the form of revised enforcement discretion of Part 11.

In July of this year, the FDA put out an announcement basically reminding industry that Part 11 is alive and well and to not be surprised if the FDA comes knocking on your door to check that you are in compliance. It's main theme: "the agency will use its enforcement discretion" during the audit process for 21 CFR Part 11-compliant systems. Some predict that a revision to Part 11 may be on its way, and it would be time for one. In the past decade, technology has changed rapidly and it continues to do so. Enforcement of Part 11 now will allow the FDA to gauge how well industry has grasped the regulation and what changes are needed.

What this means is *now* is the time to take a close look at your company's data systems. How are you controlling, maintaining, archiving, and retrieving data that are vital to your products quality control? The last thing you want is the FDA to inspect your systems and find fault with it.

Here are some things to keep in mind:

- Good electronic records have qualities such as authenticity, reliability, integrity, trustworthiness and accessibility.
- The system and supporting processes of the data must be of the highest quality to ensure data integrity.
- What back up systems do you have in place? Protect your data from network crashes and power outages before critical electronic records are lost.
- Technology must be combined with best practices policies and procedures to ensure compliance.
- All changes to records should include a time-and-date stamped audit trail.
- Electronic signatures should include printed name of signer, date and time of execution and the meaning of the signature, such as approval.
- Establish password and identification controls and change them every 60 to 90 days. Ensure that terminated employees no longer have access. Build in security for accessing systems data by authorized individuals with various permission levels.
- Avoid combining paper systems and electronic systems. Migrate to a fully automated electronic records and signature system.

It's been a rough decade for industry to comply with Part 11 regulations. Both industry and the FDA have struggled to define requirements for electronic records, basically learning together as time progressed. Now that the FDA is taking a step to analyze industry's ability to comply with current regulations, it's in industry's best interest to take a close look at their compliance systems. In the end, doing so may help define the next generation of electronic records and signatures.

Quality

Get Lean! Using Six Sigma and Lean Strategies to Improve Quality

The goal of lean is to eliminate waste and non-value-added steps at all points in the manufacturing process. To accomplish this, lean implements continuous improvement practices and eliminating waste across the enterprise. Technology has been successful as key to achieving this end. While saving money might be an initial consideration with lean strategies, customer satisfaction is of utmost importance to any organization. By concentrating on customer satisfaction and value while eliminating waste, a company can build profits as well.

According to the Lean Enterprise Institute (www.lean.org), there are five principles of lean techniques:

1. Specify value from the standpoint of the end customer by product family.
2. Identify all the steps in the value stream for each product family, eliminating whenever, possible those steps that do not create value.
3. Make the value-creating steps occur in tight sequence so the product will flow smoothly toward the customer.
4. As flow is introduced, let customers pull value from the next upstream activity.
5. As value is specified, value streams are identified, wasted steps are removed, and flow and pull are introduced, begin the process again and continue it until a state of perfection is reached in which perfect value is created with no waste.

Lean principles can help businesses reduce costs, improve product quality, streamline processes and increase customer satisfaction, says the Institute.

Six Sigma, on the other hand, focus on defining specific processes to produce an exact level of quality that can be repeated. In order to do so, processes must be documented, monitored and analyzed. Working together, lean initiatives and Six Sigma principles can make an effective organization that eliminates waste, reduces cost and improves profitability.

According to the Lean Enterprise Institute, to achieve a waste-free production process, organizations must be willing to supervise the flow of products and services through entire value streams that flow horizontally across technologies, assets and departments to customers. Companies who do so can better respond to changing customer needs, with higher quality and with lower cost. Lean principles can also improve communication and accuracy of data, a definite plus for compliance.

When you apply these lean and Six Sigma principles to an automated quality management system, you create the ideal foundation for succeeding. Technology

makes it easier to view your processes, document them, and measure your success using consistent measurements. You can make more accurate predictions without a try-and-see approach. Technology enables you to be more flexible and respond to customers faster.

Most importantly, by using an automated quality management system with your lean initiatives, you make the system create the lean environment for the organization, rather than relying on a few people who have learned lean principles. Therefore, lean initiatives continue to thrive and grow in the organization, regardless of personnel changes.

Lean and Six Sigma aren't limited to the factory or even the supply chain. All parts of the organization can use these principles to improve processes: train employees, manage documents, monitor suppliers, create audit trails, and meet compliance. Even administrative processes can utilize lean principles to reduce and eliminate waste.

Going lean isn't easy and requires an organization to gain commitment from the entire organization, set reasonable goals and monitor improvements. You need to establish common processes and extend them to a common technology platform. The focus should be on establishing repeatable performance and profitability through customer satisfaction.

Risk

MHRA Looking for Quality Risk Management Systems -- Sound Familiar?

The UK is on to something … British inspectors will be looking for a "risk register" and a defined document management control system including periodic reviews of risk management assessments when inspecting drug manufacturers. It seems both sides of the Atlantic are on board with quality risk management, and for good reason.

The Medicines and Healthcare products Regulatory Agency (MHRA) was set up in April 2003 from a merger of the Medicines Control Agency and the Medical Devices Agency. According to the website (http://www.mhra.gov.uk), the MHRA is the government agency which is responsible for ensuring that medicines and medical devices work, and are acceptably safe. The MHRA is an executive agency of the Department of Health. MHRA defines Good Manufacturing Practice (GMP) as "a part of quality assurance which ensures that medicinal products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorisation *(sic)* (MA) or product specification. GMP is concerned with both production and quality control."

Likewise, the Food and Drug Administration (FDA) says that "good manufacturing practices are a quality system that follows certain basic principles that govern the manufacturing process, documentation, employee training, handling of complaints, and management of records. " They also cite that good manufacturing practices require that domestic or foreign manufacturers have a quality system to do business in the United States. However, the FDA says that the GMP requirements were established to be flexible in order for each manufacturer to decide individually how to best implement the necessary controls by using scientifically sound design, processing methods, and testing procedures. The flexibility encourages the use of modern technologies to achieve higher quality through continuous improvement. (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/default.htm)

Reading through the FAQs on MHRA's website, you can get an idea of what the agency will be evaluating and enforcing in quality risk management. First of all, quality risk management is required. "All manufacturing authorisation holders, third country manufacturing sites, blood establishments, blood banks and active pharmaceutical ingredient manufacturers must have a system for QRM. Inspectors will review the QRM system as part of the Quality Systems section of the inspection (along with complaints, recalls, deviations, and product quality reviews etc) … It is an expectation of Chapter 1 that companies embody quality risk management. "

Companies must have a standard operating procedure (SOP) to describe how they approach QRM. SOPs need to define how the management system operates and its

general approach to both planned and unplanned risk management. The SOP should include scope, responsibilities, controls, approvals, management systems, applicability, and exclusions.

Additionally, MHRA requires a “risk register” or similar document to “list and track all key risks as perceived by the organisation and summarise how these have been mitigated. “ It also requires that a management process be in place to review risk management and incorporated into the quality management review process.

Clearly, the MHRA gave this a lot of thought and the guidance is very detailed. What stands to be seen is whether companies will be able to implement it as well as the requirements suggest. The FDA has seen its challenges with GMP regulations and quality systems. As consumer demand for regulation continues to drive new, more stringent regulations, organizations are forced to look at their quality management systems and ensure that they are following good manufacturing processes. If not now, they will surely be hearing from an auditor from at least one side of the Atlantic.