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Managing Compliance Risks with EAM / CMMS

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With recent changes at the FDA, it is increasingly important for Life Sciences companies to fully leverage EAM/CMMS software to manage compliance risks. This white paper will take an in-depth look into asset-related risks and the recent trends surrounding FDA inspections and product recalls. In addition, it will cover industry best practices for managing compliance risks with EAM/CMMS software.

Asset Related Compliance Risks

Equipment and instruments touch each aspect of a product throughout the manufacturing process. These assets are a critical component in determining the quality of the product in each stage of the manufacturing process from raw ingredients to final form including packaging and shipping.

In addition, assets are capital intense to purchase and maintain overtime. Facilities constantly need to increase the utilization and uptime of their assets in order to drive the highest return on investment.

When it comes to compliance, equipment and instruments are highly visible to inspectors and investigators. In fact, the equipment is often seen first during an inspection. An auditor will record the asset number and review it's history later on. Throughout the inspection, the equipment and instruments remain highly visible.

3 Overarching Compliance Risks:

- Risks to product quality and consistency and, therefore, patients and the public - This is the FDA's purpose
- Risk to the safety of personnel as a result of equipment failure
- Risk to the environment through the release of chemicals/drugs into the air, water and soil

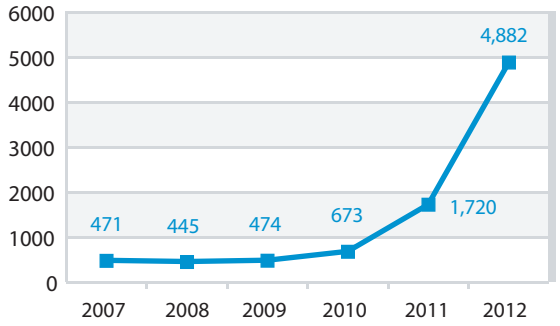
Here are some common examples of the type of compliance risks assets can pose:

- Risk of operating outside of a validated state
- Lack of controlled inventory of equipment
- Past due or missed calibration or PM
- Lack of proper follow up on an out of tolerance calibration
- Lack of proper control of spare parts
- Lack of proper follow up on cleaning / sterility issues

FDA's Focus from 2012 to 2014

The year 2012 was the last year for a drastic increase in the number of warning letters given by the FDA. In 2013, the FDA's budget was reduced, which led the Agency to conduct fewer inspections. With fewer inspections, the number of warning letters produced by the Agency also declined. Furthermore in 2014, the FDA proposed to increase their budget by $821 million in which 94% would be paid through user fees. Despite the proposal to increase the overall budget, the FDA decreased human drug, biologics and medical device programs by $15 million citing that "'these are tight budget times, and the FDA budget request reflects this reality.'"

FDA Warning Letters - Fiscal Years 2007-2012



*Source: http://www.fda.gov/downloads/ICECI/EnforcementActions/UCM346964.pdf

The FDA's website provides a snapshot of information on 483s that were issued during 2014. With a reduced budget on the Life Sciences industry, the FDA focused on these significant areas which were frequently cited as observations:

- Lack of or inadequate procedures - Procedures for corrective and preventive action have not been [adequately] established. - 21 CFR 820.100(a)

- Written procedures not established/followed - "Written procedures are not [established] [followed] for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product. - 21 CFR 211.67(b)
- Calibration/Inspection/Checking not done - Routine [calibration] [inspection] [checking] of [automatic] [mechanical] [electronic] equipment is not performed according to a written program designed to assure proper performance. - 21 CFR 211.68(a)
- Instrument calibration - You did not calibrate instruments or controls used in manufacturing or testing a component or dietary supplement [before the first use] [at the frequency specified in writing by the manufacturer or at routine intervals or as necessary] to ensure the accuracy and precision of the instruments or controls. 21 CFR 111.27(b)
- See more on the FDA's website: http://www.fda.gov/ICECI/Inspections/ucm424098.htm

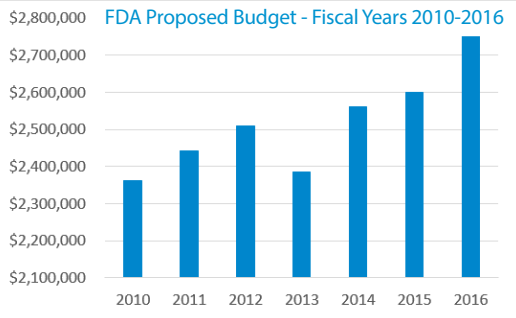
In addition to the frequent observations cited by the FDA, product recalls are also an important and costly result of a compliance failure. In each of the example scenarios, the recalls were voluntary. Most recalls surround product contamination, particulate matter and product sterility. Because of this, there is a huge push for cleaning and maintenance across the Life Sciences.

Here are a few examples of product recalls in 2015:

- "Voluntary recall…due to FDA observations pertaining to aseptic and GMP practices at the manufacturer's site potentially impacting product sterility"
- "Voluntary nationwide recall...The foreign particle was confirmed as human hair free-floating within the solution"
- "Voluntary recall…due to a confirmed customer report of several dark, fibrous particulates floating within the solution of the primary container. The particulate was confirmed as a common non-toxic, non-invasive mold. A loss of sterility is a primary concern when there is a presence of mold in a sterile, nonpyrogenic solution."

A Bigger Budget for the FDA

In the 2015 Justification of Estimates for Appropriations Committee, FDA Commissioner Margaret Hamburg requested a budget of $4.7 billion, an increase of approximately $400 million from 2014. With this increase, the FDA is looking to expand foreign inspections and decrease inspections done in the United States by 40%. However, with fewer domestic inspections planned in 2015, the FDA will rely on a risk-based selection model in which companies that have proven high-quality manufacturing and have a history clear of cGMP violations will be less likely to be inspected.



*Source: http://www.researchamerica.org/advocacy-action/research/federal-funding-research/food-and-drug-administration

The Cost of Non-Compliance

It is challenging to quantify the cost of a warning letter from the FDA due to the immense number of variables and intangibles associated with it. Life Sciences companies know that the impact and cost to their company from a warning letter or 483 can be quite considerable.

Here are the top 5 immeasurable costs of a warning letter:

1. Reputation Damage

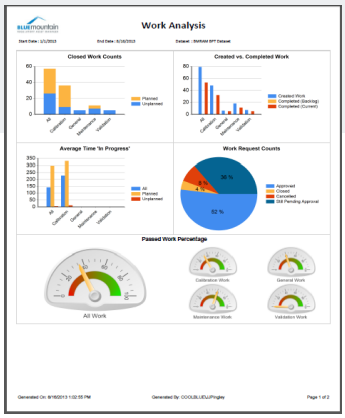
Publicly posted warning letters are the leading cause of reputation damage among Pharmaceutical, Biotech, and Medical Device companies. The news media loves to raise awareness of FDA warnings on Life Sciences companies especially if there is a direct tie from the warning letter to the consumer. Reputation damage as a result of public fear has been seen in numerous and high profile cases in the past. The effects on the manufacturer's reputation are long lasting in the consumer's minds.

Key Metrics for Quality Manufacturing

By consolidating maintenance and calibration in a single application, companies are able to better manage compliance risks. Reporting can help to identify key trends across entire facilities and on an individual equipment basis. While these trends help to improve quality and manage compliance risks, they also aid in balancing investment, so that companies improve product quality, while ensuring adequate return on investment.

Here are some examples of typical equipment analysis metrics, trending reports and KPIs:

- Mean Time Between Failure (MTBF)
- Planned vs. Unplanned Work
- Overall Bad Actor Rating - which weighs unplanned work, failed calibrations, usage, and cost overages
- Past Due Work
- Calibration Interval Analysis
- Lifecycle Cost Analysis
- Average Time 'In Progress' for Maintenance, Calibration and Validation Work
- Time to Complete Work Orders
- Trending Asset Failures
- Asset Maintenance and Calibration Cost Trending



This is an example of a work analysis report that displays completed v. opened work, percentage of passed work and average time in progress for work orders.

2. Competitor Leverage

This goes hand and hand with reputation damage. As warning letters are posted publicly and the news media highlights them, competitors will utilize a company's mistake to enhance their own market position. In the past, competitors have offered free products when their competition receives a warning letter as a means for consumers to make the switch. Warning letters present a competitor with leverage that could forever damage a company and cost a countless number of future sales.

3. Loss of Business

Warning letters can affect contracts, both new and current. The federal and state governments and private companies may not pursue, stop pursuing or cancel current contracts with a company based upon the degree of severity of a warning letter.

4. Stockholder Confidence

Undoubtedly, shareholders will lose confidence in a company that receives a warning letter or 483. If stockholders begin to sell or stop buying company stock, the company will suffer greatly – especially with the loss of potential new shareholders.

5. Workforce Diversion

Another cost that companies typically do not consider is the warning letters / 483's effect on the workforce. Warning letters divert management and other personnel's attention, away from their daily activities, to work to correct the errors and avoid possible litigation.

Since it is so difficult to place a value on the cost of non-compliance, Life Sciences companies should turn their focus to understanding the types of observations that can impact their company.

FDA's Office of Pharmaceutical Quality

The Office of Pharmaceutical Quality (OPQ) will be used to carry out the FDA's long term plan to establish a uniform quality program for drug manufacturers. The OPQ's oversight will include both domestic and foreign facilities with the overarching goal to shift the mindset of pharmaceutical manufacturers from meeting compliance to developing quality drugs.

In order for the FDA to continue to regulate an ever-increasing number of both foreign and domestic products given their budget constraints, the Office of Pharmaceutical Quality will work to define a process for uniform oversight of new drugs, generic drugs and OTC drugs. With a single, team-based quality assessment, the FDA will be able to efficiently inspect facilities and ensure that quality drugs are available.

In addition to the constraints that the FDA is facing, there are a number of long term goals the Agency is looking to implement. The FDA wants to create a marketplace in which companies focus on manufacturing quality products rather than meeting regulations. This is a subtle shift in thinking but will result in manufacturers creating better treatments for patients. With a focus on quality, it is even more important to carefully manage compliance risks by leveraging EAM/CMMS applications.

To shift focus to quality, the FDA has proposed a new set of inspection techniques. Uniform drug manufacturing oversight means that rather than just 483s and warning letters for companies that violate regulations, the FDA will provide a full scale assessment of product manufacturing and rate the facility for each inspected area based on 6 different scores. According to FDANews, the 6 proposed scores include: critical failure, major failure, minor failure, acceptable, exceeds, and superior.

These six scores give the FDA the ability to recognize manufacturers with superior quality. Scoring also provides a way for the FDA to compare facilities on a standardized scale – a new factor in their risk-based inspections. The FDA will also consider if a facility is meeting GMP compliance, has previous violations, and their ability to respond. Companies who play an active role in quality and who have a history clear of GMP violations will be less likely to be inspected by the FDA.

Purpose Built EAM / CMMS for Life Sciences

There are many full-feature and/or modular ERP systems that provide asset management functionality. An all-encompassing ERP system is often sought out by corporate executives, and while it may deliver a full view of an organization, it will not provide best-in-class maintenance and calibration functionality that drives compliance and productivity. End users will sacrifice specific features that would have otherwise accompanied asset management software designed specifically for GMPs. It would also be significantly costly for companies to build work-arounds in ERP or generic EAM systems.

A purpose-built system is developed from the ground up to serve the needs of the Life Sciences – starting with compliance. The future road map of any truly purpose-built software should also revolve entirely around the needs of the industry. The company outside of the product should understand the challenges of the industry and work to further study how they can improve their product to better meet their customers' needs.

Most purpose-built GMP asset management systems come with out of the box functionality that provide immediate benefits. In terms of compliance and the FDA, it is vital that the EAM/CMMS was built from the ground up to support electronic signatures (21 CFR Part 11) (which will aid in going paperless down the road) and an audit trail of all changes made to an asset, work order, or another record stored in the EAM. These two functions are among some of the most basic, core needs for GMP facilities.

An EAM / CMMS also needs to be validatable. In this area, it is important to purchase from a vendor who has experience installing their software in regulated industries in which validation is a requirement. The vendor can support validation efforts by providing services to perform IQs, OQs & PQs accounting for any customizations made in the configuration process. It will benefit a company far down the road to have a reliable vendor that can aid in re-validation efforts and minor configuration changes.

EAM Functionality to Manage Compliance Risks

There are two important factors to note surrounding EAM/CMMSs in GMP environments:

- Compliance requirements can be costly and time consuming – during initial configuration of a software and on-going usage.
- Maintenance and calibration work should be streamlined and simplified for technicians.

This is where a purpose-built solution will provide significant ROI for an organization, because it is packaged with functionality that drives productivity, while providing necessary tools to manage compliance including customizable workflows with e-signature capability.

Here are a few examples of functions/concepts that can be used to manage compliance risks with EAM/CMMS software:

1. Paperless / Mobile

Compliance risks are greatly reduced by going paperless and utilizing mobile devices. This is because data entry is streamlined. Technicians are no longer hand writing details on work orders and then typing them into the system at a later time. Safety checks are in place to catch mistyped data and alert the technician of potential mistakes. The technician can provide an immediate e-signature verifying that the work order is completed and transition it to a review state to be approved. Paperless and mobile devices reduce errors, prevent lost work orders, and ensure that everything is completed and approved in a timely manner.

2. Reporting

Reporting is also a key component in the management of compliance risks. Common compliance based reports include audit trails, calibration trending, reverse traceability and past due event reports.

3. Non-Conformance Workflows

In the event that a calibration fails, the EAM/CMMS needs to immediately trigger a non-conformance report (NCR) and alert the proper department to follow up with the NCR. Management can clearly and easily review NCRs making sure they are completed.

4. Change Control

The ability to track change controls is vital in managing compliance risks. EAM/CMMS software will record sign-offs and store details of the change request.

5. Like-for-Like Parts

An EAM/CMMS will track and manage like-for-like spare parts so that technicians are not undergoing a change request each time they are required to replace a 'low-risk' part.

6. Global Solution & Integration

Another key component in managing compliance risks with an EAM is the standardization of maintenance and calibration across an organization. The FDA wants to see consistency across all facilities. By utilizing a purpose-built EAM/CMMS application globally, companies will not only satisfy the FDA, but will also drive quality manufacturing. Siloed facilities are eliminated – which increases sharing, learning and process consistency across facilities / managers. In addition to using a multisite EAM/CMMS, it is also vital to integrate with other applications, such as MES, LIMS, ERPs, etc., to improve compliance.

Conclusion

With the FDA's drive for quality manufacturing, companies in the Life Sciences industry should utilize best-in-class maintenance and calibration software to manage compliance risks. The cost of non-compliance can be significant and also, unpredictable. This leaves GMP manufacturers with the constant challenge of balancing reasonable investment with compliance. Purpose-built EAM/CMMS software will satisfy this balance by providing the necessary functionality to both manage compliance risks and drive productivity.

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About Blue Mountain Quality Resources

Blue Mountain Quality Resources is the leading developer of industry standard asset management products and services—designed exclusively for the Life Sciences industry since 1989.

The company's Blue Mountain Regulatory Asset Manager® was the first regulatory asset management system, designed specifically as a harmonization of calibration, maintenance and validations systems into a single comprehensive solution for Life Sciences companies.

For more on products and services available from Blue Mountain Quality Resources call us at 800-982-2388, email us at bluemountain@coolblue.com, or visit www.coolblue.com.

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