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Driving Down Compliance Costs with EAM

Multisite EAM / CMMS

Multisite asset management software is in growing demand in the Life Sciences industry. Companies are looking to gain a detailed and standardized view of their facilities in order to drive corporate efficiencies and to meet the industry demands mentioned in this white paper. Multisite CMMSs and EAMs allow companies to standardize maintenance and calibration across all facilities. In addition, multisite software provides a foundation in which companies can improve processes and procedures that will drive down the overall cost of production, labor and compliance.

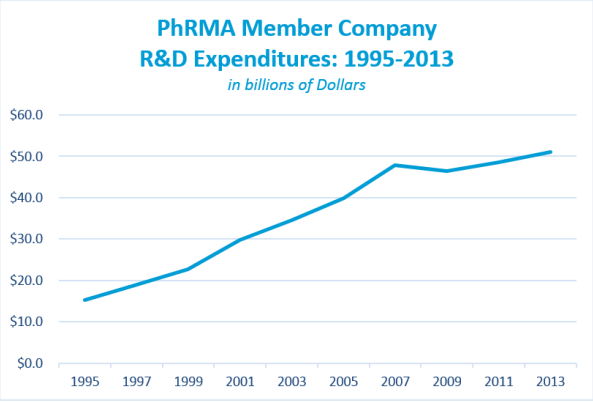
Evolving Industry Landscape

Organizations across the Life Sciences are experiencing the need to adapt and progress as a result of an ever-changing industry. These trends in the Life Sciences industry are driving an overarching need for companies and their facilities to 1) continuously increase productivity, 2) drive lower production costs and 3) balance GMP compliance with investment.

Here are 4 significant industry trends in Life Sciences:

1. Massive Industry Growth

Across industry segments including pharmaceutical, biotech and medical device, there is a significant amount of growth and investment. A strong representative of industry growth is the increasing amount of R&D spending from 1995 to 2013 represented in this PhRMA graph:



Src: Information and Graph from PhRMA. Visit them online http://www.phrma.org or http://www.phrma.org/sites/default/files/pdf/2014_PhRMA_PROFILE.pdf

2. Expanding Global Competition

Another significant trend in the Life Sciences industry is globalization and an increase in competition among domestic and foreign companies. This trend is best represented by the compound annual growth rate (CAGR) from 2002-2009 of import shipments of FDA-regulated products:

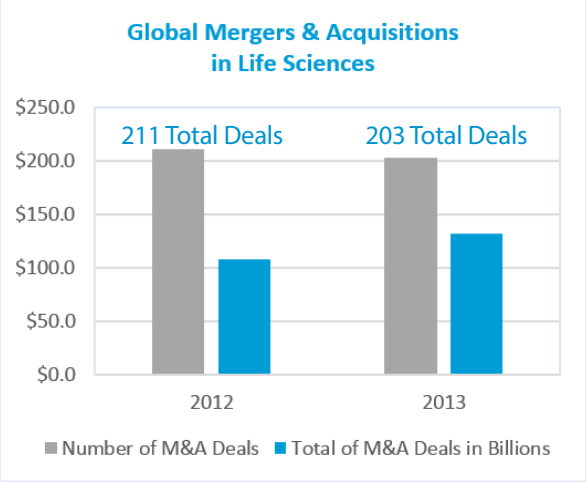
Import Shipments of FDA-regulated Products

Category	CAGR (2002-2009)	Description
Drugs	12.9%	• Prescription and OTC drugs for human use
Devices	20.8%	• Medical devices for human use • Products that emit radiation (e.g. microwaves, laser, x-ray machines)
Biologics	15.8%	• Blood products, vaccines, tissues for transplantation

Src: FDA http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/GlobalProductPathway/UCM262528.pdf

3. Frequent Mergers and Acquisitions

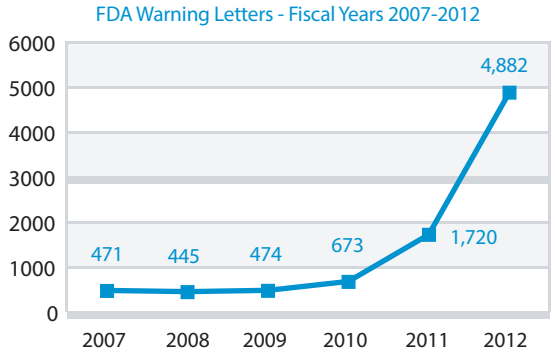
There is an overwhelming trend for some companies to diversify and others to consolidate through mergers and acquisitions. This trend is mainly a result of other trends such as global expansion and massive industry growth . These trends are forcing companies to be more productive and compliant while lowering operating costs. However, aside from the cause of this trend, it provides its own distinct pressures in the Life Sciences industry. The following graph from Marie Daghlian of the Burrill Report displays this growth:



Src: Burrill Report http://www.burrillreport.com/article-global_life_sciences_ma_deal_values_hit_131_8b_in_2013.html

4. Tougher FDA Enforcement

The final industry trend is a growing demand to improve manufacturing quality and compliance as a result of aggressive FDA activity. The FDA has heightened inspection techniques and levied a larger number of consent decrees and warning letters. This graph from the FDA website of the number of warning letters given each year highlights enormous growth from 2011 onward:



Src: FDA http://www.fda.gov/downloads/ICECI/EnforcementActions/UCM346964.pdf

The root cause of these trends boil down to an overall need for facilities to be as efficient as possible in order to remain competitive. However, even with consolidation and pressure to reduce costs, organizations across the industry are making investments into their facilities.

8 Internal Drivers for Multisite Asset Management Software

With a full range of industry trends from an increase in FDA activity to growing globalization, many companies are reviewing their need for multisite asset management software. There are eight specific internal business drivers that cause companies to merge disparate EAM/CMMS systems into multisite applications.

1. Eliminate Siloed Departments

Facilities are not able to share information with each other when they are not using a standardized application. With the desire for each facility to share knowledge and processes with one another, it is essential that they are using the same software. This will facilitate communication on a common basis.

2. Provide Scalability

With a multisite application, scalability is streamlined. In order to meet increasing demands for productivity, organizations need to easily on-board new employees and facilities. Multisite software allows companies to leverage a single implementation or configuration across all of their facilities allowing for instant scabaility and business growth.

3. Increase Effectiveness

Knowledge sharing is one of the most important aspects of driving efficiencies within a corporation with multiple manufacturing plants. Management needs to communicate effectively between departments and facilities. With enterprise software, the ability to share is simplified because key performance indictators, reports, processes and configurations can be standardized. With a multisite EAM or CMMS solution, managers have the ability to communicate over common processes and metrics which allows them to learn from one another and improve the effectiveness of their maintenance and calibration programs.

4. Gain a Centralized View of All Facilities

From a management perspective, it is challenging to drive improvements when manufacturing plants use varying software for maintenance and calibration. Furthermore, it is difficult to gain a single, consolidated view of facilities. Enterprise asset management software can reveal KPIs and

Choosing a Multisite EAM/CMMS
Factors to Consider

Purpose-Built Software

- Feature set focused on meeting specific needs of an industry
- Reduces number of unnecessary features which reduces overall cost
- Eliminates work arounds that come from using generic software
- Web-based software decreases validation efforts and cost

Business Process Review

- Provides opportunity to improve processes prior to selecting a new EAM

Extending Functionality

- Identify new areas of functionality that may not have been part of the original scope
- Analyze benefits of consolidating software applications used across an organization into a single solution

Implementation Styles / Types

- Even though multisite software runs as a single application, there are a number of styles and types of implementations to use so the EAM meets multiple facilities' needs
- Shared or Individual Configurations?
- Shared or Individual Functionality?
- Custom or Template Approach?

Scalability and Server Requirements

- Choose a system that will provide adequate scalability
- Consider corporate IT structure or using a private cloud

Purpose Built for Life Sciences - Workflow Example

metrics across an organzation which allows management to pinpoint common issues and trends.

5. Integrate with External Systems

In order for a company to improve effectiveness and compliance, they need an multisite maintenance and calibration application that will integrate with external systems such as an ERP, LIMS, MES or parts management system. Integration will streamline and standardize all business processes, enforce consistency and reduce human error across applications. Integration plays a role in gaining a centralized view of your facilities. By integrating an EAM system with other external systems, organizations create the necessary interaction so that facilities work together successfully and efficiently. In addition, integration streamlines overall business processes and communication among departments involved in product development.

6. Standardize Workflows and Processes

Multisite asset management software will drive consistent workflows and processes throughout an organization's facilities. This, in the end, will streamline processes and drive down the cost of compliance.

7. Improve and Lower Compliance Costs

The FDA expects consistency across facilities within an organization. They have demonstrated this in recently issued multisite 483s/warning letters. A multisite software solution will provide the necessary consistency in workflows and processes to drive compliance and satisfy the FDA. Integration with external systems such as an ERP, MES, LIMS, parts management, etc. is also an important factor in providing consistency across facilities and applications.

8. Reduce Validation Costs

By sharing software across facilities, companies drastically reduce the cost of validation. With multisite applications, validation is only executed on a single application and can be utilized across facilities. Rather than validating individual software at each facility, companies only need to validate minor configuration changes.

At the foundation of the internal business drivers lies the overwhelming desire for management to meet the demands of industry trends through the improvement of quality, compliance and other manufacturing areas. A multisite asset management application (EAM or CMMS) is an essential tool to drive success and standardized processes.

Organizational Impact of a Multisite EAM / CMMS

Multisite EAM/CMMS software directly influences an organization's ability to drive down compliance costs by increasing productivity and profitability through a standardized platform. When discussing the impact of multisite software on an organization, it is also important to consider varying implementation styles.

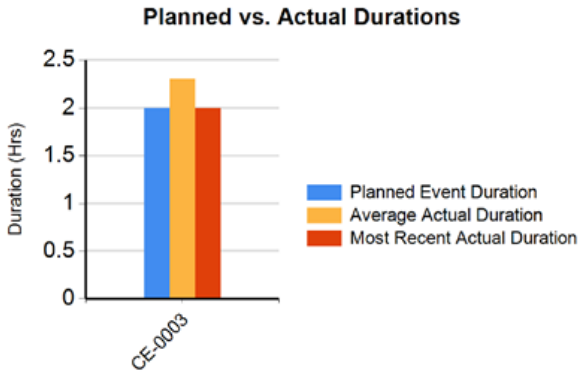
Here are two common examples of implementation styles:

- Companies can implement an EAM/CMMS at one facility with a rollout plan for other facilities
- Companies can implement an EAM/CMMS at all facilities at once and rollout additional functionality over time

In either scenario, an initial facility carries the brunt of the cost to implement the software. As more sites come on board to use the asset management program – whether is all at once or over time, the cost to implement is reduced per additional facility. This is one of the largest impacts of implementing a multisite asset management solution. Sharing software across an organization aids in diluting the initial investment as new facilities are added to the implementation. This will significantly increase the overall return on investment. Rather than paying for numerous and disparate asset management solutions, a company pays once for software & licenses, etc. and minimal cost thereafter to bring each facility on-board with a multisite EAM/CMMS application.

Aside from the benefits associated with cost savings, there are numerous other returns that stem from implementing an EAM/CMMS across an entire organization. Listed are a few of these benefits and the impact they have on an organization:

- Standardized control of maintenance, calibration and validation across facilities in your organization
- Standardized data collection across all facilities which provides real-time metrics



This chart is an example of real-time metrics that can be generated

- Real time interoperability with external applications such as MES, LIMS and ERPs
- Eliminated need for multiple IT systems
- Reduced compliance risks with standardized control of maintenance, calibration and validation
- Improved productivity in each facility and in corporation as a whole
- Improved manufacturing quality across organization with NCR and CAPA traceability
- Eliminated siloed facilities – which increases sharing, learning and process consistency across facilities and managers
- Reduced production costs across the corporation (as a result of increased equipment lifecycle, less downtime and scrap)
- Increased corporate visibility – data from each facility becomes easily available to upper management, other facilities and additional software since it is accessed in a central application and integrated into supporting programs

Conclusion

The list of organizational impacts in the previous section is not an exhaustive list but gives an overall sense of the impact that multisite EAM/CMMS software can have on a company. Overall, these impacts lead to an increased operational efficiency throughtout the organization.

In addition, the benefits of multisite EAM/CMMS satisfy the industry trends and internal business drivers that companies are experiencing in the Life Sciences industry. This happens by ensuring the productivity and efficiency of maintenance and calibration departments. Mostly, going multisite with an EAM solution or selecting an EAM that will be implemented across facilities will provide a clear view for management to gain perspective and measure the performance of each of the facilities with common processes and metrics.

Ultimately, all of the benefits and ROI gained from implementing a multisite EAM/CMMS lead to an improved competitive edge and reduced compliance costs.

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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PO Box 830, State College, PA 16804-0830