



➤ Unique Needs of Contract Manufacturers

Unique Needs of Contract Manufacturers

Contract manufacturing organizations (commonly referred to as CMOs) in the Life Sciences industry are in growing demand. As a contract manufacturer, you have a unique set of needs when it comes to asset management specifically focused around equipment maintenance, calibration and validation. In this whitepaper, we outline these unique needs when it comes to selecting an EAM solution.

3 Industry Trends Driving Contract Manufacturing

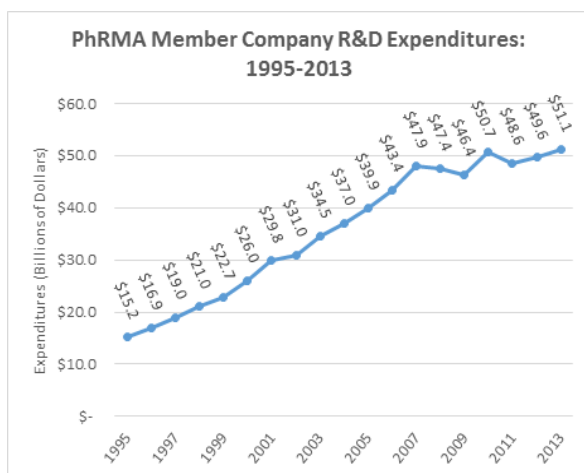
The growing demand for contract manufacturing is a result of a combination of 3 trends in the Life Sciences industry. As a whole, this industry is experiencing significant growth in the midst of new laws and regulations and an increase in competition from foreign manufacturers. Here are the 3 industry trends driving contract manufacturing:

1. Lower Production Costs Remain Key to Success

Foreign imports of FDA regulated products have tripled between the years of 2000 and 2010. With an increase in globalization, there is significant growth in competition among Life Sciences companies. Contract manufacturers provide a low cost alternative to in-house manufacturing.

2. Industry Growth Demands Scalability

Across industry segments including pharmaceutical, biotech and medical devices, there is a significant amount of growth and investment. Industry growth leads to a need for scalable contract manufacturing. A strong representative of industry growth is the increasing amount of R&D spending between 1995 to 2013 represented in this PhRMA graph:



Source: http://www.phrma.org/sites/default/files/pdf/2014_PhRMA_PROFILE.pdf

3. Increasing FDA Activity

The final industry driver is the increasing demand to meet GMP compliance and manufacture quality products as a result of aggressive FDA activity. The FDA has stepped up inspection techniques and levied a larger number of consent decrees and warning letters. Many Life Sciences companies are looking to contract manufacturers to manage GMP compliance within their production cycles.

While all three of these industry trends present a unique set of demands, there is one common factor among them - the need for companies to outsource manufacturing. Contract manufacturing organizations are key to Life Sciences companies' success. CMOs aid companies in meeting these industry demands by offering scalable manufacturing (often at a lower cost than in-house), consolidation of factories and management of GMP standards and also, to a degree, FDA audits.

CMOs manufacture products for many customers, each with unique requirements. Each of their customers expect them to deliver the highest quality in their manufactured products while maintaining compliance and reducing costs.

What Makes CMOs Different from Life Sciences Manufacturers?

When it comes to a contract manufacturer's facility, there are two distinct differences that define the specific needs of CMOs over other Life Sciences companies. These factors include that CMOs serve multiple customers and live in a highly competitive landscape.

Serving Multiple Customers

Typical Life Sciences companies may manufacture many product lines and generally over a long period of time. Contract manufacturers, however, produce many product

lines for many customers in a short term period – meaning that their facilities and equipment structures change frequently. Equipment configurations can change from batch to batch and from customer to customer. This is why it is important to have a single system that allows for tracking production equipment and instrumentation at the individual batch level. This requires a CMMS or EAM designed for the task. A CMO may have hundreds of batches with many customers over the course of time.

Serving multiple customers require:

- Comprehensive equipment lists including availability, design capability and performance characteristics of equipment – Equipment lists are used to work with customers in designing their processes and also for marketing purposes.
- Complete history and status of equipment used for each batch - The information is typically referenced in the batch record and therefore GMP-centered.
- Recipe and Batch Automation – The ability to create snapshots of equipment layout, configuration and usage for any given time. Many companies integrate the data within the electronic batch record.
- Software to Support Streamlined and Frequent Audits - Contract manufacturers need fast access to equipment records and audit trails during both FDA and frequent Customer audits
- Tracking of Equipment Configurations including
 - Frequently Changing Physical Locations
 - Control System Parameters - Version/Recipe
 - GMP Change Control
 - Equipment Traceability - where used - lot, batch, etc.

Highly Competitive Landscape

The Life Sciences industry as a whole is very competitive, however, when it comes to contract manufacturing having low operating costs and competitive prices means the difference between thriving and going out of business.

Highly competitive landscape requires:

- Need for purpose-built asset management software – CMOs need a solution that delivers maximum value for their given requirements. When it comes to an EAM or CMMS, contract manufacturers need a purpose-built, scalable and fully functional system to meet all of their unique needs.
- Maximizing ROI within both the Software and Facility – Contract manufacturers look to utilize software functionality for maintenance and calibration while maintaining product quality. This includes functions such as harmonizing maintenance and calibration, workflow automation, embedded documents, paperless and mobile device usage.
- Extending Equipment Lifecycle – One significant way to lower product costs is to extend the equipment lifecycle. This can be done through spare parts management and improved maintenance and calibration scheduling and execution.

Unique Needs: Purpose-Built EAM & CMMS

CMOs serve multiple customers in a highly competitive landscape. This creates a list of distinct requirements when it comes to selecting and using an enterprise asset management solution.

A big component in the selection process is whether the software is purpose-built for the Life Sciences industry. Purpose-built software is not loaded with unnecessary or unrelated features, but instead, includes a number of features that specifically target functions and needs of contract manufacturers. The chosen enterprise asset management solution should assist CMOs in serving their many customers and remaining competitive.

Below is a list of the needs of CMOs and what to look for in an enterprise asset management (EAM) or computerized maintenance management system (CMMS).

6 Unique EAM & CMMS Needs of CMOs

1. Complex Equipment Lists

CMOs need a robust facility, equipment, instrumentation management system – driven by the Quality Systems Inspection Technique (QSIT) approach to create and maintain comprehensive equipment lists including availability, design capability and performance characteristics of equipment.

2. Equipment History / Statuses Stored in Batch Records

CMOs need a GMP-centered solution that utilizes processes and lot functions to store history and status of equipment used for each batch in a batch record management system.

3. Recipe and Batch Automation

CMOs need the ability to create snapshots of equipment layout, configuration and usage for any given time so that they can integrate data with electronic batch records.

4. Streamlined and Frequent Audits

CMOs need a solution that maintains detailed audit trails, GMP-centered workflows and powerful reporting capabilities so that they can gain fast access to equipment records and audit trails during both FDA and frequent customer audits.

5. Equipment Configurations

CMOs need a powerful EAM or CMMS that tracks equipment configurations including:

- Frequently Changing Physical Locations
- GMP Change Control and Control System Parameters
- Equipment Traceability - where used - lot, batch, etc.
- Manage Corrective / Preventive Maintenance, Calibration and Validation

With these features, CMOs can cultivate detailed specifications for developing customer processes and marketing their capabilities.

6. Extend Equipment Lifecycle

Finally, CMOs need to harmonize equipment maintenance and calibration, spare parts management, scheduling and work execution functionality to extend equipment lifecycles so that they can drive lower production costs.

Conclusion

CMOs need a solution that delivers maximum value for their given requirements. In order to maximize their investment, CMOs need a purpose-built EAM or CMMS that includes functions such as:

- Harmonized maintenance and calibration
- Recipe and Batch Automation
- Detailed Audit Trails
- Comprehensive Equipment Lists
- Tracking of Equipment Configurations

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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