



From Conception to Completion: Delivering Drugs of the Future

Contract Manufacturing Organizations (CMOs) have long been associated with the global pharmaceutical industry primarily as outsourcing providers of finished medicines. In today's ever changing world of Drug Delivery, the CMO "label" has been extended to include organizations that design, develop and manufacture components and finished devices that deliver medicines. CMOs include those that provide a range of proprietary products such as injection pens, oral actuators, dispensing valve and pumps as well as those who provide bespoke products.

In order to keep pace with the requirements of the pharmaceutical industry and growing competitive landscape, CMOs are adopting lean manufacturing as a way of life.

Contract manufacturing versus in house manufacturing – a changing landscape?

With increasing costs and stricter regulatory restrictions, many pharmaceutical, medical and healthcare companies are choosing to outsource their manufacturing processes to CMOs in order to improve productivity and efficiency. CMOs can provide innovative and value added processes. Further advantages of a small-scale manufacturer are the increased flexibility and reactivity and the ability to converse with the whole supply chain.

Global pharmaceutical market has grown at the slowest rate in this decade and is expected to slow down further. This is being shaped by declining research and development productivity, current global financial crisis, increasing genericization and fewer and smaller blockbusters. In order to sustain growth and shareholder value many companies are driving imperatives focused on investments in new technology platforms, building a presence in emerging markets and enhancing efficiency in operations.

Continuing developments in drug delivery which often involve complex drugs, targeted delivery sites, and "smart" devices for increased safety and compliance are adding to the challenges of today's modern pharmaceutical company. Patent protection, life cycle extension and healthcare reform also play a major role in their ability to compete not only in emerging markets but global markets as a whole.

Pharmaceutical companies have previously discovered that one way to optimize internal company cost and to improve efficiency is to concentrate financial and human resources on the company's long term strategies and process, including drug discovery and marketing, and to outsource non-core processes to companies specialized in effectively providing a specific product or service. An example of successful outsourcing is in the area of analytical testing and product manufacturing services.



Ironically, these are also areas in which the pharmaceutical company has complimentary or parallel experience and resources internally.

In the case of drug delivery devices, pharmaceutical companies often lack the in house expertise to develop and manufacture therefore must look to outsource to a CMO. The CMO cannot only provide a generic or bespoke device solution but also gives them the flexibility to investigate and evaluate multiple vendors and pick from a menu of services.

Device Outsourcing Options

Generally speaking, if a pharmaceutical company is seeking to incorporate a drug delivery device as part of their product portfolio, their primary choices are often limited to a Specialist Device Company or a Contract Manufacturing Organization.

A specialist device company can typically offer a range of "off the shelf" device options which may or may not be customizable for a specific indication, product, or market. Specific examples include pMDI metering valves, pumps, injection pens, auto injectors and a selection of dry powder inhalers.

CMOs on the other hand, have the ability to work directly and often exclusively with a pharmaceutical company to design, develop and manufacture bespoke drug delivery devices. There is, of course, considerable overlap in today's world. Many specialist device companies are utilizing their core skills in plastic molding and component assembly, to expand their service offering toward the production of other drug delivery devices. Equally, traditional CMOs, historically categorized as "custom molders, are building a strong intellectual property product portfolio to compliment their full service offering.

Smaller but not less capable

Unlike the majority of large multinational CMOs, smaller companies are typically privately owned and operated. They have the ability to respond quickly and make investment decisions without limitations and shareholder considerations. There is a true commitment toward open book costing and transparent sharing of information. Many are focused solely on the pharmaceutical or healthcare markets. Success as a small operation within a regulated environment is driving a lean manufacturing and modular approach to resources and capabilities.

Like the pharmaceutical companies, smaller CMOs are driving lean manufacturing and outsourcing to a competitive advantage. Outsourcing for tool construction and assembly equipment manufacture insures specialist choices, lead time reduction and desired value. Other support services such as legal, accounting and even program management can be outsourced to allow overhead reduction and a more direct cost focus.

Partnerships with product design companies coupled with in house experience in design for manufacture means success in meeting overall expectations. A cellular manufacturing approach increases flexibility for both the client and CMO. In that case, neither are tied to existing locations or facilities and modular construction can shorten lead times meaning on demand and on time facilities.

Smaller CMOs have also applied lean manufacturing to supply chain



management. Kanbans, Vendor Managed Inventory, and partnerships with customers and suppliers ensure efficient operations and reduced risk.

Lean manufacturing approach

Lean manufacturing or lean production, often simply, "lean," is a production practice that considers the expenditure of resources for any goal other than the creation of value for the end customer to be wasteful, and thus a target for elimination. Working from the perspective of the customer who consumes a product or service, "value" is defined as any action or process that a customer would be willing to pay for. Basically, lean is centered on *preserving value with less work*. Lean manufacturing is a variation on the theme of efficiency based on optimizing flow; it is a present-day instance of the recurring theme in human history toward increasing efficiency, decreasing waste, and using empirical methods to decide what matters, rather than uncritically accepting pre-existing ideas.

Lean identifies three kinds of wastes, *muda* (waste of time and materials), *mura* (unevenness or variation) and *muri* (the overburdening of workers or systems).

As a relatively small CMO, Presspart supplies both a proprietary line of products and bespoke components and devices. Several examples are shown below to demonstrate the benefits of applying lean manufacturing. Included is a recent turnkey manufacturing project highlighting how the manufacture of a drug delivery device within a lean environment can ensure the product is fit for purpose and meets client expectations for design for manufacture, cost, timing and overall value.

Example

The following example represents a typical challenge faced by smaller CMOs. In order to maintain a competitive advantage many smaller CMOs are running lean throughout the organization including a balance of resources and a critical mass to undertake major projects. Others do not have the specific resources or skills in house to deliver capital intensive, complex programs. Presspart was faced with a similar challenge when it was recently awarded the business opportunity to manufacture a multicomponent drug delivery device.

The full turnkey project required the construction of a new cleanroom for device production, the building and commissioning of multiple mold tools and a complex assembly machine, full validation and approval of all processes, components and final product, plus a complete start to finish program management.

Although a major challenge, the project requirements gave Presspart the opportunity to incorporate lean manufacturing throughout the program. A modular ISO class cleanroom was constructed to contain the assembly and metrology operations. The design was such that the mold machines could remain external to the cleanroom with component removal and transport via flow controlled conveyors and cabinets containing six axis robots. This design minimized part damage, reduced energy consumption and allowed for continuous assembly operations especially during tool change over and machine downtime.

Mold tools and assembly equipment were constructed by third parties. External specialists provided additional resources and expertise to assist



with the program management and validation requirements. In the end the project was completed in 12 month to budget and to customer expectations.

Although somewhat simplistic in comparison to a large manufacturing operation, Presspart has demonstrated that application of lean can be done within a smaller CMO and that both client and supplier can realize substantial benefits and increased value.

Future trends

Contract manufacturing can provide a competitive advantage for many pharmaceutical, medical and healthcare companies. Companies that integrate management of CMOs into their business model have the opportunity to reduce capital expenditure and attain greater flexibility.

Increasing product complexity, need for speed and changing market dynamics are just several factors driving outsourcing. Constant pressure to reduce cost and a growing competitive market will continue to prompt pharmaceutical companies to seek the best possible supply options for their drug delivery device needs.

Conclusion

Lean manufacturing represents one of the most favored business programs today. By focusing on using less human effort, fewer inventories, less space and less time to produce high quality products, CMOs can eliminate waste in new product development, manufacturing, supply chain management and distribution. A partnership with a lean CMO, small or large, can cut lead times and investment, increase flexibility and reduce costs. Successfully delivering drugs of the future will require CMO that can develop and manufacture complex devices as efficiently and economically as possible while being highly responsible to customer demand and regulatory requirements.

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