Bigger, Faster, Stronger—The New Fully Integrated CMO

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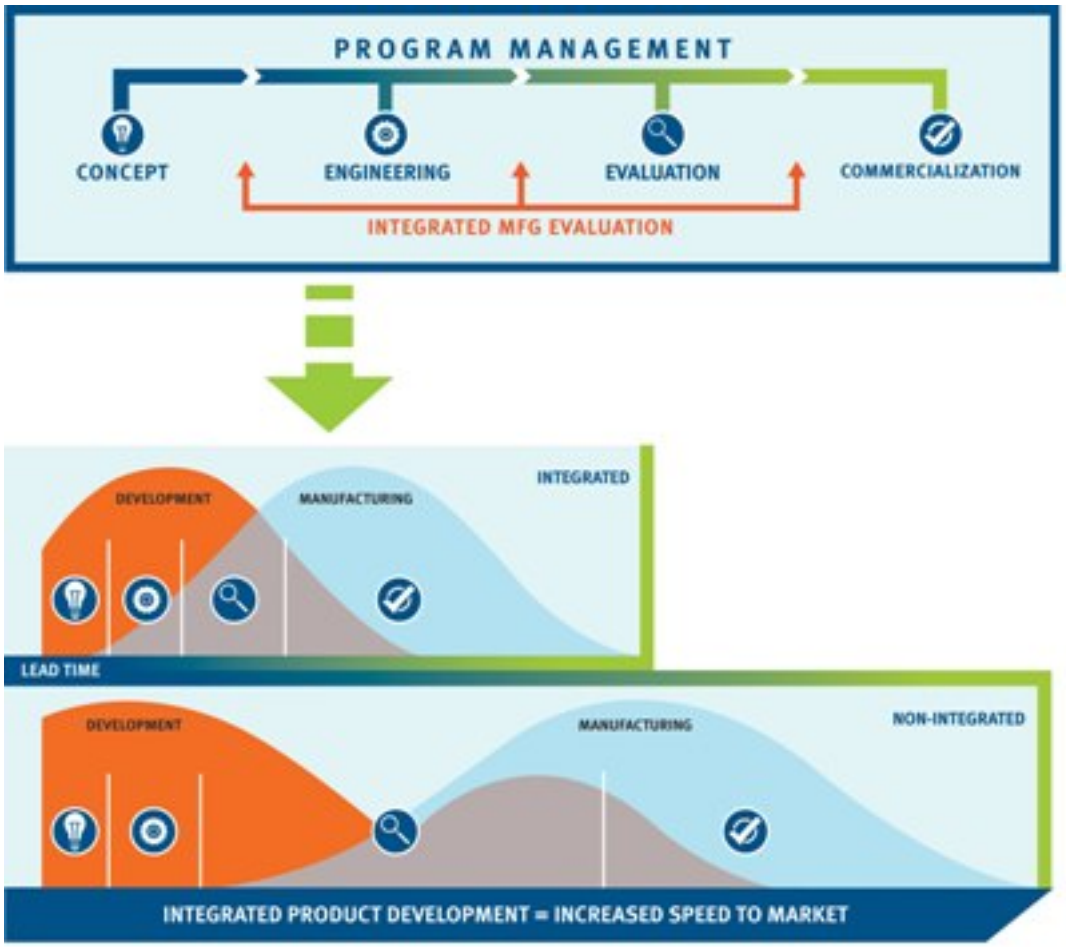
In today's medical device manufacturing space, OEMs are seeing partners who can handle not only the product development and prototyping of their idea, but those who have the ability to take that idea into production and manufacturing. This article looks at the value of working with a fully integrated development and manufacturing partner.



[1]The desire to develop new, innovative products in the shortest amount of time with the least amount of cost has never been more in demand. At the same time, it has never been more difficult due to the ever-changing and increasingly demanding regulatory landscape. Coupled with radical advances in technology and the competitive nature of medical products, developing new medical devices and combination products can seem very intimidating. So how can OEM medical device and pharma companies bring clarity, consistency, and success to the development and commercialization of new medical products? Consider the value of working with a fully integrated development and manufacturing partner (CMO).

Over the past two decades, OEM medical device and pharma companies have increasingly leveraged their CMO partners' development capabilities to reduce overall product development cost, launch risk, and time to market. In the early stages of this trend, the focus was on the CMO's ability to provide component-level DFM (Design for Manufacturability) and prototyping, with the vast majority of product development residing with the OEM or other independent design contractors. The basic rationale behind this approach was to gain early manufacturing insight, leading to increased learning by the CMO and access to the CMO's manufacturing expertise, to enable a smooth manufacturing launch.

Over time, OEMs have continued to expand the range of development services desired from the CMO base. Currently, leading CMOs have increased capabilities to the point of being able to provide turnkey product development solutions with limited OEM oversight. These leading CMOs have dedicated product development centers, with a full, multi-disciplinary engineering staff; a development-oriented quality system with design controls; and complete prototype and clinical build capabilities. Facility infrastructure will often include analytical, mechanical, and electronic testing labs, as well as cleanrooms and modular manufacturing space that can flex to the OEM customer's needs.

These fully integrated CMOs are unique in that their approach to product development is driven

by the vision of the manufacturing process. This approach offers some important benefits:

- Alignment of Objectives—The CMO and OEM both have a vested interest in a robust product design reaching a validated production state in the shortest time possible.
- Supply Chain Management—It is more efficient for an OEM to manage an integrated development and manufacturing partner than to manage multiple niche providers.
- Effective Configuration Management—The same development team can facilitate and manage the PSM, UFMEA, DFMEA, PFMEA, and DV.
- Interaction Management—An integrated development and manufacturing partner is able to provide expertise on component-level DFM, system-level DFA (Design for Assembly), and understanding of interactions between components in the assembly and in-field usage.
- Quality Up Front—Increased focus on acceptance criteria earlier in the development cycle, resulting in fewer surprises in manufacturing.
- Early Manufacturing Strategy Development—The fully integrated environment promotes creating a strategy around building product at the earliest possible time, with the phase-appropriate level of process development and manufacturing equipment. This approach embraces the philosophy of “Fail Fast. Build and Test, Early and Often.”
- Integrated Cost Management—Product costs as well as capital equipment and tooling costs are evaluated throughout the development cycle to ensure that overall COGS is in check.
- Early Manufacturing Involvement (all the way back to concept development)—Required to truly influence the design for low risk, cost, and time to market.

Eight Simple Questions to Ask When Evaluating Your CMO Partner’s Product Development Function

1. Does a dedicated development function exist within the CMO?
2. How many people are dedicated to product development? Into which capabilities are the people deployed?
3. Does the development function have its own engineering, facilities, and equipment to support your full product development needs, including clinical builds, rather than having to schedule resources within a production facility?
4. Does the CMO have an effective Program Management function to serve as your single point of contact, managing activities throughout development and into production, or will you be expected to manage multiple area leaders and contact points?

5. Does the development function have a quality system to support your program, including Design Controls if applicable?
6. Does the CMO utilize a stage gate review process to ensure critical elements are being monitored such as user requirements, product specifications, product pricing, and manufacturing capital costs?
7. How well integrated are the CMO's development and manufacturing capabilities to ensure early manufacturing involvement?
8. Does the CMO have expertise in both the development and manufacturing of your product type?

Fully harvesting all of the benefits listed can be difficult even in a fully integrated manufacturing firm. One way these companies increase consistency and success is with well-trained program managers. Successful device development requires program managers that understand the product development process as well as critical manufacturing principles. To further optimize the integrated development process, program managers will pull/manage activities from development through production.

Each OEM must decide what level of partnership works best with its unique structure, internal capabilities, and growth plans. Some are committed to internal product development, and require only DFM and prototype services, while others seek full service partners to enable development of more products while maintaining current staffing. In either case, the full service provider should be flexible enough to integrate based on the OEM customer's desired level of service. The provider should also be able to integrate with 3rd party design and engineering firms that may also be partnered with the OEM customer on a complex program.

Conclusion

Before continuing down the existing status quo path to development and commercializing in a highly regulated environment, think about the importance of the following two questions: "How critical will it be for my company to hit the master schedule?" and, "How important will it be to adhere to the project budget, including both product and capital costs? If these questions rate high on the list of critical measurable objectives, it may be worthwhile to place increased due diligence around understanding how an organization can leverage fully integrated CMOs. Industry has shown that this can be a value-added and efficient approach to increasing the number of innovative products to a company's portfolio.

For more information, visit www.phillipsmedisize.com [2]. [2]

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