

The Right Idea

Inhalation device manufacturing requires a specific skillset, so a pharmaceutical company must do its homework to establish the ideal solution provider for its product

When pharmaceutical companies look for a manufacturing partner for their inhalation device, they not only need someone who can work by the exacting standards of the industry, but also a company that can maintain flexibility and creatively problem-solve to meet their needs. At the same time, the manufacturing partner must remain adherent to good manufacturing practice (GMP) controls.

This search for a partner who can be both flexible and exacting takes place within a changing landscape for pharmaceutical manufacturers. As hundreds of new pharma companies are being founded around the world with backing from bioscience entrepreneurs and venture capitalists, these companies face manufacturing challenges that are very different from those seen by a more traditional pharmaceutical company. Even within traditional firms, reductions in research and development budgets are changing approaches to business. Companies are searching for partners who can help them fill the gap with tasks that have previously been handled internally. Therefore, contract manufacturers must adapt their practices to serve the needs of both of these very different clients. Pharmaceutical companies, meanwhile, must seek manufacturers who have proven themselves able to adapt to a variety of needs and challenges. Even when a project seems straightforward from the outset, unexpected hurdles can quickly cause complications, and the experience of an expert manufacturing partner can prevent the project from being derailed.

But how should pharmaceutical companies identify manufacturers

that can help them tackle unforeseen challenges? Fortunately, there are characteristics that can help identify a manufacturing partner that can provide the breadth and depth of services that are needed in today's climate.

Outcome-Based, not Process-Based

High on the list is a manufacturer's ability to be outcome-based, rather than process-based. In the development of a new drug product, a manufacturer should be willing to re-examine its standard practices in order to best meet the client's needs. This can take the form of greater flexibility to meet aggressive deadlines, or a willingness to add new technologies to expand manufacturing capabilities. Manufacturers that are too rigid in their adherence to their own process can offer little innovation to a company that is trying to expand or enhance its product capabilities and competitive edge. Companies that are seeking to adapt their drugs for inhalation delivery should be aware that there are often significant challenges in achieving this, but a reliable partner will be able to work with the customer via careful collaboration and process customisation to meet their goals.

Facilities, Expertise and Leverage to Meet Client Needs

A broadly-skilled manufacturing partner should have different facilities to meet the unique needs of the client. While

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Figure 1: A broadly-skilled manufacturing partner should have different facilities to meet differing client needs

commercial sites should be focused on efficiency, service and quality, many clients also have a need for pilot facilities focused on experimentation and quality optimisation. Clearly, while a practice such as Lean Six Sigma (LSS) methodology – used at some commercial manufacturing sites – can be very beneficial in driving efficiencies once a product is commercialised and being mass-produced, such disciplines do not necessarily fit the needs of a company that is just beginning to adapt its drug for a new delivery method, or for a company in an unusual situation such as an unexpected market shock or a failure by another supplier. A manufacturing partner should have the facilities, flexibility and resources to react to these situations, assemble the necessary solutions and deliver on short notice. This highlights an additional advantage of working with a manufacturing partner of significant size and financial stability – pharmaceutical companies can rely on their manufacturer's leverage with suppliers to help address challenges along the way.

In addition to offering facilities to meet the breadth of client needs,



Figure 2: Patient-friendly features such as a dose counter can build brand loyalty and preference

a partner with robust capabilities also can draw on global resources to help scale up or address other challenges in the production process. It can assemble a team of people with diverse experience, providing clients with a deep pool of knowledge. Manufacturers should possess expertise in formulation, state-of-the-art technology, and a deep understanding of regulatory guidelines to deliver the best value in contract manufacturing services.

A Dedication to Maximising Efficiency

As mentioned previously, LSS methodology may not be a practical fit for a product in the development stage, but in the later stages of manufacturing it can be a significant help. A manufacturer that utilises LSS methodology can provide clients with added assurance that its processes

have been thoroughly examined and optimised for efficiency. However, pharmaceutical companies should ensure that a manufacturer is not just paying lip-service to the practice, but rather that it is embedded in the culture, and that key manufacturing experts and team leaders have completed assignments as LSS Black Belts. A manufacturer that has made this practice second nature will offer the best possible value.

In addition to a dedication to efficiency, pharmaceutical companies should seek a manufacturer with experience in design for manufacturability and scale-up (DFMSU). This, too, can help avoid costly setbacks in the development process. DFMSU expertise is something that many pharmaceutical manufacturers cannot provide in-house, leading to delays in scaling up, regulatory approval, and manufacturing at a commercial scale. When a manufacturer can offer expertise in DFMSU from the beginning of product development, the client can be assured of a more economically efficient path forward.

Proactive Innovation

Pharmaceutical companies should seek manufacturing partners who work proactively to ensure their products and processes are robust. Even when a product is successful, design costs and new technologies should be examined on a regular basis to keep up-to-date and reduce design structure. Manufacturers must also strive to improve their efficiency in order to control costs. Applying LSS methodology to guarantee a manufacturing process runs as smoothly as it can helps keep clients as protected as they can be. Steps like this can make a significant difference in ensuring that clients' products stay competitive through their life cycles. A robust manufacturer can also provide value-added services, such as investing its own time in demonstrating feasibility of a product improvement before proposing the solution to the client.

The ability to keep pace with change is another important skill for a manufacturer to demonstrate. Whether a pharmaceutical company has developed a more advanced treatment or is simply looking for assistance in life cycle management of an existing drug, a manufacturer should be adept at responding to and accommodating needs for change. Currently, one of the most important evolutions in the manufacturing process is developing products that are more patient-friendly. Pharmaceutical companies are aware that patients' needs are becoming a factor in the prescription decision, and products that do not differentiate themselves well, or that are not patient-friendly, are having a harder time achieving success. Today's informed consumers are confident in demanding products that fit their lifestyles and meet their needs.

In the realm of metered-dose inhaler (MDI) technology, patient-friendly features such as dose counters and dosing feedback mechanisms not only help patients to stay on top of their dosing and remaining supply, but can also build brand loyalty and preference. Research has shown that patients are seeking simple ways to know when their inhalers should be replaced, and that they respond well to dose counters that help them feel more secure in their device (1). A proactive manufacturer can offer updated designs that take the patient's voice into account and carefully consider the patient's interface with the device. Beyond building patient loyalty, product innovations such as this can also aid in regulatory approval.

Value through Synergy

For many pharmaceutical products, the manufacturing process encompasses much more than the drug itself. The technologies that go into the delivery system can also play a major role in the process. Pharmaceutical companies should consider the complexity of their goals when choosing a manufacturer. For many products,

Figure 3: Working with a manufacturer that can produce both valves and canisters can help ensure a successful fit into the pharmaceutical client's programme

Images: 3M Drug Delivery Systems



companies will be better served by a manufacturing contractor that has additional expertise in technologies such as particle engineering, componentry, hardware design and coatings. With a combination of services under one roof, a manufacturer can provide technical and competitive advantages, and can also work more efficiently with pharmaceutical partners.

In the MDI realm specifically, working with a manufacturer that can produce both valves and canisters can help ensure a successful fit into the pharmaceutical client's programme. When these components can be provided by a single source, the client's hassle is minimised, and they also receive the benefit of the in-house expertise that goes with both components. Furthermore, a manufacturer with robust business in both these areas can help ensure a continuous supply by leveraging a vertically integrated supply chain.

Gaining an Advantage with the Right Manufacturing Partner

Though not comprehensive, these characteristics can help serve as a starting point for pharmaceutical companies that are in search of a manufacturer to help develop their inhalation delivery device. As described, the right manufacturing partner can offer its clients significant added value in terms of expertise, flexibility,

efficiency, innovation and access to broader resources. In the competitive pharmaceutical industry, having a partner that provides these kinds of benefits can help ensure a smooth path for companies looking to enhance or launch their product in the expanding marketplace.

Reference

1. 3M proprietary patient research, 2006

About the author



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