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Right partner is key to combination products

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Right partner is key to combination product development and manufacturing

Extensive project management expertise and logistical control know-how are obviously required when working on a combination product, from the concept stage to its eventual launch. Cross-functional teams from both the biopharmaceutical company and the device supplier must work together for several years to coordinate efforts in a collaborative manner, overcome related challenges and ensure that the right steps are taken. Taking into account the number of biologics coming into the market and the entry of biosimilars, we see an increasing number of biopharmaceutical companies in need of such services provided by a broad number of suppliers and specialists across various geographic areas.

Over the years, a few early-mover biopharmaceutical companies gained valuable experience by producing their own devices, working with the suppliers of devices and by establishing a good rapport with companies providing related services. These early-movers have experienced first-hand the extensive number of pieces within the combination product puzzle that needs to be put together to move forward with a device such as an auto-injector.

Some of the choices that need to be made by the biopharmaceutical company include selecting a suitable primary container, filling supplier, regulatory consultants, human factors engineering (HFE) experts, final assembly integrators, and so on - all vital to the successful launch of your device. And the benefits of bringing an innovative device to the market clearly make the investments of time, finances and resources worthwhile for the biopharmaceutical companies.

Development

Taking a product, such as an auto-injector, from early design towards mass production is a complex process. Development involves several stages such as planning, design, engineering and process validation. As a project moves forward, having both design and development teams in the same company is ideal, but not always possible. For example, mechanical or technical design of the device may come from the device company, but the biopharmaceutical partner may choose to utilize an external industrial design company for appearance of the device. Involving another party may certainly add a new flavor to the uniqueness of the product, but doing so may also slow down the overall development of the device by simply adding to the growing number of voices involved in your project. At the end of the day, there are pros and cons to both approaches.

During the development process a delicate balance exists between providing device design features that fulfil end-user needs and making certain that device design is manufacturable. It is between these two areas that one has to find equilibrium; if they come into conflict with each other, the end-user needs should always have priority over the manufacturing process, so long as it does not affect the safety and effectiveness of the device. Finding a balance is the key. SHL, for example, works closely with customers to develop devices that complement the manufacturing process.

Capabilities

Manufacturing advanced drug delivery devices requires an extensive range of capabilities. Tooling, moulding, automation, assembly and metrology are just a few of the many capabilities that are utilized. While maintaining such capabilities in-house is ideal, in some cases, it is just not practical due to the extensive capital investment that a drug delivery device supplier is required to make. In addition to purchasing and maintaining the required machinery, developing the expertise needed to run this equipment at an optimum level is challenging and takes time. For these reasons, some drug delivery device companies, such as SHL, have followed a staged approach to incorporate key manufacturing capabilities 'in-house' over several years and many suppliers have been forced to accelerate this expansion in recent years due to an increase in orders and a desire to maintain a sufficient level of capacity.

Tooling and automation are two areas that deserve special attention by biopharmaceutical companies as these capabilities are sometimes outsourced by device suppliers. Tooling is a significant expense in any drug delivery device program and lead times must be planned for carefully. For high volume projects, multiple sets of tooling are needed for production, safety stock and risk mitigation.

Final assembly

Once the sub-assemblies of a device are produced, the next step is integrating them with the biologic-filled primary container to create a completed combination product. Biopharmaceutical companies basically have three options to consider at this stage: do final assembly themselves, outsource to a third-party, or find a drug delivery device partner that can provide this service.

In response to customer requests to provide final assembly of combination products, many device suppliers, including SHL, offer final assembly, labeling and packaging services for devices to pharmaceutical and biotechnology companies. In the case of SHL, a specialized company, SHL Pharma, was established, streamlining the production and distribution process for SHL medical products and improving end-product quality and speed-to-market for customers.

From a quality and regulatory point-of-view, final assembly facilities should be ISO13485 certified and registered with the FDA as a drug establishment, qualified to handle and distribute pharmaceutical products. Additionally, they should conform to all other regulatory requirements for medical devices and pharmaceutical packaging and distribution, as per 21 CFR Parts 820, 210 and 211. The staff involved at this level will have both drug and device expertise to help ensure the safe production of the combination product.

In addition, when a project will soon enter the final assembly stage, there are a number of new considerations that also must be addressed, such as types of packaging, labeling, instructions for use [IFUs], inserts and more. Protective packaging not only holds the device for shipping, it helps to protect it if designed properly. Clear IFUs will also help to ensure that end-users know how to use your combination product properly. Drug delivery device suppliers should independently, or in cooperation with external experts, be relied upon for guidance in these areas.

Inspiring integration and the way forward

Enhancing the convenience and ease of administering biologics is a proven strategy for biopharmaceutical companies to augment product differentiation and to compete in an increasingly competitive market. As patients become more familiar with various types of drug delivery devices, they will expect suppliers of these devices to continue to innovate and to take their true user needs into consideration. Biopharmaceutical companies that pro-actively partner with experienced drug delivery device suppliers will be able to ensure that such needs are met and that projects can be completed on time.