Phillips Medisize

Partnerships Built on Innovation

THE POWER OF DRUG-DEVICE COMPANY COLLABORATION

During the Pharmapack Europe Conference (Paris, France) – at 4pm on Wednesday, February 10th, 2016 – Bill Welch, Chief Technology Officer, Phillips-Medisize Corporation, will give a lecture entitled "Integrated Development and Scale-Up of Combination Products". Here, he provides us with a preview of his forthcoming Pharmapack talk.

Many biologic, biosimilar and small molecule drugs need the assistance of mechanical systems for self-administration, ranging from complex delivery devices such as metered-dose inhalers, infusion pumps, injectables and prefilled syringes, to simple delivery devices such as droppers. The trend towards growing self-administration and patient convenience increases the desire for safety mechanisms. From a pharmaceutical company's perspective, this is very important because it helps drive compliance to therapy and improves outcomes for patients. As a result, device development is increasingly focused on innovative devices, in particular smaller and smarter combination products.

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A unique delivery device can also be an important differentiating factor and unique selling point, thus helping in strong brand positioning. However, there are many challenges to creating a successful combination product including regulatory, clinical, human factors and drug/device interactions. Add to these challenges the need to manage complicated supply chain logistics, from design, testing and development through low-volume clinical trial manufacturing and scale-up into higher-volume production for commercialisation. The most minor detail can derail a successful product development effort, resulting in time and resources lost and crucial deadlines missed – potentially causing the product development or regulatory submission to stall before it ever reaches the market.

When product launch success depends upon speed-to-market, drug and device companies benefit by joining forces. Such partnerships can free pharmaceutical and biotech companies to focus on their core competencies, while leveraging their suppliers' existing, proven, regulatory-compliant design ability and manufacturing processes and infrastructure. Tapping into the design expertise of device companies helps pharma companies poise their product project for

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success as early collaboration, from initial design concept phase, allows the device partner to help anticipate potentially problematic areas that can occur during pilot production, clinical trials and eventual high-volume manufacturing.

assists the customer in meeting key delivery and launch dates.

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When the pharma company engages its manufacturer early on in the development process, the need to perform knowledge and technology transfer is eliminated because the supplier is able to understand what can be achieved in, for example, the injection moulding processes and is able to optimise the design for manufacturing or assembly. Furthermore, critical tolerances are fully understood and the exchange of information and data becomes seamless. All of this

facturing/design for assembly (DFM/DFA) as foundations of the combination product development process, followed by the granting of contract manufacturing licenses. An example is the development of the SoloSTAR disposable pen by Sanofi for Lantus (insulin glargine) and Apidra (insulin glulisine). The pharmaceutical company, Sanofi, granted the contract manufacturing licenses to Phillips-Medisize for the pen and involved us in the early design phase.

Phillips-Medisize also has a history of manufacturing complex dry-powder inhalers and has been involved in the development of several different inhaler programmes, including work as the development partner of the first dry-powder inhaler.

In my Pharmapack presentation I will discuss a well-rounded approach for biopharma companies interested in developing and commercialising successful combination products, by highlighting key device development and scale-up activities and their relationship to the overall combination product development process.

Presentation Key Points:

- Smaller and smarter combination products to support the trend toward patient-administered drug delivery
- Integrating HFE and DFM/DFA as foundations of the combination product development process
- Early manufacturing involvement to speed up time-to-market and reduce risk by "getting it right the first time"
- Development of a manufacturing scale-up strategy, concurrent with the development process.