What's the Outcome?

New and improved drugs are released every year and many companies have initiatives to supply them. While proficient in drug development, most of them do not have the expertise required to fully produce a drug delivery device. Instead, they are increasingly looking to external partners for device designs and manufacturing

Bill Welch at Phillips-Medisize

The global delivery of healthcare has become more focused on medical outcomes, achieving results for patients and tying industry incentives to those results. As with any fundamental change in business structure, this is happening slowly and at different rates around the world. The case for change, however, is strong and compelling.

Population growth and rising incomes create further demand for access to healthcare; incidences of lifestyle-related health conditions like diabetes occur more frequently; and technological innovation continues to support increasing targeted disease and associated therapy identification, whether through genetic analysis or the discovery and commercialisation of large molecule therapies like biologics. The value of the ensuing biologics market is forecast to grow by 60%, rising to a value of $291 billion annually between 2014 and 2020.

With a stronger focus on outcomes, it will not be sufficient for biopharmaceutical innovators to only think about the elements of the solution – like devices and connected services, for example – shortly before market launch. A more rounded approach to creating value in healthcare delivery is needed. Tactically, this requires evaluating the system holistically (what results will we deliver, and why?) as well as each strategic element (how will the conclusion be achieved?) at least three years prior to the treatment being made available (before Phase 3). In doing so, outcome delivery and improvements become integrated parts of the answer. It is all part of providing end-to-end solutions that are focused on results, as delivering these will equal income in the future for the industry.

Image: © Phillips-Medisize

An electronic auto-injector

How to Get There

The path to this style of care entails a strong device strategy, creating a delivery system suitable for the intended patient population and drug formulation. This approach considers therapeutic conditions from multiple angles to uncover risks and opportunities in delivery innovation, establishes a development route and produces a device roadmap from trials to market approval, and even includes post-approval enhancements. A comprehensive device strategy balances the company's need for innovation and cost-effective drug delivery systems with the total disease management requirements associated with outcome-based healthcare. From a development standpoint, presence of a defined plan drives direction – from concept feasibility through to production – and addresses the fact that 'me-too' devices do not create differentiation or add value.

Large molecule biologics bring new difficulties to the biopharma industry. One concern is new delivery challenges for patients, which often take the form of self-administered injections. Viscous solutions often need special care to ensure proper dosing. A more complex dose delivery leads to lower adherence rates and, ultimately, reduced patient results. In an effort to enhance compliance and therapeutic outcomes, biopharma organisations are placing more focus on delivery devices, including connected ones to facilitate data sharing between patients and caregivers. For injection systems, this information may take the form of injection speed, dose volume and the date and time of delivery. Connected drug transfer systems enable the patient and caregivers to have a 360° view of both the patient and the disease, to not only manage adherence but improve results by understanding the effect of the regimen.

Strategic Partnerships

During the first 20% of the product development timeline, 80% of a good's cost and quality is often determined. Development programmes that reach market acceptance frequently implement a device strategy that promotes the evolution of connected systems and tools that are useful, usable, desirable and manufacturable. As an example, integrating design for manufacture and design for assembly activities early in the process ensures that the concept will achieve the quality, cost and risk targets established. In this sense, the approach drives a cohesive production plan spanning early clinical trials, validation, supply chain network and volume manufacturing.

Recognising the increasingly integrated nature of drug delivery development, some companies provide device strategies and connected health capabilities. These organisations partner with clients, both large and small, in order to help them uncover innovative approaches and create solid device or connected system strategies focusing on the patient and improved disease management. This is followed by the next phases in the development process. An effective partnership established before the conception of the product assures that a client is well-positioned to provide a rapid, low-risk manufacturing launch by the time the drug is brought to market.

Partnerships that facilitate a smooth transition through each stage have distinct advantages, such as reduced time and cost as well as minimised regulatory and market risk. On the contrary, a disjointed approach marginalises development, presents lurking hazards, isolates strategic design decisions and negatively impacts downstream activities. Furthermore, if manufacturing developments are abruptly introduced at the end of the design phase, it is possible that they will not align with the plan, and these late-stage changes could threaten both stakeholder requirements and programme feasibility. It is important that biopharma collaborators mutually understand the value of device strategy and are committed to connecting the early strategic effort to the intended solution.

Facing Forward

Design development and user considerations, while important aspects to consider, are minor compared to the greater value proposition provided through the committed implementation of device schemes. During the years of growth to come, the biopharma industry will benefit from forming partnerships built on innovation that consider the entire opportunity lifecycle.

The future of drug development is focused on tailored therapeutics centred on a strong delivery device strategy. A forward-thinking collaboration between a drug developer and their companion device development partner that is helping them to offer connected health tools, software applications and infrastructure, as well as a long-term vision of the strategic platform for the drug and its delivery system, will not only strengthen commercial return, but also help to deliver on the promise of outcome-based care.

About the author

Bill Welch has over 25 years of contract design, development and manufacturing experience, primarily serving customers in the drug delivery, health technology and diagnostics markets. In his current capacity as Chief Technical Officer at Phillips-Medisize, he leads a global, over-500 person development, engineering, tooling, programme management and validation organisation with more than 75 concurrent schemes. Bill has been with Phillips-Medisize since 2002.
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