INTRODUCTION
LEVERAGING NEEDS-CHARACTERISATION TO FUEL SMARTER DESIGN

By Mark Tunkel and Craig Scherer

In today's increasingly competitive pharmaceutical marketplace, combination product speed to market is no doubt uppermost in the thoughts of biologics manufacturers. However, today's market dynamic begs for a more strategic approach to innovation based on the sheer number of available options for pharma industry developers to choose from. Companies that make patient needs-characterisation the launching point for development efforts will quickly discover this approach can be vital to navigating these development decisions successfully, and driving patient adoption and healthcare provider prescription rates.

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QUESTIONS OF SPEED & ACCURACY

Being the first to hit the ground running in delivery device development doesn't ensure success. Making development decisions based on timeline alone may get a product to market faster but deliver a sub-par user experience with low adoption. At the same time, layering in too much technology and complexity to compete with competitor product features alone may actually make it more difficult for users to stay on regimen.

At its core, needs-characterisation is designed to help companies strategically define device development plans with the best chance for market success. Beyond the drug, needs-characterisation gives pharmaceutical companies a broader context for not only patient device use and lifestyle, but also that of caregivers and healthcare professionals – all of which contribute to the success or failure of an injectable device.

Needs-characterisation primarily leverages ethnographic research (Figure 1), a qualitative method in which in-context observations are supported by in-depth interviews with both patients and relevant healthcare professional stakeholders such as physicians or nurse educators as part of due diligence to help define the requirements of a device. The deeper level of patient understanding that needs-characterisation offers helps developers understand and define where it is appropriate to integrate technology such as data management and, equally importantly, where it is not (Figure 2). By virtue of its focus and timing, it can lead to demonstrably differentiated devices that are not only safe and effective, but also capable of simplifying what is difficult for patients to manage, destigmatising a disease state, and helping navigate feature trade-offs that drive key patient population demand.

Perhaps the most substantial risk today in delivery device development is not giving equal weight to needs-characterisation from a user perspective as the weight given to a drug, primary packaging, regulatory, or a technical perspective for the sake of making it first to market.

Mr Mark Tunkel
Partner & Business Development Director
T: +1 773 907 9500
E: mtunkel@insightpd.com

Mr Craig Scherer
Co-Founder & Senior Partner
T: +1 773 907 9500
E: cscherer@insightpd.com

Insight Product Development
4660 N Ravenswood Avenue
Chicago
IL 60640
United States

www.insightpd.com

Figure 1: Applied ethnography to evaluate lifestyle influences impacting medication administration.

Figure 2: In-context research to understand the influence of technology on medication administration and larger health management issues.

CURRENT TRENDS FUELLING THE MARKET

There's certainly no shortage of challenges today for pharmaceutical manufacturers. Current trends driving accelerated competition include the sheer volume of biologics expected in the market, evolving perceptions among payers and physicians surrounding combination product efficacy, and the consumerisation of healthcare driving new expectations.

Let's consider the value of leveraging needs-characterisation in response to just a few of these market dynamics in play today:

THE PROLIFERATION OF BIOLOGICS

While growth forecasts vary, there's no question that biologics will at least double their share of the drug market by 2020. Given the promise this drug category holds for myriad treatment indications across disease states, this market trajectory is expected to continue well into the future.

Multiple disease states often represent unique patient attributes and drug delivery challenges. By virtue of their multi-indication nature, the proliferation of biologics also signals the need for a more strategic approach to delivery systems development with user needs-characterisation at its core.

Take for instance a biologic indicated for multiple disease states. Patient needs across each of these distinct disease states might necessitate entirely different proprietary delivery systems to serve each patient group effectively, given their unique physical capabilities and limitations (Figure 3). Conversely, closely examined user needs might dictate the development of a single device that accommodates both patient populations. Decision-making challenges in either instance are further compounded by the large number of commercially available devices from auto-injectors to patch-pumps that claim to work across an array of different parameters.

Of course, companies equipped to develop their own custom delivery devices must also factor in patient complexity when making their selections from the same vast array of delivery options – beyond overcoming the inherent challenges of large molecule drug delivery. In every scenario, a developer must also consider the follow-on biosimilars for these biologics that will also require delivery systems. This final consideration poses unique challenges for incumbent manufacturers, as interchangeability applies to the drug alone – not delivery systems as with other combination products.

THE CONSUMERISATION OF HEALTHCARE

The trend towards large tech manufacturers entering the healthcare space is having substantial influence on consumer expectations for technology's role in helping them manage things beyond a therapy regimen. With both Apple and Samsung now in the market with their Health Kit and Gear Fit consumer health devices and apps, pharmaceutical companies are also tasked with delivering user interfaces and experiences on a par with what people expect from the large tech companies. Needs-characterisation can serve as a launching point for developers to identify meaningful ways to leverage current trends in the consumer space strategically – from the "gameification" of healthcare that utilises incentive-based regimen adherence, to the personalisation of mobile phone health applications – and migrate them to drug delivery.

PHYSICIAN AND PAYER PERCEPTION

Perception is truly reality in matters of therapy decision-making among physicians and healthcare payers. With more than one biologic therapy available for individual disease states, physicians are far less inclined to prescribe those they've received direct or indirect negative patient feedback to. Cumbersome regimens and overly complex feature sets are likely to deter treatment adherence and contribute to unfavourable physician perception and lower prescription rates. Lack of patient

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Figure 3: Observing the impact of physical and cognitive challenges and the limitations for certain disease states.

Figure 4: Examining the impact of patient environment on adherence and disease-state management through patient interviews and observations.

therapy adherence represents a substantial business risk, as an individual patient's treatment regimen can cost tens of thousands of dollars. For payers it's critically important that an injectable delivery device not only performs but also drives patient adherence (Figure 4), thus delivery systems that integrate technology in an effective way toward this end are viewed increasingly favourably.

While direct patient feedback is one source fuelling physician and payer perception, lack of awareness is another. Proactive physician and payer education by drug delivery manufacturers that supports the performance and efficacy claims of new therapies not yet widely adopted is paramount to competing. Across physician and payer audiences, an injectable product's fate in the market is increasingly based directly on user needs, and the delivery device's efficacy in meeting those needs – both real and perceived.

NEEDS-CHARACTERISATION SUCCESSES

Prime examples of effectively leveraging needs-characterisation at the offset of a device development programme come from the start-up world. Both Sanofi's Auvi-Q, an auto-injector for epinephrine, which talks the user through the injection process, and Insulet's advanced miniature insulin pump, OmniPod, demonstrate how a clear understanding of user needs and tailoring the features of a therapy device to serve targeted patient groups can drive market success.

Epinephrine pens were widespread in the market with the same form factor dominated by the same pharmaceutical players for years. The developers of the Auvi-Q epinephrine delivery system – twins Evan and Eric Edwards, were inspired by their own personal experience surrounding epipen usage, and the critical situation that could ensue if one of them were to go into anaphylactic shock in the presence of those that have never administered epinephrine. In response to this critical need, their company developed a portable delivery system the size of a credit card that provides audio feedback to guide epinephrine novices effectively through the process of drug delivery.

Similarly, having experienced the limitations that insulin delivery regimens represent to the highly active segment of the diabetes population first-hand, the developer of OmniPod delivered a paradigm-changing delivery alternative. The system's subcutaneous patch delivery allows patients to manage their insulin therapy through a personal digital assistant (PDA) at a pre-set dosage and delivery rate without worry or involved attendance in effect to eliminate lifestyle interruptions inherent to traditional regimens. By recognising the lifestyle needs of this patient group and understanding the limitations that traditional insulin pumps and injectors imposed on them, the company was well positioned to respond directly with an adherence-driving solution.

Each of these market successes were primarily driven by the key user insights of each developer, underscoring the tremendous value of needs-characterisation in strategic device development.

Making applied ethnography primary to a development program can serve as the baseline for understanding user needs and context that can be synthesised with technology, establish clear options for device delivery and derivations of options, translate those options to functional requirements for robust, producible devices, and ultimately create a roadmap for innovation across entire device portfolios positioned for market success.

Mark Tunkel is a Partner and Director of Business Development at Insight Product Development. With more than 20 years of global business development experience and a deep understanding of the marketplace challenges and trends impacting the pharmaceutical industry, Mark has advised many of the world's leading companies on their product development and innovation strategies with an emphasis on driving realisation and the most favorable business outcomes. Mark holds a BA in Political Science from Indiana University.

Craig Scherer is Senior Partner and Co-Founder of Insight Product Development. Since 1988, he has helped Insight grow into a leading design firm that serves companies globally in a variety of health care spaces. He plays an active role in project management, working with start-ups to the Fortune 50, and has been central to the company's innovations for clients, which have garnered numerous industry accolades. Craig holds a BFA in industrial design from the University of Illinois at Urbana-Champaign, and an MBA from the University of Illinois at Chicago.

Insight Product Development is a design innovation consultancy in Chicago that leverages more than 25 years of professional insights to create strategy that's actionable, technology that's scalable, and design and development that translates into marketable success for its clients in the pharmaceutcial delivery device space.