THE CHALLENGES OF A CHANGING MARKET & THE BENEFITS OF DEVELOPMENT FLEXIBILITY

In this article, David Fink and Sheila Trgovac, both Vice-Presidents, Strategic Development at Ximedica, describe how adopting a flexible development model in mid-to-late development brings benefits through to commercialisation, especially in the context of a changing market.

Today's pharmaceutical industry faces greater challenges to effective drug delivery, including a growing list of novel drugs like biologics, biosimilars and customised therapeutics, as well as the trend towards self-administered treatment. Additionally, the increasing focus on human-centred engineering in concepting and testing delivery solutions is emerging as a high priority driver in the development continuum. If applied successfully, human factors and usability engineering minimise use risk and increase treatment acceptance throughout the development, regulatory submission, and commercial launch stages.

NAVIGATE THE PATH TO MANUFACTURING

Traditionally, a long-term manufacturing strategy heavily influences much of the mid-to-late stages of the development process as it is planned in tandem with the initial commercial launch goal. A high-volume product model driven by commercial demand forecasts justifies this path but can also lead to a significant investment in capital equipment, automated assembly processes and design validation – increasing time to market and delaying revenues. Mistakes made here can be costly, extending commercialisation and further postponing revenue. But, if ignored, these mistakes may drive down adoption and, more importantly, forfeit an optimal treatment solution for patients.

Looking at new therapeutics, a more modest commercial volume forecast – or one that gradually ramps up – provides an opportunity for a less rigid development approach and better accommodates the evolving drug delivery field. Ximedica leverages a powerful ISO-certified quality management system that meets this flexible development strategy.

Consider the stages of development to put this approach into perspective: detailed design, design for manufacturability, verification and validation, clinical trial design and execution, and preparation for commercial launch. With a flexible model, the intent is to reduce risks further, through cycles of testing and iterating designs (e.g. performance, usability, manufacturing and commercial) and ensuring an optimal treatment solution is in place when the drug comes to market. This includes potential reductions in time to market and/or opportunities for market entry in a managed volume path.

FLEXIBLE DEVELOPMENT MODEL

Ximedica frequently employs a flexible development model in the mid-to-late stages of development. For example, in detailed design work, using rapid prototype mould tooling options frequently answers fundamental performance and assembly

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questions. Progressing to more accurate and durable tooling resolves tolerance challenges in system performance, fit and assembly. Traditionally these activities, including initial design for manufacturability, have been the focus of the engineering and design assurance functions. However, development teams should not lose sight of the benefits to challenging the usability of the product.

MANAGE DEVELOPMENT RISK

Performing an early risk assessment with a clear understanding of the intended end user and how they will use the product successfully within the treatment regimen is an imperative for planning a successful regulatory and commercial development path. This foundational usability work, however, is often overlooked or frequently delayed to later stages – making corrections more time consuming and expensive. Often, difficult trade-offs or compromises are made downstream that could have been easily corrected if the core needs and risks were addressed upstream. Unfortunately, these trade-offs may manifest as use errors in validation studies – leading to a major programme setback.

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ADD VALUE WITH HUMAN FACTORS AND USABILITY WORK

Ximedica's human factors and usability team works alongside the engineering team, testing the product's usability against the design inputs generated from a solid user-requirements foundation. Frequent formative studies need not be expansive or costly. Such studies can ease uncertainties and build confidence in the end solution if used effectively. These frequent iterations also build confidence with the marketing and commercial teams as they participate in product testing with end users. For example, there may be hand dexterity challenges with the targeted patient population that can be tested and iterated in volume even at this development stage – ensuring a user-friendly solution and increasing product adoption.

After risks have been mitigated, Ximedica routinely uses bridge tooling for gaining confidence in the end product and putting an early, tangible device in the hands of end users and marketing and commercial teams. In particular, this gives marketing and commercial teams an in-depth look at the device to help prepare for product launch. Ximedica has successfully exploited quality bridge tools through validation, late-stage clinical study, regulatory approval and early commercial launch. This path is the stepping stone to developing a final manufacturing solution with shorter and less impactful development times and without excess capital expenditure.

Development of the assembly solution can follow a similar path, where teams commonly start with manual assembly and toggle to semi-automation before turning to full automation. Ximedica frequently uses this manual assembly process through clinical study and concurrently develops a semi-automated process. Performance, assembly and usability risks are addressed and mitigated in this manner.

BENEFIT FROM SECONDARY PACKAGING

Another example of flexibility in the mid-to-late stages of development resides with secondary packaging. Driven by regulatory pressures but, more importantly, human-centred engineering, secondary packaging is emerging as a key element in a treatment's successful presentation to end users. Primary packaging development starts early in the project or is leveraged from prior projects. Secondary packaging is developed concurrently with a develop-test-and-iterate approach for a successful treatment application. With usability in mind, this approach identifies potential use errors early, saving time and capital.

A solid understanding of the intended use flow of the solution can inform packaging and presentation of the entire treatment to users for successful end use. It should not fall entirely on the instructions for use (IFU) to inform the end user how to use the product properly. Appropriate placement of the IFU, sequencing the various device

components according to use flow, geometry and diagrams, and images printed on the package all enhance the secondary packaging and user understanding. Formative studies allow a chance to test the secondary packaging early and often with the intended users. Ximedica uses this path to test frequently, reducing the risk of use errors and significantly contributing to successful regulatory submissions.

The changing pressures of delivering an effective drug device are increasing in demand and require a more flexible development approach. Ximedica views this as an opportunity to evaluate options proactively where a finished manufactured solution is not necessarily the best product launch strategy. This flexible approach, combined with early usability considerations and optimised secondary packaging, will not only reduce regulatory risk and increase product adoption but also reduce time to market, contribute to greater revenue realisation and optimise the efficacy of the final treatment solution.

ABOUT THE AUTHORS

David Fink has more than 40 years of successful new product development experience in the medical device industry ranging from early-phase research, strategy and business development through detailed design to commercial launch. His role at Ximedica is working closely with client companies to align their project needs effectively with Ximedica's extensive development capabilities. Prior experience includes more than 20 years at Covidien/Kendall, most recently serving as Director of Research & Development, managing multiple development groups in the fields of cardiology, radiology, respiratory care and advanced wound care. Mr Fink's experience includes 12 years in antimicrobial device platform development.

Sheila Trgovac partners with clients to translate their strategic objectives into meaningful development of innovative and impactful healthcare products. She draws on her extensive experience in product development and marketing to help clients bring new products to market faster, more efficiently and with greater market potential and impact at every stage of the development process. She has 12 years' experience in medical device, pharmaceutical, business management, account management, marketing and, most recently, drug delivery device development. She has a BSc in Bioengineering from Penn State University (PA, USA) and a Masters in Management from Harvard University (MA, USA).

ABOUT THE COMPANY

Ximedica is a full-service design and development firm focused on medical devices, combination products and consumer health. Its drug delivery expertise includes topical, transmucosal, inhalation and injection. It is ISO 13485:2016 certified and US FDA registered.

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