IMPROVING PATIENTS' SELF-INJECTION EXPERIENCE

Jeff Lettman, Senior Research & Design Engineer, and Josh Hopkins, Engineering Manager, Noble, explain how they worked with a client to develop a product that would function with the pre-existing drug delivery device to help rheumatoid arthritis patients with reduced dexterity. Through direct interaction with patients and a review of research, the team worked with engineers and the client to create an ergonomic sleeve that avoided the need for a push-button operation.

The rapid advancement of biologic therapies has created numerous opportunities for improving patient self injection. As a result, every year, more patients are being introduced to both established and new devices for home treatment.

However, studies have shown some patients find it hard to follow the required steps outlined in instructions for use (IFU) documents[1] while others struggle with a variety of physical and emotional factors that impact the injection experience and can even cause inconsistencies in treatment.

To help improve the patient experience, Noble provides drug delivery device trainers and onboarding solutions. Furthermore, it also provides a variety of customised solutions to address patient needs and works with industry leaders to bring these solutions to market. Its focus on expediting design solutions for a variety of clients results in a better patient experience.

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IMPROVING SELF INJECTION FOR PATIENTS WITH RHEUMATOID ARTHRITIS

The challenges patients face can be difficult to determine. Even with the benefit of direct interaction, recognising opportunities to improve the patient experience often relies on research-based insights as well as a bit of serendipity. If an unfulfilled need for a specific patient population is identified, Noble can help turn this insight into real products, which ultimately improve patients' use of drug delivery devices.

Noble was approached by a client to develop a product that would function with a pre-existing drug delivery device to improve rheumatoid arthritis (RA) patients' overall injection experience. The development process typically

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Figure 1: The sleeve provides an ergonomic grip when used for an injection.

> "According to a multinational survey of 200 RA patients and 100 nurses, easy grip and ease of performing self-injections were the two most important attributes identified by both groups."

includes a research review that provides better insight into prioritising patient needs and wants. Grounding the investigation in research papers, market research and customer surveys provides a cornerstone when defining the patient problem and creating a streamlined solution to meet patient needs.

It was identified that patients with reduced dexterity may prefer an ergonomic grip when self-administering medication. According to a multinational survey of 200 RA patients and 100 nurses, easy grip and ease of performing self-injections were the two most important attributes identified by both groups.[2] Injecting without having to push a button is important for patients with RA, and the survey found that patients had clear personal preferences for which autoinjectors they found easiest to use.

Based on this conclusion, Noble decided to focus on understanding every aspect of the patient injection experience, including dexterity issues. Having identified potential for improvement in this specific area, a client-led targeted market research plan was developed to better understand patient needs. This led to the idea for a sleeve that would provide an ergonomic grip and eliminate the need for the user to press the activation button during injection (Figure 1).

DEVELOPMENT OF THE SLEEVE THAT MADE IT POSSIBLE

The client initiated the project with Noble during market research, which made it possible to hit the ground running on design and development of the sleeve.

When developing this new sleeve, Noble needed to define the product it intended to create to improve the self-injection experience for RA patients.

The requirements for our proposed solution, such as starting the injection without pushing a button directly, were created to define the functionality of the product without unduly restricting the engineering team when it came to implementation. Additional technical and measurable requirements, like removal and assembly forces (based on human factors studies), were also included.

For this project, a design that could strike a balance between several high-priority patient needs (easy to attach/remove, allow for autoinjector cap-removal, simple two-step activation, etc.) was a necessity. This also needed to be cost effective in order to maximise potential impact. Unfortunately, these goals can often be diametrically opposed. However, in this project, Noble was able to keep the part-count low and still improve the user experience.

The sleeve was designed to incorporate a soft rubber over-mould, and the careful design of the substrate allowed for much of the user and autoinjector interface to be incorporated into a single part, with the over-mould providing a clean exterior appearance. Early integration of finite element analysis tools (Figure 2) allowed for the accurate prediction of performance prior to prototyping, and a reduction of weight, material and cost during design optimisation. Similarly, mould flow analysis saved a tremendous amount of time by eliminating excess trial production runs and costly tool modifications.

Since the target patient population has reduced dexterity, creating easy-to-open packaging with contents that are readily removable was critical. As with other elements of the project, packaging costs also needed to be managed. To answer these challenges, a folded, single-sheet design was created, which minimised cost while still managing to incorporate an easy-open flap, and a raised platform which made the sleeve easy to grasp and remove.

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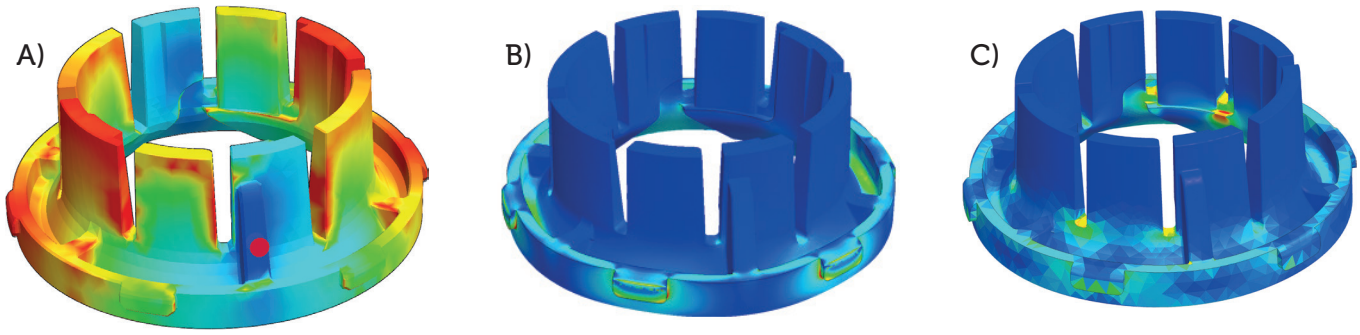

Figure 2: Engineering analysis in product development. (A) mould flow analysis during part fill; (B) von mises stress analysis during assembly; (C) the engineering strain analysis during cap removal.

This hard-won knowledge, combined with a design optimised for manufacturing, allowed for a fast-tracking of the sleeve which will be introduced into the commercial market this year.

THE DEVELOPMENT PROCESS PROVIDED BY NOBLE

In the earlier stages of a project, the team works with pharmaceutical and biotech companies in a creative and expansive mindset to maximise the opportunity. When developing a solution to best answer that opportunity, it is vital to the project's success that the purpose, features and functionality of the proposed solution are clearly and explicitly defined. However, it is often necessary to jettison some potential features or functionality to ensure that those key to the project's success are achievable – which can be challenging. Noble guides clients through this process, codifying project initiatives and prioritisation so that there is a mutual team understanding and goal.

Noble works closely with clients to transform commercial team initiatives and generic patient needs into specific user needs and marketing requirements. This leads to the creation of realistic and measurable goals early in the project, ensuring that client expectations are exceeded when trainers and medical devices are in patient hands.

In the exploratory stages, it is important to select – from the wide variety of proposed solutions – only those most in line with stakeholder needs. For this reason, Noble provides users and clients with prototypes as early as possible, which can be used to champion a project internally or be utilised in robust user studies and market research. Our on-site prototyping capabilities allow for rapid turnaround times to test early-stage prototypes. In this specific case, iterating through various form factors (Figure 3) for the sleeve project early in the design phase allowed Noble to understand how the sleeve would be utilised during the injection process.

Noble not only leads product development activities and documentation, but also provides unique and comprehensive support to pharmaceutical companies to meet their internal documentation and deliverables according to the nature and classification of the product.

As an example, our team leads and documents all development activities such as regulatory, human factors and risk management deliverables to guide programme development in the US, EU and any other global markets for commercial teams. It is imperative for Noble to provide services such as regulatory reviews, clinical evaluations, risk management activities (i.e. hazard analyses and failure mode analyses) and product benchmarking studies to its clients with the goal of providing a speed-to-market approach that is advantageous for clients and patients alike.

This, coupled with Noble's strategic intellectual property approach, means an idea can be transformed into reality quickly. Noble grants clients the opportunity to provide hundreds of thousands of medical devices and trainers to their patients to differentiate their brand and ultimately improve the patient injection experience.

Once design freeze occurs within the process, Noble manages all verification and validation testing for clients, leads formative and summative studies for US and global markets and drives design transfer activities for production. Speed-to-market is increasingly important due to the competitive pharmaceutical landscape, and Noble has global manufacturing sites and partners that are involved early in the design phase to expedite the design transfer process.

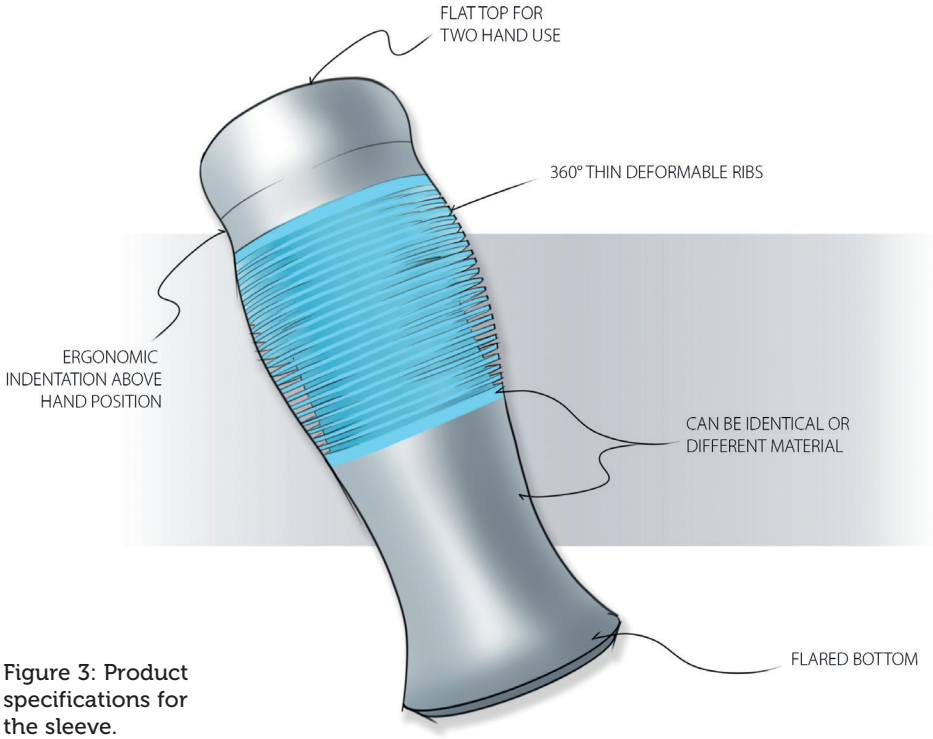

Figure 3: Product specifications for the sleeve.

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SUMMARY

Noble manages the entire design transfer process for all trainers and medical devices, providing fully validated processes and finished goods for global markets with manufacturing capabilities to accommodate commercial team pipelines ranging from highly complex electromechanical and connected IoT devices to low- or high-volume mechanical trainers and devices.

Figure 4: A user simulates sleeve utilisation during an injection.

Early concept development through to the later stages of product development and production concludes with shipping impactful products to patients around the world to improve the patient injection experience (Figure 4).

Studying and understanding the patient self-injection process is paramount to Noble's core mission of improving the injection experience and overall patient adherence through training and support materials.

ABOUT THE COMPANY

Founded in 1994, Noble is the global leader in medical device training solutions, patient onboarding strategies and multisensory product development for the world's top pharmaceutical brands and biotechnology companies. Focused on driving innovation, Noble works closely with brand, device and commercialisation teams to develop turnkey solutions that improve onboarding and adherence, bringing value to clients and patients alike.

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ABOUT THE AUTHORS

Josh Hopkins, Engineering Manager, is responsible for design, engineering and development of regulated and non-regulated medical devices. He has over nine years of medical device and pharmaceutical development experience including a focus in product development, risk management, programme management and human factors engineering. Josh has earned a Bachelor of Science in Biological Engineering and a Master of Science in Biomedical Engineering from the University of Florida (FL, US).

Jeff Lettman, Senior Research & Design Engineer, has over 10 years of experience in applied research specialising in mechanism design, mechanical optimisation and finite element analysis. He is responsible for devising proof-of-concept projects to validate the feasibility and manufacturability of new products and features, as well as reducing Noble's intellectual property to practice. During his seven-year tenure in technical operations and applied research at Lockheed Martin, his diverse experience ranged from leading R&D teams to facilitating testing at LM locations across the US as the subject matter expert in thermal and vibration screening. Jeff holds a Bachelor of Science in Mechanical Engineering from University of Florida and a Master of Science in Mechanical Engineering from the Pennsylvania State University (PA, US). He is currently attending University of Central Florida for his PhD in Mechanical Engineering.

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