NETWORK PARTNERS GROUP: DESIGNING FOR HUMANITY

The Essence of Human-Centered Design

By: Karly Bonzi

Medical packaging plays a vital role in patient safety, medication adherence, and overall healthcare quality. This article explores the significance of human-centered design (HCD) in the context of medical packaging, with a specific focus on putting patients' needs and preferences at the forefront.

Current challenges in medical packaging encompass a range of critical issues within the healthcare industry. Patient safety concerns are a challenge, as inadequate packaging can lead to contamination or accidental misuse. Additionally, medication adherence issues pose a significant problem, as complex packaging designs or confusing labeling can hinder patients from following prescribed treatment regimens effectively.

Principles of HCD

Human-Centered Design (HCD) in the context of medical packaging refers to a design approach that places patients' needs, preferences, and well-being at the core of the packaging development process. It involves a systematic and empathetic approach to understanding the unique requirements and challenges patients face when using medical products. This approach ensures that the design of medical packaging not only meets regulatory and safety standards but also prioritizes usability, accessibility, and patient satisfaction. The importance of patient-centric approaches in healthcare cannot be overstated. Patients are the end-users of medical products, and their experience directly impacts treatment adherence, safety, and overall healthcare outcomes. By placing patients at the center of design decisions, medical packaging can enhance patient engagement, encourage proper medication administration, and ultimately improve healthcare quality.

The Design Process

Human-centered design is an integral part of a medical packaging engineer's role. This process entails a series of meticulously defined stages. Starting with the Empathize stage, the engineers immerse themselves in understanding the unique requirements and challenges faced by patients. During the Define stage, engineers translate the gathered insights into precise problem statements, laying the groundwork for targeted design solutions. In the Ideate stage, the engineers encourage creative brainstorming to generate diverse packaging concepts, balancing functionality, and user-friendliness. Subsequently, the Prototype stage involves creating physical models of potential designs, facilitating visualization and feasibility assessment. The Test stage plays a pivotal role, involving the collection of user feedback, usability testing, and iterative design refinement to ensure that the packaging effectively caters to patient needs.

Adapting the HCD process to medical packaging is a challenge and must be executed with cross-functional teams to ensure success. Packaging engineers collaborate with experts in healthcare, regulation, materials, and design to ensure that the packaging not only meets patient-centric criteria but also adheres to stringent industry regulations and safety standards. This collective effort brings together the expertise of various professionals, delivering packaging that prioritizes patient safety, adherence, and overall well-being. The packaging engineer can assume the role as a dedicated advocate for human-centered design in medical packaging.

Regulation and Compliance

In the United States, the Food and Drug Administration (FDA) has increasingly stressed the integration of human factors engineering into the design and development of medical devices. In 2016, the FDA released an official guidance document that outlines the application of human factors and usability engineering to medical devices. Also, the FDA has recently released similar guidance for combination products. While compliance with these guidelines is not mandated, they are recommended by the FDA to aid medical device manufacturers in optimizing device design to minimize potential user errors and associated harm. Incorporating a HCD approach as part of a medical device manufacture's Design Control process is the best way to ensure compliance to FDA requirements as well as the EU MDR, which has an increased focus on use and risk.

For more guidance:

https://www.fda.gov/media/80481/download?attachment
https://www.fda.gov/media/171855/download

Conclusion

In conclusion, human-centered design is a vital aspect of the work undertaken by medical packaging engineers. The packaging engineer is advised to deploy the tools of an industry best practice of welldefined stages – Empathize, Define, Ideate, Prototype, and Test for a successful human centered design output. HCD empowers medical packaging engineers to create solutions that not only meet regulatory requirements but also prioritize patient safety, adherence, and overall health. This patient-centered approach enhances the quality of patient care and affirms the engineer's role as a dedicated advocate for human-centered design in the realm of medical packaging.

If you're in need of expertise to guide you through the design process and provide a packaging solution that incorporates human-centered design, the packaging engineering team at Network Partners Group is available to help.