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ADDRESSING HUMAN FACTORS **ENGINEERING** AND COMBINATION PRODUCT REGULATIONS THROUGH INNOVATIVE SAFETY SYSTEM SOLUTIONS

In this piece, Sarah Malka, Commercial Integration Project Manager, and Anastasie Formey de Saint Louvent, Europe Product Manager, both of BD Medical – Pharmaceutical Systems, describe how BD integrates human factors engineering and patient-centric design into an innovative partnering model for the development of new products, such as the BD UltraSafe Plus™ Passive Needle Guard.

GLOBAL NEED FOR INJECTION SAFETY

Today's pharmaceutical landscape is deeply evolving. More than 35 million global healthcare workers face the risk of sustaining a percutaneous injury with a contaminated sharp instrument every year. This results in one million sharps injuries a year, from which 60-80% go unreported. Self-injecting patients are also concerned by the risk of needle-sticks during at-home use resulting in an increased preference for safety features.

Anti-needle-stick legislation is becoming more stringent as regulations are tightening and expanding globally, most recently with the 2013 adoption of the 2010/32/EU Sharps Injury Prevention legislation in Europe. As a result, companies have to adapt quickly to this legislation and provide hospitals and end users with drugs that can be easily and safely used.

EVOLVING PHARMACEUTICAL LANDSCAPE

Several additional key elements impact today's injectable pharmaceutical market. Amongst them, increased sensitivity and viscosity of parenteral drugs, incorporation of end user experience and needs into product development, and tighter control of healthcare expenses from governments are playing a major role. Moreover, differentiation and lifecycle management are crucial for pharmaceutical companies to overcome competitive pressure.

This leads to more advanced delivery solutions and sophisticated combination products which are being rigorously regulated.

In the US, combination products are defined as a single entity (combined into one), co-packaged (sold together) and cross labelled (dependent) [1] product.

With the growing implementation of the combination product regulations in the US and all over the world, not only should all the players work together, but excellence in regulatory support and knowledge of the paradigm change driven by combination products are critical to the success of a product launch. Selecting the best partner to supply container closure systems components or devices is vital as time, data sharing, and human factors engineering (HFE) are the essence of the future for pharmaceutical products.

Pharmaceutical companies need to partner with manufacturers of components of container closure systems or devices that are able to provide cross-functional expertise on the impact of the new combination product regulations through documentation sharing with relevant data to support product development.

HOW HFE CAN LEAD TO DIFFERENTIATED PRODUCT DESIGNS

Importance of Patient input from Conception to Launch

HFE inputs have become central in product development, particularly for combination

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products. This iterative design approach is a body of knowledge about human abilities, human limitations, and other human characteristics that are relevant to design. As described in Figure 1, the integration of HFE in the product design is a result of several steps of concept generation and experimental investigations based on requirement definition and design verifications. This puts the patient at the center of combination products development considerations.

As a result, pharmaceutical companies can improve and prove product usability. It has been established that patient-centric designs can improve patient acceptance of the treatment and thus improve effectiveness.

BD Medical – Pharmaceutical Systems has been an early innovator in developing safety engineered solutions for the market, partnering with numerous customers to ensure their commercial success. HFE has been in the center of these developments from a very early stage. With the creation of BD's Human Factors Institute in 2013, BD offers structured expertise in concept development and patient-centric design to its customers, guiding them through every step of the HFE process.

HFE & DEVELOPMENT PARTNERSHIP AS INNOVATION DRIVERS

BD product developments are made with input including end-users' needs and preference evaluation. The BD UltraSafe Plus™ Passive Needle Guard (Figure 2) is an ideal example of product development adapted to new market requirements. As patients tend to self-inject more, there is a need for ergonomic and easy-to-use devices. In addition to an innovative passive safety technology preventing any risk of needlestick injury at the time of needle withdrawal, the wider finger flange and unique ergonomic plunger rod were the results of patient centric studies,[2] ensuring successful use for self-injected viscous drugs.

The BD Ultrasafe Plus™ Passive Needle Guard includes enlarged finger flanges in order to facilitate self-injection. In light of end-user feedback, BD also developed an add-on finger flange to be used as an accessory to this device. This add-on enables dexterity-impaired patients to inject themselves comfortably. The selection of the shape for the add-on finger flange of BD Ultrasafe Plus™ Passive Needle Guard was the result of an HFE-based development, centred on the needs of this specific target population.

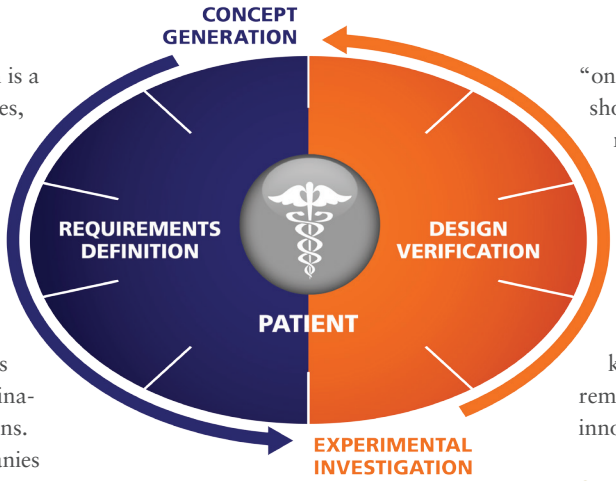

Figure 1: Integration of human factors engineering in the product design.

The first step in defining the appropriate product was to select the overall shape. An exhaustive analysis of targeted patients' preferences has been performed. Pre-selected add-on finger flange shapes were tested on patients with reduced manual dexterity, including patients with rheumatoid arthritis and multiple sclerosis.[3] After several iterations of usability studies, results indicated that downward-pointing designs and concave shape to support grasp are preferred by these patients.

In addition to this initial design evaluation, another series of usability studies has been conducted to evaluate the patient preference on texture. Patient focus groups were conducted and resulted in a better understanding of the impact of texture on patient perceived injection comfort for an add-on finger flange. As expected, data suggests that adding specific textures leads to preference of specific end-users. There is no "one fits all" solution. For example, results show that grooves in addition to texture may be perceived as uncomfortable for MS patients.[4] This evaluation led to the design of the BD Ultrasafe Plus™ add-on finger flanges.

Figure 2: The BD UltraSafe Plus™ Passive Needle Guard – an ideal example of product development adapted to new market requirements.

As the next generation of drugs is being developed, BD is evaluating new technologies to meet unique market needs. Patient acceptance and safety remain some of the key drivers to BD's innovative solutions.

SUMMARY

Changing landscapes require pharmaceutical companies and their partners to adapt and develop more ergonomic products, ensuring patient acceptance. To demonstrate ease of use and reliability of the developed products, additional studies are requested by the regulatory agencies. HFE, based on end-user needs, should be in the center of these studies to ensure their acceptance. Choosing a device and container closure system partner with expertise in product design and combination product regulations is imperative to ensure a successful product launch.

REFERENCES

1. *21 CFR 3.2(e), US FDA, April 2014*
2. *Data on File*
3. *Data on File*
4. *Data on File*

ABOUT BD

BD is a leading global medical technology company that develops, manufactures and sells medical devices, instruments and reagents. The company is dedicated to improving people's health through the world. BD is focused on improving drug delivery, enhancing the quality and speed of diagnosing infectious diseases and cancers, and advancing research, discovery and productions of new drugs and vaccines. BD's capabilities are instrumental in combating most of the world's most pressing diseases.

Founded in 1897 and headquartered in Franklin Lakes, NJ, US, BD employs nearly 30,000 associates in more than 50 countries throughout the world. The company serves healthcare institutions, lifescience researchers, clinical laboratories, the pharmaceutical industry and the general public.

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