Phillips Medisize

Partnerships Built on Innovation

HUMAN-CENTRED DESIGN AT THE HEART OF A SUCCESSFUL PRODUCT DEVELOPMENT PROCESS

In this article, Bill Welch, Chief Technology Officer, and Jeremy Odegard, Design & Development Center, both of Phillips-Medisize, provide an insight into how the company's human centred design approach fits into its integrated product development process.

During the development phases, pharma and medical device companies can encounter obstacles complying with the US FDA's drug and medical device regulations, as well as other global regulations that determine which current good manufacturing practices (cGMPs) and quality system regulations apply for product manufacturing. There is also the need to manage complicated supply chain logistics from design, testing and development to low-volume clinical trial manufacturing as well as the scale-up to higher-volume commercial production. The most minor detail can derail the development of a successful product, resulting in lost time and resources and deadlines missed. This could cause product development or regulatory submission to stall before it ever reaches the market.

Project complications and delays can arise as a result of collaboration among disparate organisations. For example, a design firm might not understand what can be achieved in injection moulding processes.

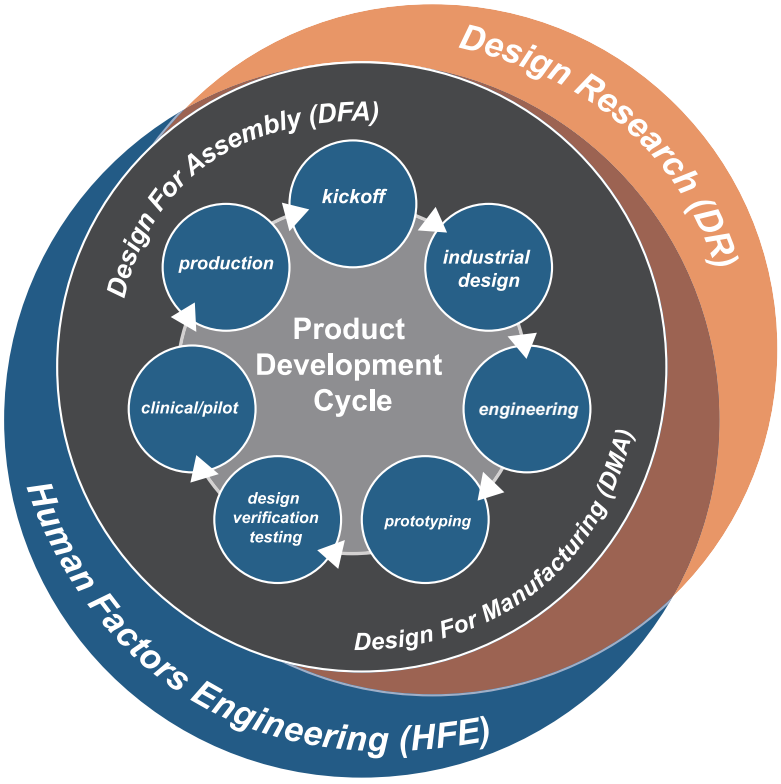

Figure 1: Phillips-Medisize's integrated product development cycle.

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Further, designs may not be optimised for manufacturing or assembly. By applying adequate due diligence in choosing the right partner, pharmaceutical or biotechnology and medical companies can improve the odds of launching a successful new drug product into the marketplace – on time, and on budget.

INTEGRATED PRODUCT DEVELOPMENT

Phillips-Medisize's integrated product development process combines human-centred design principles with a solid design for manufacturing (DFM) and design for assembly (DFA) philosophy. It addresses design research, industrial design and human factors engineering (HFE) focusing on product usefulness, usability, desirability and manufacturability (see Figure 1).

The key benefits of this are product adoption and compliance; predictable processing; overall product quality improvement; cycle time reduction and stakeholder satisfaction.

The human-centered approach is not limited to a single phase nor is it a standalone module that can simply be attached to the front-end of a program. It needs to be embedded into the cultural fabric of an organisation in order to be effective.

HUMAN-CENTRED DESIGN PRINCIPLES

Design Research

Design research activities are typically conducted at the front end of a development cycle in order to establish a firm foundation for future design work (Figure 2). This is required to determine the needs of end users, uncovering attributes that will resonate with them on an emotional level. Common design research methods include targeted interviews, contextual observation (for example, witnessing a surgical procedure in an operating room, or shadowing a diabetic patient through their daily testing and insulin injection routine in the home), participatory workshops, analogous product benchmarking, and trend tracking. These processes allow a cross-functional development team to appreciate circumstances, environmental conditions, and user expectations in an effort to identify design opportunities. Discoveries made through design research inform the development process, improving the likelihood of success upon market introduction.

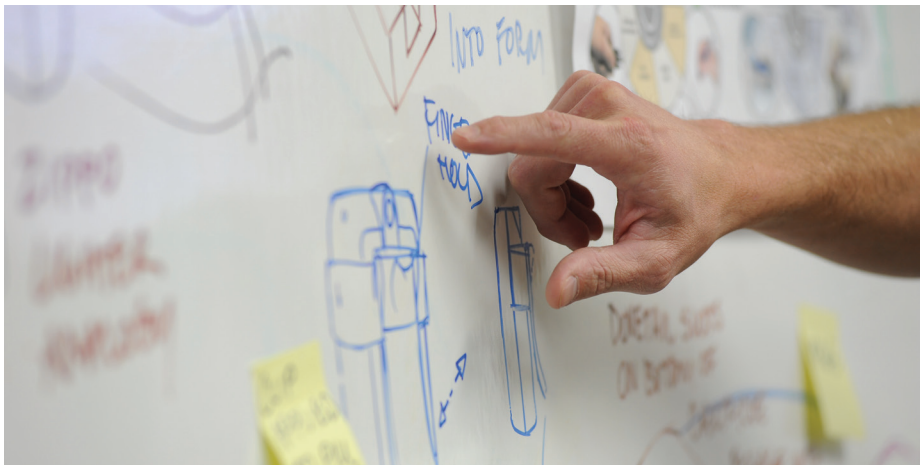

Figure 2: Design research is typically conducted at the front end of a development cycle in order to establish a firm foundation for future design work.

Industrial Design

Industrial designers build upon the foundation of design research, translating discoveries, product performance goals and marketing objectives into tangible concept directions. Product form, user interface, ergonomics, aesthetic detail treatment, material selection, and manufacturing approaches are all considered during this phase which typically begins with collaborative brainstorming from multiple professional disciplines. Industrial designers then narrow their focus to a manageable set of concepts that may be evaluated through illustrations, preliminary CAD models, and physical prototypes.

Human Factors Engineering

The objective of HFE is to minimise use-related risks and ultimately to ensure safe and effective use. HFE activities may include product handling studies, usability testing with representative users, and final verification/validation studies to satisfy regulatory expectations. HFE methods are applied throughout the development cycle to mitigate product related safety risks and justify design decisions.

HFE starts early in a design cycle and should be an integral part of the development process. Design inputs such as user profiles, use environment, and other contextual influences must be considered as early as possible. Proper planning, execution and documentation of HFE activities throughout the development process should streamline the submission process for regulatory approval.

A focused Human-Centered Design approach promotes intuitive, usable, and desirable devices (Figure 3).

"Almost all of the extremely diverse medical sectors use and benefit from our HCD approach, among them diabetes, ophthalmology, oncology, gynecology, cardio-vascular surgical intervention. In the field of medical devices, we are involved in the development of 'knock-your-socks-off' technologies and applications – developed all the time – for ever more complex Class III devices, those still requiring pre-market approval. Class III devices are usually those that support or sustain human life," said Phillips-Medisize Chief Technology Officer Bill Welch.

DFM AND DFA

Design for manufacturing (DFM) and design for assembly (DFA) are also foundational elements of a robust product development process. Much like human-centred design principles, a sound DFM/DFA philosophy should be a cultural mindset, becoming ingrained in

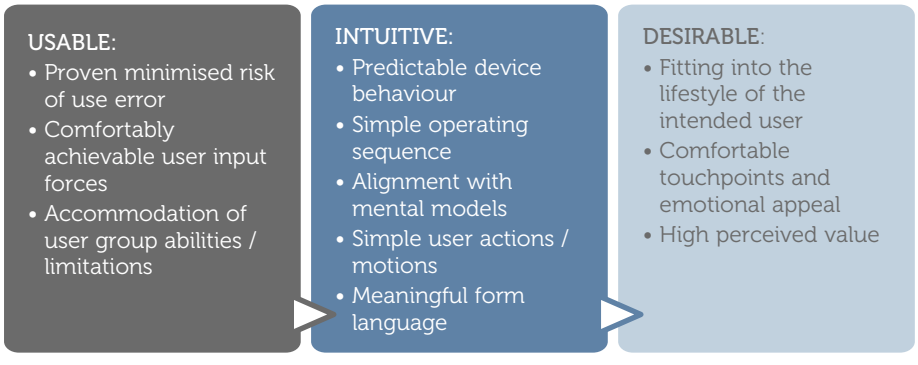

Figure 3: Summary of criteria for achieving usable, intuitive desirable device design.

all phases of development. While HFE evaluation throughout the process is typically focused on the user's experience, DFM and DFA are focused on manufacturing quality, cost and risk. Certain aspects of DFM, such as design guidelines for moulded plastic or metal parts, have proven manufacturing process principles behind them and applying just a handful of established DFM guidelines for moulded parts can prevent a majority of design issues.

The same can be said for DFA, in which planning for manual, semi-automated, or automated assembly from the early stages can prevent issues that would otherwise be found during clinical, pilot, or manufacturing launch builds when mitigation of issues becomes much more costly. Designers, engineers and manufacturing representatives must collaborate early and often to develop designs that meet targeted quality and cost objectives, and other established program goals.

DFM AS A GUIDING PHILOSOPHY

Successful DFM requires a culture that unites product development and manufacturing and appreciates early manufacturing involvement from the concept phase. Since most of the product cost (as well as quality and risk) are driven by decisions early in the design cycle, the product development team must include expertise in DFM for the intended manufacturing processes. In the spirit of innovation and creating improved patient outcomes at a lower cost, it is recognised that DFM guidelines must sometimes be challenged. In these cases, the product development team must be committed to risk mitigation by applying computer aided engineering (CAE) tools such as mouldflow, finite element analysis (FEA), and tolerance analysis to an unfinished design, and subsequent prototyping to verify the CAE output.

In the case of injection moulded plastic components, the design team understands that part design dictates mould design and can envision how steel is wrapped around part geometry to create tooling capable of meeting the required volumes and quality requirements when in production. From a development standpoint, both the mould geometry and injection moulding process must align with the part requirements, mould construction, and moulding process.

Finally, the culture must support the belief that DFM must be applied across the product development process by a fully engaged multidisciplinary team including manufacturing representatives. DFM cannot be viewed simply as a checklist to be completed or a task in the development cycle. Early manufacturing involvement not only brings DFM expertise to the product development team, it also promotes concurrent early learning and buy-in by the manufacturing team, reducing lead time and risk downstream.

COST-DRIVEN SOLUTIONS

Many customers are interested in getting their ideas transformed into a functional product, relying on the expertise of the Phillips-Medisize Design Development Center (DDC) to handle all the industry-critical factors in the shortest possible time. The company has developed an own-product development process to provide time and cost optimised procedures, allowing it to develop the simplest devices to highly complex systems.

Based on an article that appeared in Medical Plastics News, Issue 23, p 14.

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