



Partnerships Built on Innovation

# HUMAN-CENTRED DESIGN & INHALATION DEVICE DEVELOPMENT

In this piece, Bill Welch, Chief Technology Officer, Phillips-Medisize, explains how the term “smaller and smarter” applies in the development of inhalation devices, and describes how his company’s human-centred design approach, integrated with design-for-manufacturability and design-for-assembly principles, is perfectly positioned for producing the next-generation of smaller, smarter inhalers.

## THE NEED FOR HUMAN-CENTRED DESIGN OF INHALATION DEVICES

Numerous studies have shown patient issues with both the use of and adherence to prescribed inhaled therapies for asthma and COPD, whether maintenance or rescue inhalers. A simple web search will produce evidence of multiple studies indicating that greater than 30%, and in some cases up to 80%, of patients do not use their inhalation devices correctly. Additional studies report similar percentages in adherence to inhaled therapy.

Compromised adherence means the patient is not receiving the desired pharmacological benefit of their medication despite an effort to do so. Adherence may be negatively impacted by confusion, frustration, inconvenience, embarrassment, or a variety of other usability issues. Conversely, compliance can be maximised by providing the patient with an easy-to-use device and monitoring tools that promote the prescribed inhalation regimen.

In order to minimise the opportunity for misuse and improve adherence, an inhaler must be intuitive, usable, and desirable. This is the objective of the newest generation of “smaller and smarter”, patient-administered inhalation devices, developed following what is known as the “human-centred design” approach.

## WHAT IS HUMAN-CENTRED DESIGN?

Phillips-Medisize’s integrated product development process combines human-centred design principles with a solid design-for-manufacturing / design-for-assembly (DFM / DFA) philosophy. It addresses design research, industrial design and human factors

engineering (HFE) – simultaneously addressing a product’s usefulness, usability, desirability, and manufacturability (see Figure 1).

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

The human-centred approach is not limited to a single phase nor is it a stand-alone module that can simply be attached to the front-end of a product development 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. 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 (i.e. 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.

### Bill Welch

Chief Technology Officer  
T: +1 715 386 4320  
E: [info@phillipsmedisize.com](mailto:info@phillipsmedisize.com)

### Phillips-Medisize Corporation

1201 Hanley Rd  
Hudson  
WI 54555-5401  
United States

### European Headquarters:

**Phillips-Medisize**  
Edisonstraat 1  
2181 AB Hillegom  
The Netherlands

T: +31 252 576 888  
E: [eu\\_sales@phillipsmedisize.com](mailto:eu_sales@phillipsmedisize.com)

[www.phillipsmedisize.com](http://www.phillipsmedisize.com)

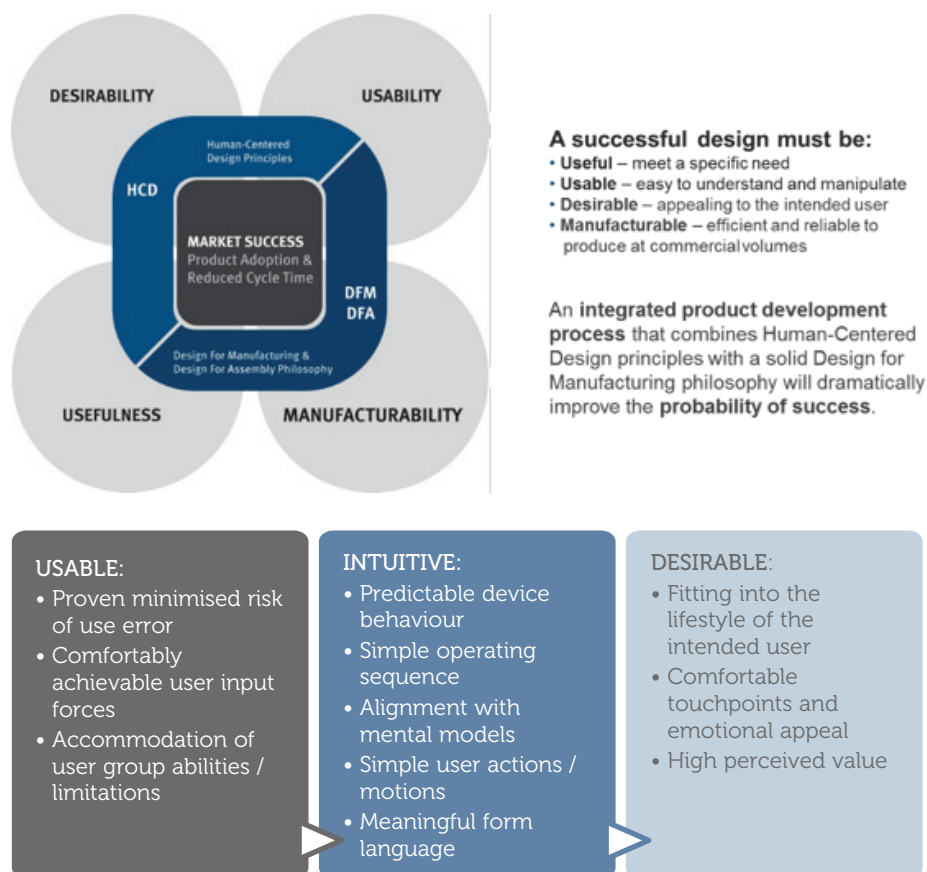


Figure 1: Summary of criteria for Human-Centred Design.

## 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. Collaborative brainstorming with a cross-functional team helps to ensure consideration of multiple viewpoints. Industrial designers produce illustrations, preliminary CAD models, and physical prototypes to define conceptual directions. Through co-operation with their engineering peers, industrial designers strive to narrow the focus to a single concept direction that can be carried forward into subsequent development phases.

## Human Factors Engineering (HFE)

The objective of HFE is to minimise use-related risks and to ensure safe and effective device 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 begins early in a design cycle and should be included as

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.

In classic models of human-centred design, the focus is on useful, desirable, and usable products. However, in the realm of drug delivery devices, including inhalation, the concept of manufacturability must receive equal emphasis. Manufacturability encompasses the healthcare market demands for quality and cost effectiveness, both of which must be aligned with the competitive landscape in order to achieve clinical and market success. To gain market acceptance, the next-generation inhalation devices must compete with the existing standard of care for overall cost of treatment. Expected benefits include eliminating unnecessary hospitalisations, emergency room visits, and office visits.

## "SMALLER AND SMARTER"

The term "smaller and smarter" is regularly applied to describe next-generation, patient-administered devices, including inhalation devices.

## Smaller

"Smaller" refers to the patient expectation of inhalation devices engineered to be compact and portable, in order to allow discreet usage and improve adherence. For example, the Exubera dry powder insulin device was considered very large and bulky. After the system failed to gain acceptance among patients and physicians, it was discontinued after less than a year on the market. Meanwhile, the mechatronic liquid insulin inhaler from Dance Biopharm, Inc (Brisbane, CA, US), is about the size of a deck of playing cards. The Dance inhaler, known as Dance-501 (see Figure 2), is in clinical trials today and, while a smaller device does not guarantee clinical, regulatory, or market success for the entire system, the form factor selected is similar in size to mobile phones that have proven consumer acceptance.

## Smarter

Smarter, on the other hand, has multiple dimensions to be optimised based on the device and user needs.

The first dimension of smarter is the creation of more intuitive devices, thereby decreasing patient errors while increasing adherence and desirability of the therapy.

The second dimension of smarter is to improve on its primary intended function: more effective, targeted delivery of the drug, and greater efficiency of delivery such that less drug product is required to produce the desired benefit. This dimension provides a potential cost savings that will support improvements in other parts of the system, such as inclusion of electronics and software.

A third dimension of smarter is the integration of electronics to improve functionality via a mechatronic delivery system. Dance's Dance-501 and the Tidal inhaler from Teva (Petach Tikva, Israel) (acquired as part of the MicroDose Therapeutx acquisition in 2013) are both examples of next-generation inhalers using novel mechatronic systems and the patient's tidal breathing potentially to gain increased delivery effectiveness while reducing device misuse.

The final dimension of smarter is wireless connectivity to communicate with smartphone apps and/or cloud databases that can share information with both the patient and caregivers to improve adherence. CareTrx from Gecko Health Innovations (also acquired by Teva), and Propeller Health's (Madison, WI, US) system, are examples of device add-ons and software systems specifically targeting this facet of smarter inhalation systems.



Figure 2: The Dance-501 inhaler from Dance Biopharm is an example of a smaller, smarter inhaler.

In evaluating the landscape of next-generation inhalation devices, there are devices that will accomplish most or all of the above

elements of “smaller and smarter”. Those inhalation devices that successfully achieve a smaller and smarter patient solution are

excellent examples of applied human-centred design principles, creating more usable, intuitive, and desirable devices for patients.

## SUMMARY

The human-centred design approach has been driving the trend toward development of smaller and smarter, next-generation inhalation devices. When successfully executed, the process will produce devices that are more useful, usable, and desirable than current-generation devices. Through application of the design research, industrial design, and human factors disciplines in concert with DFM/DFA philosophies, the patient will receive an inhalation device that minimises opportunities for error and promotes greater adherence to the prescribed therapy.

# THE WIRELESS CONNECTED INHALATION DEVICE

The primary demand for wireless, connected inhalation devices is to provide a technology solution for improved monitoring and adherence tracking, both for patients and caregivers. A commonly requested system is one which provides dose history transmission to a local device, such as a smartphone, and then to a data-base for caregiver access, if desired.

A key enabler for connected inhalation devices is the increasing availability and lower costs of wireless communications. One option, known as Bluetooth Low Energy, also known Bluetooth LE, BLE or Bluetooth Smart, can give patients and caregivers tools to manage adherence using familiar mobile phone technology and user interfaces, as well as compatibility with healthcare data exchange standards.

## Why Bluetooth Low Energy?

BLE was created in 2010 on the release of the Bluetooth Core Standard 4.0. This wireless technology is perfect for low power consumption, small size, and high compatibility to smartphones.

The iPhone 4S was the first smartphone to offer Bluetooth 4.0 compatibility, with adoption now essentially universal in smartphones. BLE radio hardware to be placed in the drug delivery device can be extremely compact, with applications that include hearing aids and other microelectronic devices.

The BLE protocol is optimised to carry small data payloads at infrequent time intervals. Examples of good uses include continuous glucose monitoring, infant temperature monitoring, and drug delivery device dose history, whether for inhalers or other device types. In all of these cases, only small amounts of data are required to be transferred, the data transfer need not be continuous, and therefore the BLE radio will be on < 0.1% of the time.

## How Does BLE Reduce Power Consumption?

The key principal is to connect the sending device to the receiving device at periodic intervals – the connection interval – to exchange data and then put the devices’ radios to sleep until the next exchange time. By limiting the “awake” time of the radios, power usage is reduced. Further, the BLE radio architecture uses relaxed frequency channel characteristics to further reduce power consumption.

However, this mostly-off operation imposes a significant overhead on data transfer, so if large amounts of data have to be sent, it has to be chopped up into small segments and a part sent every connection interval.

By contrast, Bluetooth “Classic” protocol allows a data transmission to have variable length that can be chosen to suit

the size of the data transfer. Bluetooth “Classic” is better suited than BLE for applications requiring data streaming for large amounts of data, with the trade-off of increased power needs.

## BLE Compatibility with ISO 11073

The ISO 11073 Standard for Medical Devices creates a mechanism to exchange health care data between devices and users of the data, such as electronic medical record software. The standard describes a method to send the information about data formatting along with the data so the receiving end can parse the data without prior knowledge of its formatting. The standard is independent of the data transport system – it applies equally to any wired or wireless protocol.

Since most BLE usage for medical devices require a gateway device such as a smartphone, it is common to use the smartphone app to ‘transcode’ the device data into 11073-compatible data format before it is pushed to the cloud and other devices with which it needs to be compatible. For reference, see: “Personal Health Devices Transcoding White Paper”. Bluetooth Special Interest Group, Oct 21, 2014.

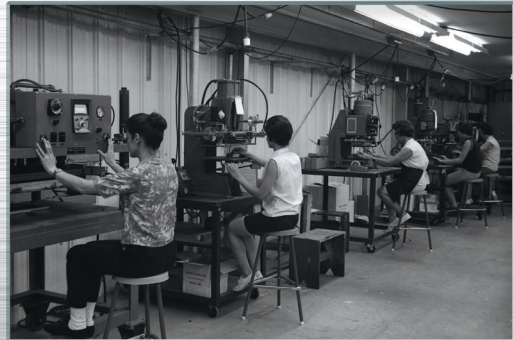
## Summary

BLE, with its low power, small size, and near-universal compatibility, is an enabling technology for wireless dose history transmission, for use both by patients and caregivers, for application with small data size and modest transmission speeds.

# At Phillips-Medsize We're All About Process



This



Not This

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So, when you work with Phillips-Medsize, you can be certain we'll exceed your highest expectations **the first time and every time**.

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