

# Drug Delivery<sup>®</sup> Technology<sup>®</sup>

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## DESIGNING GREATER ORAL DOSAGE FORMS



The science & business of drug development in specialty pharma, biotechnology, and drug delivery



**Ansgar Santel, PhD**  
The AtuPLEX  
Technology for  
Therapeutic  
siRNA Delivery in  
Oncology



**Shahrzad Missaghi,  
PhD**  
The Influence of Tablet  
Shape, Geometry & Film  
Coating on Drug Release  
From HPMC ER Matrices



**Brian Windsor,  
PhD**  
Particle Engineering  
Solutions for Drug  
Delivery Challenges

### IN THIS ISSUE



INTERVIEW WITH  
3M DRUG DELIVERY SYSTEMS'  
DIVISION VP & GM  
**JAMES VAUGHAN**

**Medical Device  
Design** 18  
Alan Morris

**Fight Within  
Pharma** 22  
Derek G. Hennecke, MBA

**Polymer-Based  
Compounds** 28  
Bill Martineau, MBA

**Monoclonal  
Antibodies** 42  
V.P. Chekhonin, MD  
V.P. Baklaushev, MD

#### FEATURING

**SPECIALTY**   
Strategies For  
Business Development **PHARMA**

**GLC Market  
Trends** 70  
Cindy H. Dubin

**Pharmacogenomics** 76  
Katheryn Symank

# ADVANCED DELIVERY DEVICES

## Human Factors Engineering: Improving Medical Device Design to Ensure Safe, User-Friendly Medical Devices

By: Alan Morris and Andreas Knaack

What made the ubiquitous iPod such a success? It wasn't the first MP3 player on the market; it had less storage capacity, fewer features, and cost more than many of its competitors. On paper, when comparing specifications alone, it shouldn't have been top of your shopping list. There has been much analysis over the years as to why it's been such a market success, but one major factor that most everyone agrees on is the user experience: from connectivity to iTunes, the über-cool form factor, and most importantly, the instantly engaging navigation experience. In addition, there are no moving parts, unique single-thumb navigation that immediately connects with today's SMS generation, and a graphical user interface all just makes sense.

But imagine if your iPod was intended to deliver life-saving drugs in a medical emergency? Imagine you were taking the dog for a walk and suddenly experienced chest pain? How rapidly would you be able to select the *acute myocardial infarction app*? There's every risk you'd end up lying prone on the sidewalk, clutching your chest, with only the thumping beat of your favorite music available to treat your arrhythmia.

As with all good design, the iPod was designed with a specific purpose in mind. Its interface demands exploration and (initially) trial and error. A first-time user might struggle to select and play a specific music track and then adjust the volume to a comfortable level without any guidance, which is acceptable for a digital music device. But an inexperienced user of a medical device can't afford such luxuries when required to rapidly deliver a life-saving treatment in a pressure-cooker emergency scenario.

The team at Apple understands the value of the user experience, and whilst the iPod is a consumer product, this doesn't

mean the same outlook need not apply to your medical device. Like an iPod, a thoughtfully designed user interface will help build sales through product demonstrations and word of mouth, create a loyal customer base, and generate repeat purchases. It will help build and maintain your brand. It will also comply with the mandatory FDA guidelines and may ultimately protect you and your company from costly litigation.

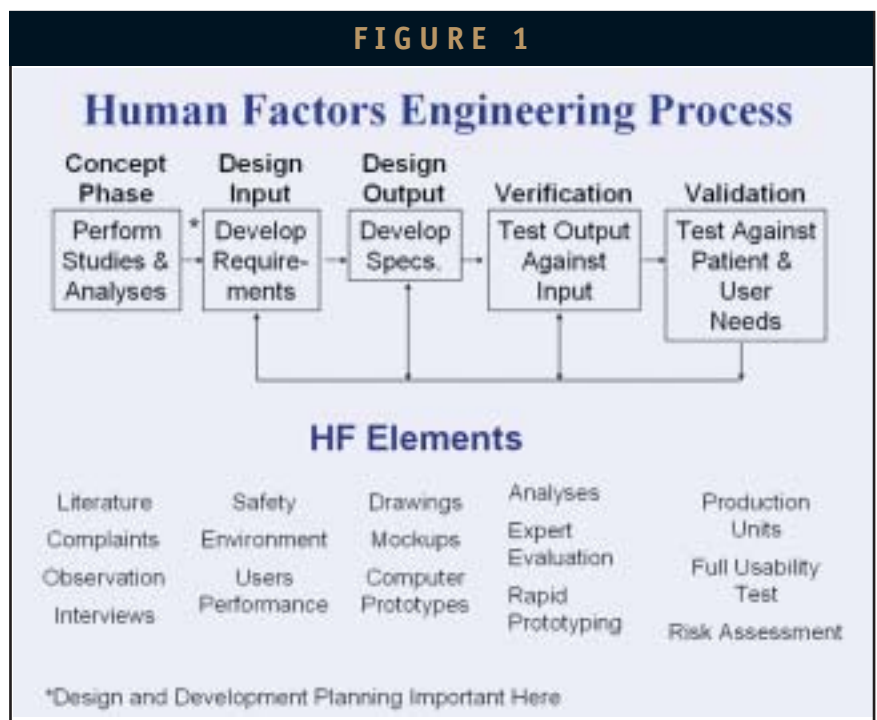
There is a global trend to develop medical devices that provide treatment to patients in their homes. This in turn requires a drug delivery medical device that enables the user to self-administer drugs. The typical users may be elderly, impaired, distracted, rushing, or overly confident in their abilities in spite of having not read the instructions. All of these scenarios can lead to error if the device isn't well designed.

The FDA receives on average 100,000 medical device incident reports per year, and more than a third involve user error. In an FDA recall study, 44% of medical device recalls are due to design problems, and user error is often linked to the poor design of a product. Drug developers need to take safe drug dosage into consideration, and this consideration requires the application of thorough processes for Risk Management and Human Factors Engineering (HFE).

### THE DANGERS OF MEDICAL DEVICES

Although unintended, medical devices can sometimes harm patients or the people administering the healthcare. The potential harm arises from two main sources: (1) failure of the device and (2) actions of the user or user-related errors. A number of factors can lead to these user-induced

FIGURE 1



# ADVANCED DELIVERY DEVICES

errors, including medical devices are often used under stressful conditions and users may think differently than the device designer.

## HUMAN FACTORS ENGINEERING (HFE)

The best way to address these dangers is through the implementation of an HFE program throughout a product's development. Human Factors is the study of how people use technology. It focuses on the science and methods used to make devices easier and safer to use. When applied to medical devices, including those for drug delivery, HFE helps improve human performance and reduce the risks associated with use. HFE refers to the application of human factors principles to the design of devices and systems. It is often interchanged with the terms human engineering, usability engineering, or ergonomics. Specific benefits of HFE include the following:

- Significantly reduced risk of device-use error
- Better understanding of device status and operation
- Better understanding of a patient's current medical condition
- Easier to use (or more intuitive) devices
- Reduced need for training
- Reduced reliance on user manuals
- Easier-to-read controls and displays
- Safer connections between devices
- More effective alarms
- Easier repair and maintenance

But let's not forget our iPod example. The more thoughtful and integrated the HFE, the more likely the product is to succeed (all things being equal). If your device is beautifully integrated in its design, engineering, and ergonomics, you are a long way toward achieving a successful product.

## FDA GUIDELINES

The FDA imposes stringent standards on medical devices, requiring them to meet the Quality Systems Regulation (QSR)/CGMP - Design Controls. Manufacturers are also required by the FDA to demonstrate how human factors considerations were met throughout a product's development. To assist you in your process, there is the HFE standard *ANSI/AAMI HE74:2001 Human Factors Design Process for Medical Devices and the IEC 60601-1-6*.

The *ANSI/AAMI HE74:2001* describes almost everything a designer needs to know. It provides an overview of the HFE process, including planning, methods and techniques, and risk and cost benefit analysis. It highlights the need for user input; scaling the HFE work; documenting the HFE activities; and design evaluation, verification, and validation. Figure 1 illustrates the stages in the HFE process.

## HFE IN PRACTICE

As discussed, HFE is not a separate component of a product development program. In fact, you must start thinking about usability from the moment you decide you are going to develop your device and constantly check and evaluate usability throughout the device development. At Invetech, we've been using a user-centered design philosophy for more than 20 years, enabling us to develop better and safer products and devices for an international client base. The following are some of our key learnings.

### **INTEGRATING HFE EXPERTS &**

**ENGINEERING TEAMS:** Our approach is based on a complete integration of HFE experts with the engineering design team from the very beginning of a development project. This integration ensures that the technical team receives direct and continuous input into their design activities, while interchanging technical ideas, challenges, and solutions with our HFE experts.

### **UNDERSTANDING THE USER'S**

**ENVIRONMENT:** At the outset of a product development activity, time is taken to immerse our team in the target workplace with the aim of developing a deeper understanding of the real-world challenges facing our customer. Contextual enquiry and observational research are at the heart of this immersion activity, enabling us to gain valuable insights into the unmet needs of the target user group(s). Through intense immersion into the users' environment, often achieved through site visits (hospitals, laboratories, doctors offices, domestic homes) and interaction with end users, we gain real-world insights that then drive product engineering.

### **CONCEPT DEVELOPMENT &**

**ASSESSMENT:** When these insights are identified, the design process can begin. Concepts are generated considering technical and commercial feasibility whilst concurrently addressing critical user needs. Design details like product dimensions, size of user interfaces and screens, access to consumables, etc are developed in close cooperation with the technical team. The results are initial product sketches and usability mock-ups (simple three-dimensional models to enable quick conceptual evaluations). Procedures for use need to be logical, intuitive, and consistent. Key safety concepts in design include making things easily visible, simplifying the operation, avoiding reliance on memory, avoiding reliance on vigilance, and making it easy to reverse an error.

### **SAFETY ASSESSMENT, ANALYSIS &**

**DESIGN REFINEMENT:** When such concepts are defined, both engineers and HFE experts can conduct safety analyses based on methodologies, such as FMEA (Failure Mode Effects Analysis) or FMECA (Failure Mode Effects and Criticality Analysis). The team assesses what can go wrong for each identified use case. While the technical team assesses this with a focus on technical failures, HFE experts are assessing potential errors induced by users when interacting with the device. Failure modes of each use case are

# ADVANCED DELIVERY DEVICES

assessed with respect to their impact on the result and then weighted by probability, severity, and often detectability. Through this evaluation, a criticality number for each identified failure mode is assigned. Once identified, the team then develops mitigating designs for each significant (ie, carrying a high criticality number) failure mode. Preferably, the mitigation is a design solution that prevents the failure mode or significantly reduces its probability to a level that is acceptable. When doing so, it is also important to assess the reliability of such preventive design solutions (keeping in mind that a safety measure that doesn't work reliably does not add value).

**USER ASSESSMENTS & STUDIES:** The next step in this process is the generation of simple full-size models that emulate key parameters and features. Working with a range of end-users, typically covering from 5%-ile to the 95%-ile user, these early models provide remarkable input into the overall product design. Additional methods to be considered depending on the nature of the device are research studies (focus groups, one-to-one interviews, contextual inquiry) task analysis, usability, and safety bench tests. We will routinely test a range of designs with the target user group to gauge reaction to size and form, to step through workflows, to undertake operating procedures, and evaluate maintenance and servicing opportunities.

**DESIGN REFINEMENT:** Incorporating the feedback from these studies into the design process and refining the requirements in parallel, the engineering team and the design team are then performing the first iteration detailed design, resulting in fabrication and test of early prototype units. Typically at least one or two more prototype iterations will follow, and for each iteration, the human factors assessment is repeated, ideally with a varying range of users to broaden the statistical relevance of the feedback. Typically, the completed design needs to be validated, and again, it is important to not only consider the function of the product but to also assess its usability.

## SUMMARY

Drug developers planning to develop medical devices must consider the challenges of human factors when developing and designing this type of new product. The benefits to be gained by cohesively integrating HFE into the device are not only the mandated technical compliance, but also enhanced opportunities to build sales and gain a loyal customer base. And to integrate HFE into your device, you must integrate your human factors and engineering teams from the very start of a development and throughout the development program. Hence, it is successful integration and the quality of your HFE team personnel that will help drive your product's success.

A good team will undertake systematic assessments of who your target device users are, under what conditions will the device be used (use environment, situational factors), and what might be the use-related hazards. But beyond the tangible, a good HFE team can add the intangible "delighters" to your device. To fall back on the music analogies, just as a hit song generally has a hook that sticks in your mind and has you humming it in the shower, so can clever HFE be memorable. It might include the tactile nature of the keypad controller you use to operate the device, the clever yet clearly written instructions, the sound of the alarm that differentiates your device from a sea of others, or even mechanical noise it makes while processing a protocol. All of these elements combine to create a memorable user experience just as 70% of all MP3 owners have when they switch on their iPod.

So, next time you hear someone in marketing proclaim "we expect our new gadget to be the iPod of medical devices," you are well placed to inform them of what is actually required to achieve this, which extends well beyond reliance on merely a beautiful product form. ♦

## BIOGRAPHIES



**Alan Morris** is a Business Development Manager with Invetech. He has 18 years of experience in consumer product and medical device design. He has a background in industrial design and is particularly

passionate about good Human Factors Engineering. He has been known to write a letter or two to companies whose products, operating systems, and/or instruction manuals fail the common sense test.



**Andreas Knaack** is the Director of the Biomedical Instruments & Devices division at Invetech. He is responsible for the strategy, sales, and delivery of custom product, instrument,

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