The Challenges of Developing Medical Devices for Consumers

by Norm Delisle, VP Engineering

A Tale of Two Markets

When a family member is in the hospital – even for a routine treatment – it feels like time is standing still and nothing in the world matters more than helping them through the ordeal – both to feel better quickly and to survive the invasive experience. Hospitals are wonderful places when you need them. But you don’t want to spend any more time there than absolutely necessary.

My son undergoes frequent intravenous antibiotic treatments to help fight respiratory infections. When he was young, this meant three weeks in the hospital – usually twice per year. My wife and I would keep him company during as much of the day as possible and usually one of us would spend the night there too. Today, thanks to the advent of home infusion pumps, he can undergo the entire intravenous treatment without spending a single day in the hospital. It still is not fun, but it is far less disruptive to his life and ours.

Developing products for home use brings a new set of challenges to the already difficult processes of developing safe and effective medical devices. If these new challenges are well understood and effectively addressed, they can lead to medical devices that not only save lives and improve outcomes, but also make medical care itself a lot less traumatic.

This article explores in depth the best practices of the consumer product industry and how those practices can be blended with the best practices used today to develop professional medical devices.
INTRODUCTION

Increasingly sophisticated medical care is moving from hospitals and clinics and into the home. Medical devices for consumers have advanced from thermometers and blood pressure monitors to infusion pumps, AEDs, hemodialysis systems, and wearable wirelessly-connected monitoring and drug delivery systems. To help manufacturers deal with the unique challenges, the FDA has launched a Medical Device Home Use Initiative.

Consumers are playing a bigger role in their own healthcare taking pressure off the overburdened medical infrastructure and increasing their potential for healthier lives and improved outcomes. This shift creates new market opportunities for medical device manufacturers.

Many product development teams might be ill-equipped to meet the unique needs of these new users. Most of the key medical device design drivers are changing radically:

- Lower product cost
- Shorter time to market
- Frequent replacement cycles – shorter product market life
- No servicing needed during the product’s lifetime
- Emphasis on user experience and appeal, not just usability
- Compact size, ruggedness and portability
- Higher manufacturing volumes
- Advanced technologies

Successful consumer product companies have been able to meet many of these challenges. However, most consumer product companies do not have in place the quality processes necessary to develop medical devices. It takes the experience, knowledge and processes of medical device manufacturers to meet all the medical device regulations and standards while developing safe and effective products.

With our 16 years of experience working in both the medical device and consumer product markets, we have learned that the best practices of each industry can be blended to meet the challenges of developing medical devices for consumers.
Medical Device Development Using Consumer Product Best Practices

### Lower Product Cost With No Servicing Needed During Its Lifetime

Medical devices typically cost thousands or even tens of thousands of dollars. These costs are beyond the reach of most consumers. To succeed in a competitive consumer-driven medical device market, medical devices must be affordable – with costs below a hundred dollars for many types of devices.

The consumer product industry has extensive experience developing affordable products by making effective trade-offs regarding the cost versus the value of functions and features. A systematic method, such as Value Engineering, must be applied at appropriate points of the product development cycle starting with the earliest product concept phases. The bottom line is that the ratio of function to cost must be managed carefully.

As product volumes increase, economies of scale can also help reduce costs with good return on investments in custom chips and assemblies. Costs of goods sold (COGS) are further reduced using a greater degree of automated assembly and manufacturing test than is typical for most medical devices.

### Shorter Product Lifetimes

Most hospital and pre-hospital medical devices have an expected service lifetime of five or ten years or more. The design, supply chain and manufacturing processes are tuned to make sure that the device can continue to be manufactured and repaired for fifteen years or more. A significant portion of R&D budgets is devoted to sustaining engineering to qualify substitute parts or suppliers and to redesign around parts that are no longer available.
Consumers have grown accustomed to seeing frequent releases of new and improved versions of high-tech products. For example, Apple introduces new models of iPhones every fall. Loyal customers are willing to fund this frequent replacement pace, thereby creating a significant source of recurring revenue for consumer device companies.

Will this same consumer market expectation carry over to medical devices? As competition for consumer medical devices heats up, consumers are likely to expect their medical devices to use the latest technologies and provide a fresh appearance like competitors’ newly introduced devices. This rapid paced market dynamic is a fundamental business difference that medical device firms will need to embrace.

**Shorter Time To Market**

The development of a typical medical device can take three years or more. In contrast, the development of a typical high-tech consumer product is typically less than a year, sometimes as short as 6 or 9 months. For a consumer medical device that will have a market lifetime of only two years, you cannot spend three years developing a product or you end up with a market gap where your older product loses market share.

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Can a medical device be developed in less than a year? For a development team accustomed to three-year development cycles, accelerating time to market seems like an almost insurmountable challenge. However, many medical device companies are able to develop major product upgrades or feature enhancements to an existing medical device in less than a year.

Realistically there are practical limits to time to market especially if clinical studies are needed. Strategies such as pipelined development of a new product and its successor are sometimes possible. Reusable device platform strategies can also be effective schedule reducers. Automation of design verification within the context of agile design/build/test cycles can also significantly reduce development time.

Due to quality standards, regulations and overall safety, shortcuts cannot be taken. However, in most organizations, schedules can be shortened and quality improved at the same by using a lean philosophy to avoid time-consuming rework (such as unplanned PCB spins) by finding and removing defects earlier in the development process via more thorough design reviews. Additional schedule acceleration methods include mitigating project schedule risks using rapid design/build/test cycles for prototypes, and employing more efficient and effective tradeoff studies and decision making.

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But for any of these strategies to be successful, a different mindset is needed to drive more efficient processes without any compromise to quality. The new mindset cannot usually be found in consumer product companies where quality processes are not tuned to achieving medical device quality. Instead, this is another area where inspiration comes from blending the best practices of both industries.

**Emphasis On User Experience And Appeal, Not Just Usability**

Today, a professional medical device undergoes usability testing – using both formative testing to help shape the design and summative testing for verification and validation. Compliance with usability standards such as IEC 62366 is required.

Purchase decisions for professional medical devices are based on specifications – devices are selected because they provide all of the required functions and features and the medical device manufacturer has a strong reputation for quality and service.

Consumers make purchase decisions differently. The color of the product, its form factor and its general appearance can have a strong influence. Cost is nearly always a major factor: ironically, sometimes a higher cost increases the appeal when there is a strong emotional connection to quality or status – such as for cars and smart phones. The dynamics of medical devices for the home could see drastically different buying patterns yet to be fully explored.

A consumer medical device needs to present the appearance of a reliable, solid, innovative, high-tech product. At the same, it needs to be rugged enough for home use and abuse, and nearly fool-proof in its usage. Does it also need the pizazz of a high-tech consumer product? If so, are you prepared to deliver?

**Compact Size, Ruggedness And Portability**

Tablets keep getting slimmer. Why? It is certainly not because slimmer is easier or less expensive to design and manufacture. And it can be argued that the quest to shrink the size has progressed beyond what users really need. But it increases the coolness factor and it sells products.

Consumers expect a lot of high-tech features to be packed in very small packages. They might be willing to purchase a medical device in a ten-pound box, but only if there are no smaller and lighter alternatives available. Higher production volumes help enable the design investments needed to achieve smaller designs.

**Consumers might be willing to purchase a medical device in a utilitarian ten-pound case, but only if there are no smaller, lighter and more attractive alternatives available.**

For wearable devices, small size is critical. A chest-worn ECG sensor, or a drug-delivery patch must be
so small (and light weight) that the users forget they are wearing them. A wrist-worn wearable medical device needs to be about size of a watch to be accepted by consumers.

Achieving smaller size can have implications on the technologies used. For example, with a portable device, ultra-low power electronics is needed to keep the battery size small. Advanced sensor technologies might be needed. And ruggedness and ingress protection cannot be ignored.

**Higher Manufacturing Volumes**

A typical professional medical device might be manufactured and sold at annual volumes of thousands, or maybe tens of thousands of units. Successful high-tech consumer products, like video game controllers, will sell many millions of units per year. Will consumer medical devices reach these same volumes?

There is already strong evidence with devices such as home blood pressure monitors where there are over a dozen medical device manufacturers with a global market of over $2B that is expected to double of the next couple of years.

Many types of consumer medical products and accessories, such as blood sugar monitors and their test strips, syringes, and ECG electrodes, are already manufactured in high volumes by medical device manufacturers. However, more complex professional medical devices are typically not designed for high volume manufacturing.

For most medical devices, some attention is given to design for manufacturability and some level of automation might be applied during assembly and manufacturing test. However, scaling up manufacturing volumes by a factor of ten cannot be achieved without a stronger manufacturability focus throughout the design cycle to support more highly automated manufacturing approaches.

**Advanced Technologies**

Home medical devices will be expected to pack in the latest and greatest high-tech features. Wireless technologies will be expected to provide trouble-free secure and reliable connections. Batteries are expected to charge faster and provide much longer run times. Users will be disappointed if their medical devices do not keep pace with their other high-tech products.

This area alone is a sea-change for medical device manufacturers who are more accustomed to embedding only tried and true technologies and components with very long assurance-of-supply agreements. With the design objective for long product market life lifted, it is possible to use technologies that are the best today even if they might not be readily available in ten years.
Suitability for use in consumer products is not necessarily the same as suitability for use in medical devices. Each technology must be evaluated with respect to safety and security risks as well as usability and necessity for effective clinical usage.

Consider the utility of wireless connectivity. In a consumer medical device, it enables remote monitoring for changes in the patient’s condition or compliance checking in a drug delivery device. Data collected might also yield insights that lead to more effective home treatments and devices for a wider range of conditions and patients. Data collected can also be essential for investigating any incidents that might occur. However, in a medical device, care must be taken to ensure that the wireless technology is secure and it cannot interfere with the device’s essential functions.

BLENDING THE BEST PRACTICES

Integrating the best practices of consumer product development into your medical device development process does not necessarily require a complete rewrite of your Quality Management System (QMS). A good strategy might be to blend in the new practices as a set of Corrective and Preventive Actions (CAPAs).

For example, a CAPA for shorter time to market would start by analyzing the root causes of why it typically takes your organization so long to develop a new medical device. Specific preventive practices can be put into place, bench-marking and leveraging associated best practices from the consumer device industry. And follow-up activities can be planned to monitor the effectiveness of improvements as they are put into place on consumer medical device projects. It is all too easy for the team to slip back into their comfort zone with the net result of missing the market window.
SUMMARY

How can your team gain a deep enough understanding of the best consumer product development practices?

Key Challenges:

- Traditional medical device development processes do not yield products with the lower costs, higher volumes, shorter time-to-market, and more frequent replacement cycles needed to succeed in consumer markets.

- Consumer product companies successfully meet consumer market demands, but their quality practices do not meet the standards and regulations of medical devices.

Recommendations:

- Before launching a consumer medical device development project, assess your organization’s capabilities for meeting the new demands of consumer medical devices that are described in this paper.

- Retune your development processes to blend the best practices of both medical device and consumer product development.

ABOUT ANDREWS-COOPER

Andrews-Cooper was founded by two engineers who worked for a major manufacturer of medical devices and consumer products. Since 2000, we have continued to specialize in the development of both medical devices and consumer products. Our experience includes wearable connected medical devices, and high-volume, and low-cost wireless consumer products for health and wellness. Our product development methodologies and processes incorporate best practices from both worlds and are backed up by an ISO 9001 and 13485 compliant Quality Management System.

Andrews-Cooper has built a business focused on solving real engineering problems. Our deep experience and diverse expertise allow us to serve our customers at the highest level. We have found that a partnership approach is the best way to ensure the job is done right. We offer this paper in order to stimulate conversation as to how best to help our medical device customers thrive as this transition to consumer-based care continues.

Consider these challenges as your organization prepares to develop medical devices for consumers. For more information on how A-C can help, please visit our website at www.andrews-cooper.com, or contact us directly.

Norm Delisle is the VP Engineering at Andrews-Cooper. He oversees our client projects and manages our QMS. He has developed numerous successful products during his career ranging from medical devices, consumer products, automated manufacturing systems, transportation systems, electronic instrumentation, and a variety of software applications. His Systems Engineering focus is built on extensive experience in general management, project management and software and electrical engineering. Mr. Delisle is a seasoned consultant, mentor and public speaker, and has taught graduate courses and corporate training seminars in quality management, project management, and software engineering.