method sense

More than Design: Tips for Successful Medical Device Development

by Russ King

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More than Design: Tips for Successful Medical Device Development

Medical device company executives seeking a 510(k) pre-market approval path, or who have electronics or software included in their product, need to be aware of the most common regulatory affairs, quality and safety components, as well as some frequently overlooked tips that will save money.

by Russ King, MethodSense

Since 2008, the economic landscape has created numerous challenges for emerging medical device companies, especially when it comes to available capital. Economic and political uncertainties continue to temper enthusiasm for medical device markets. While a significant number of medical device innovations never make it to market for logical reasons, we'll never know what lost opportunities have occurred due to the poor economy.

That being said, there appears to be a light at the end of the tunnel for emerging medical device companies. The capital market seems to be loosening up, with baby boomers and technology transfer accounting for expanding opportunities for Med Tech companies. In support of an aging population that hungers for an improved quality of life as they grow older and our thirst for bigger and better technology solutions, universities and businesses are emphasizing technology transfer. Technology transfer ensures scientific and technological developments are accessible to a wide range of people who can further develop technology into new products, processes, applications, materials and services. There are entire university departments that focus on identifying research with potential commercial interest, especially as it relates to healthcare.

Consequently, our life science consulting practice is seeing a growing number of emerging companies with executives who are new (or nearly so) to the business of medical devices. The fresh executive talent coming to the medical device industry might benefit from a few guiding tips as they think through a framework for their company.

Tip #1: There's More to Being a Medical Device Company than IP and R&D

Most emerging medical device companies tend to focus their energy on product development and R&D. This is understandable because medical device founders are often experienced innovators with limited business experience. As innovators, there's a natural affinity to maintain a continued focus on R&D. Having a clear IP position and strategy is an important factor for attracting capital, which could further emphasize the importance of R&D, product development and market analysis.

Nevertheless, being, living and growing as a viable medical device company catering to the U.S. market requires much more than R&D, positioning your IP and measuring how big your market is. It involves developing an operational framework that structures your organization as a medical device company (Figure 1) and enables the commercialization of your product. This includes:

- Regulatory Affairs
  - 21 CFR Part 820
  - 21 CFR Part 11, if your device incorporates software
- Quality Management
  - Design Controls that are included in Part 820
  - QMS requirements you might find in Part 820 and ISO 13485
  - Risk Assessment and Risk Management found in FDA Guidances and ISO 14971
- Safety
  - IEC 60601-1 testing
  - Clinical data or a clinical trial

When wrestling with regulatory, quality and safety issues, executives fresh to the medical device industry often take uncertain or delayed steps as they navigate the path to becoming a medical device com-

pany. The biggest mistakes we see emerging medical device company executives make include delaying the development of their regulatory strategy and their quality system, which are critical components to the structure of Med Tech companies. Failing to attend to their development will only increase costs over time.

It is also vital not to misgauge the complexities and nuances of commercializing medical devices from a regulatory and quality perspective. Misunderstanding what it takes to comply with the regulations, build an adequate quality system or neglecting to adequately plan for demonstrating product safety will increases costs.

It is also a mistake to take regulatory or quality "short cuts." In our experience, we've never seen a short cut in this industry that *didn't* increase costs. For example, it sounds like a time saving step to buy a set of quality system templates and "fill in the blanks." However, most packaged templates exhaustively represent the entire regulations line-by-line and tend to be built for organizations with at least a couple of dozen employees. The work required to integrate a system of templates to your particular product, company size and practices usually costs much more than the anticipated savings.

Ultimately, executives will save money by developing the infrastructure and processes that qualify their business as a viable medical device company. To save time, money and stress, develop and deploy the appropriate regulatory strategy, the most efficient and compliant quality management system (QMS), aggressively perform actions needed to demonstrate product safety… then keep it up.

Tip #2: Know the Industry Expectations for a Medical Device Company

Most medical device executives know they need FDA approval to legally market and promote their product in the U.S. Beyond FDA approval, understanding how to effectively commercialize a medical device product means adapting to industry and legal expectations for operating as a medical device company. These expectations ensure that you deliver safe and effective products. Knowledge and experience is required to do this effectively and to avoid costly mistakes.

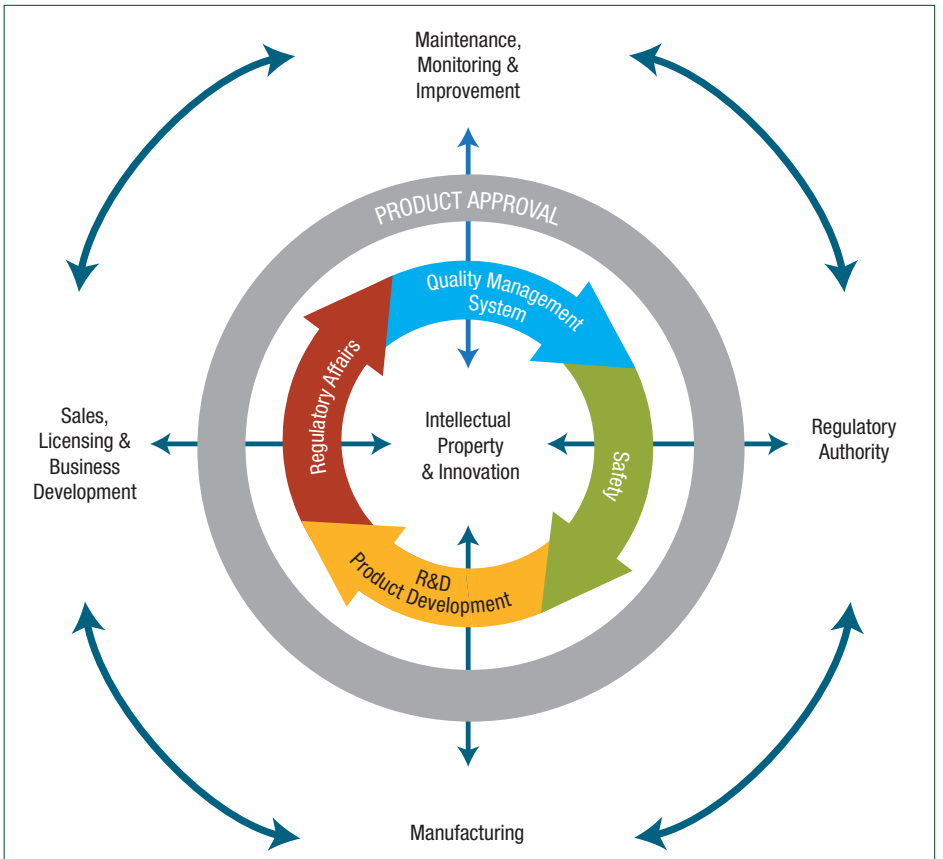

Figure 1 The framework is not intended to represent a roadmap or commercialization pathway, but instead a conceptual framework that every medical device company must work within. It works itself from the inside out first and then, if the company is working, all the functions should inform the others.

At this point, it's important to realize that although we talk about the FDA as a regulatory body, it is, in fact, a law enforcement agency with the powers associated with such authorities. The FDA can cite, fine and prosecute for violations of laws, such as 21 CFR Part 820 or 21 CFR Part 11. The laws the FDA enforces are administrative laws that are part of a national regulatory scheme, like police law and international trade.

Medical device companies not compliant with 21 CFR Part 820, and other applicable regulations, make themselves vulnerable to FDA enforcement practices. The tricky part is that the FDA doesn't tell you how to operate as a compliant company. You have the flexibility to implement the necessary processes to satisfy the applicable regulations and support them with your own compliance practices. However, you're expected to fully understand the intent of the regulations and meet those expectations—regardless of your size and resources.

While FDA enforcement actions rarely result in jail time for executives, they can force expensive corrections and cause significant damage to your reputation. Truly,

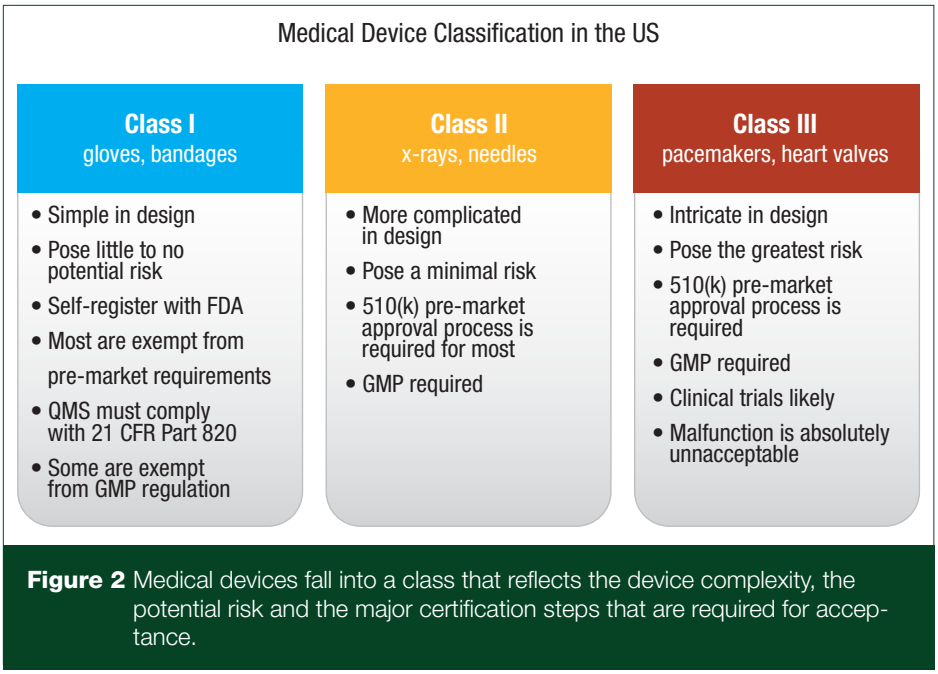

Figure 2 Medical devices fall into a class that reflects the device complexity, the potential risk and the major certification steps that are required for acceptance.

it's best to comply willingly and faithfully and view the regulations as a way to create a more streamlined and efficient company.

Tip #3: An Early, Practical Handle on 21 CFR Part 820 Improves Your Company

The purpose of regulatory affairs is to ensure that your company complies with applicable laws and regulations. These regulations, such as 21 CFR Part 820, are intended to ensure devices entering the marketplace are safe and effective. If you don't fully understand 21 CFR Part 820 and how to apply it properly to your company, find someone who does. Having experience in this area is critical to efficiently implementing compliance that supports your business goals.

21 CFR Part 820 focuses on current good manufacturing processes (cGMP) and controls used for the design, packaging, labeling, storage, installation and servicing for all finished devices intended for human use. You should know that 21 CFR Part 820:

- Is an FDA-mandated system of product design
- Requires you to document the evolution of the life of your product
- Applies a market-first product development focus
- Requires a team-oriented approach to product commercialization
- As a process, tends to challenge product design to the point of improvement

Compliance is a necessary expense; don't put yourself in a position where it costs more in dollars or opportunity than it should. Take extra care early on to develop processes that, when followed, meet your compliance obligations in a way that supports your business goals and personality (Figure 2).

Tip #4: An Early, Practical Handle on Design Control Ensures a Quality Product that Safely and Effectively Meets a Real Market Need

21 CFR Part 820 prescribes specific design controls, or processes, for bringing medical devices to market. The objective of design controls is to develop and implement a sound process for reaching an acceptable level of efficacy and safety for medical device products. Generally speaking, design controls implementation occurs in phases that move a product along a commercialization path and are often characterized in the following way:

- Design and Development Planning
- Design and Development Input / Output
- Design and Development Verification
- Design Validation
- Design Transfer
- Design Changes
- Design History File

If implemented well, design controls create a number of surprising benefits, including a better documented product that is more attractive to buy or acquire. They result in a more efficient development cycle due to a reduction of mistakes thanks to early analysis of key questions and a clear distribution of a team's responsibilities.

Design controls should work as a preventive approach to the quality of your medical device and the mitigation of risk. Prevention is an efficient and cost-effective way to control manufacturing processes and maintain quality. While it may not be possible to eliminate all potential risks, we consistently observe in our clients a very poor appetite for realized risk that was otherwise mitigable.

Tip #5: Don't Forget Safety Testing and the Value of Risk Management

In our experience, the most frequently forgotten aspect of medical device development and commercialization from emerging companies is establishing a safety profile of a product. While clinical data or clinical trials may be necessary for establishing safety for some products, many Class II devices that follow a 510(k) clearance pathway require minimal, if any, clinical data to support safety claims. Once the need for clinical data is either planned for or eliminated, establishing the safety of a medical device through additional testing tends to be less of a priority.

Depending on the technology incorporated into your medical device, applicable safety standards need to be identified during the design stages of the product. The most widely accepted benchmark for establishing safety for electrical medical devices is a standard called IEC60601-1, where compliance has become an acceptable means for satisfying electrical safety requirements for the commercialization of electrical medical devices in the European Union.

60601-1 has undergone revision recently. The third edition is enforced now in the EU and the second Edition is currently applicable in the U.S. The FDA will require the use of the third Edition of the standard for new devices as of June 30, 2013. In this new edition of the standard, there is strong emphasis on risk assessment, ISO 14971

and, in the U.S, a focus on device usability as an important factor contributing to the safety of the device.

Product testing to 60601-1 is a very technical exercise that involves laboratory testing against the standard by a test house, such as Underwriters Laboratories. If you are complying with the third Edition, there is the additional task of demonstrating safety through extensive, component-by-component, risk assessment.

While complaints about the complexity and cost of safety testing in general and 60601-1 in particular have many sympathetic ears, safety testing has significant benefits. Meeting the demands of safety testing is a necessary step for electrical medical devices in the commercialization process. Through test house examination and risk assessment, it forces a very deep understanding of your product, which can be invaluable for product improvement, market positioning and sales, and exit strategies.

Tip #6: All Software Has Bugs – Manage Them

Improved technologies and automation capabilities continue to be applied to medical devices, benefiting both patients and device users. With the addition of sophisticated electronics, PLCs, off-the-shelf software components, custom software applications, and the proliferation of mobile devices, software-driven devices now permeate medical device markets (Figure 3).

As previously noted, 21 CFR Part 820 includes a requirement for validation. In this instance, validation means confirmation that the product is capable of meeting its particular requirements for intended use. 21 CFR Part 11 is the FDA regulation that applies specifically to software.

Proper software validation dramatically reduces the occurrence of software incidences. By thoroughly testing a product against actual use cases, and correcting incidences before releasing the product to the public, you will prevent potential product recalls and field fixes, control the need for new software builds and releases while reducing the need and expense of help desk support.

Once you've determined your innovative idea is indeed a medical device, it's time to start thinking like a medical device company, not just group of innovators. Using a framework of regulatory affairs, quality management and safety puts your business on the right road to meeting requirements. While at first blush it seems these three components might be separate functions, they don't function well in silos. They do best when implemented as part of a company-wide compliance strategy. As you begin the process of designing your regulatory strategy, you may be surprised to find that by pulling a thread in one part of the framework, what was thought to be an unrelated part will move, too. It takes knowledge and experience with the components of the commercialization process to become and remain compliant. Be sure to think of regulatory affairs, quality and safety as an ongoing part of your business strategy for the most successful outcome.

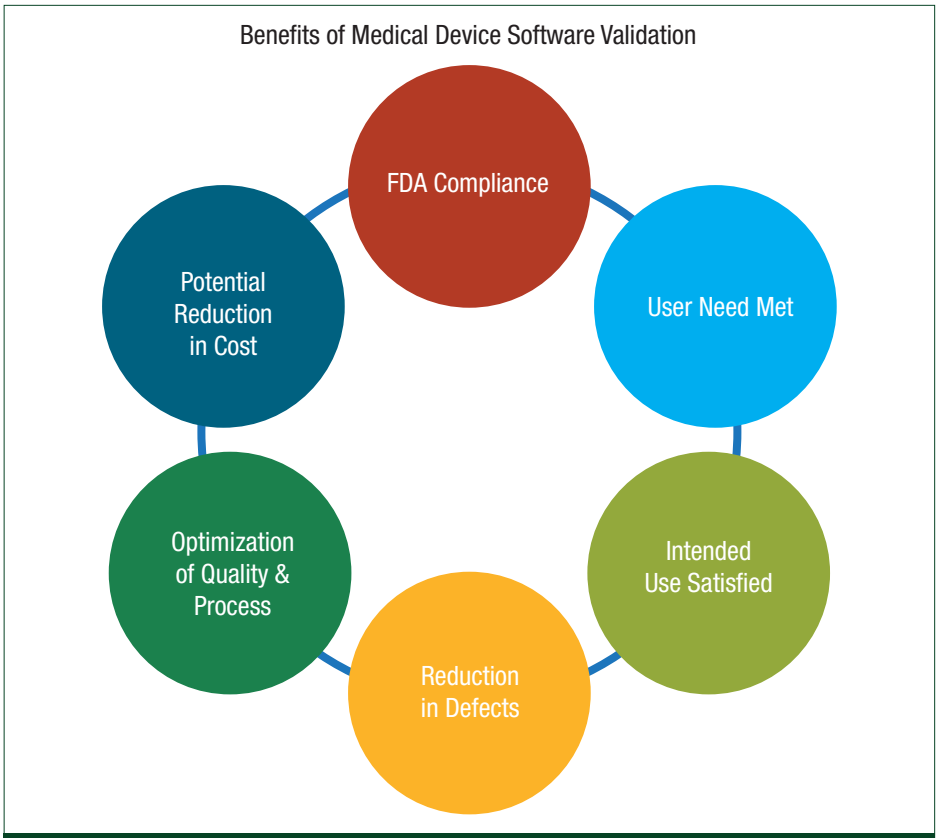

Figure 3 Software validation. This is a graphical representation of the benefits of validation and the last tip.

MethodSense
Research Triangle Park, NC.
(919) 313-3962.
[www.methodsense.com].