



Medical Device Commercialization Best Practices

The evolving regulatory landscape and the accelerated pace of medical device innovation are increasing pressure on medical device developers to speed their time to market while providing higher quality products, at less cost.

Navigating this shifting terrain and enabling a quick time to market can often be a challenge. In this eBook, we sat down with Cognition Corporation, compliance and medical device solutions specialists, to gather their insights on the commercialization challenges that medical device developers face and the best practices to overcome them.



The overarching belief is that the commercialization of medical devices has become more complex as regulatory and healthcare requirements have evolved. How would you describe the evolution of the regulatory landscape in the U.S. and how do you think it is impacting the commercialization of medical devices?



We see the regulatory environment becoming more complex but the biggest challenge is the changing nature of the regulatory environment. New standards, updates to current standards, and the move towards more device based systems make it more difficult than ever to bring a new device to market. Many new devices are combination products so there is a need to merge the drug side with the device side. This create an interface between two areas that do not have a long history of interaction. Also, the inclusion of medical devices using apps, mobile devices, Bluetooth, and cloud services bring additional new challenges for security and reliability. We seen this trend accelerating. A growing number of new startups are combination products with internet connections.



What are the biggest mistakes that you have seen medical device developers make when taking their device to market?



The biggest mistake we see is waiting too long to pay attention to compliance. Many smaller companies think of themselves as engineers and scientists and think of regulatory and compliance as add on activities to be addressed “later.” This causes a lot of backfilling of information and added expense. It can often lead to rejected or challenged submissions. Companies need to take FDA into account at an earlier stage, have more rigorous attention to compliance mandates, and prepare a reimbursement strategy. We see these mistakes happening enough to conclude that regulatory and compliance efforts are still often consider bolt on activities instead of simply being part of good development processes.



What best practices do you recommend medical device developers employ to speed commercialization?



Focus on “FDA Early” meaning include compliance thinking as early as possible in the product development process. Understand the regulations and standards that apply to your product and make small investments early to include Risk Management and Design Controls to your process. It is costly to remediate, costly to resubmit, costly to fail. Early attention to detail always pays off in the long run.



How do you see the industry evolving over the next five years and what is your forecast for the years to come?



We see the device industry moving quickly to develop devices to be used by patients with reduced need for doctor or hospital visits. This is being driven by cost reduction demands on the industry. Wireless, cloud connected devices allow healthcare professionals to monitor patients remotely, thus saving time, money, and inconvenience due to travel. Security will become even more central as devices can be hacked, data breached, and drug delivery devices can malfunction leading to patient death. The industry will grow with more complex devices, smaller devices, and lower cost devices. Companies who combine all these elements together in a device will see growing demand. Regulatory bodies will struggle to keep up with new technology so device makers should take an aggressive role by working with the regulatory agencies to help develop rational, comprehensive, understandable standards. Get on an FDA panel, join an ISO committee, be part of an INCOSE working group.



Cognition Corporation has been offering solutions for product and process development for more than fifteen years. Cognition has two core products: Cognition Cockpit™ and Enterprise Cost Management™ (ECM). Thousands of users worldwide have used Cockpit and ECM to manage their product development and to meet performance, cost, risk, and targets.

Additional Insights:

-  [Whitepaper: Focusing on Risk Management & Usability in the Design Control Discussion.](#)
-  [Whitepaper: Avoiding Deficiencies in Design Verification and Validation](#)
-  [Struggling with finding a fully validated Requirements Management Tool? Check out the Cockpit Validation Kit](#)



Join Cognition Corporation on October 5-6, 2016, as David Cronin
CEO, Medical Device Commercialization Chairs the:

[American Medical Device Summit 2016](#)

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