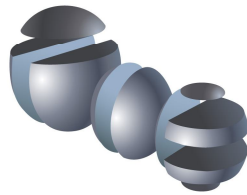


The Automation
of
FDA
Medical Device Design Controls

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Introduction

Early stage medical device companies provide the innovation and intellectual property that feed the medical device industry with great ideas and life saving devices; but understanding FDA regulations and reaching commercial markets can be extremely daunting for new companies.

Mature medical devices companies who have successfully traversed the complex maze of FDA regulations and are effectively marketing their device are often left with a legacy of individual processes, systems, and tools known as “point solutions” that are fragmented and have broken down over time.

The two scenarios above both describe medical device companies, but they are operating on opposite ends of the company growth spectrum. One also has to consider that the natural market evolution for most early stage medical device companies is to get acquired, and anything that can be done to help make the M&A (mergers and acquisitions) process easier can result in big payoffs down the road.

“Turbo Taxing” the medical device design process to help pull a company through the FDA regulated processes, shortening design cycles, and improving management efficiencies is all possible through process automation and the use of integrated tools.

Imagine the cost savings and increased sales that could be realized by bringing a device to market “faster, better, and cheaper” simply by reducing the waste in the design process through effective use of process automation (work flow) and an

integrated tool suite at an enterprise level.

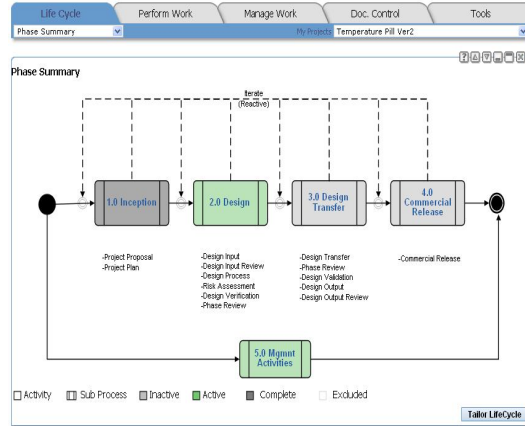


Figure 1
Process Driven Design Controls

Operating within FDA mandatory regulations concerning medical device design controls is the way of life for any company that wants to improve the lives of others through the design and marketing of medical devices. It is not usually the technical hurdles that challenge the engineering team but the “bureaucracy of change” that impedes the progress of technical advancement. This “bureaucracy of change” includes formal design controls, peer reviews, document management, and technical/managerial oversight. This bureaucracy is very important to the design process and leads to high quality medical devices, but can add significant overhead in terms of cost and time to a project. Most companies simply write off this overhead to the cost of doing business without realizing the price of these inefficiencies.

Imagine being able to reduce the time to design a device by 30% on a multiyear project. Not only is overhead being reduced by 30% but sales also rise by realizing margin increases of new

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product releases much sooner. As one sales executive complained, “why does it take engineering so long to develop product? Every month we delay we are losing hundreds of thousands of dollars due to potential margin increases.” Simply said, the sooner innovative medical technology gets to market, the greater the impact is to people’s lives, which results in improved business opportunities.

Library of Processes

Early stage medical device companies need guidance on how to travel through the maze of FDA regulations. This requires scalable infrastructure to manage change control, design documents, assemble IDEs (Investigational Device Exemption), and manage clinical trial information in electronic form. Companies need a set of FDA processes in compliance with FDA regulations, ISO standards, and industry best practices to draw upon.

Imagine having a set of tools such as an electronic document management system automating the formal peer review process, audit trails to aid in FDA inspections, an integrated CAPA (Correction Action, Preventative Action) system, and the ability to capture patient complaints and report MDR (Medical Device Reporting) information all in a single system.

Startup companies don't always need all this capability in the early days however, so a “cafeteria approach” to accessing these tools makes the package even more desirable as it allows a company to pick and choose from the set of libraries and tools as they are needed. A company may choose the processes and

tools required at each particular stage of company growth. For example, companies don’t need a patient complaint tracking database when prototyping a novel technical design. But once that design is mature enough to enter clinical trials, a complaint database is required.

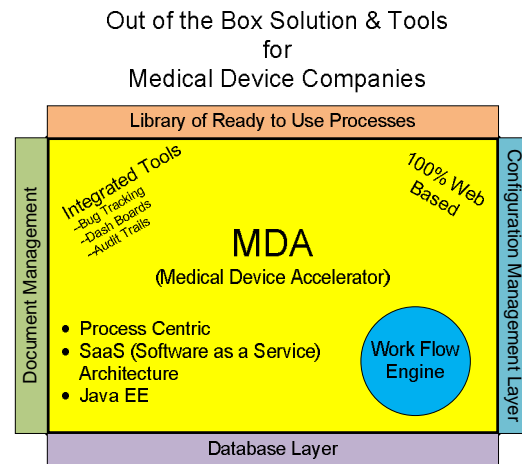


Figure 2
Process Framework

For mature medical companies that are looking to improve their overall company performance, processes from the process library can be modified with little effort, or new processes can be made from scratch based on the current company's SOPs (standard operating procedures).

Process Automation

Process automation helps reduce time and effort to process and gather information. It is mandatory to go and review past DHFs (Design History Files) of previous projects when entering into a new project. Often this is done through a multiple step process including reviewing paper files and pulling information from multiple electronic systems.

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Imagine having a single source where all documents, lessons learned, and project comments are located in one place and can be easily reviewed. Information like this could also be included in the processes definition conveniently documenting objective evidence of such activities making future visits from the FDA much smoother and efficient.

Document Management

Document management is a key element of any medical device company from the earliest days of the company's formation. Many companies are still using paper systems or a non-integrated "point solution". It's paramount that a company can demonstrate good change control of their documentation and show objective evidence of the approval process.

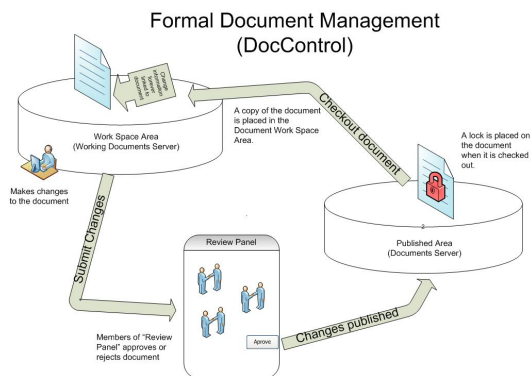


Figure 3
Document Management

Important documents must go through formal peer reviews to ensure appropriate technical and managerial oversight. Formally reviewing a document however is laborious and time consuming task. Very often a document goes out for review and is rejected for some reason, but the author is never made aware of the rejection and the document goes into limbo.

Process automation can eliminate document limbo. Information about the process, the state of the project, and the review process is constantly being "pushed" out to the team No longer is it necessary to go and manually pull information about the "state of things". For example, if Marketing rejects the document, a rejection notice is automatically sent out, allowing the author to take immediate action.

Document states and meta-data can also be used to describe the maturity of a document and intended use. For example, a document with the state "pilot" indicates that the document has gone through a TRB (Technical Review Board) but is not fully tested. Documents can be tagged with meta-data helping to determine which documents get submitted to the FDA or are part of the DMR (Device Master Record).

Conclusion

Developing and marketing medical devices is a noble and rewarding endeavor, but a very complicated and expensive enterprise. Through process automation and an enterprise suite of integrated tools, medical innovations can reach commercial markets faster and cheaper than ever before.

Tietronix has developed a web based tool called Medical Device Accelerator (MDA) that performs the tasks described in this paper. For more information about FDA process automation using MDA, please contact the author or refer to the company's web site.

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