How Medical Device Control Helps the Startup

You received seed money for the development of your medical device idea. You know that time is money and you have limited funding so you don't want to waste time. You probably know that the US FDA requires you to develop a medical device following the Design Control process, but what is Design Control? Is it just more unnecessary government regulation requiring filling out of a stack of forms or is it a useful and helpful aid to producing a product on time and within budget?

I was involved in the management of design and development of medical devices for many years at companies ranging from startups to Fortune 100. I earned five patents. As I'm sure you do, I preferred to have my people design and work in the lab instead of filling out paperwork. It slows you down and is annoying. Who wants to chase document signatures? Who wants to explain in writing the obvious?

Well, after many years of design and development experience, I came to see that the use of design controls actually shortened development times and made life easier for the entrepreneur, while facilitating FDA approval.

When I left the corporate world and began consulting with medical device companies, my first engagement was with a Boston medical device startup company that had prototypes being tested in several Boston area hospitals. At one point, they realized that each of these prototypes was different, but they didn't know what the differences were. They had lots of marked up drawings and red lined specifications, but couldn't relate these to any specific prototype. My first task was to put on my Engineer hat and figure out what the differences were. Then, I created a design control system for them so this wouldn't happen in the future.

WHAT ARE DESIGN CONTROLS?

Design controls for a medical device is a system of procedures and documentation relating to its design and development that are required by the FDA for Class II and Class III (and certain Class I) devices. These are not detailed instructions that you follow, but requirements relating to early, middle-stage and later activities of product development. How you meet the requirements is left to your judgement. FDA may reject your judgment if they feel you do not have adequate control of the design process. Thus, it is helpful to work with employees, collaborators and/or consultants who are familiar with FDA requirements from early on in the process of invention and development.

PLANNING

Planning for integration of design controls should be integrated at the beginning of a project to develop a medical device. A plan defines responsibilities – who is responsible for what and who is not. It defines the interfaces between groups – who are the interfaces with Engineering and

what information gets transferred. It defines the documentation required – who creates it, who approves it. It takes time and effort to write a good plan. But, the written plan will help you and protect you. It will help justify the allocation of your efforts to your investors. If you don't have a good plan, FDA could conclude that your development was haphazard and reject your submission.

REQUIREMENTS

Of course, you know what you want to develop. Who knows better than engineering professionals what device features are needed in the marketplace? Let the manufacturing experts figure out later how to make the medical device and how to make it at a reasonable cost. That's not your concern. Just start designing; we will fill out the paperwork as we go.

The above scenario is a recipe for disaster.

Perhaps Engineers don't know market needs that well. Fun fact: the first subway was built in London long ago. The subway engineers, logically designed the subway cars without windows because there was nothing to see. They soon had to redesign the cars. People refused to ride in windowless cars. Maybe our ideas will result in a product that costs too much and can't compete. Maybe that device can't be manufactured using existing equipment, tooling and processes. If we spend some time upfront defining the users, their profiles, characteristics, and what the product should do, in consultation with marketing and other groups, you will avoid headaches downstream. A good detailed user and functional requirements list, in addition to avoiding the above problems, will help generate an accurate cost/time/resource estimate that will help you avoid a subsequent crisis with investors. FDA will expect you to have documentation tracing each requirement to a successful test.

Documented and approved design outputs protect you. They confirm that you completed the design process accurately, on-time and within budget, and produced the product that everybody agreed they wanted. Or, such documentations will demonstrate that variances were made for good reasons.

DESIGN INPUT

Design inputs set forth the initial requirements of the planned medical device.

DESIGN OUTPUT

Design outputs include specifications, manufacturing process and inspections, and need to be directly traceable to design inputs.

DESIGN REVIEW

Design review is a formal review of the design by function (such as engineering, manufacturing, marketing and sales, IP, etc.).

It takes much time to prepare a design review. Presenting a design review can be scary. But, it's better to learn now if you are off track than later when it will be more painful to fix the design. Frequent design reviews with an interdisciplinary audience lessens the impact of any problem.

Design reviews, like other elements of Design Controls, need to be documented in the Design History File (DHF, see below), including review date, participants, design version/revision reviewed and review results.

DESIGN VERIFICATION

Design verification is the process that confirms that the design outputs conform to the design inputs, and needs to demonstrate that the specifications are the correct specifications for the design.

DESIGN VALIDATION

Design validation ensures that the device conforms to defined user needs and intended uses under actual or simulated use conditions. This can include software validation and risk analysis.

DESIGN TRANSFER

Design transfer is the process whereby the device design is translated into production, distribution and installation specifications. Changes in design or manufacturing would necessitate documentation of this and the other elements of Design Controls.

DESIGN CHANGES

Design changes is the process in which design changes are identified, justified, tested, approved and documented.

I have seen many projects where verbal undocumented design changes led to several product prototypes different from each other. Getting design changes documented, tested and approved may appear to slow you down, but it actually helps save time by avoiding a potential disaster later in the process. FDA expects a detailed change control process, especially when contract developers and contract manufacturers are involved.

DESIGN HISTORY FILE

The Design History File (DHF) is a formal document or index of documents that memorializes each of the above elements, the dates of formal meetings, participants and processes and

outcomes, which can trace the development of the medical device from invention to submission of the application for FDA licensure.

You accomplished all this good work. Where is the documentation? Can anybody find it in a few months or a few years when it's time for an upgrade? Are you relying on your memory? The time to create a numbered organized file of documents is well worth it to avoid confusion at a later time. This is especially true in the context of regulatory reviews when you must quickly produce requested documentation to an FDA auditor.

It is necessary but not sufficient to have test data showing the device is safe and effective. FDA, based on review of years of field problems, recalls, etc., has come to require Design Controls, documented in a DHF, to minimize the chances of unanticipated problems that might otherwise show up in the field.

CONCLUSION

Design Controls are a requirement for regulatory approval of Class II and Class III (and select Class I) medical devices. Far from 'check the boxes' documentation to be gathered at the point of submitting a licensing application, these processes need to be planned, documented and integrated into the development of the medical device in real time, from beginning to end. But more than simply a bureaucratic or administrative record keeping requirement, Design Controls can avoid unnecessary delays and increase the quality of your medical device product candidate, both in terms of performance and safety. This is why it is extremely important and valuable to work with employees, consultants and vendors who have familiarity with the development of regulated medical devices. Kinexum consultants will be happy to help you to plan, implement and document Design Controls that are optimized for favorable review by the FDA.

- Edwin

Edwin Waldbusser
Kinexum Medical Device Regulatory Consultant
EdwinWaldbusser@Kinexum.com