EBOOK

THE BEGINNER'S GUIDE TO DESIGN VERIFICATION AND DESIGN VALIDATION FOR MEDICAL DEVICES

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When your medical device product development project gets to Design Verification and Design Validation, do you feel like it's almost there?

Meaning, finally, you can see the goal of market release coming soon? Or is it more like being stuck in the middle?

From my product development experiences, entering into design verification and design validation is always bittersweet.

It's exciting because getting to design verification means we've accomplished quite a bit. It's also terrifying because the work ahead can be frustrating, time-consuming, and ambiguous.

In this guide, we'll go through the basics of design verification, design validation, best practices you should deploy, pitfalls you should avoid, and plans that will make it all come together.

VERIFICATION AND VALIDATION FOR MEDICAL DEVICES

Let me share a few perspectives from a project. Then I'll get into explaining exactly what design verification and design validation are, how they're similar, and how they're different.

The company I was working with was developing a novel medical device. Early design and development activities were trying. The team changed, and the design changed. There was a lot of back and forth with little to no progress at times.

But then we found ourselves at the edge of design verification and preparing a FDA 510(k) submission.

As the project manager, I realized getting to this point in the project was a significant milestone. But I'm not a complacent person. The goal is market launch.

And when you're about to enter into design verification and design validation, you quickly realize how important the earlier design controls activities are to your project. You'll find yourself asking a series of questions familiar to companies that have gone through this before:

- Did you capture the *right* user needs?
- Are your design inputs written well enough?
- Do you have sufficient design outputs?
- What happened during design reviews?
- Does the design plan specify enough detail (or too much)?

So there we were, about to begin design verification. We had a barely defined plan for all the design verification activities and nothing really figured out for design validation yet. Then we had to dive right in.

While we were addressing design verification, a key stakeholder only heard that we were preparing the 510(k), which, in their mind, was more meaningful and significant. Should I have explained the importance of design verification and design validation to them? Or were they right to focus on the 510(k) submission?

Maybe it's a matter of semantics. Not sure it matters either way.

Regardless, let's get into the specifics of design verification and design validation that the key stakeholder wasn't interested in.

Let me dive into explaining what they are, how they are the same, and how they are different.

WHAT IS THE DIFFERENCE BETWEEN DESIGN VERIFICATION AND DESIGN VALIDATION?

Design Verification and Design Validation can be confusing. To help clarify, think of it in terms of these two simple questions:

- Design Verification: **Did you design the device right?**
- Design Validation: **Did you design the right device?**

Be sure to note the subtle, but extremely important, difference.

All too often in medical device product development, the terms "verification" and "validation" are thrown around. Many times they are lumped together as "V&V" as kind of one thing or phase. I'm not here to debate whether this thinking is right or wrong.

There are times when I see Design Verification as something very different from Design Validation. And plenty of other times when I refer to V&V.

Let's clear up a bit of terminology about "verification" and "validation". These "V" words without descriptive adjectives are too vague.

For instance, if someone asks you about verification, you need them to clarify what they mean. There are multiple types of verification and validation: Design, Process, and Software are the most common in the medical device industry.

And each means something different. Also, to complicate matters a bit, outside the medical device industry, verification and validation also mean different things.

The focus of this post and the relevant terms for design controls are Design Verification and Design Validation.

I'm only focusing on these versions for the time being. So from this point forward in this post, if you read "verification" I'm referring to Design Verification and "validation" refers to Design Validation.

DESIGN VERIFICATION: BEST PRACTICES, PITFALLS, AND HOW TO DO IT RIGHT

More often than not, design verification involves suites of tests and trials. A careful product engineer, however, can save testing time with inspections and analyses.

The key is to avoid being overly broad. Think narrowly instead. The goal is to confirm whether your design outputs meet your design inputs. Or, as the FDA puts it: "Verification means confirmation by examination and provision of objective evidence that specified requirements have been fulfilled."

While it is true and very likely that design verification will involve testing, there are other acceptable verification activities. Design verification activities can include tests, inspections, and analyses (for a full list, refer to the FDA Design Control Guidance section "Types of Verification Activities" on page 30).

The natural tendency is to rely too heavily on testing for design verification. This is why you have to think about design verification when defining design inputs.

VERIFICATION TESTING PITFALLS

There are plenty of cases where inspection and analysis activities just aren't sufficient for verification. In these cases, testing is the only way.

Keep in mind, though, that testing has plenty of potential pitfalls.

Testing gets expensive because you usually need a lot of test articles. That may mean you need to involve third-party testing resources, which are costly.

Testing is time-consuming for similar reasons. If you're testing multiple test articles and involving third-party testing firms, then even small communication gaps can create a domino effect of delays.

Testing is often subjective. If you try to do the testing yourself to save money and time, you can end up with unreliable results. Simply put: If you don't test to an accepted method or protocol, your tests are not objective.

Loop in test engineers as soon as possible. The sooner they're involved, the more likely you'll be able to avoid these pitfalls.

HOW TO DO VERIFICATION TESTING RIGHT

The foundation of an effective verification testing process is defining design inputs.

Ask yourself what your device needs to do and what it needs to go through to achieve its intended purpose. This is where you might think about, if you're designing a catheter, for instance, how much liquid it needs to move, and how fast.

Define what conditions are best for your device and how those might change. Intended use might be in a hospital room, for instance, but the device might also need to accommodate the patient being moved to a different room or to an operating suite

Make these design inputs as clear, discrete, and actionable as possible. Ambiguity leads to mistakes, and mistakes require rework. Rework is expensive and risks slowing down the product development process, leaving your business to burn through more cash and your team demoralized.

Write design inputs that are testable. The problems you're identifying through this process must be resolvable via testing. If they're not, then you need to analyze and break the problem down into simple enough steps and items that testing can help.

By the end of the process, you should have a list of design inputs and verification tests for each that will demonstrate that the device does what you intend it to do. With the right foresight, you can even develop some of these tests during product development. The earlier you think about testing, the better.

DESIGN VALIDATION: BEST PRACTICES, PITFALLS, HOW TO DO IT RIGHT

The purpose of design validation is to prove you designed the right device. Doing so means proving the medical device meets the user needs and intended uses.

Design validation is a design controls activity that happens pretty late in the product development process. Despite that, validation is a measure of defining user needs, one of the first activities in product development.

According to FDA's definition, "Validation means confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled."

DESIGN VALIDATION PITFALLS

It's easy to miss parts of the process. There's no way around the fact that if your design validation process doesn't include testing packaging and labeling, and at least simulated use, then it's not going to be effective.

You can't skip testing. Testing is absolutely necessary. Tests demonstrate that your medical device functions as expected and meets the user needs you defined. You can also incorporate inspections and analyses as part of validation in addition to testing.

Don't exclude the packaging and labeling. Your medical device isn't just the hardware. A medical device includes everything from the label, the instructions for use, the packaging, and everything inside your packaging. Validation must address all of it.

Your clinical evaluation doesn't have to be actual use. Actual use requires quite a bit of additional criteria for most devices. You can't just go and have your medical device applied in actual use without addressing this criteria first. As you pursue comprehensiveness, don't assume that validation requires actual use of your device. Your clinical evaluation can be simulated use.

HOW TO DO DESIGN VALIDATION RIGHT

There are several best practices nearly every design validation process must involve.

Your design validation process must include initial production units. This means the medical devices used for validation have to be built in the production environment, using drawings and specifications (i.e., design outputs) by production personnel.

Design validation must involve clinical evaluation. This means that the end-user(s) should be involved, and the device should be tested either under simulated use or actual use. Simulated validation often includes mathematical modeling. You'll want to compare your device against others with similar purposes.

Use the medical device under the specific, intended environmental conditions. This includes any changing conditions, such as devices that must remain operable as patients move from room to room.

Keep your design records organized. These tests will generate a variety of records and results, all of which you should document in your design history file. A good quality management system (QMS) will also help you maintain these records and surface gaps.

HOW TO INCORPORATE DESIGN CHANGES FOLLOWING VERIFICATION AND VALIDATION

At some point, you're going to need to update your product.

These changes and product updates could be necessary before or after you launch your product. Testing in the verification and validation processes might reveal the need to make some changes to the initial design before the product even launches.

Post-market information, such as nonconformances, customer feedback, or corrective and preventive actions (CAPAs) might inform the decision to make changes after launch, too.

Regardless of when you decide to update the product, the process for making that change is the same. It's a familiar process because it resembles what you did during design and development.

With your new information in hand, from pre- or post-product launch, start reviewing. Go back through all your user needs, design inputs, and design outputs. Update everything in light of the new information you have.

After a thorough review, it's time to start verification and validation again.

Yes, again.

No matter when in the product lifecycle you make the change, you can't skip verification and validation. Even in mid- and post-market stages, before and after product updates, you have to be ready to verify and validate.

That doesn't mean you're starting from scratch every time. You can always leverage previous lessons, experiences, and data. But you do have to verify and validate again.

The types of design changes you've made will determine how much verification and validation you'll need to redo. But there simply can't be a point in the process where you're unsure whether you've made the right device and that it's working correctly. This means verifying and validating, every time.

HOW TO CREATE EFFECTIVE DESIGN VERIFICATION AND VALIDATION PLANS

Plans are what separate your process from chaos. If you don't have verification and validation plans in place, it's easy for things to go off the rails, rework to become necessary, and delays to accumulate.

Worse, without plans, you're setting yourself up to make the same mistakes again. When things go wrong, you can improve the plan and ensure the same problem doesn't recur.

PLAN V&V ACTIVITIES IN PARALLEL

There is a direct relationship between verification and validation. There are ways you can accomplish design verification and design validation with the same activities, if planned properly.

Thinking about how you'll validate a particular user need can happen when these are defined.

Design validation, though, can be a bit tricky, especially in determining if you've effectively demonstrated your medical device meets user needs.

There is usually more of a human element to validation, and subjectivity can be an issue. Plus, the ways you choose to solicit end-user feedback is important.

Are you going to be present and observe the end-user? Are you going to send the medical device, complete with packaging, labeling, and instructions for use, to the end-user, and require a survey be completed? How will you know you successfully completed design validation?

These are all considerations of validation planning.

BUILD IN THE RIGHT TIMING FOR DESIGN VERIFICATION PLAN

The key to making a good design verification plan is timing. Don't wait to construct a design verification plan right before starting verification. Instead, make a verification plan when you define design inputs.

Many companies rush to the design verification stage and work on their plans then. The opposite approach might actually be more beneficial. Spend more time defining design inputs so design verification becomes smoother.

The sooner you make your design verification plan after defining your design inputs, the more each can inform the other. This is why I stress the importance of considering how you'll verify design inputs when you're defining design inputs.

When you're defining inputs, think about how you'll verify them; when you're verifying inputs, do so soon after defining them so your thought process is top-of-mind.

KEEP YOUR VERIFICATION AND VALIDATION DOCUMENTS IN ONE CENTRALIZED LOCATION

Design verification and design validation produce a lot of documents. If you have to run these processes multiple times, you'll want to be able to track the most recent version and maintain traceability through all the past versions.

The Greenlight Guru software enables you to create and update a traceability matrix in minutes. Instead of asking employees or consultants to pore through design control objects, link those objects with complex configurations and documents with just a click.

Since verification especially is about ensuring your outputs match your inputs, having a purpose-built medical device QMS (MDQMS) that can link both together in one place is essential. Centralization makes both processes easier to do and easier to track. With closed-loop traceability and version control, you can also reduce error-prone, manual work and strenuous, expensive rework.

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