



How Software Verification Streamlines FDA Approval for Medical Devices

The road to FDA approval for your medical device can be challenging to navigate. As with any innovation, you are on a tight deadline going to market because you want your project to beat the competition. Moreover, you have a strict series of regulations to follow. Medical devices are generally complex pieces of equipment that contain a significant amount of software. This means the medical device software itself must be FDA compliant.

Facing setbacks during FDA approval in regards to these systems can put substantial strain on both your schedule and your costs. There are, however, proven steps you can take to avoid deployment delays. Verifying that your solution is compliant with FDA standards and regulations ahead of time can help you approach the formal submission process with fewer risks—and greater rewards.

The Pressures of FDA Compliance

Although software solutions are widely used to control medical devices and enable interaction with the device users themselves, many medical device clients are unfamiliar with the overall software development and verification processes. Consequently, they may attempt to pull together an internal software development team to create the software for their medical device. Yet, without the proper understanding of software FDA compliance, they will ultimately end up with an undocumented (or sparsely documented) and incomplete software development project.

The regulations around medical device software development are incredibly complex, and insufficient software development can be especially harmful and expensive for your project's bottom line. Any gaps in the documentation or flaws with the software will inevitably lead to an unproductive verification process. As such, a critical stage in the development of medical devices involves the specification of its software requirements. Organizing these details first helps ensure that your software development and software verification processes will be streamlined.

Understanding Your Software Requirements

A common issue that adversely affects the development and verification process involves a lack of review and evaluation applied to the software requirements phase. Unclear or ambiguous requirements can lead to incorrect software and invalid verification. This is why both software developers and software verification engineers need to thoroughly review and critique the software requirements. Developers can easily run into problems—even if their software is technically correct—all because they do not understand FDA compliance and the need for software to strictly adhere to those defined requirements.

Once the software development is complete, software verification engineers can analyze whether the medical device software behaves according to its intended functions. These engineers need to conduct detailed tests to confirm that all requirements have been implemented. Unfortunately, some medical device verification teams may not place the required level of scrutiny in the appropriate software areas. Those sections that directly impact user and patient safety must have a higher level of verification involved. A high-quality software verification process will be designed to examine all aspects of your software solution, so nothing is overlooked.

Key Functions of the Verification Process

Working with a separate team for the verification process will give your solution the diligent screening it needs before you submit it for FDA approval. The medical device software and any associated artifacts must be run through a series of tests to confirm their reliable performance. Of course, providing all of the necessary documentation can be difficult if your team does not follow a proven process for software verification. Carefully following these steps will help move your project toward a successful outcome.

1. Verification Planning

The formal process of software verification needs to begin with a detailed review of the Software Requirements Specifications. At this point, your verification engineers should identify the necessary Verification Test Suites that will be utilized to test your solution. An impact analysis for all Verification Test Suites also needs to be completed in this stage so that your team can clarify the project timelines and deliverables.

2. Verification Test Suite Development

Once the test suite design is finalized during planning, the development stage will apply the necessary test steps for verifying that the software conforms to the requirements. Additional ad-hoc testing may also be executed at this time to verify completeness of the test suites. Any issues identified with the requirements and/or the software during test suite development should be logged in a defect management system for review and resolution.

3. Verification Test Suite Traceability Management

During design and development of Verification Test Suites, a traceability matrix will need to be created. This trace matrix ensures that all software requirements are covered by a test suite and that the entire verification process will yield complete and accurate results.

4. Verification Test Suite Execution

A formal execution of the Verification Test Suite should occur when a “feature complete” release of the medical device software is available. Objective evidence of the test suite executions must be collected and saved in order to prove requirements conformance. Any issues identified with the verification tests must be recorded in a tracking system, as well as any problems that are found with the software or requirements. If any requirements fail verification testing, then a new software release and subsequent round of formal verification testing will be required.

5. Verification Test Reporting

After completion of formal verification execution, summary reports must be generated. One report will summarize the results of formal verification and include which test suites were executed in each round of testing, any defects recorded during testing, and the trace matrix to prove all requirements were tested. If any defects that were recorded during testing or during development are not resolved, an “open anomalies” report must be generated to describe the defect and the risk and justification for leaving the defect “open” (i.e., not fixed in the software).

These summary verification reports will need to be reviewed and approved by appropriate members of management. Those responsible for the verification process will need to be extremely thorough, as a low-quality software verification process will just add extra costs down the line, or even force you to run through the entire development and verification process again. If your solution was not scrutinized under the correct programs, you risk hitting a more serious roadblock for your FDA approval. Partnering with a diligent team of verification engineers makes all the difference.

The RND Group: Difference in the Details

In order to avoid software-related delays with your FDA compliance and approval, your project will require an in-depth and predictable software verification process. This is why The RND Group always leans toward a more exhaustive review. For example, even though a unit of code may not require an extensive set of unit tests, we are still inclined to develop unit tests for all code. Our clients rely on us to have an extremely detailed process, and we are proud to adhere to a “no stone left unturned” attitude.

At the same time, we also insist on following a consistent process. This allows us to be respectful of each client's budget and timeline. The RND Group's outputs are consistent from project to project because we have spent decades refining our process. Part of that means being flexible enough to meet our clients' unique needs, as every medical device has its own set of software verification requirements.

Our company's history offers a distinct advantage. Everything we do revolves around medical device software development, and we continue to attract and employ passionate, intelligent software engineers. Our teams are uniquely prepared and trained to both develop and verify sophisticated FDA regulated software for medical devices. This training and mission to "do things right the first time" is paramount to minimizing how long it takes to deliver your medical device to the world.

Securing FDA Approval with Software Verification

We understand that time pressures are often a major concern for medical device innovators. You are striving to deliver a safe, feature-rich, quality solution to the market before your competitors, and avoiding delays is a top priority. All the while, you to prove FDA compliance in order for your medical device to start making a difference in people's lives.

Having an independent team of engineers testing your software is of the utmost importance. But not every firm has a dedicated verification team. This is why The RND Group has separate departments for software development and software verification. This enables us to work with clients across a variety of stages in product development. Whether you need a team of experts to manage your software verification and validation, or you want to every stage of your medical device software to be managed under one roof, we can help.

The RND Group always takes a collaborative approach with clients. An initial consultation can help us both determine whether we're the right partner for your project. Please contact us at sales@rndgroup.com to learn more.