



# VERIFICATION AND VALIDATION TESTING CHALLENGES OF MEDICAL DEVICES

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## Introduction

The adoption of medical devices has evolved in the healthcare industry in recent years. Medical devices are used to diagnose and for therapeutic purposes. As they grow smaller and more complex, verification and validation (V&V) of devices become more important.

Design V&V of medical devices ensures that specific design requirements and user needs are met. For example, companies

must ensure that devices are within the acceptance criteria defined by test methods and specifications and can be used consistently. In addition, companies need to validate that the device meets customer requirements. They should also prioritize the security and safety of devices, for it involves the risk of life.

## End User of Medical Device

The end user for medical devices depends on the specific device and its intended use. Here are some common users for different types of medical devices:

- 1. Regulatory Bodies and Healthcare Institutions:** Every medical device must comply with regulatory standards during all software development life cycle phases and undergo approval before being used in clinical settings. Furthermore, healthcare institutions and regulatory bodies are part of the target audience for medical devices. These institutions assess the devices' safety and quality, ensuring they meet the necessary standards and can be used safely by healthcare professionals or patients. Medical devices should be verified and validated to comply with the regulatory requirements.
- 2. Researchers and Scientists:** Medical devices used for clinical trial purposes or in laboratory settings have a target audience of scientists, researchers, and technicians. They are designed to assist in experiments, data collection and analysis, requiring V&V.
- 3. Caregivers:** Caregivers may include family members, professional caregivers, or healthcare providers who deliver care outside clinical settings. Specific medical devices are targeted toward caregivers who help and support individuals with medical needs, such as fall detection systems or remote patient monitoring devices, to facilitate caregiving tasks and enhance the quality of care. So, there is a need to perform rigorous V&V of medical devices.
- 4. Patients:** Some medical devices are designed to be used by patients themselves and help them manage their health conditions or monitor their vital signs. These devices are often user-friendly and portable, allowing patients to use them at home or on the go. Examples include blood glucose meters for diabetes management and communicator devices, which can collect data from pacemakers to the server. There may be cases where, while the device functionality is working fine, it is not easy for patients to operate it. We must verify user acceptance requirements of medical devices.
- 5. Healthcare Professionals:** Many medical devices are designed to be used by healthcare professionals such as doctors, nurses, and technicians. These devices are typically used in hospitals, clinics and other healthcare settings. Devices can be surgical instruments, imaging equipment (X-ray machines, MRI scanners, programable recorder monitors), and monitoring devices (pacemakers and blood pressure monitors). Healthcare professionals are the primary users of these devices and require specialized training to operate them effectively. We must test scenarios to consider the feedback of healthcare professionals because if the usage of medical devices is not handled correctly, it can give false results.



## Importance of V&V Testing in Medical Devices Software Development

V&V ensures medical devices' safety, effectiveness, and reliability. Here are more reasons why they are crucial:

- 1. Product Quality:** Verification focuses on verifying the device design and ensuring it meets the specified requirements. In contrast, validation ensures the device performs as intended in its planned use environment. Manufacturers can identify and rectify design or manufacturing flaws by thoroughly testing and validating their devices, optimizing performance, and enhancing product quality.
- 2. Regulatory Compliance:** Medical devices are subject to stringent regulatory requirements such as those set by the U.S. Food and Drug Administration (FDA) or the European Medical Device Regulation (MDR) to ensure patients' safety and product performance. By conducting thorough V&V activities, medical device manufacturers can provide the necessary evidence to regulatory authorities for market approval or clearance.
- 3. Risk Mitigation:** Medical devices have the potential to impact patients' health and well-being directly. V&V activities help identify and mitigate risks associated with device malfunctions, design flaws, software errors, and other potential hazards. By assessing and addressing these risks early in the development process, manufacturers can enhance the safety and reliability of their devices, thereby reducing the likelihood of adverse events or harm to patients.
- 4. Enhanced Confidence and Reputation:** Rigorous V&V processes demonstrate manufacturers' commitment to producing safe and effective medical devices. Manufacturers can build confidence among regulatory authorities, healthcare professionals, and patients by thoroughly testing their devices and providing evidence of their performance. This, in turn, can lead to a positive reputation in the industry, fostering trust and facilitating market acceptance.



## Challenges During V&V

Verification testing ensures the device meets its design specifications, while validation testing ensures it meets its intended use in the target population. Medical device firms face several challenges arising due to various factors, including rapid technological advancements, regulatory requirements, and the need for specialized skills.

### a) Complex domain and requires continuous learning:

- Medical device testing can only be performed with specialized domain knowledge in medical device design, software development for medical applications, and clinical research. It requires experience in medical domain knowledge along with embedded hardware.
- The medical device industry constantly evolves, with new technologies, materials and regularly emerging regulations. Therefore, professionals in this field must continuously learn and stay updated with the latest advancements.
- Medical device development involves collaboration among various disciplines: engineers, clinicians, regulatory experts and marketing professionals.
- Ensuring effective communication and collaboration across these diverse teams can be challenging, as individuals from different backgrounds may have different perspectives and priorities.

### b) Regulatory Requirements:

- We must follow guidelines such as ISO 13485, ISO 14971 and IEC as part of the medical devices process.
- Medical devices V&V follow regulations from various authorities, such as the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA).
- These regulations mandate rigorous testing and documentation, increasing the time and cost of V&V testing.
- All the artifacts and evidence related to V&V testing must be provided to the FDA for approval.
- We should protect sensitive patient health information as part of the HIPPA standard.

### c) Challenge with Device Compatibility:

- There are multiple components involved in the medical system. Even after separately testing the components, there is a need to perform system, integration and exploratory testing to detect the defect. This increases the cost of medical devices.
- Currently, most people rely on mobile platforms for almost every need. Verifying mobile apps on different mobile platforms is a challenge.

### d) Complex Systems:

- Medical devices are often complex systems with multiple components, interfaces, and interactions. Testing such systems can be challenging, particularly when the device is integrated with other systems or devices.

### e) Safety & Security Considerations:

- Medical devices are designed to be used in sensitive and often life-critical situations. Therefore, it is critical to consider safety during V&V testing. Testing must ensure that the device meets the safety standards and does not cause harm to the user or patient.
- In some cases, real patient data is involved in testing, requiring another layer of protection.

### f) Test Environment set up:

- High cost is involved in setting up Lab stations and maintaining the same.
- All the hardware should be calibrated so that it requires a lot of cost and resources.
- To avoid any damage, the hardware should be handled carefully, as the cost of medical hardware is very high.
- Every test requires different configurations of devices /families to execute it. All the test machines have different configurations and hardware, so in regression, the test should be performed on the appropriate station.

### g) Automation:

- Medical devices are dependent on hardware and software. In the early stages, hardware may not be available, making writing automation scripts a challenge during the initial project phase.
- It is likely that one technology cannot interact with all devices. We need to develop a library that can interact with different technologies.

### g) Limited sample size:

- In some cases, testing a medical device on a limited sample size may not represent the device's performance in the broader population.
- This limitation can impact the device's ability to receive regulatory approval and limit its market adoption

### g) Requirement Analysis and Tracing:

- Medical devices' requirements should be clearly defined and tested thoroughly. Ambiguous requirements may cause a patient's death.
- There should be traceability between the requirement code and test cases. Sometimes, requirements are split across multiple test cases, so the tester needs to verify that the requirement is thoroughly tested.
- Safety analysis and mitigation need to be done for all the requirements.
- We should not consider any assumptions during the V&V of medical devices.

## Best Practices to Handle Challenges in V&V

Resolving medical challenges is a complex and ongoing process involving various stakeholders: researchers, healthcare professionals, policymakers and the pharmaceutical industry. Here are some fundamental approaches and areas where progress is being made:

- To ensure the quality of the medical device, multiple phases of testing should be done, such as debug run, stability run, dry run and formal. All assets should be baselined in the stability run. Any further changes should be tracked via the issue tracker tool.
- Each phase of testing should involve testing at a subsystem level. We must perform individual component testing using unit and integration testing at the development level, sub-system testing at the component level, and system testing to verify end-to-end flow.
- SCA (System change analysis) should be done at the project's beginning to identify all the updated, impacted or new requirements. The test plan should be designed accordingly.
- REA (Ripple effect analysis) should be performed for all the changes in hardware or software, and testing should be performed accordingly.
- All tools and utilities should be validated, and validation reports should be baselined.
- There should be a quality management system, and all the guidelines of ISO 13475, ISO 14971, and ISO 62304 followed.
- All equipment that requires calibration should be calibrated regularly, and the calibration report should be baselined.
- Creating test data with real devices is difficult, so we should have simulators to produce a real-time scenario.
- We should be able to create a production equivalent test station to reproduce the field scenarios. This will help replicate the field setup for the tester to debug the issue.
- To remain relevant in the medical industry, providing continuous training and the latest updates to utilize best practices is essential.
- AI and big data analytics have the potential to revolutionize healthcare. These technologies can assist in writing better use cases for testing.
- Governments and regulatory bodies play a crucial role in facilitating medical advancements. Timely and efficient regulatory processes can ensure the safety and effectiveness of new treatments, devices, and therapies while promoting innovation. We should consider regulatory recommendations while doing V&V.





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