For some medical device startups and scale-ups, achieving International Electrotechnical Commission (IEC) 60601-1 approval is easier said than done. It's a complex process that requires teams to think critically about the safety and performance standards of their electronic medical devices.

IEC approval comes with many technical requirements. Complying with these laws and regulations is especially difficult for early-stage medical device startups and scale-ups. Unfortunately, one simple mistake during the application process can dismantle an organization's progress toward completion. These setbacks can prevent even the most growth-oriented life sciences teams from achieving their regulatory approval objectives.

To streamline the IEC 60601-1 approval process, teams must keep pace with application best practices and protocols. Use the expert insights found in this article to successfully navigate the IEC 60601-1 approval process.

5 Steps to Achieve Rapid IEC 60601-1 Approval

When it comes to identifying and improving the safety and performance standards of electronic medical devices, we've seen first-hand how quality can be used as a competitive advantage. In fact, our quality management system has helped thousands of quality professionals build safe and effective medical devices.

IEC 60601-1 requirements are in place for good reason. These standards outline the core safety measures that product development and quality teams must commit to while building electric medical devices. However, it's worth noting that IEC 60601-1 conformity is entirely voluntary.

Regardless, we view IEC 60601-1 approval as a necessary step to improve the overall quality and performance of your unique electronic medical device. With that in mind, here are the five steps that your medical device company must follow to achieve IEC 6060-1 approval.

1. Develop a Project Plan

First thing first: Start by developing a project plan. This process involves creating a master outline of the manufacturing processes and testing procedures used to validate the safety and effectiveness of your electronic medical device.

An IEC 60601-1 project plan also ensures that your team understands the technical requirements of the project prior to activation. An electronic quality management system enables efficient and effective project planning. It's a vital piece of equipment that can help your team proactively mitigate quality and compliance issues.

2. Identify Device Class

Which product category does your device fall under?

By identifying the unique classification of your device, you can more easily interpret and comply with applicable laws, standards, and regulations. IEC offers a variety of benchmark criteria used to appropriately classify electronic medical devices, including humidity protection, electrical grounding, installation method, and more.

In general, product classification is guided by the intended use, administration, and effectiveness of the electronic medical device. If your product comes in routine contact with patients, expect a more stringent review of product classification.

3. Conduct Risk Management Analysis

Next, conduct a risk management analysis. IEC 60601-1 requires life sciences organizations to evaluate and monitor risk associated with both the essential performance and safety of the medical device.

According to the Johner Institute, essential performance is defined as "freedom from unacceptable risk directly caused by physical hazards when equipment is used under normal condition and single fault condition."

Meanwhile, basic safety is defined as the "performance of a clinical function, other than that related to basic safety, where loss or degradation beyond the limits specified by the manufacturer results in an unacceptable risk."

In the event that major risks are identified, investing in quality management software can help your team proactively manage and mitigate compliance roadblocks. Qualio's electronic quality management system is the first web-based tool purpose-built to help quality teams centralize data and quality processes. The unification of data and quality processes is one of the first steps teams can take to eliminate risks associated with both essential performance and basic safety.

4. Activate IEC 60601-1 Test Plan

An IEC 60601-1 test plan is used to demonstrate the overall performance and effectiveness of the electronic medical device. The test plan is also used to demonstrate compliance with all applicable standards under IEC 60601-1.

The test plan should follow a set protocol. These protocols define the testing strategy, performance criteria, and user roles and responsibilities.

As a best practice, be sure to identify how the test will be conducted. Are you planning on running the test in-house, or will you be outsourcing to a quality and compliance team? A quality management system is another vital tool for teams interested in conducting off-site testing. Most electronic quality management systems make it simple and easy to access documentation related to the test plan and associated protocols.

5. Prepare and Submit Report

After testing, prepare and submit your IEC 60601-1 application. The Federal Drug Administration (FDA) recommends preparing the following premarket documents:

- Cover Letter

- Declaration of Conformity

- Supplemental Documentation

To streamline file organization and accessibility, many quality teams invest in document control systems. The very best document control systems facilitate real-time access to

important quality and testing information. A cloud-based system supports unlimited file storage and promotes cross-team collaboration.

Quality Management for Electrical Medical Device Manufacturing

By following the steps outlined above, your life sciences organization will be well-positioned to achieve rapid and sustained compliance.

However, the work doesn't stop there.

As a suggested bonus step, it is recommend evaluating the effectiveness of your quality management system and processes. Are there any gaps in your organization's current approach to quality? Are you monitoring for and mitigating product risk?

Achieving IEC approval for your electrical medical device protects your end-users and promotes increased product effectiveness. But it's only a small piece of the puzzle.

The electronic quality management system (eQMS) you choose is a big one