

Allux Medical, Inc. Eliminates 2 Days from Clinical System Build and Test

"With the QuadTech Sentinel II System, we can complete assembly, test for electrical safety, close the lot history records and ship to clinical sites all in the same day."

Michael Rode
Quality Engineer
Allux Medical, Inc.

Summary:

- Increased overall throughput
- Increased flexibility in build schedule
- Eliminated 2 days from build and test
- Saved \$3,000 per device built
- Achieved consistent test reports for each device

The Challenge:

Allux Medical, Inc., a medical device company, develops devices to locally modulate the immune system for the treatment of inflammatory diseases. They needed a method to quickly and efficiently assess the electrical safety of their devices.

The two options used for electrical safety testing of their devices were:

1. Hire an outside contractor to do testing at the Allux Medical facility.
2. Take the devices to a local testing lab.

The challenges with the first option were many; the major challenge being schedule - getting the contractor's schedule to align with device build schedule. Secondly, the contractor was not local, so issues and resulting corrective actions were communicated via email and telephone - resulting in at least a day delay per communication.

The second option wasted nearly 2 hours of valuable employee time in driving to/from the local test lab to deliver and pick up the devices. This came with a high price tag of over \$3,000 per device. And the test lab would require that the device be left with them for a full day - impacting already tight build schedules.

The Solution:

The customer chose the Sentinel II System which includes a Guardian 6100 Plus Medical Safety Analyzer, a 1500VA AC Source and CaptivATE Automation Software.

This solution enabled the customer to complete all electrical safety testing, as required by IEC 60601, in house and in less than one hour per device.

Benefits:

Doing electrical safety testing in house has allowed the customer to cut at least two days from building and testing a clinical device while saving at least \$3,000 per device. With the Sentinel II System, the customer can complete assembly, test electrical safety, close the lot history records (consistent test reports) and ship to clinical sites all in the same day.

The Sentinel II System has also allowed the customer to examine their devices and processes and make improvements at earlier stages in the build process. And they have been able to utilize the Sentinel II System for development testing to ensure that new designs will pass electrical safety testing.

This company will achieve ROI for this test solution in 5 months.