

## Case Study: TG3 Electronics, Inc.

**MedAccred Accreditation process helps shift internal focus from reactive to preventive at manufacturer of engineering input devices**

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The practice of healthcare in a modern setting is increasingly defined by the ongoing adoption of electronic technology to diagnose and help manage patient care. Test and treatment protocols rely on sophisticated devices to help staff save time, aid in an accurate diagnosis, and improve treatment.

Producing electronic devices for the medical arena relies on critical manufacturing processes for reliable, effective, and consistent solutions. The MedAccred Accreditation program offers a dependable pathway for manufacturers to ensure and confirm that critical procedures and materials meet or exceed industry accepted quality standards.

Controls and operator interfaces for medical devices require sophisticated electronics that are critical to the functionality. That's where TG3 Electronics, Inc. adds value as part of the medical device supply chain. TG3 Electronics is a Kenosha, Wisconsin, manufacturer of standard and custom keyboards, control panels, and custom display devices for the medical, manufacturing, government, and other markets. As a designer of custom input devices, TG3 provides the user interface that communicates to the equipment or device.

TG3 Electronics has been ISO 9001:2015 certified since 2005 and added ISO 13485:2016 in 2020, after deciding to pursue MedAccred Accreditation. The incentive to get MedAccred certified occurred when learning that one of their largest customers had decided to require MedAccred Accreditation from all their suppliers.

### 'Taken to an entirely new level'

The people at TG3 Electronics pride themselves on developing well-designed products, along with focusing on engineering expertise and customer support as the bedrock of their success. According to TG3's Director of Quality Jim Rigney, "When we started making products for the medical industry, our culture started shifting to a deeper focus on quality. The MedAccred process has taken us to an entirely new level."



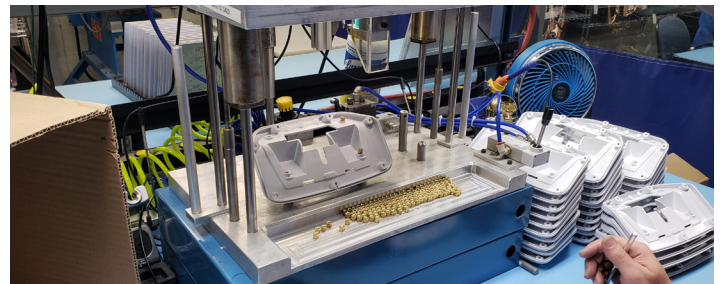
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TG3 Electronics has been building electronic devices for 36 years that includes printed circuit board (PCB) assembly operation. PCB assembly operation is one of the accreditations offered by MedAccred. TG3 Electronics' pursuit of MedAccred Accreditation for PCB Assembly began with the formation of an internal team, dubbed by the participants as the "MedAccredibles". The cross-functional team included

representatives from various TG3 Electronics departments, including Quality, Purchasing, Manufacturing, and Engineering.

The initial gap analysis performed by the team as part of the audit process identified several missing procedures that were required to meet the MedAccred requirements. According to Jim Rigney, "Our initial time spent on evaluating, creating, and updating procedures spanned over about six months with four people spending about 50% of their time on it." TG3 Electronics was assisted in this process by the Medical Manufacturers MedAccred Accreditation Pathway (MedMAPP), a program that provides federally-funded resources and expertise to improve the competitiveness of U.S. manufacturers.

Jim went on to add, "The largest challenge was addressing our gaps, while doing our "day" jobs. It was a long and tedious process to create or modify all the procedures, review them, approve them, and then train all of the appropriate people. We created or modified over 50 procedures to meet the requirements of our first accreditation audit."



### Outcomes of the MedAccred process for TG3 Electronics...

- Realized significant growth within the first year after MedAccred participation
- Materials and Purchasing controls improved
- Monitoring of incoming materials and products increased
- Logging and documentation procedures have been enhanced to improve product shelf life
- Significant savings realized in scrap, rework, and design costs
- Improvements in product pricing position are apparent
- Decreased effects on processes and output due to personnel turnover

The outcome of all this work was that TG3 Electronics was awarded an initial MedAccred Accreditation for PCB Assembly in 2020 and has continued to pass subsequent audits. However, there's much more to the outcome of this story.

### 'Improved quality culture'

Going through the process of MedAccred Accreditation has significantly improved the quality culture at TG3 Electronics. As Jim Rigney explains, "MedAccred has empowered our Quality department with the leverage to make necessary changes and enforce more strict standards for the production floor. We are doing a better job of training our operators and explaining the importance of complying to MedAccred industry-managed audit criteria."

Jim goes on to add, "We are also changing from a reactive to preventive approach, along with catching issues at the source to fix them and reduce rework. We use tools like PFMEA, Fishbone Analysis, Design Reviews, and others to focus on preventive controls that have avoided thousands of dollars in scrap, rework, and design changes. We are also converting our lagging metrics into leading ones to make better business decisions while we can still make a difference. Everyone knows what needs to be done, and there are no cutting corners."

### 'Significant growth'

Tim Hansen, TG3 Electronics Director of Sales, sums up the value of the MedAccred Accreditation process by saying, "It is clear that MedAccred has brought TG3 to a higher standard. We saw significant growth within the first year after our MedAccred participation and we expect more in the future. Much of the growth has been directly due to opportunities we have received for being a MedAccred Accredited Supplier, along with our in-house Engineering services. We continue to have a line of opportunities in our sales pipeline from multiple divisions of our sponsor company, due to our accreditation."

Jim Rigney sums-up by saying, "Probably the biggest improvements from the MedAccred audits are the additional controls in our process to catch issues at specific points in a process, so they can be corrected before multiple defects occur."

### Summary

The value of the rigorous MedAccred Accreditation program to TG3 Electronics has proved to be significant and long-lasting.

Quality is a constant and necessary theme for medical device manufacturers, like TG3 Electronics. In a business where health and quality of life issues are in the forefront, a focus on achieving manufacturing process quality is not just a goal, but a necessity.

Contact Tim Hansen at [thansen@tg3electronics.com](mailto:thansen@tg3electronics.com) to learn how TG3's MedAccred Accreditation can benefit your next healthcare product design.

### TG3 Electronics Inc.

TG3 Electronics, Inc. is a Kenosha, Wisconsin-based designer and manufacturer of engineering input solutions for the Medical, Law enforcement, Retail, Manufacturing, and Government markets. Founded in 1986, the company has manufacturing sites in the U.S. and China.



### MedAccred

Med Accred is an industry-managed, consensus-driven approach to ensuring critical manufacturing process quality through the medical device supply chain. Audits are conducted on behalf of subscribing members using collaboratively-created audit criteria. Accreditation is granted and accepted by the MedAccred subscribing OEM members. Audit criteria incorporates industry-accepted performance standards and manufacturer specifications that meet regulatory requirements.

Learn more at: [www.p-r-i.org/medaccred](http://www.p-r-i.org/medaccred)

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