MULTITECH®

ISO 13485 Quality Management System

Organizations holding the coveted International Organization for Standards (ISO) rating are recognized around the world as being industry leaders that are committed to delivering products and services that are high quality, well tested, proven and exceed customer expectations. For years, MultiTech has maintained its ISO 9001: 2008 certification. To build on this tradition, MultiTech achieved the quality management system ISO 13485:2003, which further reduces risk and improves product quality and component traceability. Although many of our medical device customers require this certification, companies of all types can benefit from the confidence in selecting a product manufactured with this system in place.

Understanding ISO 13485

ISO 13485 is an enhanced quality management system specifically targeted toward the medical device world. It incorporates a risk management approach to product development and product realization. Process validation is greatly enhanced, which aids to improve the quality of the design and the manufactured product. In addition, product traceability is greatly enhanced to the component level.

Benefits to MultiTech customers

The whole system drives improved overall product quality. In addition, for cases when product quality may come into question, the system requires advanced notification to customers, which will prevent questionable product from reaching end customers.

bsi. ISO 13485 Medical Devices Quality Management
FM 586973

bsi. ISO 9001 Quality Management
FM31060

MultiTech's pursuit of ISO 13485 certification

Many of our medical device customers are requiring their suppliers be ISO 13485 certified. This certification allows MultiTech to quickly fulfill this requirement for all potential medical device customers.

ISO 13485 matters to customers outside healthcare industry

It directly applies to healthcare, but also can be applied to all customers, regardless of the industry. Many customers are pleased to know that MultiTech has an enhanced quality system in place.

Aligning with MultiTech's prior quality standards

Much of the ISO 13485 aligns with ISO 9001:2008. The major difference is around risk management, product/ process validation, customer notifications and traceability.

For more information, please visit www.multitech.com or contact our sales team at 763-785-3500 or sales@multitech.com.