

Case Study: Segue Manufacturing Services, Inc.

Audit Process and Accreditation are Critical to Product Quality Improvement at Segue Manufacturing Services

MedAccred@p-r-i.org / +1 724 772 1616 / www.MedAccred.org

As modern medical devices and equipment get more sophisticated, the integration of complex electronic content into ever smaller packages creates challenges for design, manufacturing, and testing. The efficient integration of sensing and control functions in a device or system requires intricate internal wiring that is designed and manufactured to perform effectively, save space, reduce or eliminate errors, and meet or exceed quality requirements.

The process of design, manufacture, and integration of complex cable and wire harness assemblies in medical systems is a custom operation that requires a particular “quality mindset” from the start. Wire harnesses used in medical equipment applications must be reliable, safe, and consistent. From initial discussions to determine process quality parameters to final product delivery, many companies rely on independent organizations, like MedAccred, to review and accredit their systems and procedures.

‘An emphasis on quality’

Focus on delivering quality is a constant theme of Segue Manufacturing Services, Inc. with headquarters in North Billerica, Massachusetts and Xiamen, China. Among other services, Segue Manufacturing builds custom wiring systems for the medical, industrial, transportation, and defense markets. The company embarked on the MedAccred Accreditation process for the production of wire harnesses at its Xiamen facility, and started well in advance of audit to prepare for what they sensed would be a critical exercise.

According to Stephanie Lin, VP and General Manager of Segue Xiamen, MedAccred Accreditation is recognized by the top medical enterprises in the world. The company chose to pursue MedAccred Accreditation for its Xiamen wire harness activities to better serve its medical enterprise clients and to provide improved products and services for new customers.

Going through the process and reaching the outcome of quality accreditation is important to Segue Xiamen, which was one of the first companies in China to attain ISO 13485 certification in 2005. It is also certified to ISO 9001:2008 and IPC 620-A-WHMA and IPCJ-STD-001D. Its products are fully CE, UL, and CSA compliant. Segue Xiamen is also a founding member of the Chinese version of the IPC620 program for wire harness training.

This emphasis on quality led Segue Xiamen to form a cross-functional group eight months prior to the MedAccred audit. Internal representatives from management, engineering, production, quality

assurance, purchasing, customer service, and human resources worked together to sort through and understand the MedAccred AC8121 Cable and Wire Harness Assemblies audit criteria, and identify the adjustments that were needed in their company systems and training.

‘Improved training and processes’

One of the requirements of the MedAccred wire harness accreditation process is that participants must also undergo IPC 620 CIT (Certified IPC Trainer) or CIS (Certified IPC Specialist) wire harness certification training. Segue Xiamen personnel went through this extensive training course and Stephanie Lin enthusiastically notes that three employees now hold CIT certification, and over 50 hold CIS certification.

Stephanie identified two internal processes that were significantly improved due to the MedAccred audit. The first of these was Segue Xiamen’s warehouse storage process, where equipment and controls were upgraded according to audit requirements to eliminate potential oxidation of both materials used in production, and in the storage of finished products.

The second was improvements in their tin process which is used to coat copper wires to protect them from oxidation and improve durability. Segue Xiamen engineers looked at their tin analysis and monitoring before and after use, reviewed their tin replacement schedule, and inspected the tin furnace container. Following the MedAccred requirements, they transformed each of the steps in this process and eliminated any changes in tin composition used in their wire coating procedure. This led to improved consistency in coating and ensures that the end-product will meet accepted standards going forward.

Outcomes of the MedAccred process for Segue Xiamen...

- Reduction or elimination of product quality process risk
- Increased business due to ease of customer certifications
- Ongoing improvements in product quality

By working through the requirements in the MedAccred criteria, implementing software and hardware changes, and upgrading equipment and training, Segue Xiamen successfully passed the MedAccred Cable & Wire Harness audit and was awarded Accreditation by the MedAccred subscribing companies.

Segue Xiamen has been committed to the quality production of medical cable and wire harnesses for a long time, according to Lin. Going through the MedAccred process, she added, enabled them to reduce or even eliminate some potential process quality risks through adherence to the strict requirements of the audit criteria. This was, according to Lin, the greatest benefit to the company after passing the accreditation.

More specifically, Lin noted that after achieving MedAccred Accreditation, they were able to meet the production schedule and achieve zero complaints after fulfilling an order for respirators that increased by over 30 times from the prior year. Plus they were able to pass another prospect's global supplier certification very smoothly, leading to their first project from the company.

'The intangible effects of accreditation'

Efficient operation and consistent, predictable outcomes are the goals of medical device manufacturers, where device failure is unacceptable. Stephanie Lin went on to underscore this by saying that risk management is the perpetual theme of many medical enterprises. "Through MedAccred Accreditation," she stressed, "process risk control is now deeply rooted in the hearts and minds of Segue Xiamen people." "For example," she added, "when we initiate a project with a customer, we consciously refer to the requirements of MedAccred. In the long run, the quality of the product will significantly improve because of MedAccred."

Summary

According to Stephanie Lin, the MedAccred accreditation process has enabled Segue Xiamen to identify areas for improvement, increase efficiencies, reduce process risk and increase customers. It also helps assure that the company is providing quality products that can improve patient care worldwide.

Segue Manufacturing Services

Segue Xiamen Manufacturing Services, Inc. is a U.S. owned-and-operated, global contract manufacturer of custom cable and wire assemblies, electrical control and distribution panels, and electro-mechanical systems and subsystems. Established in 1991, the company is headquartered in both North Billerica, Massachusetts and Xiamen, China.

For more information go to: www.segue-mfg.com

MedAccred

MedAccred 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

