SINBON ELECTRONICS

Quality Manager at SINBON Electronics, Molly Xu, explains how the MedAccred Cable and Wire Harness accreditation process provided them with a fresh outlook and renewed confidence, paving the way for global business success.

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A few years ago, one of our large medical customers required that our Cable and Wire Harness Assembly manufacturing processes conform to IPC/WHMA-A-620 Class 2, or a higher-level standard, and that expert auditors should be used to validate our capability. It was then that we first became aware of the MedAccred program and what it could do for SINBON Electronics.

Prior to MedAccred, we handled process control by undertaking routine internal reviews and those administered by our customers. As we entered the MedAccred accreditation process, we conducted an internal review of the MedAccred Cable and Wire Harness audit criteria and built a dedicated team to help us prepare over a six-month period.

To meet the rigorous MedAccred Cable and Wire Harness requirements we made several adjustments to improve our internal process controls. For example, the lighting condition of the factory was improved to meet the IPC 620 standard. We also certified our personnel to meet IPC 620. Prior to MedAccred, we

The MedAccred Cable and Wire Harness audit lasted four days and was conducted by a true subject matter expert in Cable and Wire Harness. The audit was challenging, but our team in Jiangyin was successfully able to demonstrate that our manufacturing processes were fully compliant. We were proud to become the first company in Asia to become MedAccred accredited to Cable and Wire Harness. The MedAccred audit and accreditation process has replaced our routine audit. Undertaking accreditation, and re-accreditation, has driven SINBON to continuously improve, enabling us to increase efficiencies and reduce cost for both us and our customers. This has led, for example, to a reduction from 500 to 300 defective parts per million for one of our customers. SINBON has also become more knowledgeable in the cable and wire harness manufacturing process and enhanced our engineers' ability to solve difficult problems. Following our MedAccred Accreditation, we had increased confidence to present our factory to the world with a new, positive and professional attitude. Most importantly, since achieving our MedAccred Accreditation, more medical customers have become aware of SINBON and that has helped us to grow our business.

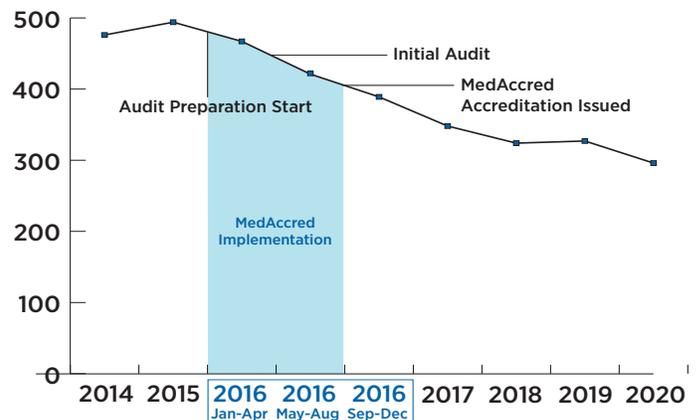## Since the MedAccred audit, SINBON has seen...

- **Reduction from 500 to 300 defective parts per million for one customer**
- **Increased awareness from new medical customers**
- **Growth in business**
- **Gained new knowledge of the Cable and Wire Harness process**

only trained operators and inspectors with an internal coach using internal standards and personnel. We now use trained operators and inspectors in line with IPC 620 and consistent with industry requirements. In addition, we used the IPC standard to create work instructions and ensured that maintenance and calibration of all production equipment was implemented in such a way as to ensure consistent performance.

Process DPPM

SINBON Electronics

SINBON Electronics, based in China, was founded in 1989, and is a leading solution provider of electronic component integration design and manufacturing, offering an extensive range of value-added services to their customers in medical health, automotive, green energy, industrial applications, and communications.

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.