

ELYTONE ELECTRONIC CO., LTD.

Azita M. Davis, VP International Business Development (North America), describes how Guangdong, China facilities' journey to become MedAccred Accredited for Printed Circuit Board Assembly has improved quality and led to new business opportunities.

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We first learned about the benefits of obtaining this elite Accreditation during a meeting with a top-10 global medical company. MedAccred was not an organization we were previously aware of, but it soon became clear that it would help to increase our stature within the medical device industry. Following this meeting we quickly formed a team to get started on our path towards Accreditation.

'We could show our commitment to quality'

Elytone has been a leader in safety and reliability for the past 40 years and we have ISO 9001 and ISO 13485 certification at all our facilities. However, MedAccred Accreditation was another way that we could show our commitment to quality to our customers. MedAccred would provide independent feedback of our process capability, ensuring processes are tightly controlled and that our products are safe. In this global market, to manage suppliers remotely is a challenge, and finding qualified suppliers is often costly and time-consuming.

Since the MedAccred audit, Elytone has...

- **Reduced the number of defective parts and improved product quality**
- **Increased exposure to medical industry executives**
- **Set itself apart from many other contract manufacturers.**

We were happy to participate in a program which, as a powerful marketing tool, would set us apart from other suppliers. We prepared for the MedAccred Printed Circuit Board Assemblies audit three months ahead of the audit date, and MedAccred provided valuable information to guide us through the process. We checked the production schedule, and double-checked each process and control, from the incoming material received to the finished units to be shipped. The audit cost was very reasonable and we could see that it would be a good investment for any company.

The audit was very thorough, with strict requirements made on the process control from the design to the finished unit. We spent a week with a seasoned auditor who had 39 years of experience in this field.

He asked us a comprehensive range of questions regarding the systems and processes, and thanks to our robust preparation, we were well-positioned to give good answers.

'MedAccred Accreditation has set us apart'

Our MedAccred Accreditation now ensures that the highest possible standards are practiced daily in our factory which ultimately result in improvements to quality and patient safety. It has also brought us various benefits, the most important one for us being exposure to executives of major companies within the medical device industry. MedAccred Accreditation has set us apart from many other contract manufacturers and has helped us to maintain a much deeper and better relationship with our partners. MedAccred Accreditation has contributed to a reduction in defective parts and improved the quality of our products.

Elytone believes in quality for all aspects of the business and has created a working environment that promotes quality and wellness throughout our company. We value and recognize good quality work, and life-long learning is promoted by providing training opportunities and seminars for all employees. Sustaining a quality work environment adds to the quality of our products and has resulted in Elytone having one of the lowest employee turn-over rates in our industry.

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.

Elytone Electronic Co., Ltd

Founded in 1980 in Taiwan, Elytone is a contract manufacturer specializing in medical and professional-grade systems, assemblies, and components. All of Elytone's facilities are ISO 9001 and ISO 13485 certified.