

East/West Manufacturing Enterprises Earns ISO 13485:2016 Certification and Continues Record Growth

Austin, Texas based Electronic Contract Manufacturer Meets ISO Quality Standard for Medical Devices

January 7, 2019 Austin, TX - East/West Manufacturing Enterprises (East/West), an [electronic contract manufacturer](#) today announced that it has achieved ISO 13485:2016 certification, an internationally recognized quality standard specific to the medical device industry. East/West also renewed its ISO 9001:2015 certification, and is one of the only contract manufacturers in central Texas to have both quality management certifications.

The ISO 13485 standard has been created and influenced by the major medical device regulatory bodies across the world. ISO 13485:2016 is an international standard that defines common medical regulatory concepts to provide assurance that a company meets certain quality management system expectations. The 2016 version of the international standard is a major revision of the 2003 version, with an increased focus on risk management and risk-based decision-making processes at both the quality management system and product levels.

In addition to achieving [ISO 13485:2016 and ISO 9001:2015 certifications](#), East/West experienced strong growth and improvements in 2018. Highlights include:

- Record Q4 2018 revenue increase of 50% over the same period last year
- Ten new customers during the year
- SMT equipment purchases enabling a capacity increase of 2X
- In-house Certified IPC Trainer and IPC-A-610 Certified Specialists to ensure compliance with IPC 610 Class II and III manufacturing
- ITAR registration renewal for continued work on defense related technologies

“2018 has been another year of solid growth for East/West” said Andy Salo, President of East/West Manufacturing Enterprises. “We are working closely with our customers as their manufacturing arm to deliver high quality products, while achieving reduced customer costs through our process efficiency and strong distributor relationships.”

For more information on East/West Manufacturing Enterprises and its contract manufacturing capabilities, visit <http://www.ewme.com>.

About East/West Manufacturing Enterprises

East/West Manufacturing Enterprises is a full service [Printed Circuit Board \(PCB\) Assembly](#) manufacturing company that produces high quality PCBs, custom cables and electrical/mechanical assemblies for different industries around the world. We work with large and small companies to meet their demands from quick turn, low volume prototypes, to assisting with manufacturability for high volume needs. At East/West we understand that product quality is paramount, and must be matched with on-time delivery and low cost. East/West specializes in NPI for small to mid-volume orders, while offering customers a path to full production. Our success is built on a relationship of trust that we earn by consistently meeting customer needs and being flexible to help achieve strategic goals. East/West provides materials management by offering full turnkey services where we procure all parts, assemble and final test the product, and drop ship to the end user if desired.

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