PURDUE UNIVERSITY | Manufacturing Extension Partnership

Client Success Story

ESTES DESIGN AND MANUFACTURING, INC.

INDIANAPOLIS, INDIANA

Ryan Estes
Director of Business Development
Estes Design and Manufacturing

> Purdue worked hand in hand with our quality, engineering, planning and management teams at Estes to understand and refine our existing processes and help craft new ones to expedite the path to implementation and ISO 13485 certification. MEP provided invaluable coaching and practical, hands-on training during the project.

Estes Turns to Purdue to Help Grow Its Line of Medical Devices.

"We value our relationship with Purdue greatly. The services and expertise are of very high quality. This partnership has been a resounding success."

TIM ESTES
President
Estes Design and Manufacturing

ISO 13485 certification opens door to expand growing line for Indiana manufacturer.

The manufacturing industry has certifications showcasing a company's commitment to efficiency, process systems, risk management, quality control and other high-level standards.

For Estes Design and Manufacturing, Inc., achieving an ISO 13485 certification would expand its presence in a promising business line — making products for the fast growing medical device products market.

With 100 associates at its 85,000-square-foot manufacturing facility on Indianapolis' eastside, Estes set out to simplify its line of medical trays, reducing components and weight while improving the sterilization performance and materials utilized.

"Estes has a long history in the medical device market that dates back to 1983," says Ron Estes, vice president of operations. "In the last five years, our company made a concerted effort to introduce new and innovative ideas for this market. We have been dedicated to providing our clients with creative, functional concepts."

Officials at Estes were confident annual sales of its patented and proprietary medical device tray could double within three years. Of course, attaining the ISO 13485 certification to work in that market was no simple task.

"Estes knew where to find such a resource and immediately turned to Purdue," says John Brown (right), Estes' director of quality and compliance.

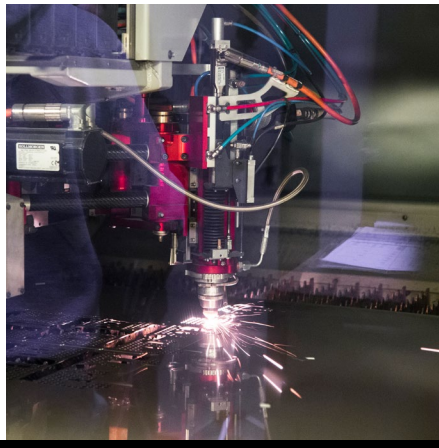
For Estes, Purdue performed a gap analysis audit and assisted with risk management training. Ted Boehm, a consultant for the Purdue Manufacturing Extension Partnership, conducted internal auditor training and served as the lead for Estes' first ISO 13485 internal audit.

Estes, founded by Purdue engineering alum Larry Estes in 1976, holds within its core philosophy the value of creative, innovative thinking as a full-service sheet metal fabricator. Estes offers customers a combination of product design, engineering, rapid prototyping and manufacturing services using advanced technology, including 3D laser welding.

Tapping Purdue to help implement ISO 13485, Estes took what would have been most likely a six-month process and compressed it to three months. Brown said it was completed with minimal production disruption or delay.

Plus, Estes was recommended for ISO 13485 certification by its registrar DNV-GL, the risk-management organization that certifies such standards, on the first attempt, a testament to the quality of work and training Purdue provided. Estes was awarded the prized ISO 13485 certification.

"Purdue worked hand in hand with our quality, engineering, planning and management teams at Estes to understand and refine our existing processes and help craft new ones to expedite the path to implementation and ISO 13485 certification," says Ryan Estes (on cover), director of business development at Estes. "Purdue provided invaluable coaching and practical, hands-on training during the project."



ABOUT MEP

Purdue Manufacturing Extension Partnership (MEP) provides high-value solutions to help Indiana businesses maximize their success. As advocates for Indiana's thousands of manufacturers, our staff identifies areas of improvement, streamlines processes, and ultimately increases competitiveness. Purdue MEP serves hundreds of companies annually by implementing continuous improvement principles in the areas of productivity, growth, and technology.

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