LITRON Quarterly

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ISO 13485:2003 Certification Audit

Litron Completes Certification Activities for Registration to ISO 13485:2003

Litron is pleased to announce the completion of activities necessary for registration to the ISO 13485:2003 Standard. This standard is the premier Quality Management System standard for manufacturing and regulatory requirements of medical devices.

"This is a milestone in Litron's journey toward becoming a premier supplier of welding and assembly services to the global medical device market. The ISO 13485:2003 Quality Management System provides us a fundamental tool for achieving comprehensive compliance for medical device manufacturing. Litron's efforts allow us to serve not only customers with US FDA concerns, but customers with Canadian and E.U. concerns as well. Customers bringing their contract manufacturing work to Litron can be certain they are working with a team of Quality, Engineering, and Manufacturing personnel that understand the quality and regulatory concerns facing the world's market today" says Tara Douglas, Quality Assurance Manager.

We would like to personally thank our staff for their hard work and dedication in preparing Litron for this audit, and all of the hard work they do, day in and day out. Great job!

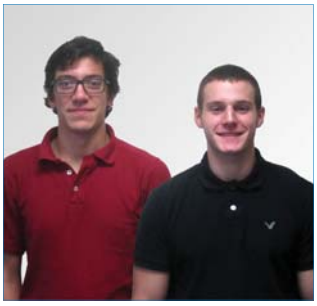
Waves of Change

What's going on at Litron?

- Litron Medical will be showing at the MD&M Minneapolis show October 29 and 30, visit us in booth #1704.
- We've completed our ISO 13485 Certification Audit, see the featured article above.
- Our Medical Division has formed a strategic partnership with key vendors for manufacturing devices (see page 2).
- Our engineering staff is growing with the addition of two graduates from Western New England University.
- Litron's Compact Glovebox Laser System is being featured at the MD&M Minneapolis show, booth #1704.

Department Profile

Dillon Young & Douglas Tong



Douglas Tong (left)
Process Engineer, Quality Assurance
Dillon Young (right)
Process Engineer, Laser Services

Recent 2013 graduates of the Western New England University Mechanical Engineering Program, Dillon Young and Douglas Tong, have joined the Litron team this summer. Filling the positions of Process Engineer Laser Services Department (Young) and Process Engineer Quality Assurance Department (Tong), these two will be playing an integral role in the day to day documentation and process qualification of programs.

"I'm enjoying working at Litron because of the diversity of the parts made here. Nearly every day I'm able to see something new, and see it made from start to finish. This keeps me interested in what I do and excites me to continue learning more about the laser services industry" says Young.

"In the short time that I have been at Litron, I have been quickly introduced and immersed into both the medical and aerospace industries. It's an exciting time to be a part of Litron as it expands, and I look forward to developing and contributing my skills with the lively team here" says Tong.

Litron would like to welcome you both aboard and congratulate you each on your recent graduations. As the saying goes, "Welcome to the real world"!

Implantable Medical Devices

Combining Best-In-Class Technologies

Since our inception in 1997, Litron has been working for the Implantable Medical Device Industry, in one capacity or another, and have worked with dozens of vendors who also support the industry. In the last few years, as we've become more heavily involved in the supply chain management portion of these builds, it has been increasingly more important to work with top-notch vendors.

To that end, we've recently formed a strategic partnership with several key vendors. This partnership has been formed to reduce risk and simplify management of implantable medical device projects.

In addition to Litron, the partnership consists of the following companies that each specialize in a portion of the business:

A strategic partnership of best-in-class suppliers formed to reduce risk and simplify management of your next implantable medical device project.

SOURIAU PA&E
SOURIAU PA&E has been producing hermetic electronic feed-thrus and packaging for implantable medical devices since 1976. Both start-up and well established manufacturers trust them on a range of applications including: cardiac devices, spinal cord stimulators, bone growth stimulators, cochlear implants, blood pressure sensors and endoscopic devices.

"SOURIAU PA&E uses unique manufacturing processes and materials to help implantable device manufacturers address complex interconnect and packaging challenges. Whether it's one of our standard, quick-turn, feed-thru designs, or a complex integrated housing, we specialize in delivering reliability and performance in small form factors."

Valtronic
Valtronic provides 30 years of experience and has been involved in over 100 Class II/III implant projects ranging from neurostimulation to drug delivery to cardiac devices. Their micro-electronic expertise is the foundation of everything they do.

"As a contract manufacturer specializing in electronic miniaturization, we offer circuit board design services through complete electronic assembly. We manage the entire electronic supply chain and are FDA Registered and ISO 13485:2003 certified."

Chameleon Design Solutions
After more than 18 yrs of OEM Medical Device Development at Hi-tronics Designs, Chameleon Design Solutions formed in 2007 and continues to develop implantable and external medical devices.

"We work closely with you to design the highest quality and lowest cost device to meet and exceed your requirements, and work hand-in-hand with our partners to design and integrate key vendor components, supporting assembly and manufacturing of your device every step of the way."

Give us a call with your implantable project needs; We're ready to help!