

ISO 13485 Registration

Registration is a document. A company's true commitment to quality can only be assessed by its investment in people dedicated to quality in everything they do.

→ We have the credentials and people to manufacture medical products of the highest quality →

The ISO 13485:2003 Standard, developed by the Geneva-based International Organization for Standardization, sets forth guidelines and requirements for quality system design in the manufacture of medical devices. This standard is achieved through a thorough audit of management practices, quality planning, effective communications and prevention of errors.

Columbia Tech received its registration to ISO 13485:2003 on April 7, 2006. Knowledgeable quality professionals regard this outcome as outstanding and a sign of serious quality commitment companywide. Only 0.04% of all companies certified to the ISO 9001 standard have achieved registration to ISO 13485:2003. Our Toronto-based Registrar, QMI, made special note of three aspects of quality at Columbia Tech upon completion of our audit:

- Strong management commitment to quality
- Detailed and thorough preventive and corrective action processes in place
- Strong employee awareness of the quality processes and procedures

Exceeding Quality Expectations

Columbia Tech currently provides design and manufacturing services to medical companies throughout the United States. The products we currently produce include therapeutic devices, colonoscopy components, endoscopes, blood profusion monitors, and MRI-related devices. As we have grown with our customers, adding the FDA registration became a logical step because, after all, ISO 13485:2003 is the ISO 9001 for medical equipment manufacturers and we've been ISO 9001-registered for nearly a decade.

Quality: Our Company Standard

"Our Quality Management System affects every aspect of our company," notes Cluis Coghlin, President of Columbia Tech. "Simply put, it is the standard by which we gauge our abilities to make defect-free products and achieve a consistently high level of customer satisfaction. Registration to ISO 13485:2003 raises the bar higher. It's all about continuous improvement."

Qualified People Assure Quality Standards

While our customers are pleased to know we are certified to ISO 13485:2003, they know what really counts is the caliber of our people. Nearly twenty percent of our workforce has quality as their primary focus and every employee knows their role in our quality system. Our quality management group and inspectors proudly maintain their credentials: RAB and IRCA certified lead auditors, Certified Quality Auditors, Certified Quality Engineers and IPC-certified trainers make up a growing list of quality specialists.

The Columbia Tech Quality Experience

Quality systems must be managed with intense focus, especially when making life-critical medical products. This is why the development of a specific quality plan is initiated immediately upon receipt of an order.

"The true impact of our Quality Management System at Columbia Tech is the confidence it builds in our relationships with customers," explains Coghlin. "We look forward to customer quality audits because they provide reassurance to our customers. Not only do they see the policies, procedures and documentation in place but, more importantly, they see the results and the pride our people take in doing an outstanding job."

Our 6-Step Quality Process

1. Establish mutually defined expectations
2. Conduct project review with cross-functional team
3. Develop and implement quality plan including documentation, data requirements, device history records and device master record
4. Manufacture product to controlled documentation and calibrated equipment by trained and experienced people
5. Verify product through inspections, process audits and 100% final inspection
6. Review data and obtain feedback to continuously improve the process

Choosing the Right Manufacturing Partner

Making the right manufacturing partner selection is critical to the overall success of your product launch. Our goal is to do our part in making your customer's first impression a positive and lasting one.

We invite you to bring us your next medical product challenge. Let us show you around and point out the numerous reasons why seeing is believing when it comes to an effective quality system. We won't just show you our ISO registration; we'll introduce you to our people. Quality people.

Please call Nora Leonard at 508.929.4619 or Email: noraleonard@columbiatech.com today!

Flexibility, Integrity, and Trust for more than 100 Years

17 Briden Street, Worcester, MA 01605
<http://www.columbiatech.com>



Certificate of Registration

Registered to:

Columbia Tech a Coghlin Company

17 Briden Street
Worcester, Massachusetts
01605 USA

which has demonstrated that its Quality Management System is in compliance with:

ISO 13485:2003

The following scope of registration applies:

Manufacturer of cables, harnesses, electromechanical panels, modules, drawers and printed circuit board assemblies, for various industries including the medical device industry.

CERTIFICATE	80029
SC Number / HACCP Code	1675 / DL 31.3
Date of Original Registration	April 7, 2006
Date of Current Registration	April 7, 2006
Registration Expires Date	April 6, 2009



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