Checklist: Choosing a Laser Technology Contract Manufacturer for Your Medical Device

What questions should you ask before selecting a laser technology contract manufacturer for your next medical device project? Here's a handy checklist (with rationales) of essential information you will need to know before making an informed decision. If a prospective provider cannot check off the items on this list (or provide a satisfactory reason for not being able to do so), move on to a reputable firm that can.

☐ Do they have their own Quality Manual?

The first step to creating a quality management system should be drafting a quality manual, which outlines an organization's goals, processes, and procedures for compliance and quality management. As part of the Laserage Quality System, the Laserage Quality Manual is organized according to the requirements of ISO 9001, with additional documentation prescribed by ISO 13485 applicable to medical device components. It reads in part:

- Our Quality Policy is achieved through the total commitment and cooperation of our employees, suppliers, and customers.
- Our Mission is to focus our attention on consistently meeting or exceeding all the requirements of our customers through continuous improvement and by building a supplier base dedicated to the same mission, while meeting any applicable regulatory requirements.
- Our Vision is to be recognized as the largest, highest quality, best valued, most responsive, full service laser processing company in the world for the benefit of our customers, shareholders, and employees.

☐ Do they have ISO 13485 certification?

ISO 13485:2003 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet regulatory requirements. The provisions of ISO 13485 are too extensive to address fully in this space, so we'll refer you to a website featuring some of the more important factors to consider written in simple terms: ISO 13485:2003 Plain English Overview. Laserage Technology Corp. is fully ISO 13485:2003 certified for medical device components.

LASERAGE® / AMETEK® ENGINEERED MEDICAL COMPONENTS

3021 N Delany Road, Waukegan, IL 60087, USA

Phone: 847 249 5900, Email: sales.laserage@ametek.com

☐ Do they conduct internal and allow external audits?

Laserage conducts external and internal audits as a routine part of our "Focus on Excellence". External audits are performed twice annually by an independent licensed ISO registrar, and internal audits are performed quarterly by trained Laserage personnel. Additionally, Laserage allows customer audits as requested, on the customer's timeline.

☐ Do they perform process validation?

Laserage offers a full range of process validation services through our Quality Engineering and Product Engineering teams to support all aspects of our manufacturing capabilities. Laserage teams will work with you to determine your validation needs.
Validation services include:

- Master Validation Plan
- Design of Experiment (DOE)
- Measurement System Analysis (MSA)
- Operational Qualification (OQ)
- Performance Qualification (PQ)
- Control Plan

Note: Equipment Qualification (IQ) is performed on all new processing equipment after installation.

☐ Do they have their own inspection capabilities?

Laserage employs state-of-the-art-inspection equipment such as:

- Automated Optical Inspection Equipment
- Programmable Pattern Recognition Systems
- Optical Binocular Microscopes
- Optical Digital Microscopes

Quality support equipment is available throughout our facility, including automated optical inspection equipment (AOI), image recognition systems, digital microscopes, other optical comparators, microscopes, and gauging devices. We utilize the latest inspection systems, including programmable CNC optical instrumentation (up to 256x magnification), programmable pattern recognition systems, digital toolmakers microscopes (up to 400x), stereo zoom microscopes (up to 40x), and a wide range of hand tools to meet your specifications. Our Quality Team regularly performs GR&R, MSA, and FAI along with OQ and PQ to compliment your growth from R&D to fully documented validation and volume production. Functional testing equipment such as Axial Load, Stress Strain, and Austenite Transformation Temperature (Af) are also close at hand.

Laserage also performs functional testing and inspections, such as force testing and micro cross-sectioning.

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Do they have an export control compliance policy?

It is our policy to be fully compliant with all applicable regulatory requirements including Export Administration Regulations (EAR) and International Traffic in Arms Regulations (ITAR) requirements.

Do they have a global code of conduct?

Our Global Code of Conduct establishes Laserage's commitment to conducting its business, on a global basis, in compliance with all known and applicable laws and regulations and in accordance with the highest standards of integrity and business ethics. It is the purpose of this policy to enumerate some of these standards and to set forth certain principles as guidelines for business decisions and actions.

Do they practice REACH compliance?

The regulation (EG) No. 1907/2006 (REACH Regulation) is an EU-Chemical-Regulation and became valid on June 1, 2007. REACH is the abbreviation for Registration, Evaluation, Authorisation, and Restriction of Chemicals. Its purpose is to provide a high-level of human health and environmental protection. Laserage is in full compliance with REACH.

Do they have a RoHS policy?

Restriction of Hazardous Substances (RoHS) Directive 2002/95/EC restricts (with exceptions) the use of six hazardous materials in the manufacture of various types of electronic and electrical equipment. Laserage has a long history of concern for environmental protection and strives to stay abreast of all environmental regulations that relate to our industry. Our RoHS Compliance Statement expresses our policies with regard to the abovementioned hazardous materials.

Do they have a full-time Director of Quality?

The Director of Quality at Laserage is Rick Capp. You can contact him to discuss product quality issues at:

- Phone: **847-856-2216**
- Fax: **847-856-3216**
- E-mail: **quality@laserage.com**

For general queries about medical device components, please send e-mail to: **medical@laserage.com**

Conclusion:

Laserage is a reliable laser contract manufacturing partner at every stage—right from R&D through pilot production to volume production, able to provide the necessary inspection capabilities for medical device development and manufacturing.

As a Laserage client, you'll benefit from the following:

- We continue to make significant investments in purchasing, installing, and maintaining the most advanced laser technology and state-of-the-art motion control systems.
- Our solutions, geared towards the medical device component market, are constantly reviewed and upgraded to keep up with the latest industry codes and mandates.
- Our expanded technologies are focused on the manufacturing of smaller feature sizes and increased precision capabilities.
- Our seasoned technical and quality engineering staff has years of experience in working with medical device OEMs.

For more information, or details on how we can add value to your project, talk to one of our customer service representatives today.

Resources:

http://www.iso.org/iso/catalogue_detail?csnumber=36786
http://www.praxiom.com/iso-13485-standard.htm
http://www.laserage.com/wp-content/uploads/2011/06/ISO_13485-2013.pdf
http://www.iso.org/iso/catalogue_detail?csnumber=46486
http://www.laserage.com/wp-content/uploads/2013/06/2013_ISO_9001-2008_Cert_2013_05_25.pdf
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http://www.laserage.com/contact/productquality

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