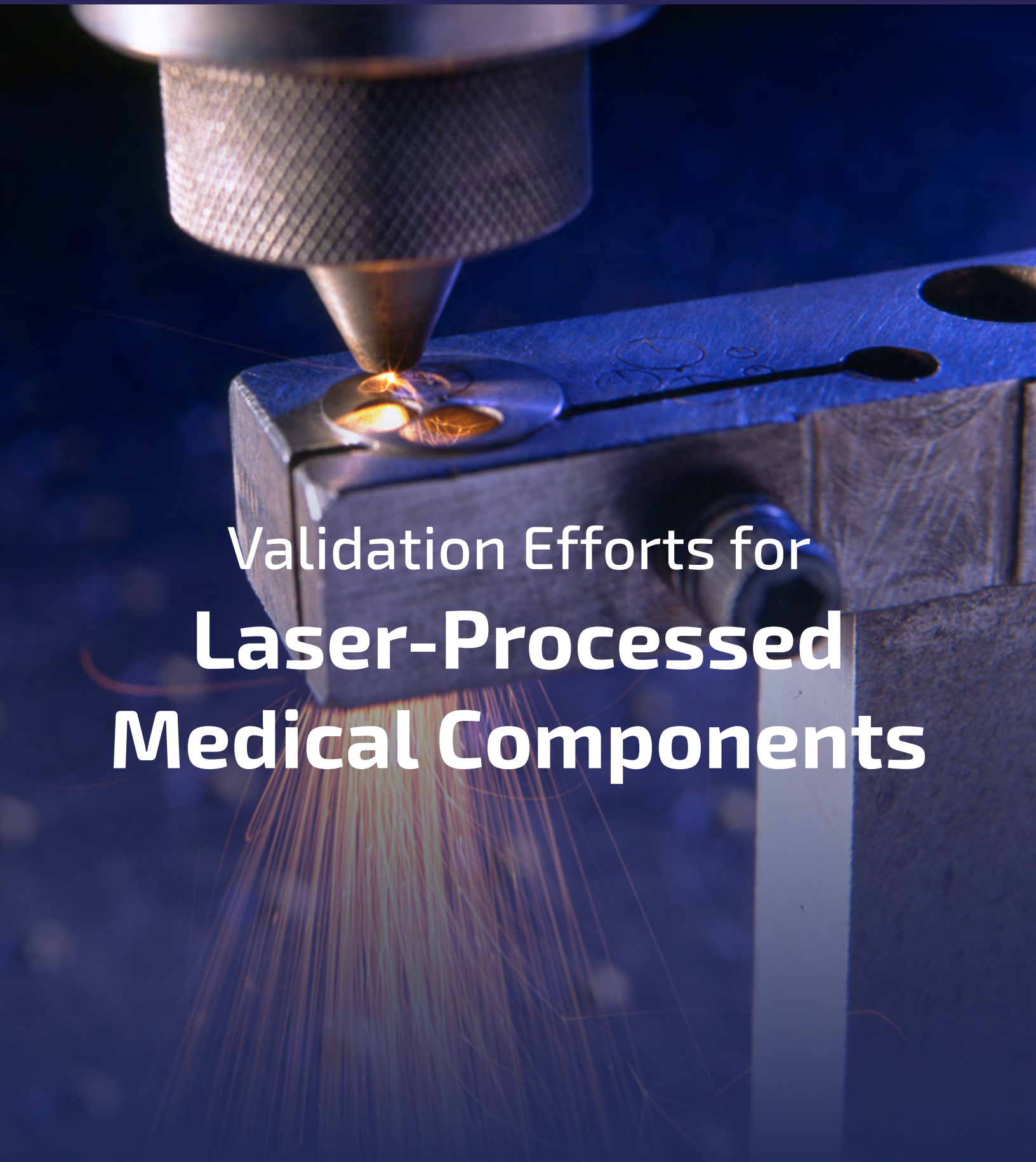
LASERAGE® / AMETEK® ENGINEERED MEDICAL COMPONENTS



Validation Efforts for Laser-Processed Medical Components

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What is Process Validation?

Process validation is the establishment of scientific evidence to prove that a process is capable of consistently delivering quality products. For highly sensitive industries such as medical devices and laser-processed medical components, process validation is required by current Good Manufacturing Practices (cGMP) and U.S. Food and Drug Administration (FDA) regulations.

From initial design to final production, process validation involves collecting and evaluating a series of data throughout the manufacturing lifecycle. By providing documented evidence about a specific process, such as laser machining for medical components, Laserage can assure customers that their products meet predetermined specifications.

Aspects of Validation

Process validation tests a number of different product attributes throughout the manufacturing process to ensure that they fulfill their intended purpose. These evaluations can be performed in-house by the manufacturer or by an unrelated third party through independent verification and validation (IV&V).

Aspects of Validation

The most commonly tested validation aspects include:

Repeatability & Reproducibility

The ability to reliably replicate either a measuring system or an entire process.

Curve Fitting & Its Range

The mathematical analysis yielding the best fit to a series of data points. Leads to the prediction of process capability with defined confidence and reliability.

System Suitability

A broad test of ruggedness for different processes within a laser manufacturing system. A specific standard operating procedure should be identified to ensure optimum operation of the system used.

Accuracy & Precision

The minimization of systemic random errors.

Stages and Types of Validation

The varied activities of process validation can be broken down into three main stages:

Stage 1:

Process Design – After a series of development and scale-up activities, the manufacturer defines the commercial manufacturing process.

Stage 2:

Process Qualification – The process design is challenged and later confirmed as repeatable for commercial manufacturing.

Stage 3:

Continued Process Verification – By monitoring routine production over time, manufacturers can assure that the process remains controlled.

The four main types of process validation include:

1.Prospective (or premarket) validation

Before implementing a new system process, this type of validation involves establishing evidence in order to prove that said process follows protocol and does what it proposes to do. This type of validation often results in the transfer of the manufacturing process from development to production.

2.Retrospective validation

Using historical data, this type of validation involves facilities, processes, and process controls that have not been formally validated in the past. Because so many existing products are subject to prospective validation, this approach is rarely used today and is typically only considered acceptable for well-established processes.

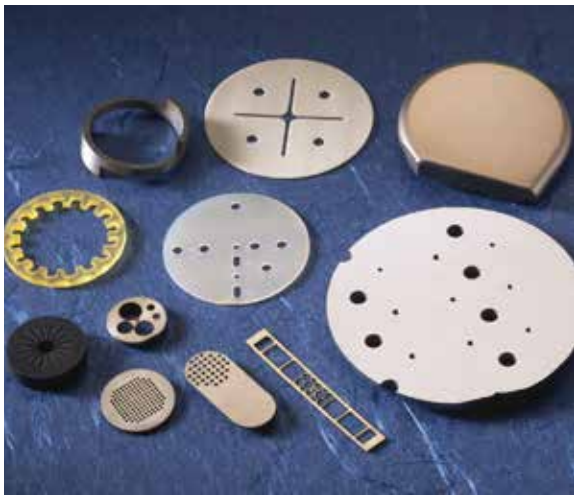
3.Concurrent validation

By monitoring various steps of the manufacturing process as well as end testing, this type of validation establishes documented evidence based on the actual process imputation.

4.Revalidation

This type of validation involves repeating any part of the original validation by reviewing performance data. This step may be required when transferring a product from one machine to another, making any major changes to the product, manufacturing process, method of inspection, or simply performing a periodic check.

For high stakes medical device manufacturing, the FDA defines process validation as, "establishing documented evidence which provides a high degree of assurance that a specific process consistently produces a product meeting its predetermined specifications and quality attributes." The administration lays out its explicit validation and verification requirements in its Code of Federal Regulations Title 21 part 820, also known as 21 CFR 820.



21 CFR 820 calls for signed and dated documentation approving the validation of processes and major equipment, such as laser technology, in accordance with established procedures. This recorded evidence ensures that manufacturers are controlling their processes and continuing to meet industry-specific requirements.

Why Laserage?

Since 1979, Laserage has been a leading laser contract manufacturer specializing in custom laser processing and fabrication of medical device components. We ensure that all of our laser-cutting, laser-drilling and laser-welding operations comply with cGMP (21 CFR 820) by implementing a robust Quality Management System including a range of product measurement, data collection and evaluation tools throughout the manufacturing process. In addition, we offer a wide range of post-laser-processing finishing operations: Nitinol forming, shape setting, tumbling, microblasting, electropolishing, passivation, and heat treating services.

Laserage Validation On-Site Activities Can Include

Measurement System Analysis (MSA)

We check the margin of error for bias, linearity, and stability within our laser processing measuring systems.

Gage Repeatability & Reproducibility (GR&R)

All of our automated CNC machining equipment is studied for quantitative variability between different parts, runs, and operators.

Operational Qualification (OQ)

Our systems and process equipment are challenged to ensure they meet operational protocol requirements including accepting data and moving items through the workflow.

Installation Qualification (IQ)

We verify that equipment has been correctly installed, computer programs have been pre-loaded and configured with the necessary files, and employees have received proper training for the job.

Design of Experiments (DOE)

We examine the cause and effect relationship between our input factors and our process output to optimize efficiency for our customers.

Performance Qualification (PQ)

We monitor our laser welding, cutting, drilling, and processing operations, as well as final products by measuring key product output variables to ensure that our equipment is performing as expected under real world conditions.

To learn more about how Laserage can help you get started on your next laser processing project, contact us today.

About Laserage Technology Corporation

Through more than 35 years of experience, Laserage has become the expert in precision laser contract manufacturing. We have state-of-the-art facilities in the Midwest and northern California, in order to better meet our customers' engineered laser solution and production laser processing requirements.

We have the experience and resources to help you reap the cost and quality benefits that laser processing has to offer. Our Design for Manufacturability methodologies help reduce the cost and number of components, as well as streamline and simplify assembly operations.

We have a deep understanding of materials, both metals and polymers, and employ design guidelines that ensure the most robust performance at minimum cost. As a full-service manufacturer, our technical competencies encompass a broad range of secondary and finishing operations, such as laser welding, passivating, shape setting and electro-polishing, with an emphasis on the specific needs of the medical, aerospace, industrial and microelectronics industries.

"Our priority has always been to build relationships with our customers based on honesty and integrity. In addition, we have always been committed to excellence at every level of our operation."

–Steve Capp, President & CEO of Laserage Technology Corporation

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