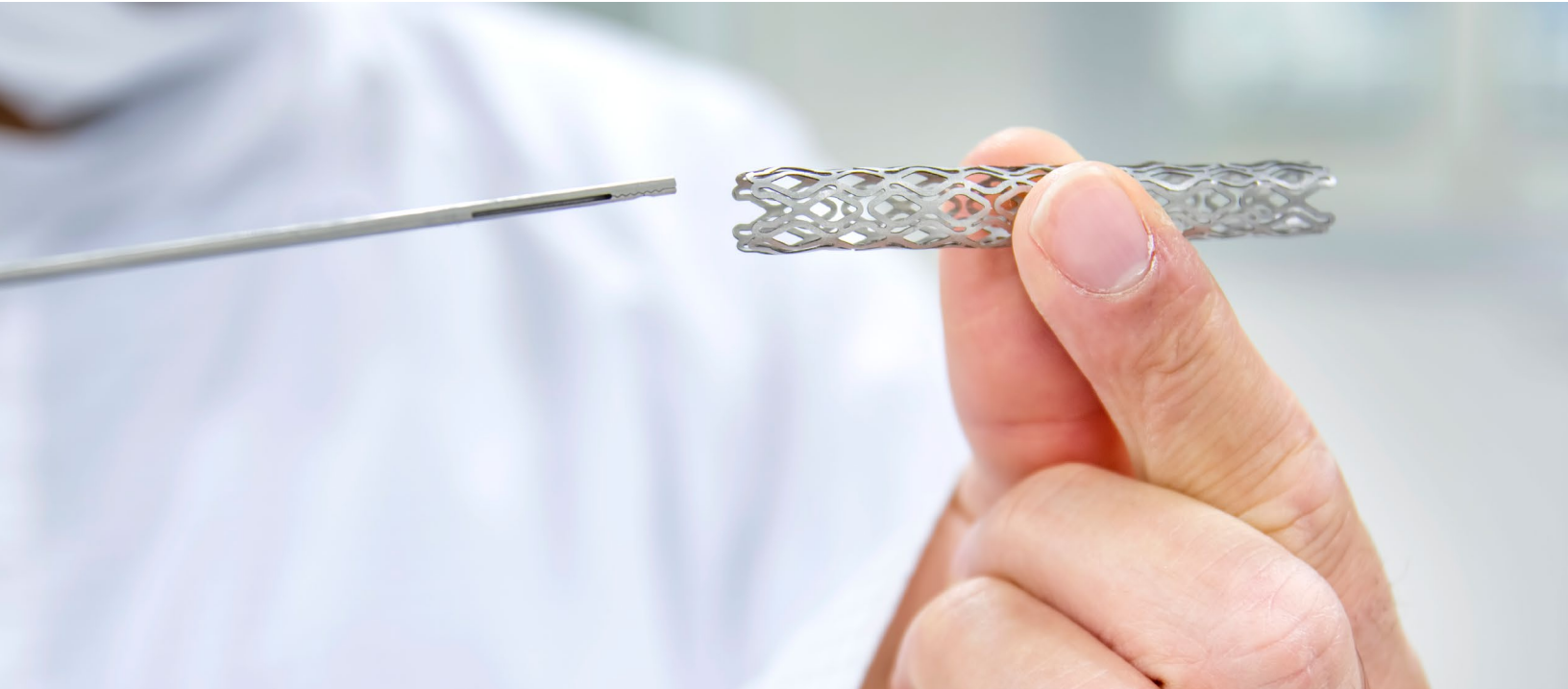# Repeatability, Reproducibility and Traceability for Medical Compliance

ZEISS Industrial Quality Solutions

For medical parts manufacturers, quality inspection is critical. Liability for defects, inconsistent quality, fluctuating supplier costs, increased globalization and device regulations all pose challenges for the industry.

The margin of error approaches zero for medical devices being brought to market. Any defects not discovered and corrected during development can result in patient injury or death, not to mention disastrous legal ramifications for the company that released the product.

This means medical manufacturers must be compliant with the FDA's current good manufacturing practice (CGMP) requirements that assure proper design, monitoring and control of manufacturing processes and facilities.

With so much riding on achieving perfection, every step of the development process must be optimized for quality through repeatability, reproducibility and traceability. ZEISS Industrial Quality Solutions provides medical device and medical component manufacturers with the high-performance equipment necessary for quality assurance.

Taking Concept to Market

CGMP requirements govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation and servicing of all finished devices intended for human use. That means manufacturers of medical parts must establish and maintain procedures for identifying parts during all stages of receiving, production, distribution and installation.

Each manufacturer of a device that is intended to be life-sustaining, life-supporting or is being implanted into the human body, therefore, has to establish and maintain procedures for traceability. This follows a part's origin backward in the supply chain and forward along the distribution chain, using identifying characteristics and records such as a control number on each unit, lot or batch of finished devices and the appropriate components.

According to Ilene Wolff, Contributing Editor at Advanced Manufacturing, "As medical manufacturers become more global, traceability has become just as important to them as it is to automotive manufacturers. And when you have the capability of 100% parts inspection, manufacturers can completely control their manufacturing processes."

Gaining Certainty through Repeatability and Reproducibility

Reporting requirements for collecting quality and metrology data are even higher for medical device manufacturers who are under the oversight of the FDA than aerospace and automotive parts manufacturers. ZEISS equipment that can be calibrated to ISO 10360 standards for coordinate measuring machines (CMMs) can assist companies in complying with stringent FDA requirements.

This international standard of measurement verification specifies the acceptance tests for the performance of a CMM used for measuring linear dimensions as stated by the manufacturer. ZEISS chooses to work by this standard because it ensures comparability worldwide. It is also the strictest standard, and not all of today's quality equipment manufacturers are able to achieve this requirement.

The ISO 10360 performance evaluation includes testing repeatability and reproducibility. Repeatability of measurements refers to the variation in repeat measurements taken by a single person or instrument made on the same subject under identical conditions. This is vital when it comes to gaining certainty in your standardization processes and relies on defining measurement conditions and then replicating the process.

Documenting a Device's History

Per the FDA, any medical device's traceability must be documented in a Device History Record (DHR). The DHR serves as a production record for medical devices that are manufactured and includes entries for acceptance records of individual units or batches of product, product counts, labels and any other applicable unique product identifiers.

"The history and information on how you made the device in accordance with the DMR is stored in the DHR," says Jesseca Lyons of Greenlight Guru, referring to the Device Master Record that contains the necessary specifications for building and testing a device. "Much like the DHF [Design History File] is the history of the design, the DHR is the history of the device." This demonstrates the device was manufactured according to the information in the DMR to required FDA standards.

The goal must be, therefore, to maintain the same conditions with the measurement process and then repeat it until the desired number of samples is recorded.

As Rick Hogan, a metrology, engineering and management consultant, explains, "When performing a repeatability test, you will want to collect data using the;

1. Same method,
2. Same operator,
3. Same equipment,
4. Same environmental conditions,
5. Same location, and
6. Same item or unit under test.

You want to collect repeatable results over a short period of time without changing anything (if possible)."

Whereas repeatability is the random uncertainty of results under the same conditions, reproducibility is random uncertainty under changed conditions. Reproducible conditions, for instance, include the change of operator and subsequent changes in time and environment.

ZEISS Offers Options to Meet ISO Requirements

As production capacity grows and efficiencies increase, manufacturers must adhere to product compliance standards with results that are repeatable, reproducible and traceable. The best way to prove product quality is with ZEISS metrology solutions, which utilize an ISO-compliant validation methodology and documentation.

While competitors' CMMs are compliant to ISO 10360-7, ZEISS offers additional technologies for meeting ISO standards. For example, the ZEISS O-SELECT optical measuring system meets the rigorous ISO requirements by satisfying three requirements:

1. Equipment:

All ZEISS artifacts used to calibrate and qualify O-SELECT measuring machines utilize DKD-certified scales.

2. Analysis:

ISO 10360-7 is the methodology used to calibrate and qualify every O-SELECT machine.

3. Documentation:

ZEISS provides records of each calibration so you can prove when and how the calibrations and qualifications were completed.

ZEISS O-SELECT's maximum permissible error is 4.5 + L/100 µm, and its repeatability is 0.9 µm. "Quickly and reliably obtaining ISO compliant, traceable and reproducible measured values was a key aspect for us in Product Development" of the O-SELECT, says Andrzej Grzesiak, ZEISS Senior Director of Metrology Systems. Through rigorous international testing and verification, you can trust ZEISS systems and calibrations.
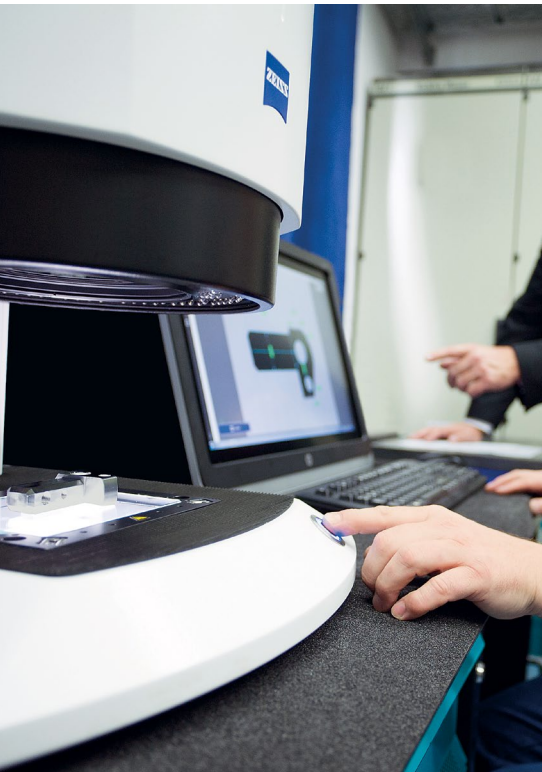
SAS Succeeds with ZEISS Solutions

SAS GmbH, a producer of drive systems that were co-developed for medical and rehabilitation technology, needed to ensure that gear mechanisms of medical devices always function perfectly. To achieve this goal precisely, and quickly, the manufacturer chose the ZEISS O-SELECT digital measuring projector for its reproducible quality measurements.

SAS had clearly-defined requirements: the optical measuring machine should be precise to the nearest one hundredth of a millimeter and deliver reproducible results to increase process reliability in production. It was also important to find a measuring projector that was easy to use and would be readily accepted by the production staff.

In the end, the decision to choose O-SELECT was prompted by the value for the investment as well as the user-friendly system. "Anyone who can use a computer will also be able to operate this optical measuring system," says Wolfgang Benne, a member of the quality insurance and gearing department at SAS.

Conclusion

By complying with FDA and ISO 10360 standardization processes for medical parts, manufacturers can improve productivity and cost savings. This gives you a competitive edge in the medical component manufacturing supply chain. ZEISS solutions, such as O-SELECT, with its digital measuring projector technology, offers an alternative to CMMs. You can provide value to your customers through repeatability, reproducibility and traceability with comprehensive historical data and reports.

Contact us for a demo of ZEISS measuring solutions for medical manufacturing.