FDA-compliant Validation of Medtech Implants and Devices

Validation is a critical component of process design and manufacturing.

The purpose of validation is to establish by objective evidence that a process consistently produces a result or product that meets its predetermined requirements. This purpose requires an unwavering commitment to quality.

How a manufacturer achieves this is categorically summarized in three stages of qualifications:

INSTALLATION QUALIFICATION (IQ): Installation qualification is establishing by objective evidence that all key aspects of the process equipment and ancillary system installation adhere to the manufacturer's approved specification and that the recommendations of the supplier of the equipment are suitably considered. More simply stated, IQ is validation of the production equipment.

OPERATIONAL QUALIFICATION (OQ): OQ establishes, by objective evidence, process control limits and action levels that result in product that meets all predetermined requirements. In the OQ stage of process validation, we establish high and low operating parameters for the production equipment. We then confirm the equipment can produce to spec within these parameters. In other words, OQ sets acceptable upper and lower operating parameters for the process and equipment.

PERFORMANCE QUALIFICATION (PQ): Finally, PQ establishes, by objective evidence, that the process, under anticipated conditions, consistently produces a product that meets all predetermined requirements. Norman Noble typically runs three consecutive lots to satisfy the PQ stage of validation.

The FDA mandates when validation is required, stating:

> "Where the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedures. The validation activities and results, including the date and signature of the individual(s) approving the validation and where appropriate the major equipment validated, shall be documented." (21CFR820.75, FDA Code of Federal Regulations)

In 21CFR820.75 of the Code of Federal Regulations the FDA also broadly outlines its requirements for process validation procedures and documentation.

FDA regulations surrounding process validation are mandatory and compliance is a legal obligation. However, the value of process validation goes beyond satisfying the letter of the law.

At Norman Noble, quality is also mandatory. With many implants and devices, lives are at stake. Norman Noble ensures the OEM, with a high level of confidence that its process validation will result in manufacturing processes that produce the same exact quality part each and every time.

Norman Noble believes so deeply in the value of validation testing, it is a non-negotiable inclusion in nearly every Norman Noble manufacturing engagement. The long-term benefits, we contend, far outweigh any upfront savings of time or money.

Process Validation ensures:

- Consistently high quality
- OEM specifications and legal compliance
- Risk mitigation for the implant recipient and OEM

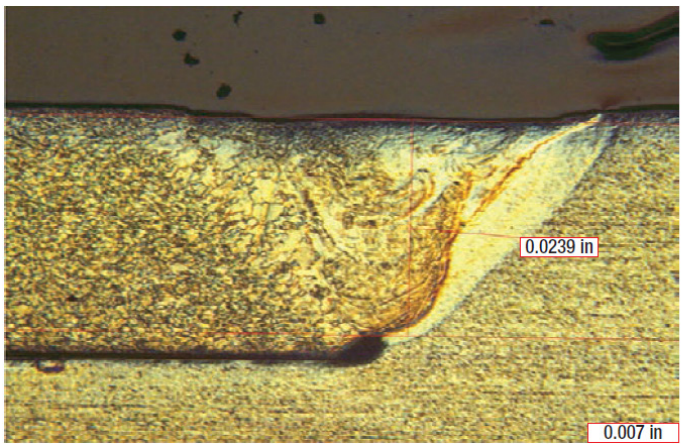
The FDA defines the parameters for validation testing for the industry, but like many things, execution

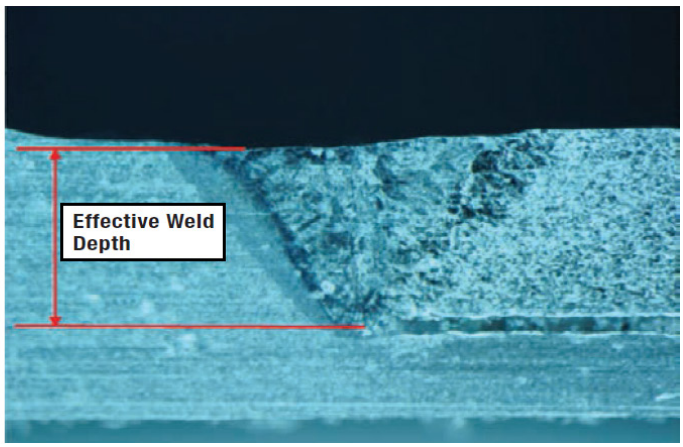
and effectiveness can vary. We control the outcome of process validation closely. When we received ISO 13485 certification in 2003, we began across-the-board validation testing and with it, a process of continual refinement.

Process validation is very much about ensuring the goals in the engineer's design are met consistently in the reality of mass production. Similarly, our principles and approach to process validation are only as good as how they play out in reality. Consider, for example, our Laser Welding Validation Process:

We validate laser welding applications to ensure weld depth penetration and/or that functional aspects comply with customer specific requirements. Weld depth penetration is confirmed through a variety of techniques, one of which includes Scanning Electron Microscopy (SEM) where parts are sectioned, mounted, polished, and then the highlighted weld nugget is measured to confirm the weld depth penetration. In some cases, we perform destructive testing of laser welded joints to ensure functional compliance with customer requirements. We challenge various laser parameters to determine optimum process parameters.

WELD DEPTH IMAGES:





Today, we have performed more than 1,700 end-to-end process validations for Class II and III medical implants and devices. Working with 20 of the top medical device OEMs, we've distilled our experience into a finely tuned, but continually progressing, set of best practices.

ABOUT NORMAN NOBLE, INC.

Established over 70 years ago, Norman Noble remains a family-owned and -operated company offering the most advanced processes for ultra-precision micromachining. The company is known forits exceptional ability to achieve sub-miniature precision beyond the reach of most manufacturers. Norman Noble is a supplier to most of the largest OEM's and well-known names in the medical device industry.

Norman Noble manufactures medical implants and devices to customer specifications in compliance with FDA regulations and ISO 13485:2016. We offer validated manufacturing processes for Vascular Implants and Orthopedic Implants. State-of-the-art processes include laser machining and welding, Swiss turning and milling, conventional and wire EDM, high-speed 7-axis contour milling, Nitinol shape setting and clean room assembly and packaging. Prototype services are available in separate and fully dedicated process development centers. FDA Registration #1531050.
For more information, please call **1.800.474.4322 or visit www.nnoble.com**.

Norman Noble, Inc.
Microprecision Medtech Manufacturing