

# Verifying design claims in medical devices



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# Executive Summary



According to the U.S. Department of Commerce, the U.S. is the largest medical device market in the world. With an estimated annual value of around \$156 billion, the U.S. represents approximately 40% of the global demand for medical devices<sup>1</sup>. And, with the industry dominated by companies with fewer than 50 employees, the continuous introduction of new and innovative medical devices can be expected to propel future growth while also making important contributions to the health and well-being of citizens around the world.

In the effort to introduce new medical devices to market, activities that serve to verify essential design features are a critical element in the overall development process. Combining multiple assessment techniques including testing, inspection and analysis, design verification is required under ISO 13485, the quality management standard applicable to medical devices throughout the world. Equally important, verification of various characteristics of medical devices and their materials can lead to the early identification of issues that could adversely impact regulatory approval or consumer acceptance.

In this UL white paper, we'll discuss the importance of verifying medical device design claims during the product development process, and identify specific design aspects that may benefit most from verification assessments.



## The importance of control processes in medical device design and development

Developing a new and innovative medical device is not an undertaking for the impatient or faint of heart. Some experts estimate that the average time to market for a new medical device is typically between three and seven years<sup>2</sup>. Further, a study conducted by Stanford University researchers and sponsored by the Medical Device Manufacturers Association found that the average cost of bringing low-to-moderate risk medical devices to market, from initial concept through regulatory approval, is around \$31 million, while high-risk devices average \$94 million<sup>3</sup>.

Medical device manufacturers can reduce the time and money required to bring new medical devices to market by implementing a rigorous product design control process. According to the U.S. Food and Drug Administration (FDA), design controls are:

*“...an interrelated set of practices and procedures that are incorporated into the design and development process, i.e., a system of checks and balances. Design controls make systematic assessment of a (medical device) design an integral part of development. As a result, deficiencies in design input requirements, and discrepancies between the proposed design and requirements, are made evident and corrected earlier in the development process<sup>4</sup>.”*

Under FDA regulations, medical device manufacturers are required to establish and maintain procedures to control the design of their devices as part of their quality management system. An effective design control process supports the fulfillment of the quality management system requirements applicable to all device manufacturers. It also provides a foundation for an efficient and resilient product design and development process, in which potential issues are more likely to be identified when the effort and cost to correct them has minimal impact on the overall schedule. Finally, an effective design control process helps to ensure that the final medical device is appropriate for its intended use while posing no unforeseen risks to patients.

# Design verification basics

Design verification is an integral part of the product design control process. Its purpose is to confirm that a medical device as designed actually meets the original design requirements and specifications. In other words, design verification confirms that the design output meets the design input.



The design verification process relies on a number of techniques to establish whether or not a device conforms with the original design requirements. These techniques can include a physical inspection of a completed device or an analysis of the performance of a device or the data that a device generates. In many cases, testing of a device may also be required to verify specific aspects. Depending on the complexity of the device, these techniques can be used alone or in combination with each other to achieve the necessary level of design verification.

While the terms are often used interchangeably, verification and validation represent two different aspects of the product design control process. In contrast to design verification, design validation involves the process of confirming by means of objective evidence that a device as designed conforms with the intended needs and uses originally specified for the device. That is, does the device deliver to patients the benefits that it is intended to provide.

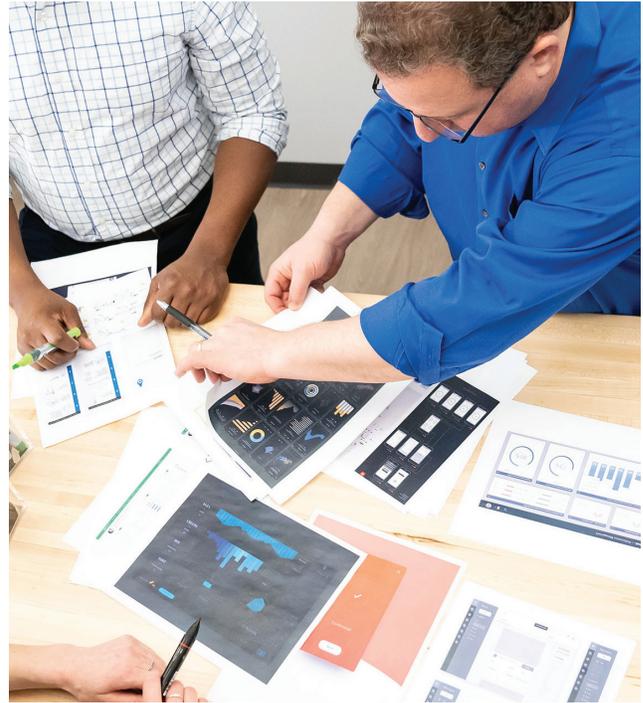
As such, verification and validation are separate but complementary activities in the product design control process. Verification is an essential quality assurance technique used in various stages of the product design and development process, while validation is a summative assessment of whether a device as produced will perform as required.

Design verification should also not be confused with production testing. Production testing is specifically intended to verify whether the manufacturing process has produced a device consistent with the product specification requirements. Therefore, the parameters evaluated in production testing are generally far more limited than those assessed during the design verification process.

# Potential areas of focus for design verification efforts

When it comes to medical devices, there are a number of product aspects and characteristics that are typically the focal point of design verification efforts. These characteristics can include the following:

- System/device integrity** — Innovative medical systems and equipment involve the structuring and assembly of a complex variety of individual components in unique configurations, which can be effectively assessed only when fully configured. Verification can be an effective technique to evaluate an assembled device and its ability to withstand the rigors of handling and use under anticipated conditions.
- Failure modes and effects** — Similarly, it is important to understand the conditions under which a medical device might fail to operate due to its design or the failure to meet design requirements, as well as the potential effects or impacts that such a failure might have on both the patient and caregivers. Verification testing is often used to identify the conditions that can lead to device failure and the likelihood of occurrence, so that design modifications can be made to minimize the potential risk.
- Material physical characteristics** — Depending on their specific intended use, advanced medical devices can be composed of a variety of materials, including metals, ceramics, polymers and even biomaterials. Each of these materials or combination of materials possess unique chemical, electrical and mechanical properties that can affect the structure, durability and performance of a device.
- Material biocompatibility** — Most medical devices are specifically designed to come into either direct or indirect contact with patients. Some devices are even intended to be implanted in patients for extended periods. Accordingly, material biocompatibility must be verified to minimize the risk of adverse patient reactions of a device, or to reduce the likelihood of device rejection by a patient.
- Thermal integrity** — Energized medical devices (whether via direct electrical service or batteries) typically generate heat. These and other thermal characteristics are especially important considerations for portable devices intended to be worn by patients. In addition, verification of a device's ability to dissipate built-up heat without creating patient harm would be important.
- Sterilization resilience** — Reusable medical devices are typically sterilized or reprocessed after each use, thereby extending their anticipated life and reducing their overall cost. However, a device subject to repeated re-sterilization must demonstrate sufficient strength and resilience to withstand damage from the sterilization process, including exposure to excessive heat and moisture.
- Packaging integrity** — The integrity of packaging and packaging materials used in connection with medical systems and equipment is a critical consideration, especially for sterile medical devices. Packaging must be able to withstand wear and degradation attributable to handling, transportation or long-term storage, and not evidence holes, tears, broken seals or other damage that could comprise a device's sterility.



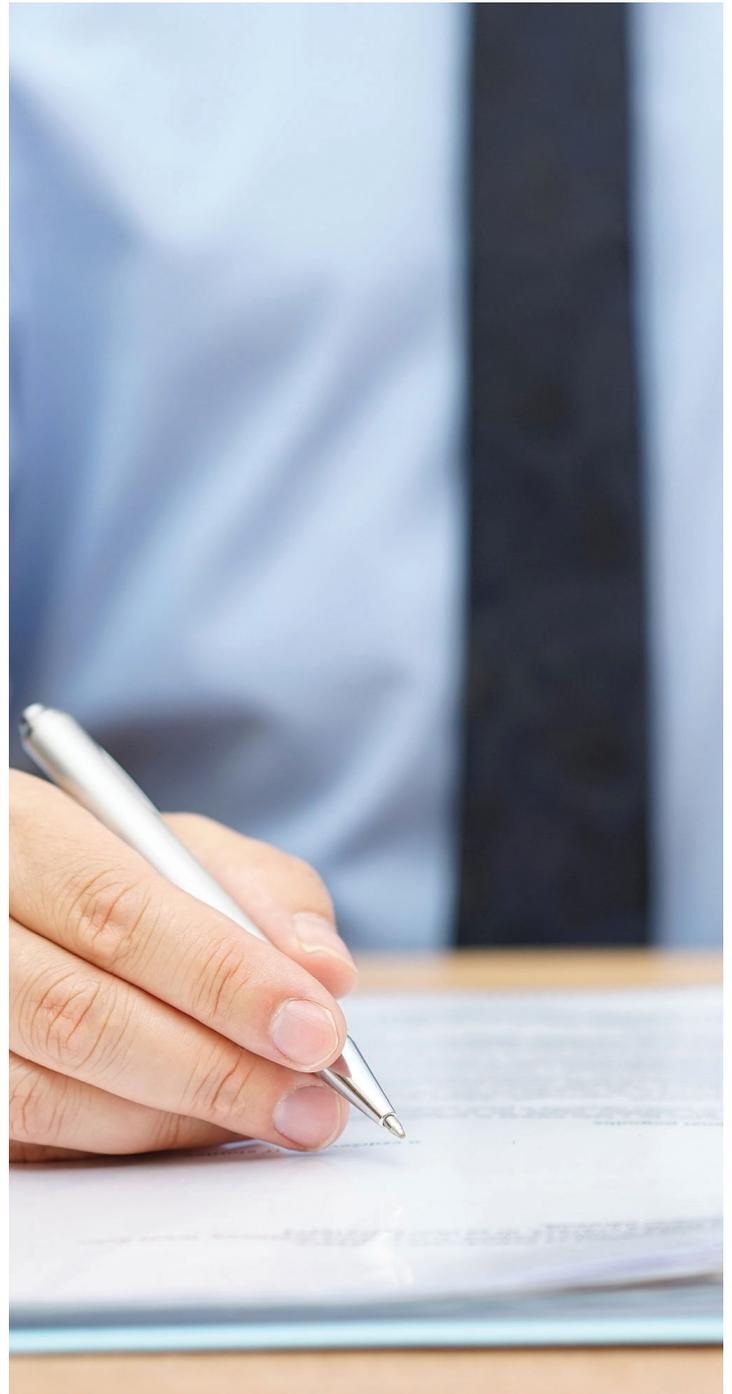
Depending on the complexity and intended use of a medical system or device, each of these verification techniques can be used alone or in combination with others throughout the product design process to help ensure that the final product meets the prescribed design requirements and specifications.

# The importance of design verification in the regulatory approval process

Design verification is an integral aspect of the design control process required of medical device manufacturers under the scope of ISO 13485, Medical devices-Quality management systems-Requirements for regulatory purposes. Specifically, the standard mandates rigorous design and development planning, with all input requirements subject to verification or validation. To demonstrate compliance with the requirements of the standard, device manufacturers must also provide verification and validation plans and maintain records of all verification and validation activities.

But the importance of design verification and the design control process in a regulatory review goes beyond mere compliance with these and other quality management system requirements. Indeed, design verification activities can provide the data necessary to demonstrate compliance with additional aspects of FDA regulatory requirements under its 510(k) Premarket Notification program. For example, the results of verification activities can be used to demonstrate compliance with specific 510(k) requirements regarding biocompatibility, sterilization and shelf-life, and EMC and electrical safety. In some cases, data produced through design verification techniques may even be used to support a manufacturer's claim of substantial equivalence with a predicate device.

And, as previously noted, having a robust design control process in place, including design verification and validation activities, allows device manufacturers to identify and address potential issues well in advance of formally seeking device approval from regulators. As such, design verification activities can serve to effectively reduce the time required for regulatory review and increase the likelihood of a positive outcome.



## Other benefits of design verification

Vague or misleading marketing claims are not new for consumer products. But, in the increasingly competitive medical device market, some manufacturers may resort to making public claims about a device's performance that are not fully supported by the available evidence. Further, as new and innovative materials reach the market, current regulations may not fully reflect emerging performance or safety considerations. In these and other cases, unverified claims are more than just an annoyance; they can place uninformed patients and healthcare providers at risk.



Design verification can play an important role in helping to bring innovative medical devices to market that provide genuine benefits without attendant risks. Objective data derived from properly developed design verification activities can be used as the basis for more complete and in-depth disclosure of the specific performance aspects of a given device, beyond that required to demonstrate compliance with applicable regulatory requirements. And data derived from verification activities can support performance claims that fall outside the scope of regulatory oversight.

In this way, design verification is about more than just meeting regulatory requirements. As part of a comprehensive design control process, design verification can help manufacturers bring safer and more effective medical systems and equipment to market. Further, design verification data can provide important information that can be used to differentiate the performance of a medical device from comparable products, giving device manufacturers a potential competitive advantage.

# How UL is working with medical device developers to verify design claims

UL has worked with device manufacturers around the world on virtually every aspect of the approval of medical systems and equipment. UL's claim verification offering is designed to support efforts by manufacturers of medical systems and equipment, and is built on an objective, science-based assessment intended to confirm the accuracy of a manufacturer's own verification efforts. The findings of the assessment are summarized in a comprehensive report, which serves as the basis for the issuance of the UL Verified Mark which can be used on a device and/or its packaging and in promotional efforts linked to the device.

The actual scope of the assessment can cover one or more aspects of a device manufacturer's design claims. More broadly, UL's verification assessments can be used to evaluate claims regarding device quality or performance. Verified claims can be especially important in supporting product marketing efforts.

UL's third-party claims verification offering complements UL's other certification and regulatory compliance services applicable to medical devices. It can help device manufacturers differentiate their products from those with self-declared claims, thereby providing buyers and patients with greater confidence regarding the quality and safety of their devices. Finally, it demonstrates a device manufacturer's commitment to providing medical systems and equipment that exceed regulatory requirements.



# Summary + Conclusion



Verification activities supporting the design of safe and effective medical devices are an essential aspect of product development efforts for device manufacturers. Regulators require that device manufacturers undertake verification testing and other forms of assessment as part of the design control process. Further, verification supports other aspects of regulatory compliance, and can also contribute to efforts to differentiate device performance from comparable products.

Verification testing conducted by an independent third party serves as an important adjunct to a device manufacturer's verification activities. It can confirm the accuracy of verification data already collected, thereby validating a manufacturer's own verification efforts, while also identifying potential gaps in the verification process. Third-party verification can also potentially address other critical aspects of a medical device.

**For more information about UL's verification offerings for manufacturers of medical systems and equipment, email [medical.inquiry@UL.com](mailto:medical.inquiry@UL.com) or visit [UL.com/healthcare](https://UL.com/healthcare).**

## End Notes

1. “Medical Technology Spotlight: The Medical Technology Industry in the United States”, entry posted on the website of SelectUSA, a program operated by the International Trade Administration under the U.S. Department of Commerce. Web. 14 August 2019. <https://www.selectusa.gov/medical-technology-industry-united-states>.
2. “How to reduce time to market for medical devices,” entry posted to the website of Medical Plastics News, 15 August 2018. Web. 14 August 2019. <https://www.medicalplasticsnews.com/news/opinion/how-to-reduce-time-to-market-for-medical-devices/>.
3. “Medical device makers spend millions to meet FDA rules, study finds,” entry posted to the website of MedCity News, November 19, 2010. Web. 14 August 2019. <https://medcitynews.com/2010/11/medical-device-makers-spend-millions-to-meet-fda-rules-study-finds/>.
4. Excerpt from the FDA’s “Design Control Guidance for Medical Device Manufacturers,” March 11, 1997. Web. 14 August 2019. <https://www.fda.gov/media/116573/download>.

