

ADDRESSING REGULATORY CONSIDERATIONS FOR MEDICAL ROBOTIC DEVICES





EXECUTIVE SUMMARY

In a little more than three decades, the use of robotic devices in medical applications has grown from pioneering experiments in robotic-assisted surgery to the widespread use of robots in almost every aspect of healthcare. While estimates of the current and projected global market potential for medical robotic devices vary widely, most experts anticipate double-digit annual growth rates over the next five years.¹ This projected market growth holds significant opportunities for the broader application of robotic technologies in the healthcare arena, and for advanced medical technology manufacturers in general.

At the same time, taking advantage of these market opportunities is likely to present significant challenges, especially for those companies unaccustomed to the rigorous regulatory approval schemes and strict oversight applicable to medical devices in the U.S., the European Union (EU), Japan and other major medical device markets. Achieving the requisite approval for the legal sales of medical devices in these jurisdictions can require a significant financial investment and take months or years to complete. Failing to understand or account for these constraints can result in delays that can seriously jeopardize the likelihood of success in a highly-competitive market.

This UL white paper presents the essential regulatory considerations that apply to medical devices, including robotic devices intended for use in medical applications. Beginning with a brief discussion of the key drivers in the growth of medical robotics, the paper then outlines the various types of medical robotic devices that are potentially subject to regulatory review, before detailing safety, quality and other requirements and considerations applicable to medical robotic technologies. The white paper concludes with a brief overview of how UL assists medical robotic technology manufacturers successfully navigate the regulatory landscape.

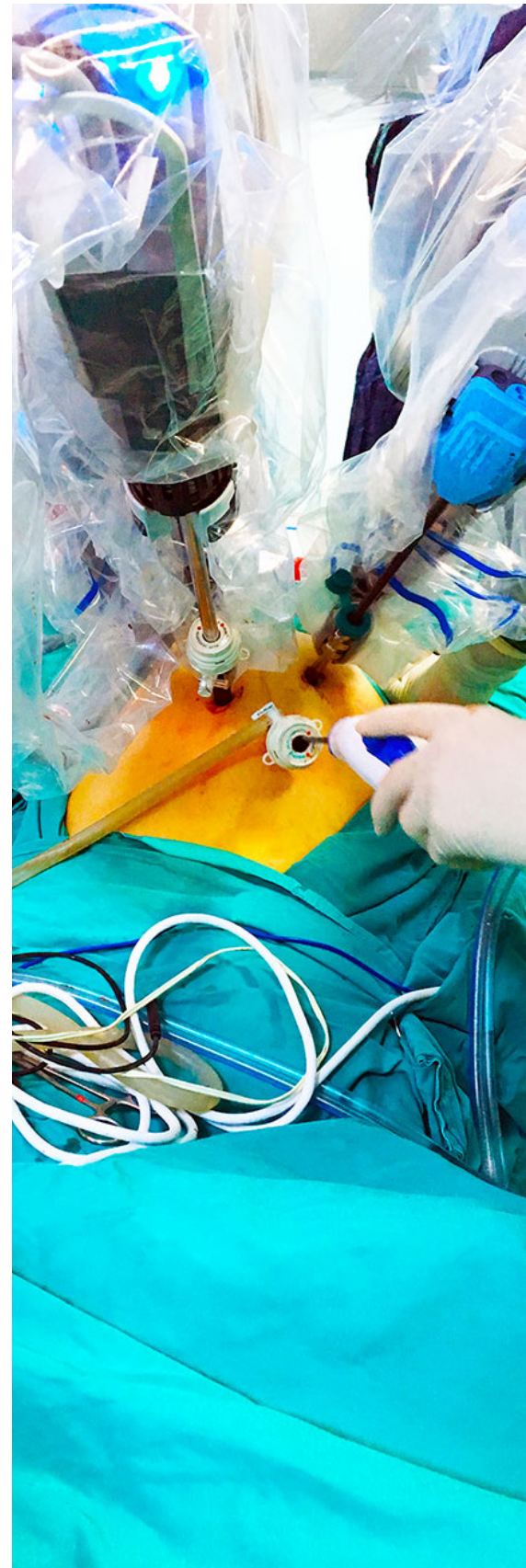
Major Factors in the Growth of Medical Robotics

While new and advanced technologies are a driving force for innovation in many industries, the healthcare industry has been slower than most when it comes to implementing technological solutions.² Although the reasons behind the laggard pace of technology adoption in healthcare are varied, the essential concerns have been (and remain) the safety of a given technology and its effectiveness in actually improving healthcare outcomes.

However, the continuously changing landscape of healthcare in the 21st century has led to the emergence of several significant factors that are likely to strengthen the case for more ambitious adoption of advanced medical technologies, including medical robotics. Those factors include:

- **Ageing global population** - According to the United Nations Population Fund (UNFPA), people aged 60 years and older make up more than 12 percent of the global population, a share that will grow to almost 22 percent by the year 2050.³ Further, the consumption of healthcare increases dramatically as people age, with the elderly spending four to five times more on healthcare services than teens.⁴ The anticipated growth in demand for healthcare services is likely to place further strain on existing healthcare systems and personnel, prompting the search for more efficient methods to diagnosis and treat patients.

- ***Increase instances of surgically-correctable conditions*** - Health conditions that can be wholly or partially treated through surgical intervention, such as cardiovascular diseases, neurological disorders and various types of cancers, are on the rise, especially among people in emerging economies around the world.⁵ As reliance on surgery increases, so too does the demand for less invasive surgical techniques that offer patients effective treatment with less recovery time .
- ***Shortage of trained medical personnel*** - With the prospect of an ageing population and the increase in demand for medical care, the availability of physicians, nurses and other trained medical professionals is expected to fall far short of the need. For example, by the year 2030, the shortfall of physicians in the U.S. is projected to exceed 100,000,⁶ with rural and underserved populations expected to be especially hard hit. Advanced medical robotics could play an important role in addressing that gap.
- ***Improved quality of robotics in routine procedures*** - In a relatively short time, medical robotic devices employed in surgical procedures have progressed from semi-autonomous devices used to assist medical professionals to fully automated robotic systems that can conduct minimally-invasive procedures with exceptional clinical success rates.⁷ In fact, medical robotic devices may actually outperform humans in some surgical procedures where a high degree of precision is required.
- ***Facilitating newer procedures/therapies*** - Although surgical devices command the largest share of the medical robotics market,⁸ there are numerous examples of the application of robotic technologies to new classes of medical devices. These range from microscopic drug delivery robots that provide targeted therapy through the bloodstream, to automated blood drawing devices that approximate the effectiveness of an experienced human phlebotomist, and robotic lifting devices that can move patients from a bed to a wheelchair without human intervention or the risk of injury.⁹
- ***Market differentiation for hospitals, healthcare providers*** - Lastly, the adoption of advanced medical technologies and medical robotics can be an important differentiator among healthcare providers. In cases where healthcare consumers have a choice, they are seeking modern facilities and providers that offer state-of-the-art healthcare services that are also effective and convenient. Care that includes medical robotic technologies can help meet this expectation.



According to a recent report by the PwC Health Research Institute, medical robotics represent one of a handful of technologies that has the potential to disrupt the U.S. healthcare industry over the next decade, along with artificial intelligence, virtual reality simulations and blockchain data protection methodologies.¹⁰ Despite a number of uncertainties regarding the future of the healthcare marketplace, the widespread adoption of medical robotics in every aspect of healthcare is certain to transform for the better the quality of healthcare for millions of people around the world.

Types of Medical Robotic Devices

The term "medical robotics" is actually used in conjunction with technology systems and devices in several different categories, as follows:

- Minimally invasive surgical devices, that can assist physicians with increasingly more sophisticated minimally invasive surgical procedures;
- Diagnostic devices, that operate both within and outside the body to capture and process information essential for effective medical treatment;
- Advanced prosthetics, such as exoskeletons, that can aid in coordination and mobility, and help patients recover from or deal with physical disabilities;
- Telepresence devices, including highly advanced videoconferencing equipment, that can bring advanced medical expertise to patients in remote locations;
- Hospital automation, such as prescription dispensing systems that dispense medications accurately and efficiently, and automated sterilizing robots that safely disinfect rooms and surfaces;
- Personal robotic assistants designed to capture vital signs, voice commands and other signs that a patient requires assistance or medical attention; and
- Public health management, for example, the use of drones to deliver emergency medical supplies to remote locations, or areas temporarily unsafe for human intervention.

It is expected that the type and variety of medical robotic devices in these categories will expand significantly as researchers identify additional ways to leverage robotic technology in the service of healthcare requirements.



When a Robot is Deemed a "Medical Device" for Regulatory Purposes

In recent years, there has been significant progress in efforts to harmonize the definition of a medical device under applicable regulatory requirements. For example, under the EU's recently published Medical Device Regulation (EU 2017/745), a medical device:

"means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, along or in combination for human beings for one or more of the following specific medical purposes:

- *Diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of a disease,*
- *Diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,*
- *Investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,*
- *Providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,*

and which does not achieve its principle intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means."¹¹

A comparable definition of a medical device is prescribed by the U.S. Food and Drug Administration (FDA):

"an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, include a component part, or accessory which is:

- *recognized in the Official National Formulary, or the United States Pharmacopoeia, or any supplement to them,*
- *intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or*
- *intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."¹²*

Regulators in Japan, Brazil, Canada, Australia and other major medical device markets apply criteria similar to those in the EU and the U.S. in determining whether a given system or device should be considered a medical device. However, despite these similarities, regulators can still exercise a significant amount of discretion in assessing whether a given system or device meets those criteria. Such variations make it difficult to state with certainty whether a specific robotic device used in a medical application will be classified as a medical device, and therefore subject to regulatory oversight, review or clearance.

Safety, Clinical and Quality Requirements Applicable to Medical Robotic Devices

Assuming that a robotic device used in a medical application is determined to be subject to medical device regulations, the next set of issues involves the specific technical requirements with which a medical robotic device must comply. In general, these technical requirements fall under one of the following three areas: 1) product safety; 2) clinical safety; and 3) quality systems compliance. The following sections identify the technical standards and requirements that should be considered when demonstrating compliance to these requirements.

Product Safety

Evaluating the safety of a given medical robotic device ultimately depends on a thorough assessment of its characteristics, unique features and its intended use. However, at a minimum, manufacturers should consider evaluating medical robotic devices against each of the following safety considerations:

- Electrical and mechanical safety - IEC 60601-1, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance, defines the requirements regarding the electrical and mechanical safety of most types of medical electrical equipment, including medical robotic devices.
- Electromagnetic compatibility (EMC) - Protection against electromagnetic interference is addressed in IEC 60601-1-2, a recognized Collateral standard that covers EMC requirements and tests. Additional EMC requirements may also be found in applicable functional safety standards.
- Usability/human factors - Usability and human factors issues specific to medical devices are covered in IEC 60601-1-6, a separate Collateral standard.
- Home care safety - Medical devices intended for use outside of a clinical environment are generally subject to the requirements of IEC 60601-1-11, another Collateral standard.
- Biocompatibility - Requirements and testing to evaluate the effect of a device through contact with and within the body are detailed in the ISO 10993 series of standards.
- Risk management - ISO 14971 is a recognized standard for the identification and mitigation of potential safety risks not addressed by other standards.
- Personal care safety - Whether or not deemed to be medical devices, robotic technologies intended to provide personal care are generally evaluated against ISO 13482, which addresses safety requirements for personal care robots.
- Functional safety - Many of the above standards may also require a functional safety assessment, in order to evaluate the full range of potential safety risks.



Clinical Safety

Regulators generally require manufacturers of medical devices to validate claims regarding the clinical safety and performance of their products. The goal of the clinical safety evaluation process is to collect and continually analyze relevant data to help ensure that a device performs as intended under anticipated use conditions, and that the nature and probability of any risks are identified and determined to be acceptable when weighed against the benefits.

A clinical safety evaluation is not a discrete event but part of an ongoing process that is conducted throughout the entire lifecycle of a medical device, from initial product design and development, through regulatory review and approval and, finally, during actual use after a device has been placed on the market. This process allows manufacturers to provide regulators and the public with ongoing assurances regarding the safety and efficacy of their devices as well as continued compliance with applicable requirements.

Specific issues addressed in a clinical safety evaluation of a medical robotic device may include:

- A review of similar medical devices already on the market to help identify known clinical safety risks;
- An evaluation of clinical investigations for compliance with the requirements of ISO 14155 to ensure their thoroughness and accuracy;
- An assessment regarding the interoperability of a given medical robotic device with other devices; and
- An assessment of robotic-specific functional safety requirements, such as those found in IEC 61508, ISO 13849, IEC 62061 and others.

Quality Management Systems Compliance

The third area of requirements applicable to medical robotic devices involves the pre- and post-market audits of a manufacturer's quality management system (QMS) required by most regulators. ISO 13485 is the internationally recognized standard that addresses QMS auditing requirements for medical device manufacturers. Mutual recognition agreements between national regulators who participate in the Medical Device Single Audit Program (MDSAP) have greatly facilitated the acceptance of audit reports conducted by authorized Auditing Organizations (AOs) in accordance with the requirements of ISO 13485.

However, regulators that do not participate in the MDSAP may not accept QMS audit reports completed by MDSAP AOs, or require that QMS audits be conducted by their own national testing agencies. Therefore, the scope of the QMS compliance challenge will depend on the countries in which a medical robotic device is targeted for sale.



Cybersecurity and Other Considerations

Medical devices and systems are increasingly interconnected with other devices and systems, and vulnerabilities in hardware and software technologies required to support interconnectivity can expose many medical devices to deliberate cyber threats. Therefore, although not yet expressly required in most jurisdictions, implementing protections against the threat of cyberattacks should be a principle consideration for developers of medical robotic technologies.

Standards that address key aspects of the safety and security of interconnected medical devices and related software include the ISO 80001 series of standards that address risk management considerations, AAMI/UL 2800, which addresses safety and security requirements of interoperable medical systems, and the UL 2900 series of standards which covers software cybersecurity considerations for network-connectable devices.

Finally, any entity planning to introduce new medical robotic technologies should consider the potential advantages of developing a formal regulatory compliance strategy. Gaining access to multiple major markets is usually an important factor in the economic success of any new medical technology, but device developers and manufacturers are often required to demonstrate compliance with different and often seemingly conflicting regulations and requirements. Developing a formal regulatory compliance strategy requires a detailed understanding of the regulatory requirements and device approval processes applicable in key target markets, as well as a plan to leverage the work of each regulatory approval received in support of future device approval applications. This approach can help device manufacturers achieve global acceptance more efficiently and economically, and better enable them to bring important medical robotic technologies to healthcare providers and patients around the world.

How UL Can Help Medical Robotic Manufacturers

UL experts are well-versed in every aspect of the testing and certification of all types of medical devices, including medical robotic devices. Some of our specific areas of expertise include:

The global market for medical robotics and computer-assisted surgical technologies is projected to reach

\$4.6 billion in
2019*

*According to a report from BCC Research



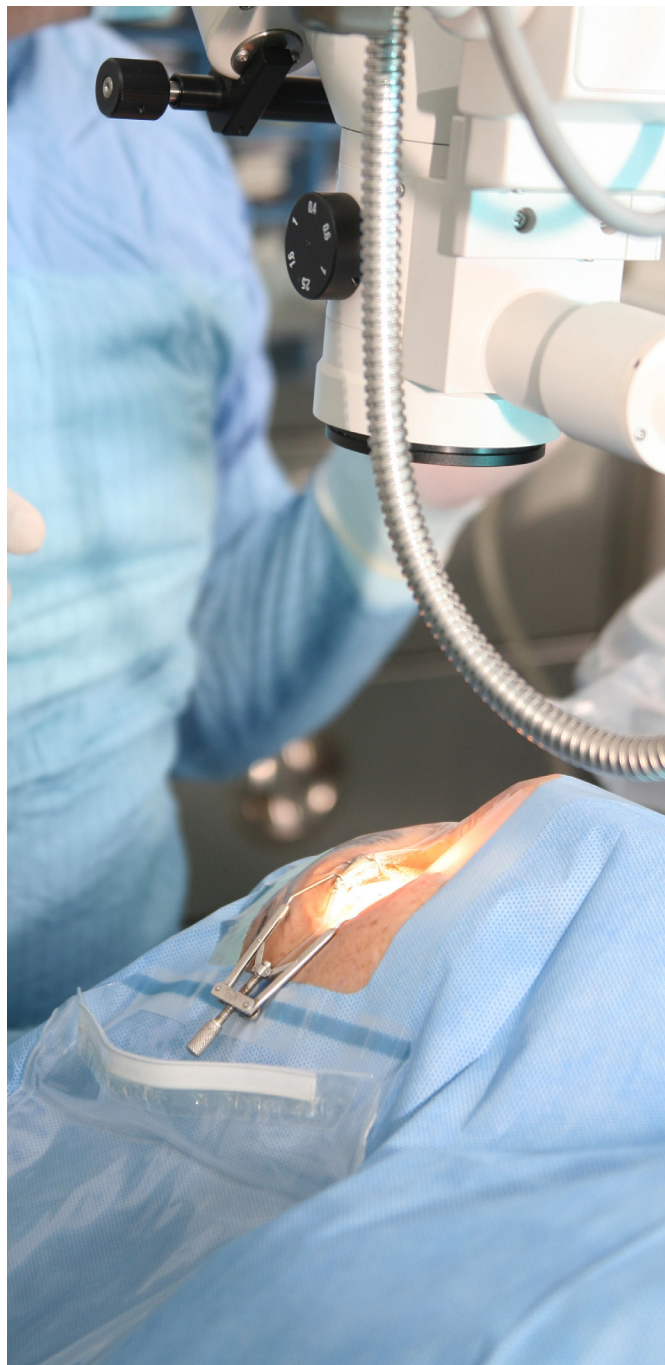
- *Usability testing* critical for safe use, applicable to single user robotic devices and multi-user robotic systems;
- *Software testing*, on software from third-parties conforms with required technical specifications as well as security criteria;
- *Cybersecurity testing*, including detailed vulnerability assessments that cover vulnerability scanning, malware scanning, static code analysis and others;
- *Interoperability testing*, allowing for the evaluation of conformance with industry communications standards and protocols, as well as ease of integration with other devices;
- *Biocompatibility testing*, including irritation, sensitization, cytotoxicity, sterility validation and more for parts that come into contact with the human body and blood supply;
- *EMC & Wireless testing*, for accurate system communication and functionality in real world environments;
- *Environmental testing*, for devices being used in adverse or extreme environments, this testing helps insure critical functions are able to work;
- *Quality System Certification*, per the international and local standards such as ISO 13485, MDSAP, ICMED and others.
- *Notified Body* - UL is a Notified Body under the EU Medical Device Directives and Regulations
- *Electrical and Mechanical Safety testing & certification*, to meet international requirements for IEC 60601 for medical robots used in both clinical and non-clinical environments.



SUMMARY + CONCLUSION

Along with other advanced technologies, robotic systems and devices have the potential to transform healthcare in the 21st century. While specific regulations and standards may vary from country to country, key considerations applicable to medical robotic devices include product safety, clinical safety and quality management systems compliance. Developers and manufacturers of robots and robot systems seeking to penetrate the medical device marketplace are well advised to investigate in advance the specific regulatory requirements and standards that are applicable to their devices, in order to facilitate their efforts to achieve market access and acceptance.

For additional information on UL's advisory services in support of medical robotic technologies, visit www.ul.com/medical. Or contact us at Medical.Inquiry@ul.com.





END NOTES

¹ See, for example, "[Medical Robots Market by Product - Global Forecast to 2021](#)", a report by Markets and Markets, Inc., February 2017. Web. 12 May 2017.

² For an analysis of these challenges, see "[5 Things Preventing Technology Adoption in Health Care](#)", a blog posting on Forbes.com, September 11, 2014. Web. 12 May 2017.

³ "[Ageing](#)", population overview statistics from the United Nations Population Fund. Web. 12 May 2017.

⁴ "[The Lifetime Distribution of Health Care Costs](#)", study by Health Services Research, June 2004. Web. 12 May 2017.

⁵ See "Medical Robots Market by Product - Global Forecast to 2021," Endnote #1 above.

⁶ "[The Complexities of Physician Supply and Demand: Projections from 2015 to 2030](#)", a report prepared for the Association of American Medical Colleges by IHS Markit, February 28, 2017. Web. 12 May 2017.

⁷ For one illustration of the success rate of medical robotics, see "[Large multicenter study shows high success rate for robotic PCI procedures](#)", posting on ScienceDaily.com, May 12, 2017. Web. 14 May 2017.

⁸ See "Medical Robots Market by Product - Global Forecast to 2021", Endnote #1 above.

⁹ Examples taken from "[9 Exciting Facts About Medical Robots](#)", from the website The Medical Futurist, 2017. Web. 12 May 2017.

¹⁰ "[Top health industry issues of 2017](#)", a report issued by the PwC Health Research Institute, December 2016. Web. 12 May 2017.

¹¹ "[Regulation \(EU\) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation \(EC\) No 178/2002 and Regulation \(EC\) No 1223/2009 and repealing Council Directives 90/358/EEC and 93/42/EEC](#)", as published in the Official Journal of the European Union, L117, 5 May 2017. Web. 12 May 2017.

¹² "[What is a medical device?](#)" website of the U.S. Food and Drug Administration, last updated December 28, 2015. Web. 12 May 2017.

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