



Celestica™

Design to Delivery:

# The Future of Robotics in Healthcare

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## INTRODUCTION

Designing robots is hard.

# Building them should not be.

Hospitals and clinics, pharmacies, rehabilitation centers, and other healthcare provider organizations are deploying robots to improve patient care outcomes and expand high-quality care to underserved populations worldwide. Demand for robotics solutions is rising and creating new growth opportunities for healthcare robotics OEMs.

Innovative OEMs are combining advanced imaging, sensing, computer vision, and artificial intelligence (AI) technologies with unique physical robotic solutions to push the boundaries of what's possible and transform the healthcare industry. Designing robots is hard, but building them shouldn't be. Overcoming the many hurdles that can block the transition of a new design into manufacturing with the quality and at the scale the industry and patients' demand can be quite daunting.

This white paper examines how healthcare robotics OEMs can accelerate the product development lifecycle from design, to build at scale, to delivery, in compliance with healthcare's stringent standards.

Data Bridge Market Research expects the Healthcare Robotics Market to grow

# \$43.22 Billion

(USD) by 2028 - 22.3% CAGR<sup>1</sup>



# Transforming Healthcare Delivery Worldwide

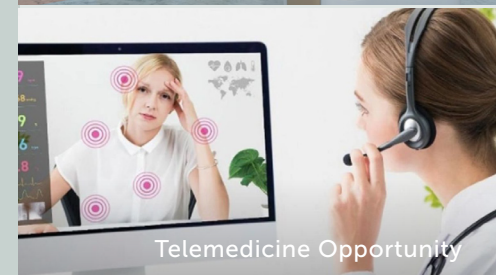
Healthcare providers use robots for a wide range of applications like performing delicate surgical procedures that extend and augment a surgeon's capabilities. For example, in March 2019, a doctor in China used remote surgical tools to implant a stimulation device into the brain of a Parkinson's patient on an operating table in a hospital that was nearly 2,000 miles away.<sup>2</sup>

Robots can also help patients who have suffered partial paralysis due to stroke, brain injury, cerebral palsy, multiple sclerosis and other neurological conditions recover their mobility, strength, coordination, and regain a high quality of life. These robots utilize sensors to examine human movement and positioning to conduct movement exercises while measuring and storing the limitations of a patient's performance for use in long-term clinical evaluations. This assists therapists in the management of treatment planning and goal setting.<sup>3</sup>

In laboratories and pharmacies, robots can relieve humans of the stress of performing a variety of mundane and repetitive tasks such as scanning and sorting incoming medical test samples and filling prescriptions.

"Robotics has made exciting advancements in healthcare technology in the past few years, and their potential to grow and improve the quality of healthcare and expand its delivery to underserved regions around the world is limitless."

Kevin Walsh, Vice President, HealthTech, Celestica





# Improving the Healthcare Worker Experience

In many large hospitals, robots are being deployed to help their staff spend less time walking and more time treating patients.

The International Federation of Robotics (IFR) reports, in a typical 200-bed hospital, nurses and other staff members walk 400 miles per week while moving equipment and removing waste<sup>4</sup>.

That means one nurse spends time walking



**3-4 MILES** each day to perform manual labor tasks

like pushing equipment from room-to-room or department-to-department and taking out the trash.

The IFR estimates that the use of Autonomous Mobile Robots (AMRs) to handle those duties significantly shortens the average distance a nurse must walk each day. Deployment of robots in these scenarios will ultimately free up nurses, allowing them to focus more of their time on patients.



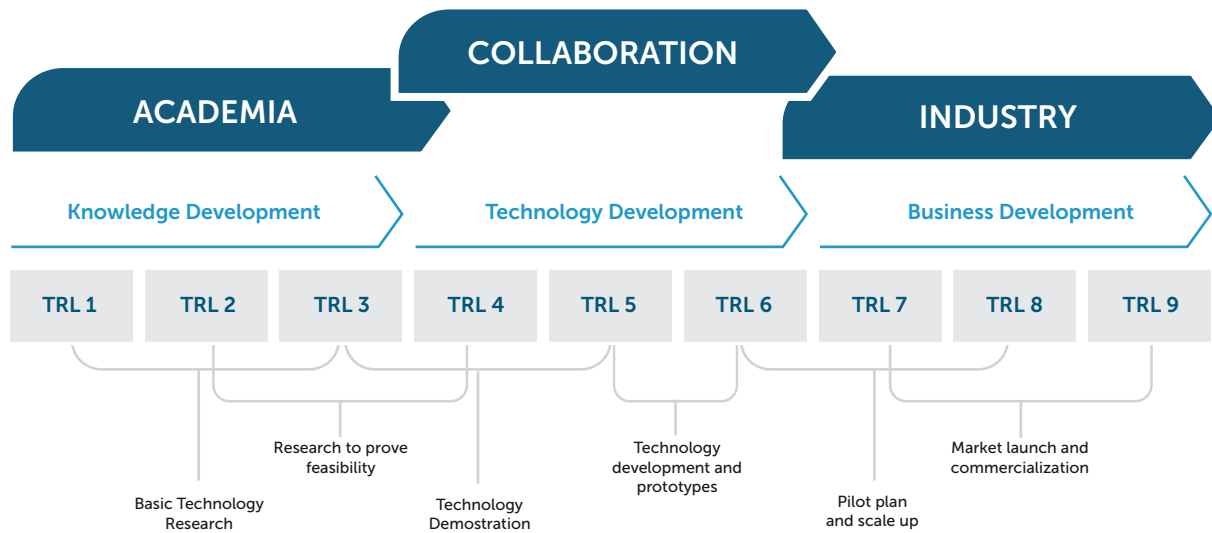
“The key to OEMs’ success is understanding the challenges that may be present during the product development lifecycle, especially during the initial design phase. Companies who do not anticipate and solve the challenges that will arise early in the product lifecycle will face significant delays to market, resulting in large financial premiums and a loss of market share in a rapidly evolving technical space.”

Kevin McFarlin, Engineering Director, HealthTech, Celestica

Space constraints, weight, power, controls, user interface, vision systems, software - all present unique challenges and are highly dependent on how the end-user will deploy the robot. Additionally, documentation, change management, supplier/supply chain management, testing/validation, quality assurance, manufacturing and assembly present a myriad of issues.

# What's Your TRL Number?

Healthcare robotics OEMs represent a broad mix of both early-stage companies and established multinationals at all stages of the Technology Readiness Level (TRL) timeline, a method NASA devised in the 1970s to estimate the maturity of technologies during the acquisition phase of a program. The use of TRLs enables consistent, uniform discussions of technical maturity across different types of technology to track where a new product sits on the wide spectrum between an idea on a scratch paper to mass production and shipping.



While a product moves from the early research and demonstration TRL phases to building prototypes, the OEM may tap local resources for sub-assemblies, prototypes and custom build products. As the OEM grows, partnering with a manufacturing company with a larger footprint enables them to scale their solutions globally.

“The earlier in the development cycle an OEM engages with a manufacturing partner with engineering and design expertise the better - ideally somewhere around TRL 5 or 6. Earlier engagements yield more design insight and can help prevent major roadblocks during the transition of the designs into manufacturing. A partner that is familiar with the industry and design constraints can really help shape the direction of the product and its eventual ability to scale into production.”

**Matthew Wicks, Director of Robotics, Celestica**

# Electronic Device History Records (eDHR)

## Improving Quality for Better Patient Outcomes

Like any other healthcare company, robotics OEMs must implement a comprehensive quality management system for the design and manufacture of their robotics solutions to achieve compliance with FDA and EU regulations that require conformance and documentation to international standards such as ISO13485. A Design for Quality approach streamlines the process of creating and submitting device history records (DHR) to regulatory agencies.

A comprehensive quality management system is much more than providing the necessary documentation required to conform to regulations. If done correctly, it's fully integrated into the manufacturing processes in the form of electronic work instructions, processes and infrastructure that facilitate higher quality work. This may be as simple as structured parts layouts for manual assembly processes or as complex as fully automated testing and validation processes that provide more comprehensive testing coverage than any manual process could provide.

**80%**  
of all warning letters the FDA  
issued in 2016 included data  
integrity deficiencies.





The manual process for creating the DHR is labor intensive and prone to inconsistent results - a recipe for failure to meet FDA requirements. A single typo or error such as a missing signature, correction initials or date on a page can delay the regulatory approval process.

Creating the DHR can be particularly difficult for start-ups or other companies that do not have much experience in manufacturing or navigating the regulatory review and approval process. It requires ensuring that all operators in the factory follow strict procedures and provide accurate records at the appropriate times.

Transitioning from paper to electronic DHR (eDHR) eliminates the reliance on manual

processes to ensure reliability and verification. An eDHR is the automated output of the enormous volumes of data that manufacturing systems generate to improve the analysis of potential issues, generate consistent results, and reduce the risk of FDA review substantially.

Once the desired output and outcome is achieved, the manufacturer has a process for building the product correctly that will make it easier to scale up volume production in the future. This also facilitates Corrective and Preventive Actions (CAPA) investigations, and limits liability and saves money when conducting targeted product recalls.

## CASE STUDY SNAPSHOT

A medical device OEM contracted Celestica to manufacture a complex surgical robot. The system includes a robotic arm and a camera module.



**1,200+**

Total parts associated with the entire assembly

**1,400-2,100 ENTRIES**

**140**

page  
DHR

**10-15**

entries  
per page

to be completed, inspected and approved



Celestica is working with the medical OEM to transition from paper to electronic DHR, ensuring 100% reliability and verification.

Medical devices must meet certain requirements and validations that are more stringent than in other industries, so a DHR plays an important role in the quality management system. A DHR, which typically runs between 16-20 pages depending on the complexity of the product, conveys to regulatory agencies a product's entire history, including who built it and when, who performed testing and when, and details on the calibration and maintenance of testing equipment.

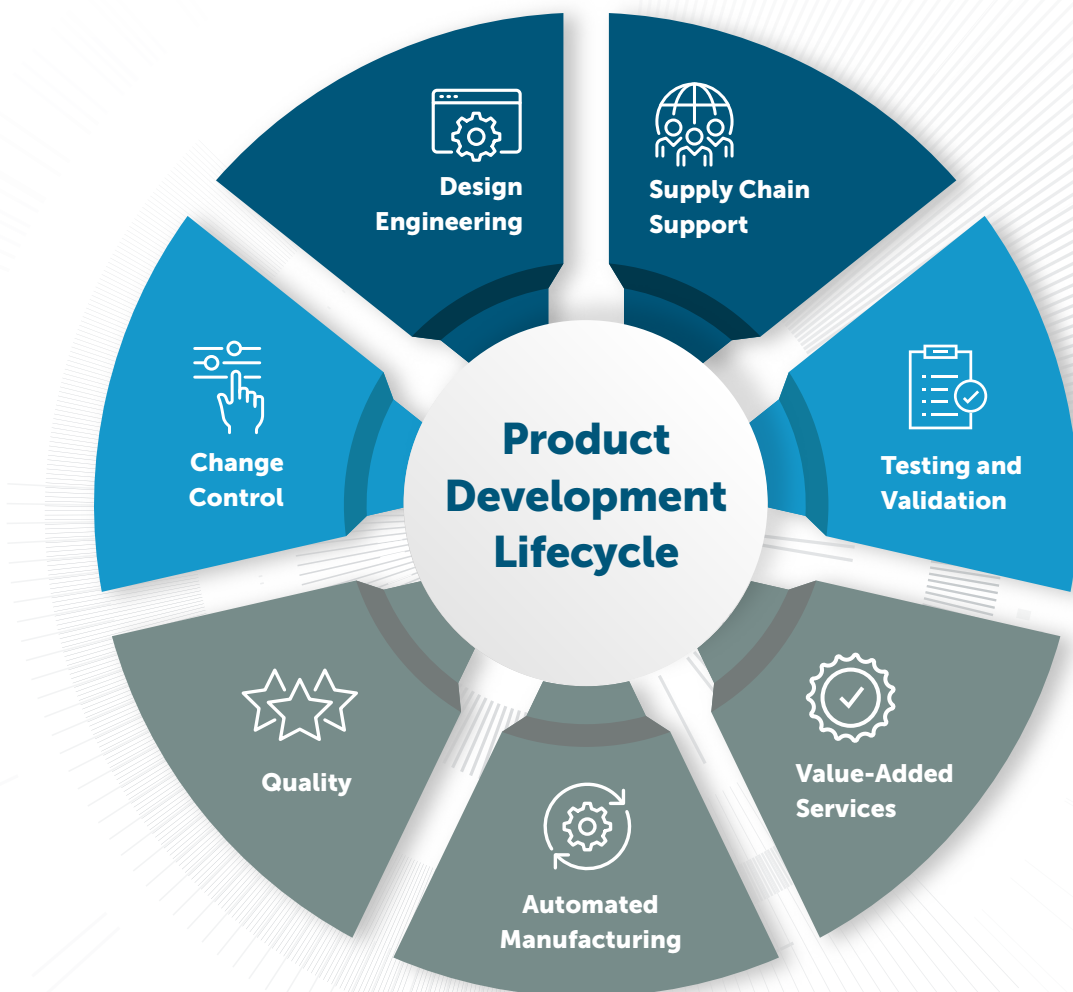
# Celestica Robotics Center of Excellence:

## An Extension Of Your Development Team

Finding a manufacturing partner that can help the product development team address manufacturability and quality early in the design process is invaluable to an OEM's ability to deliver its product to market ahead of its competitors.

Celestica partners with OEMs to help optimize the design process and ease the transition from design to commercialization and volume production.

"The primary goal when evaluating potential manufacturing partners is to identify one that will enable the internal design and engineering teams to focus on innovation," says Kevin McFarlin, Engineering Director at Celestica. "That's only possible if the partner assumes the responsibilities of maintaining and staffing equipment, quality processes, testing and validations, as well as navigating any regulatory review and approval documentation processes."



A qualified manufacturing partner skilled in services across the product lifecycle removes those burdens from the development teams' shoulders so they can focus on higher value-added projects and tasks.



### **Design Engineering**

Expertise in manufacturing robotic solutions can extend well into the core design phase of a robotics program. Decisions made and components selected can have a massive impact on the manufacturability of the robotic solution and the core design. Engineering decisions and direction that take into account manufacturability can have a positive impact on the design and functionality of the products.



### **Supply Chain Support**

Robotics systems are made up of a wide variety of very complex components, including better management systems, precision mechanisms, optical systems, power management systems, customized power and compute hardware. A good partner will have a strong bench of supply partners who can be leveraged to optimize many different aspects of the robotic solution. They will also take into account cost, quality, compliance, obsolescence, and mass production when selecting parts.



### **Change Control**

Having a manufacturing partner who can work hand-in-hand with your design engineering teams can be a lifesaver in any robotics program. Updating bill of materials (BOMs), handling revision controls, sourcing alternate suppliers, and providing feedback to the cost/schedule impact are all requirements to any change management program and a good partner will be there every step along the way.



### **Testing and Validation**

Designing the robot is only part of the equation. Extensive component and system lifecycle testing services add the confidence and reliability assurances needed for full scale production.



### **Quality**

Assembly and testing of the robotics system is a big component of the manufacturing process, but identifying the processes required along with the testing/validations of these processes add considerable value to the overall manufacturing operations. These processes and tests must be engineered and thought through to ensure a high-quality end product.



### **Value-Added Services**

The robotics system goes beyond just putting the hardware together. Oftentimes specific configurations and/or procedures must be completed to ensure the solution is functional and operational as sold/designed. Software configurations, calibrations and other specific processes are all areas to leverage your manufacturing partner.



### **Automated Manufacturing**

Depending on the volumes of the robotic solution, automating some or all of the manufacturing process may be appropriate. Evaluating the current and future production requirements and planning for growth is another area where an experienced partner can leverage expertise and experience that adds real value to your solution and bottom line.

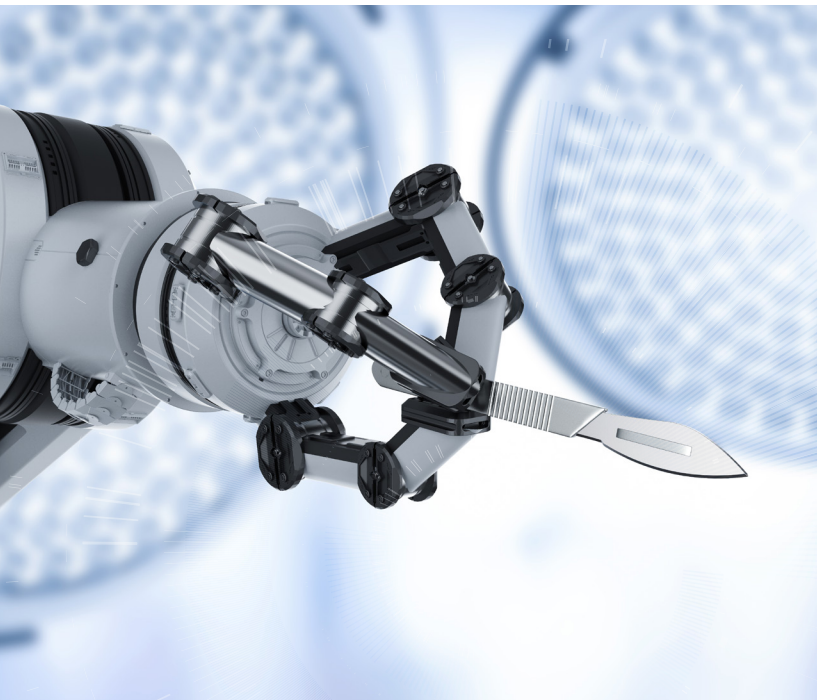
# Gaining a Competitive Advantage

The rapid advancement across technology areas such as artificial intelligence (AI), machine learning (ML) and computer vision enable innovative healthcare robotics OEMs to design robots that will increase the quality of care worldwide. The pressure is high to strike that elusive balance between innovation and accelerating product development and delivery timelines. It is virtually impossible for an OEM to do both.

Embracing a “Design for Manufacturability” mindset that incorporates manufacturing and quality control considerations into the product design phase will reduce risk, lower costs, and ensure the highest level of quality. It will streamline the regulatory review process, and ensure a new product’s long-term

manufacturability and sustainability when an OEM is ready to increase production volumes in order to enter new markets and expand its customer base.

The Celestica Robotics Center of Excellence (COE) delivers industry-leading engineering, manufacturing, and product lifecycle support services to enable customers’ in-house teams to focus on growth through innovation. The COE brings talented and experienced design, engineering, manufacturing and automation teams to provide expert insights and experiences - helping robotics companies move their innovative new solutions into full-scale production and distribution.



“When you examine the engineering expertise and skills it takes to develop a world-class robot, you realize the high-level brain power and expertise required to make it happen. Leading robotics companies understand they need to keep these valuable resources focused on adding value to their core products, evolving the design, and adding features and functionality that are second to none. A good manufacturing partner adds value in many areas to help optimize design and transition into manufacturing and full commercialization.”

**Matthew Wicks, Director of Robotics, Celestica**

To learn more, visit: [www.celestica.com/robotics](http://www.celestica.com/robotics)



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