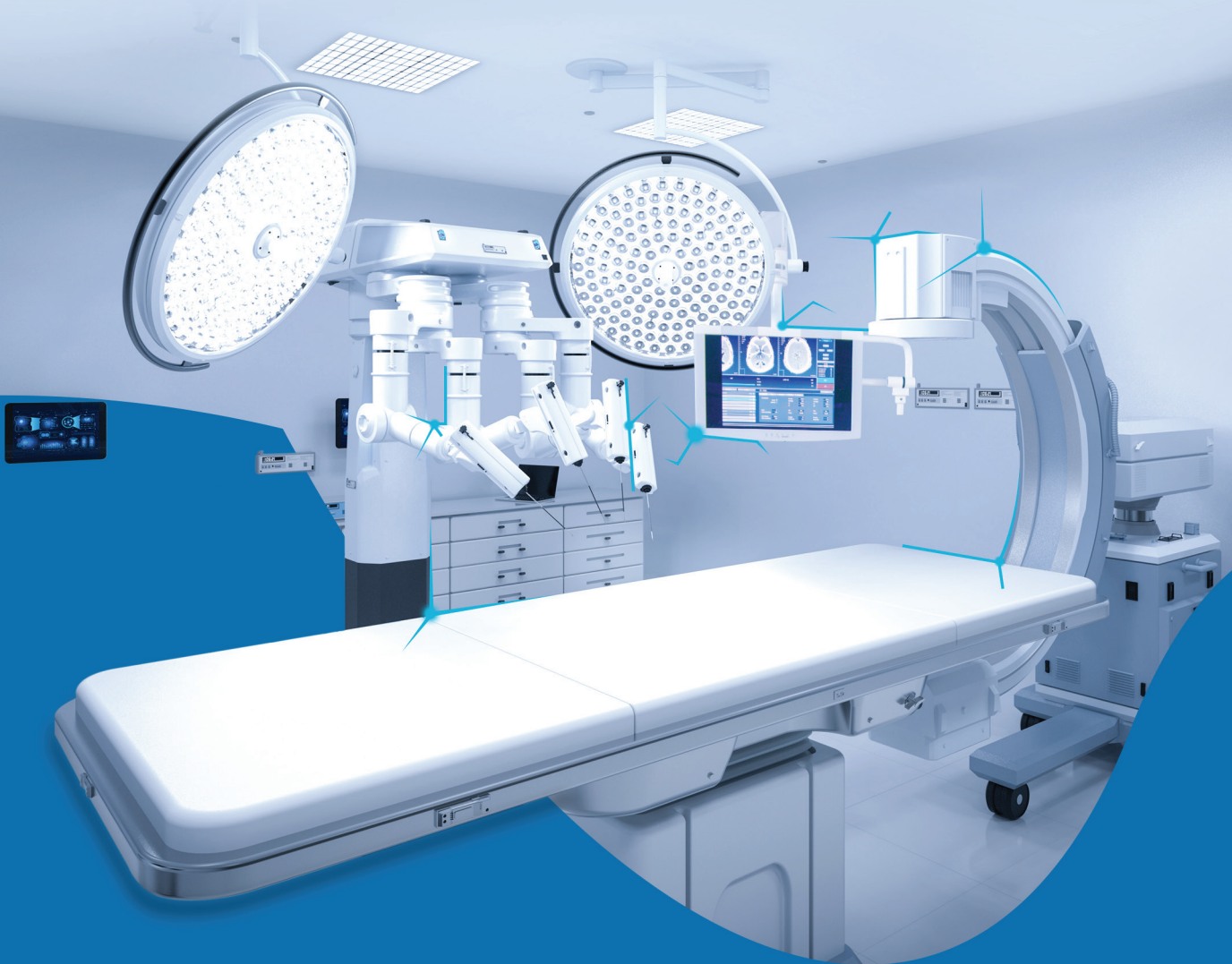# Solutions for
MEDICAL DEVICES AND HEALTHCARE

Enabling Connected Care Ecosystem

Digital Engineering and Manufacturing Services

Overview

The medical devices and healthcare industry is witnessing transformation due to converging technologies, evolving regulatory compliances, and changing market demands. Medical devices are becoming more connected than ever and are shaping new solutions to offer value for healthcare such as improved quality of life for patients with chronic illness, reduced cost of treatment, and more. The changing technology makes it imperative for medical devices companies to adopt a strategic approach by leveraging technology advancements in multiple areas such as IoT, cloud, AI, and analytics to drive innovation that addresses market needs and challenges.

Capgemini's medical device engineering practice brings solutions and services that help our clients in designing customized devices with end-to-end product development and collaborate through the complete medical device value chain. We also help clients retain their competitive edge by leveraging new technologies to optimize R&D costs and productivity, reduce time-to-market, improve supply chain efficiencies, strengthen partner ecosystem, and proactively seek new opportunities.

Offerings

Connected Products

Smart Product and System Development
- New product development
- Internet of Medical Things (IoMT)
- Edge computing and analytics

Software Product Engineering
- Software-as-a-Medical Device
- AI for cognitive platform development, clinical analytics
- Remote patient monitoring and diagnostics services

Healthcare IT & Interoperability Services
- Integration with HIS/EMR, DICOM standards

Smart Product Support
- Remote monitoring and diagnostics of medical products
- Sustaining, serviceability and technical support services
- Field service digitization (AR/VR)

Smart Engineering

Systems Development
- Systems engineering
- Value engineering and value analysis

Mechanical and Physical Engineering
- CAD modelling and advanced numerical simulation

Product and System Testing
- Verification and validation - System and software
- Connected medical products testing
- Product integrity

Technical Publication and Product Documentation
- Authoring, illustrating and publishing services of technical content
- Training content development

Digital Manufacturing

PLM

Virtual Engineering
- Model Based System Engineering (MBSE)
- Complex system simulation

Smart Factory
- Digital twin

QARA

Product and Process Compliance
- Product compliance and remediation
- Process assessment and audit
- Post market surveillance support and management
- Risk management
- Compliance support for EU MDR/IVDR

Technical Documentation and Reporting
- Product labeling and content management
- Regulatory submissions support

- Medical Imaging
- Therapeutic
- IVD
- Surgical and other domains
- Healthcare IT
- Patient Monitoring

Success Stories

Connected care solution for a cardiac rhythm management ecosystem

- Developed an end-to-end remote patient monitoring solution, a cloud based portal for patient data management and proactive monitoring

- Development of a home-based patient monitoring solution for early detection and timely care through patient engagement via mobile applications

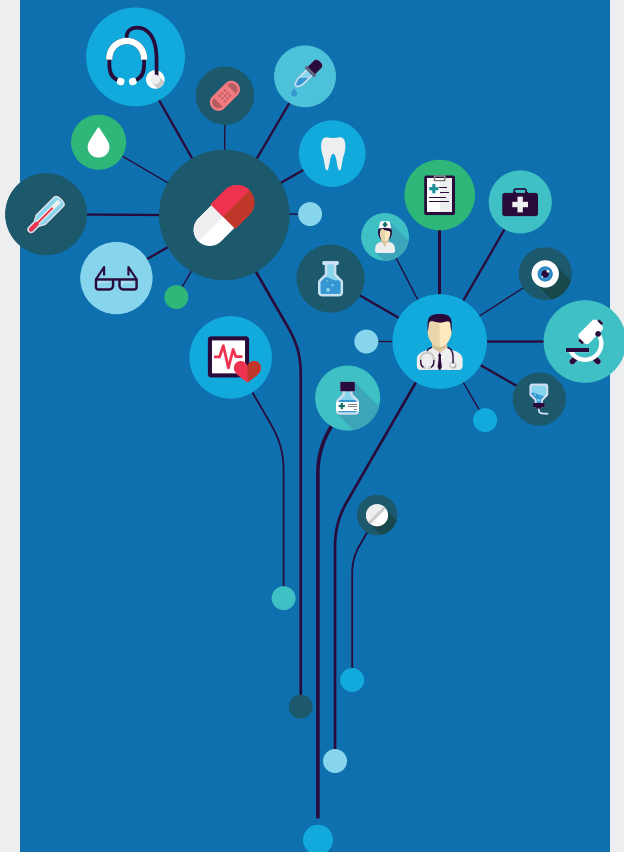## Innovation and product transformation for an emerging market

- Developed an IoT enabled solution for remote asset management

- Ability to integrate low-cost new consumables for improved top-line margins and yield at high throughput compared to the competition

- Followed an iterative development with time-boxed approach for system engineering

Continuous glucose monitoring system- from concept to manufacturing

- First of its kind compact, cost-effective and easy to use solution with the ability to mount the sensor-transmitter device on the human body with a single push button

- Reduced number of steps for sensor installation compared to the other products in market

- IOS based mobile application to receive and display the glucose values and trends

Partnered with a global imaging major to build next-generation CT system

- Collaborated for in multiple solution areas such as R&D projects, development of new clinical applications and technology refresh, usability engineering, and image processing algorithms.

- Co-development of services in healthcare-IT including cloud-based solutions, integrated remote asset management platform, cybersecurity implementation, device interoperability, and more.

Our Assets and Accelerators

iDiagnose — Framework with open source components for building and deploying deep learning algorithms in medical imaging applications on GPU platforms

iHeal — Engineering analytics framework for predictive, preventive maintenance to enable auto-healing

AutoPulse — Prognostic asset health solution that uses device and related data to provide a reliable prediction of economic life of the components and assets in operation

HL7 Connector Framework — Framework to achieve interoperability among proprietary applications to exchange clinical and administrative information

X-IoT — A middleware solution that provides ready-to-use software and infrastructure components supporting object connectivity and enabling the development of end-to-end IoT solutions

Image Quality Assessment (IQA) Tool — A semi-automated solution for testing efficacy/ accuracy of various image processing algorithms and monitoring image quality

Hybrid Test Automation Platform (HTAP) — Test automation platform, HMI, vision-based and API test automation, bluetooth interoperability and profile testing

VAVE Methodology — Smart value analysis and value engineering methodology for reduced product costs with improved quality and performance

The Capgemini Advantage

- 18+ years of experience
- 12 of the top 25 medical device companies
- 250+ regulatory submissions
- Experience in 35+ clinical categories

- **Medical Standards and Certifications**
  - **Process and quality compliance:** ISO 13485, 14971, IEC 62304
  - **Regulatory compliance:** FDA CFR IEC 60601, IEC 62366, RoHS, HIPPA, EU MDR/IVDR

- Alliance partnerships with AWS, Microsoft, Google, IBM, PTC
- Rated as a Leader in the industry

- Healthcare ecosystem partnerships with hospitals, doctors/clinicians, prototype manufacturers, test labs, external consultants

- Deep technical expertise across the product lifecycle – From product engineering to platform development and deployment

MEDICAL

Capgemini

About Capgemini

Capgemini is a global leader in consulting, digital transformation, technology and engineering services. The Group is at the forefront of innovation to address the entire breadth of clients' opportunities in the evolving world of cloud, digital and platforms. Building on its strong 50-year+ heritage and deep industry-specific expertise, Capgemini enables organizations to realize their business ambitions through an array of services from strategy to operations. Capgemini is driven by the conviction that the business value of technology comes from and through people. Today, it is a multicultural company of 270,000 team members in almost 50 countries. With Altran, the Group reported 2019 combined revenues of €17billion.

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People matter, results count.

About Capgemini's Digital Engineering and Manufacturing Services

Capgemini's Digital Engineering and Manufacturing Services brings together deep domain expertise to lead the convergence of Physical and Digital worlds through technology, engineering and manufacturing expertise to boost our clients' competitiveness. A recognized leader with over 10,000 engineers across the globe and 30+ years of experience, Capgemini's comprehensive portfolio of end-to-end solutions enables global companies to unlock the true potential of their product portfolios and manufacturing efficiencies.

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