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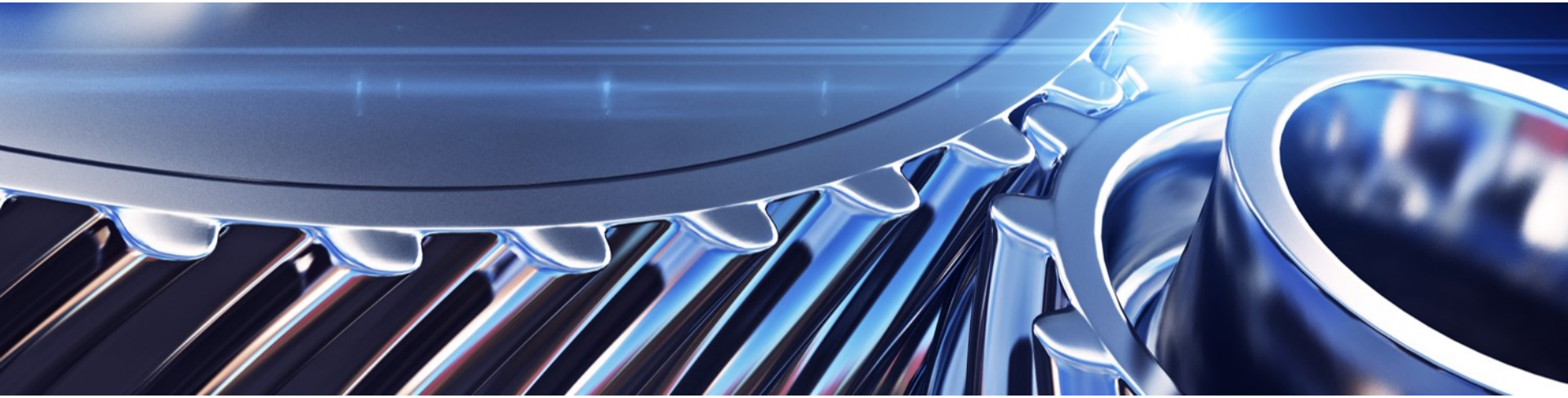

Medical Device Engineering Services PEAK Matrix™ Assessment 2019: Navigating the Innovation and Compliance Conundrum

Engineering Services (ES)
Market Report – December 2018: Complimentary Abstract / Table of Contents

Everest Group®
PEAK MATRIX™

EGR-2018-40-CA-2887

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Custom research capabilities

- Benchmarking | Pricing, delivery model, skill portfolio
- Peer analysis | Scope, sourcing models, locations
- Locations | Cost, skills, sustainability, portfolio – plus a tracking tool
- Tracking services | Service providers, locations, risk
- Other | Market intelligence, service provider capabilities, technologies, contract assessment

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Background of the research

Background of the research

- The medical device industry is faced with multiple challenges – a shift in the industry from product-centric to patient-centric solutions, increasingly stringent industry regulations, declining margins, and competition from unconventional players – to name a few
- Another set of challenges is emerging with digital technologies assuming center stage in the functioning of medical devices. The blurring boundaries between hardware, software, and network, and the interoperability requirements of connected ecosystems are leading to new challenges for enterprises in managing the development and maintenance of these devices
- To overcome these challenges, enterprises are increasingly looking toward service provider engagements. They expect service providers to not only provide the engineering headcounts across hardware and software engineering, but to also offer domain expertise, best practices from other industries, reusable frameworks/accelerators, and lab infrastructure that enable a smooth and accelerated product development journey
- With medical device companies beginning to unlock value out of service provider relationships, this traditionally outsourcing-averse vertical is witnessing healthy double-digit growth in engineering services outsourcing and the momentum is expected to continue over the next three years
- In this research, we present fact-based trends impacting the medical device engineering services market, along with the assessment and detailed profiles of 12 service providers featured on the medical device engineering services PEAK Matrix. Each service provider profile gives a comprehensive picture of their medical device engineering services vision, scale and scope of operations, key solutions, and partnerships

Scope of this report

Services
Medical device engineering services

Market segment
Engineering services

Geography
Global

Overview and abbreviated summary of key messages (page 1 of 2)

This report provides a comprehensive assessment of the medical device engineering services market and maps the leading service providers on Everest Group's PEAK Matrix. It also includes detailed profiles of featured service providers.

Some of the findings in this report, among others, are:

Market growth

- Global medical device engineering services outsourcing market stood at US$1.1 billion in 2017. It is poised to grow at a Compound Annual Growth Rate (CAGR) of ~15% during the next three years to 2020
- Product development constitutes the largest share in service provider engagements, while software engineering remains the dominant service function

Market trends

- Adoption of value-based care has bolstered the importance of three key factors for enterprises—quality and effectiveness of care, cost, and patient experience
- Enterprises are exploring the following key technologies and themes to imbibe these factors in their products:

Quality and effectiveness of care

- The use of AI enhances the quality of care by enabling on-demand predictive support, personalized treatment, and self-care
- Security of medical devices is an indispensable part of effective care as it prevents the tampering and destruction of patient data which might lead to incorrect prescriptions

Cost

- Value engineering is being leveraged to manufacture high-quality devices at lower costs by using low-cost materials, adding only basic features, or de-engineering premium devices
- Use of 3D printing is resulting in reduction of manufacturing costs as the wastage of material in making medical devices is drastically reduced

Patient experience

- Software as a medical device is more portable, convenient to use, easy to update, and easy to personalize, which in turn leads to very good patient experience
- Application of human factors engineering has made medical devices minimally-invasive, smaller, easy to use with self-explanatory functionalities, and more interactive

Overview and abbreviated summary of key messages (page 2 of 2)

PEAK Matrix for medical device engineering services

- Analysis of 12 leading medical device engineering service providers leveraging Everest Group's PEAK Matrix highlights the following:
- **Leaders:** Altran, HCL Technologies, and L&T Technology Services
- **Major Contenders:** Cognizant, Cyient, Infosys, Tata Elxsi, TCS, Tech Mahindra, and Wipro
- **Aspirants:** Mphasis and Syntel
- Focused infrastructure investments in labs and innovation centers are enabling **Leaders** to function as "partners of choice" for their customers and in overcoming the challenges of compliance, product modernization, and innovation
- **Major Contenders** have demonstrated success in client engagements via flexible contract options, responsiveness to changing scenarios, and a wide partnership ecosystem
- **Aspirants** exhibit strong capabilities in delivering software engineering services for medical devices, with a smaller play across embedded and mechanical engineering

This study offers three distinct chapters providing a deep dive into key aspects of medical device engineering market; below are four charts to illustrate the depth of the report

Medical device engineering services definition

	Ideation and design	Product development	Quality assurance	Product sustenance and support
Software1 engineering	• Requirements gathering and analysis • Application frameworks • UI/UX conceptualization and prototyping • Customer experience design	• Firmware development • GPOS/RTOS (Real-time OS) development • Human Machine Interface (HMI) development • Configuration management • Technical documentation	• Unit, integration, and system testing • Test automation • Testing based on performance, load, and stress	• Post-marketing surveillance • Defect tracking and fixing • Maintenance releases • Feature enhancements • Lifecycle enhancements • Product localization • Medical device management • Risk assessment • Customer field support
Embedded and electronic hardware engineering	• Schema, Very-large-scale integration (VLSI), Application-Specific Integrated Circuit (ASIC), Field Programmable Gate Array (FPGA), and Printed Circuit Board (PCB) design • Design for interoperability • Component engineering and prototyping		• Functional and non-functional verification • Testing fixtures and automated equipment • Testing reliability	
Mechanical devices engineering	• Gathering user and functional requirements • Component layout • System interconnection design • Material selection • Value engineering	• Hardware engineering • Electromechanical and mechanical engineering • Packaging engineering	• Product design validation • Product reliability testing • Load and stress testing • Performance and usability testing	

Project management

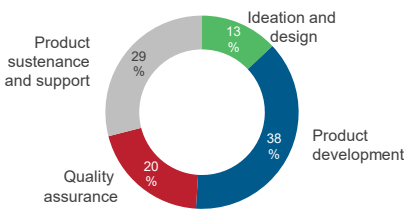
Product lifecycle management

Product compliance and certification

Revenue breakdown by value chain elements and service functions

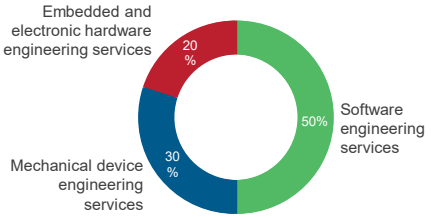
Medical devices engineering services outsourcing market – by value chain element
2017, %

100% = US$1.1 billion



Medical devices engineering services outsourcing market –by service function
2017, %

100% = US$1.1 billion



AI use cases in medical devices

Chatbots

Clinically-intelligent conversation programs are used to give "on-demand" medical support for conditions that usually require continuous observation and follow up care such as diabetes and hypertension

Voice user interface

Voice user interfaces used as virtual nursing assistants are providing answers to patients 24/7 and reducing the pressure caused due to medical labor shortage

Robot-assisted surgery

Robots can analyze data from pre-operative medical records to guide a surgeon's instrument during surgery. Robots can use data from past operations to inform about new surgical techniques

Automated image diagnosis

When a machine analyzed the images such as MRI scans and CAT scans, the rates of false positives were around 50% lower, and the rates of false negatives around 70% lower

Platforms for predictive analytics

New predictive ML models are being built to be used to predict epileptic seizures, detect symptoms of depression, and reduce the risk of contracting infections

Human factors engineering: Evolution of the pacemaker

1988

Weight: 55g
Size: 25cc

1998

Weight: 14g
Size: 6cc

Minimally invasive: Radically smaller in size and easier to implant as compared to the earlier models

2008

Weight: 23g
Size: 12.8cc

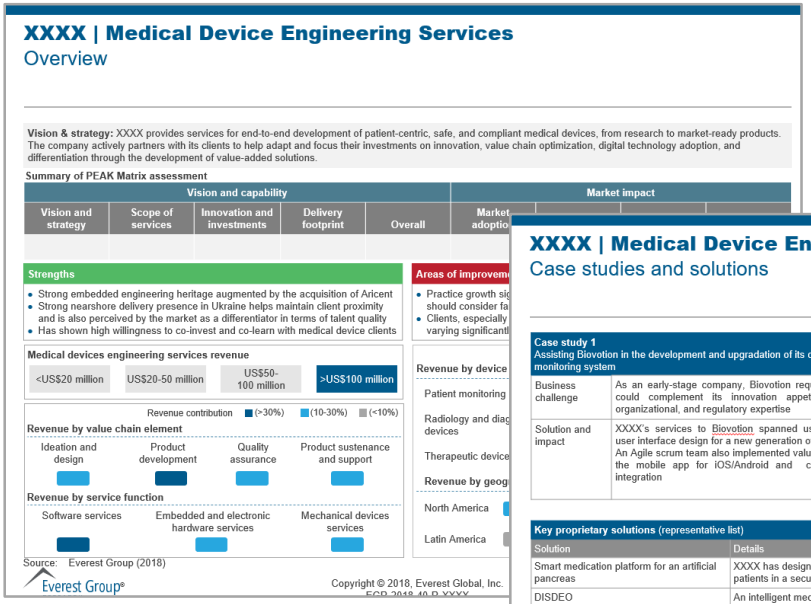
- **Highly effective design to ensure ease of use:** No requirement of mechanical adjustments with features for remote monitoring
- **Reduced risk:** Extended the life of the pacemaker using lithium batteries to reduce the risk of failure and prolong the replacement cycle

2018

Weight: 2g
Size: 1cc

- **Minimally invasive:** Pacemakers are now placed in the heart via a vein in the leg. This prevents chest incisions, scars, or bumps that were caused by the erstwhile pacemakers
- **Reduced risk:** Currently, pacemakers are completely self-contained within the heart.-This eliminates any potential medical complications arising from the wires running from a conventional pacemaker into the heart
- **Highly effective design to ensure ease of use:** Pacemakers are the size of a large vitamin capsule which adjust the heart rate automatically using advanced sensors

This report includes 12 service provider profiles detailing their medical device engineering services vision, scale and scope of operations, key solutions, and partnerships



XXXX | Medical Device Engineering Services
Overview

Vision & strategy: XXXX provides services for end-to-end development of patient-centric, safe, and compliant medical devices, from research to market-ready products. The company actively partners with its clients to help adapt and focus their investments on innovation, value chain optimization, digital technology adoption, and differentiation through the development of value-added solutions.

Summary of PEAK Matrix assessment

Vision and capability					Market impact
Vision and strategy	Scope of services	Innovation and investments	Delivery footprint	Overall	Market adoption

Strengths

- Strong embedded engineering heritage augmented by the acquisition of Aricent
- Strong nearshore delivery presence in Ukraine helps maintain client proximity and is also perceived by the market as a differentiator in terms of talent quality
- Has shown high willingness to co-invest and co-learn with medical device clients

Areas of improvem

- Practice growth si should consider fa
- Clients, especially varying significantl

Medical devices engineering services revenue

<US$20 million | US$20-50 million | US$50-100 million | >US$100 million

Revenue contribution (>30%) (10-30%) (<10%)

Revenue by value chain element

Ideation and design | Product development | Quality assurance | Product sustenance and support

Revenue by service function

Software services | Embedded and electronic hardware services | Mechanical devices services

Revenue by device

Patient monitoring

Radiology and diag devices

Therapeutic device

Revenue by geog

North America

Latin America

Source: Everest Group (2018)

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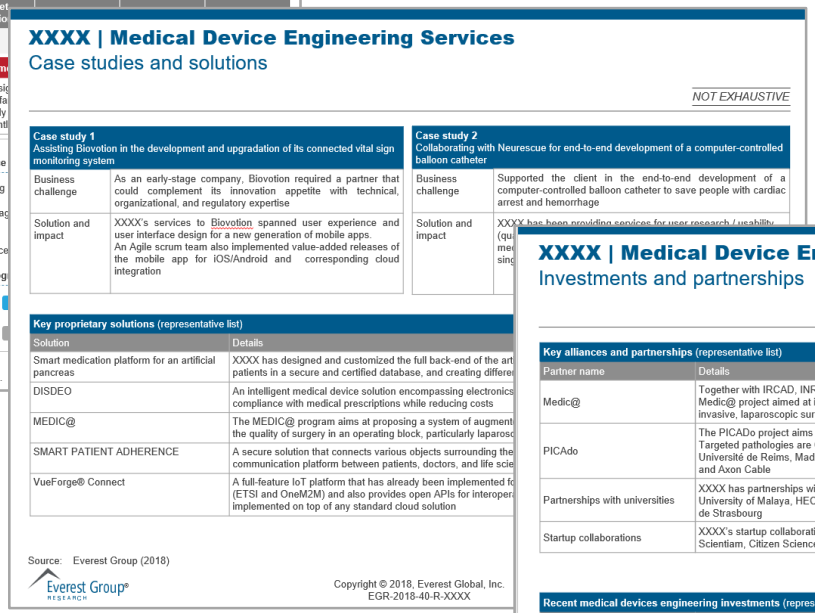

XXXX | Medical Device Engineering Services
Case studies and solutions

NOT EXHAUSTIVE

Case study 1
Assisting Biovotion in the development and upgradation of its connected vital sign monitoring system

Business challenge	As an early-stage company, Biovotion required a partner that could complement its innovation appetite with technical, organizational, and regulatory expertise
Solution and impact	XXXX's services to Biovotion spanned user experience and user interface design for a new generation of mobile apps. An Agile scrum team also implemented value-added releases of the mobile app for iOS/Android and corresponding cloud integration

Case study 2
Collaborating with Neurescue for end-to-end development of a computer-controlled balloon catheter

Business challenge	Supported the client in the end-to-end development of a computer-controlled balloon catheter to save people with cardiac arrest and hemorrhage
Solution and impact	XXXX has been providing services for user research / usability

Key proprietary solutions (representative list)

Solution	Details
Smart medication platform for an artificial pancreas	XXXX has designed and customized the full back-end of the art patients in a secure and certified database, and creating differe
DISDEO	An intelligent medical device solution encompassing electronics compliance with medical prescriptions while reducing costs
MEDIC@	The MEDIC@ program aims at proposing a system of augment the quality of surgery in an operating block, particularly laparosc
SMART PATIENT ADHERENCE	A secure solution that connects various objects surrounding the communication platform between patients, doctors, and life scie
VueForge® Connect	A full-feature IoT platform that has already been implemented fo (ETSI and OneM2M) and also provides open APIs for interoper implemented on top of any standard cloud solution

Source: Everest Group (2018)

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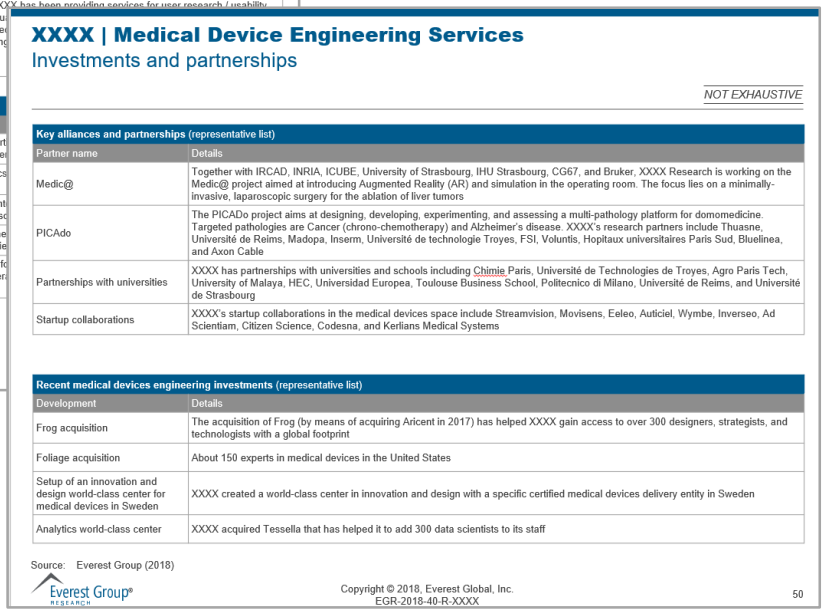

XXXX | Medical Device Engineering Services
Investments and partnerships

NOT EXHAUSTIVE

Key alliances and partnerships (representative list)

Partner name	Details
Medic@	Together with IRCAD, INRIA, ICUBE, University of Strasbourg, IHU Strasbourg, CG67, and Bruker, XXXX Research is working on the Medic@ project aimed at introducing Augmented Reality (AR) and simulation in the operating room. The focus lies on a minimally-invasive, laparoscopic surgery for the ablation of liver tumors
PICAdo	The PICADo project aims at designing, developing, experimenting, and assessing a multi-pathology platform for domomedicine. Targeted pathologies are Cancer (chrono-chemotherapy) and Alzheimer's disease. XXXX's research partners include Thuasne, Université de Reims, Madopa, Inserm, Université de technologie Troyes, FSI, Voluntis, Hopitaux universitaires Paris Sud, Bluelinea, and Axon Cable
Partnerships with universities	XXXX has partnerships with universities and schools including Chimie Paris, Université de Technologies de Troyes, Agro Paris Tech, University of Malaya, HEC, Universidad Europea, Toulouse Business School, Politecnico di Milano, Université de Reims, and Université de Strasbourg
Startup collaborations	XXXX's startup collaborations in the medical devices space include Streamvision, Movisens, Eeleo, Auticiel, Wymbe, Inverseo, Ad Scientiam, Citizen Science, Codesna, and Kerlians Medical Systems

Recent medical devices engineering investments (representative list)

Development	Details
Frog acquisition	The acquisition of Frog (by means of acquiring Aricent in 2017) has helped XXXX gain access to over 300 designers, strategists, and technologists with a global footprint
Foliage acquisition	About 150 experts in medical devices in the United States
Setup of an innovation and design world-class center for medical devices in Sweden	XXXX created a world-class center in innovation and design with a specific certified medical devices delivery entity in Sweden
Analytics world-class center	XXXX acquired Tessella that has helped it to add 300 data scientists to its staff

Source: Everest Group (2018)

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Research calendar – Engineering Services (ES)

Published | Planned | Current release

Flagship engineering services reports	Release date
Leading the Pack: Trends for the Top 200 Engineering Research & Development (ER&D) Enterprises	May 2018
Embedded System Engineering Services – Service Provider Landscape with PEAK Matrix™ Assessment 2018	August 2018
Verification and Validation (V&V) Engineering Services PEAK Matrix™ Assessment 2018: Building Differentiated Product Experience Through Intelligent Quality Engineering	August 2018
Medical Device Engineering Services PEAK Matrix™ Assessment 2019: Navigating the Innovation and Compliance Conundrum	**December 2018**
Software Product Engineering Services PEAK Matrix™ Assessment 2019	Q1 2019
Automotive Engineering Services PEAK Matrix™ Assessment 2019	Q1 2019

Thematic engineering services reports	
Top 20 Software Engineering Trailblazers – The DevOps Enablers	January 2018
Additive Manufacturing – Defining New Frontiers in Digital Manufacturing	March 2018
Supply Chain Excellence – Demystifying the Digitalization Journey	April 2018
Engineering Services Global In-house Centers (GICs) In India: Focusing on Innovation to Drive Growth and Attain Global Leadership	October 2018
The Imminent Wave of Consolidation in Industry 4.0	Q4 2018

Note: For a list of all ES reports published by us, please refer to our website page

Additional Engineering Services research references

The following documents are recommended for additional insight on the topic covered in this report. The recommended documents either provide additional details or complementary content that may be of interest

1. **Additive Manufacturing – Defining New Frontiers in Digital Manufacturing** (EGR-2018-40-R-2590); 2018. This report presents an assessment of additive manufacturing in terms of its key enterprise benefits, emerging applications, industry maturity & use cases, and growth potential. It also includes recommendations for both enterprises and service providers to leverage additive manufacturing in order to accelerate growth

2. **Embedded System Engineering Services PEAK Matrix™ Assessment: Enabling the Era of Connected and Intelligent Products** (EGR-2018-40-R-2742); 2018. As connected ecosystems gain precedence, embedded system engineering is assuming center stage in enabling the development of intelligent products and services. In this research, we present fact-based trends impacting the embedded system engineering services market along with the assessment and detailed profiles of 14 service providers featured on the embedded system engineering services PEAK Matrix

3. **Verification and Validation (V&V) Engineering Services PEAK Matrix™ Assessment 2018: Building Differentiated Product Experience Through Intelligent Quality Engineering** (EGR-2018-40-R-2741); 2018. In this report, we analyze the capabilities of 14 leading engineering service providers in the V&V segment. We have also captured the key trends and digital technologies disrupting the V&V market, and related investments made by service providers

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