CORE COMPETENCIES STAYING COMPETITIVE IN THE MEDICAL DEVICE INDUSTRY

OUTSOURCING HELPS MEDICAL COMPANIES FILL PROFICIENCY GAPS AND KEEP PACE WITH INNOVATION

> **Reduced time-to-market, time-to-volume, time-to-profit and maintaining the highest quality** in all capacities are constant medical OEM goals.

// Regulations and certifications of medical devices are rapidly evolving and expanding worldwide subjects that can add complexity in getting a product to market.

This whitepaper explains what factors are driving the growth in the medical device industry, and how these market dynamics have led to an increased demand for outsourcing of noncore OEM competencies and processes to reliable partners. It will present the many ways outsourcing can help OEMs minimize technology investments and integration efforts to accelerate time-to-market and increase their ROI. The attributes required in an ideal outsourcing partner are also discussed.

THE PACE OF MEDICAL INNOVATION

Staying competitive calls for medical equipment OEMs to constantly keep pace with the speed of innovation. Better medical treatment and care can be achieved with fast, accurate results from advanced imaging applications such as CT scanning and MRI that process and analyze large amounts of data, requiring developers to build devices that deliver ever-increasing computing performance. Supporting this demand, high performance embedded computing platforms that utilize the latest faster and more efficient processors are essential in helping OEMs keep up with the enhanced performance requirements.

However, getting a new medical device to market and meeting computing technology requirements is more complex than just replacing a processor or computer board. As medical equipment companies have realized, the list of challenges can be quite long.

The design cycle is a multi-layered process that can lead to higher overall development costs and less profitability if not managed properly. Does the company have sufficient internal engineering resources to deliver a successful design and do they possess embedded computing knowledge? In addition, designs must meet an increasing number of global medical regulations, certifications and technology standards. Direction is also necessary for risk management that efficiently synchronizes technologies and suppliers worldwide.

Market and competitive pressures are always concerns so reduced time-to-market, time-to-volume, time-to-profit and maintaining the highest quality in all capacities are constant medical OEM goals. Working against these objectives are shorter product lifecycles and shrinking market windows combined with consumer expectations for higher levels of technology sophistication. Also, managing development, manufacturing and support costs in this market is not an easy task making ongoing efficiency improvements in these areas a crucial need. That is why most successful medical OEMs practice 'lean' processes allowing them to remain focused on their core competencies.

With all that is required to launch a successful product today, and the changing market dynamics of the healthcare industry, outsourcing in the medical device industry is becoming a growing trend.

THE GOOD REASONS TO OUTSOURCE

Trends in Medical

The ongoing trend in the medical equipment market is that designs are becoming more complex. In turn, these complex designs are requiring more advanced technologies such as those necessary to process the massive amount of data the healthcare industry produces while also giving medical professionals secure and detailed information at the right point in time to cure diseases and improve patients' lives. Along with these complexities are a diverse set of regulatory requirements in multiple markets. There is a need as well for increased access to quality healthcare worldwide combined with the requirement to keep costs low and efficiencies high. Medical device companies also see revenue benefits to expanding globally. The challenges the medical industry is facing today are enormous.

Providing expertise that OEMs may lack, proven outsourcing companies are a welcome resource offering needed technology, management, manufacturing and regional knowledge essential to medical device development and market success. Freeing OEMs to focus on what they do best enabling them to create innovative and differentiated healthcare solutions, outsourcing services from a trusted advisor and partner help solve a host of go-to-market problems such as those encountered in a company's R&D, Quality Management, Regulatory Affairs, testing and production processes.

Outsourcing is valuable for small and startup device companies that have limited development budgets, personnel resources and infrastructure. But outsourcing design and manufacturing services are also helpful for large organizations. Larger companies can use outsourcing to help them be more agile and reduce costs in areas such as vertical integration, device certification or even as a resource for various development functions from software to application testing. Where outsourcing companies can show their worth is in helping medical OEMs shorten design, development and time-to-volume production enabling them to capture first-to-market advantages in the form of market share leadership that justifies premium pricing.

Reflecting this trend, medical device outsourcing is projected to reach $44.7 billion by 2017, according to Global Industry Analysts, Inc. In addition, analyst firm Transparency Market Research has a similar estimation, predicting that the global medical devices outsourcing market will grow at a Compound Annual Growth Rate (CAGR) of 11.6% between 2012 and 2018, and is likely to reach US$40.8 billion by 2018.

## WHAT TO LOOK FOR IN AN OUTSOURCING PARTNER

Longevity for innovative and sustainable healthcare solutions

Computing technology can make or break a new device design. Consequently, access to the latest processor architectures and standards-based computer solutions that offer long-term availability is a valuable asset for medical OEMs. Along with technology architecture longevity, outsourcing companies need to assure their medical customers of their ability to manage extended product lifecycles. In addition, they must be able to supply scalable, modular platforms that permit simultaneous use of components enabling OEMs to create innovative and sustainable healthcare solutions with minimum investment and integration effort. A supplier of scalable hardware solutions makes it easier for medical device developers to address different market needs and performance levels from a single basic design. To support advanced technologies, the best outsourcing companies also demonstrate their global engineering expertise and continuous medical innovation capabilities.

For devices to be successful, market windows need to be met enabling OEMs to achieve their profitability goals. Therefore, it is a necessity that outsourcing partners show established experience in helping medical OEMs reduce time-to-market and manage budget constraints. Subsequently, effective development partners must obviously possess a thorough understanding of all the aspects of getting a product to market including its regulations and certification requirements.

Expertise in the regulatory environment

The intricacy of medical device design and manufacturing demand an outsourcing partner that can help navigate through the often complicated regulatory environment. Partners must be familiar with the requirements and life-cycle management for regulatory systems from the FDA, CE, CFDA, PMDA and ANVISA as well as various import constraints that require a diverse range of activities and certifications to verify compliance. Furthermore, regulations and certifications of medical devices are rapidly evolving and expanding worldwide subjects that can add complexity in getting a product to market. Outsourcing suppliers that support medical OEMs with this level of expertise are instrumental in helping them achieve faster time-to-market and the leadership benefits that come with it.
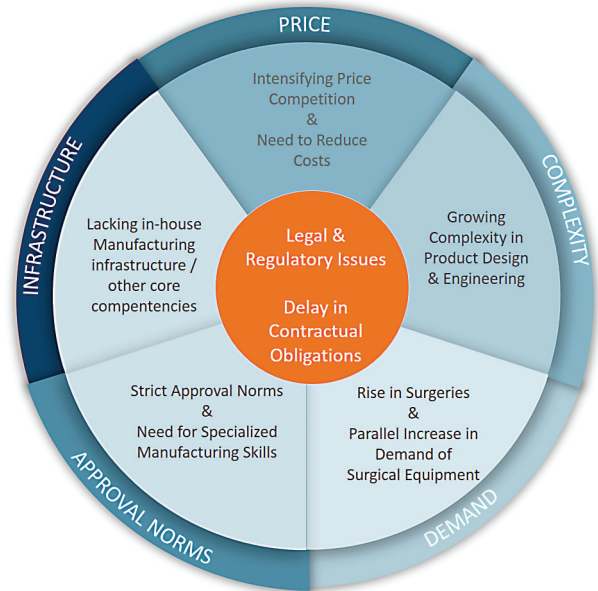
// The global market for medical device outsourcing services is growing, fueled by multiple factors.

WORKING WITH KONTRON: VALUE-ADDED BENEFITS

Meeting profitability goals

With the many outsourcing models and options available, it is important that medical device OEMs find the right partner that will best suit their go-to-market needs. High on the list of outsourcing services for OEMs is a partner that can help them meet the constant pressure to deliver higher levels of technology sophistication while also meeting shrinking market windows and improving time-to-market and time-to-profit.

With decades of experience in bringing medical designs quickly to market, Kontron is recognized as providing trusted, proven and knowledgeable outsourcing services. Ensuring complex application requirements are met, medical OEMs benefit from the company's full design capabilities that encompass Commercial Off the Shelf (COTS) and modified standards to full custom capabilities that inherently provide the system compatibility, development flexibility and product longevity required in the healthcare industry.

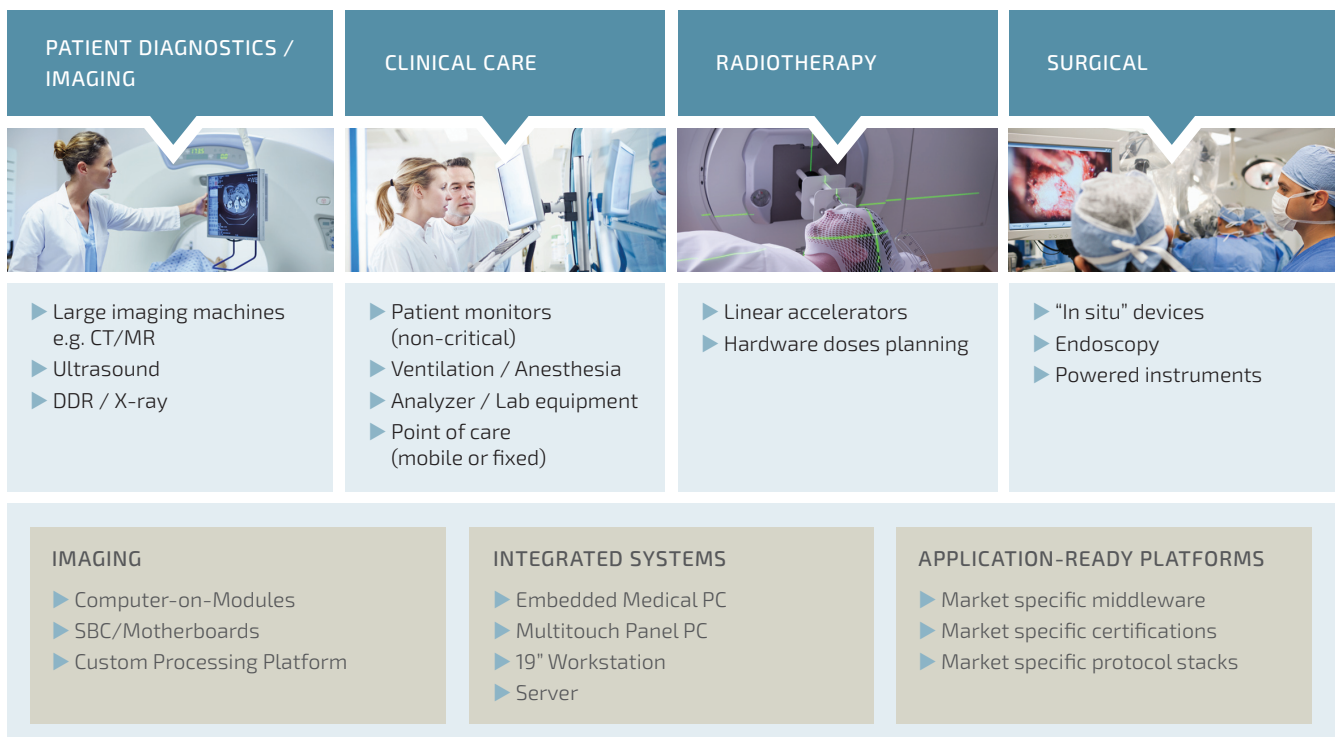## Customization with modified standard building blocks

Kontron's proven standard product portfolio provides a strong foundation for the development of customized embedded medical computing solutions that can supply measurable cost advantages for OEM customers. Advantages are gained by the cost-effective re-use of existing technology as well as from custom designs that use mature, established products helping them avoid additional costs for each design iteration or specification change. Reuse of these demonstrated technologies also enable shorter development times that result in valuable time-to-market advantages. Furthermore, with increasingly complex OS support, BSPs and middleware, which many OEMs consider the most important cost and competitive factors of a design, the basic functionalities are already financed through the use of standard products with the added confidence that they have been validated repeatedly in countless applications.

Decades of experience

Research and Development (R&D) is a critical part of creating next-generation medical devices that can improve healthcare solutions for patients. Embedded computing technology is a basic, yet important, part of any new design. However, the development of embedded computers is often not among the core competencies of medical device manufacturers. Today's rapid design cycles many times call for engineering expertise with faster, more efficient processors and higher performing computing solutions. Selecting Kontron as an outsourcing partner with its wealth of design experience allows OEMs to minimize their hardware and software investments enabling them to maximize ROI. And, by leveraging Kontron's embedded computing market leadership position with its specialized medical industry expertise, also helps OEMs to continually keep pace with the speed of technology with the help of a readily available, knowledgeable and reliable outsourcing partner.

From patient care, diagnostics/imaging, radiotherapy and surgical devices, Kontron has experience in all areas of medical device development. Assisting OEMs to precisely meet their product requirements and time and budgetary constraints, OEMs get to market faster with reduced total cost of ownership and ensured product longevity.

PATIENT DIAGNOSTICS / IMAGING	CLINICAL CARE	RADIOTHERAPY	SURGICAL
▶ Large imaging machines e.g. CT/MR ▶ Ultrasound ▶ DDR / X-ray	▶ Patient monitors (non-critical) ▶ Ventilation / Anesthesia ▶ Analyzer / Lab equipment ▶ Point of care (mobile or fixed)	▶ Linear accelerators ▶ Hardware doses planning	▶ "In situ" devices ▶ Endoscopy ▶ Powered instruments

IMAGING
- ▶ Computer-on-Modules
- ▶ SBC/Motherboards
- ▶ Custom Processing Platform

INTEGRATED SYSTEMS
- ▶ Embedded Medical PC
- ▶ Multitouch Panel PC
- ▶ 19" Workstation
- ▶ Server

APPLICATION-READY PLATFORMS
- ▶ Market specific middleware
- ▶ Market specific certifications
- ▶ Market specific protocol stacks

// OEMs can rely on Kontron's vast experience in all areas of medical device development including patient care diagnostics/imaging, radiotherapy and surgical devices.

Life-critical - quality

Quality is an essential asset of a medical device as it is necessary to maintain the healthcare industry's life-critical commitment. To allay concerns about regulatory and quality issues, partnering with Kontron provides efficiencies gained from a strong and controlled supply chain. The company has demonstrated proficiency in controlling a multitude of components and materials, each with specific requirements, associated standards and applicable regulations. For instance, Kontron facilities follow the required process standards for medical devices or are ISO 13485 certified. In addition, Kontron products are certified to UL specifications (CSA, CQC, VDE and TÜV geprüfte Sicherheit).
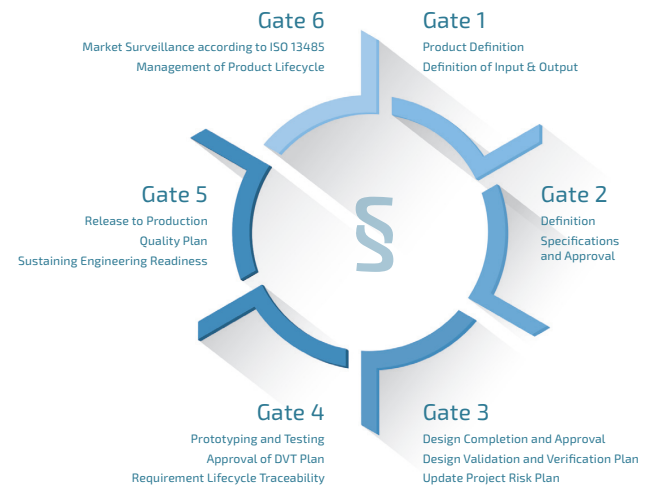
Its consistent performance, effective program monitoring, structured testing and stringent process execution per regulatory and customer mandates attests to Kontron's meticulous attention to quality. Through its continuous improvement projects, Kontron actively implements ongoing enhancements to processes, products and services both with customers and suppliers. For example, Kontron's comprehensive proactive Corrective and Preventive Action (CAPA) process is applied for any complaint or non-compliance following the 8D methodology for problem solving supported by the CAPA tool so that it can take quick action to identify, correct and eliminate recurring issues. In regular quality reviews with customers and suppliers, root causes are discussed and corrective actions are jointly defined and executed to improve the key asset of a medical product – quality.
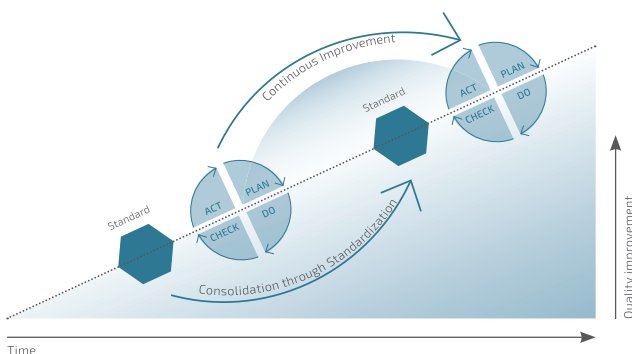
// Kontron's global quality data warehouse supports proactive corrective and preventative processes applied for all services including compliant management that require product monitoring and analysis.

Experienced Lifecycle Management for ensured long-term availability

Shorter time-to-market is attained, supported by Kontron's responsive engineering teams and knowledgeable lifecycle management. At the same time, medical devices have to be available long-term (sometimes well over a decade) and span several generations of a technology platform. Kontron's medical experts understand the importance of component selection that must cover the product's complete lifecycle since this is critical for success. Using the lifecycle management skills at Kontron, OEMs are assured of continuous support and maintenance to assist them in controlling these necessary functions that may not be one of their core competencies. Plus, Kontron is a knowledgeable asset that can recommend cost-effective manufacturing processes and resources.

Gate 6
Market Surveillance according to ISO 13485
Management of Product Lifecycle

Gate 1
Product Definition
Definition of Input & Output

Gate 5
Release to Production
Quality Plan
Sustaining Engineering Readiness

Gate 2
Definition
Specifications and Approval

Gate 4
Prototyping and Testing
Approval of DVT Plan
Requirement Lifecycle Traceability

Gate 3
Design Completion and Approval
Design Validation and Verification Plan
Update Project Risk Plan

// Kontron adheres to a fully defined gate process that takes products from the product definition phase to release to production and extended lifecycle management.

Global influence, local support

Kontron is able to provide added value through its global technology hubs in Europe, Asia and North America. This worldwide presence enables same time-zone technical support and more personalized service which facilitates cost reductions and more efficient processes.

As an embedded computing leader, Kontron has forged outstanding partnership alliances with some of the leading technology companies giving customers access to the latest technologies and products. Advance knowledge from these alliances (e.g. Intel® Internet of Things Solutions Alliance) means medical device developers are informed of upcoming processor architecture, software, operating system and component innovations so they can be prepared and make intelligent decisions about future application needs and when upgrades make the most sense.

GET TO MARKET FASTER WITH YOUR LEADING-EDGE DESIGNS

With its established deep understanding of the medical market, Kontron is the trusted outsourcing partner that can help ensure medical device design success. Using Kontron for outsourcing non-core, yet necessary services allow medical OEMs to maximize performance and focus specifically on their differentiated business and product strengths. By utilizing the extended list of proficiencies and capabilities Kontron provides that are outside their primary area of expertise, OEMs gain lean business and cost-cutting advantages from Kontron's services in essential areas of quality, certifications, R&D, lifecycle and supply chain management, testing and manufacturing.

Kontron also helps OEMs achieve additional design flexibility and product scalability from its range of COTS, modified standards and full customization products and capabilities. They benefit, too, from highly experienced technical teams worldwide, with regional service that can be relied on locally to solve problems in real time. Peace of mind and the ability to reduce design issues are gained from quality certifications and industry-leading support that comes from proven performance and successful customer programs.

Partnering with Kontron assists medical OEMs in streamlined integration of the latest technologies that add device functionality and ease of use creating a new generation of connected healthcare systems that match growing Internet of Things (IoT) requirements. Utilizing Kontron's comprehensive range of outsourcing services, sophisticated medical OEMs get the knowledgeable resources they need to create these innovative healthcare solutions, reduce resource costs and attain the agility necessary to compete more successfully.

Just click on the "product bubble" and find out mor about products and services.

// Kontron supports you with a medical proficiency gained over two decades and offers comprehensive service and solutions that meet demanding medical needs.

▶ www.kontron.com/medical-platforms

About Kontron – An S&T Company

Kontron is a global leader in embedded computing technology (ECT). As a part of technology group S&T, Kontron offers a combined portfolio of secure hardware, middleware and services for Internet of Things (IoT) and Industry 4.0 applications. With its standard products and tailor-made solutions based on highly reliable state-of-the-art embedded technologies, Kontron provides secure and innovative applications for a variety of industries. As a result, customers benefit from accelerated time-to-market, reduced total cost of ownership, product longevity and the best fully integrated applications overall.

Kontron is a listed company. Its shares are traded in the Prime Standard segment of the Frankfurt Stock Exchange and on other exchanges under the symbol "KBC". For more information, please visit: **www.kontron.com**

About the Intel® Internet of Things Solutions Alliance

From modular components to market-ready systems, Intel and the 400+ global member companies of the Intel® Internet of Things Solutions Alliance provide scalable, interoperable solutions that accelerate deployment of intelligent devices and end-to-end analytics. Close collaboration with Intel and each other enables Alliance members to innovate with the latest IoT technologies, helping developers deliver first-in-market solutions.

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