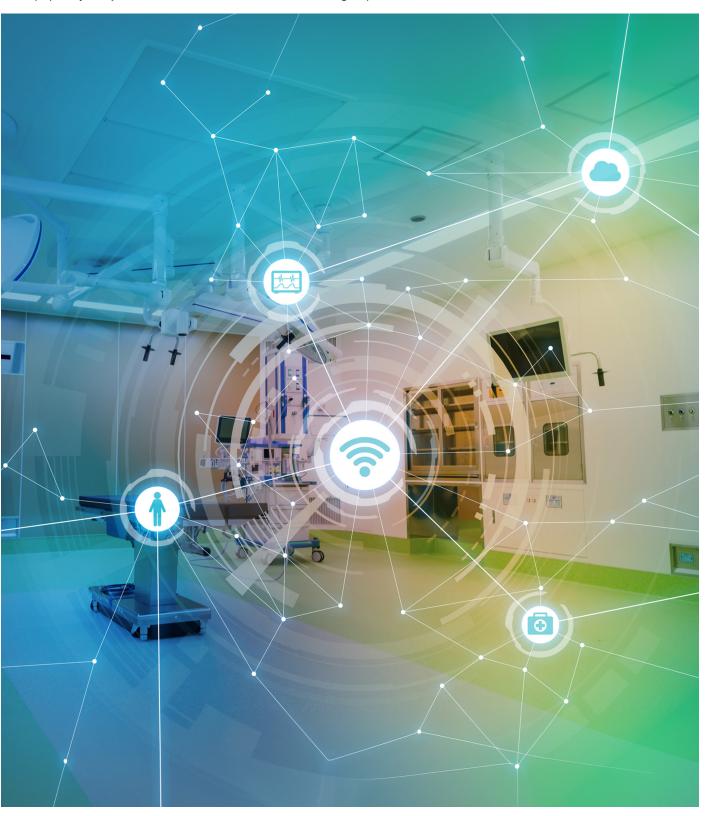


Why MedTech Companies Need to Adopt a Smart Product Sustenance Approach

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1.

Introduction

While a medical device OEM's (Original Equipment Manufacturer) growth and success are usually driven by innovation, it is its existing mature products that form the backbone of the company's present and future financial existence. The challenges of increasing cost pressures and long cycles of regulatory approvals in the medical devices industry call for its players to increase the lifespan of their existing products. This is where sustenance engineering becomes integral and key to continued success and growth. In the likely scenario that mature products may still be contributing substantially to their revenues (due to an established market), it makes immense sense for medical device companies to sustain the engineering of their products and extend their lives to maximize profits.

Typical sustenance engineering activities include:

- Incremental changes to incorporate customer feedback or introduce new features
- · Standard maintenance/bug fixes to make the product defect-free
- Obsolescence management
- Regulatory compliance updates

Product sustenance can become really challenging when the number of users of legacy/mature products is large. This is especially true when you need to keep upgrading to provide modern user experiences and maintain the scalability, performance and security of the product. Evolving regulatory requirements (from regulatory authorities like US FDA or EU MDR, etc.) can further exacerbate these challenges, requiring added focus on safety, data integrity and product security.

Since medical device OEMs have to balance their R&D budgets across both new product development and sustaining activities, it can be really challenging to keep their highly skilled resources confined to the sustenance program. The right balance needs to be struck between budgets and due consideration to their best talent's career progression needs and job satisfaction.

2.

The Tightrope Walk between New Product Introduction (NPI) and Mature/Legacy Products

Medical devices have long lifecycles and medical device OEMs must effectively balance investment across NPI and mature products. Sustenance programs at MedTech companies can often consume the bandwidth of highly skilled resources (~20-25 percent of the research and development teams). Ideally, they should be using their skills and experience for new product development; however, they often get pulled into the sustenance of mature products due to the lack of alternatives. This can impact both the organization's future and the career progression of its employees.

Sustaining projects may not always require the same level of complexity and innovation as new development projects. Thus, when a company's highly skilled engineers are assigned to sustenance tasks for long periods of time, it can negatively affect their morale and job satisfaction, potentially leading to reduced productivity and even attrition in the team. Plus, placing the best and brightest engineering talent in sustaining activities can drive up the cost of sustenance projects for most OEMs.

3.

Critical Role of Product Sustenance in the Longevity of MedTech Products

Medical device software products have long life spans and are built with many legacy and heterogeneous technologies. This impacts their maintainability and viability. Product sustenance is a continuous and dynamic process that ensures medical devices remain safe, effective and relevant throughout their lifecycle. Product sustenance services refer to the ongoing support and maintenance activities that product companies (e.g., a medical device or SAMD product organizations) provide to their customers after a product is released to the market. These services include bug fixing, performance optimization, security patches — and sometimes feature enhancements that are necessary to keep the product functioning optimally and meeting the customer's evolving needs.

Often, at a mature stage, products generally do not need disruptive or transformational innovation, but rather incremental ones, smaller updates and standard product maintenance. With changing customer needs, software products must evolve to keep up, despite the reality of cessation of active support for certain legacy technologies (necessitating the transition to new technologies). Product sustenance services help companies identify and implement new features and enhancements, and modern UI/UX to meet changing customer needs and stay ahead of the competition.

Overall, companies must ensure that their customers continue to have a positive experience with the product by addressing the following key aspects during sustenance engineering:

- **Regular Maintenance:** Maintaining product quality is critical for building trust with healthcare providers and patients. Sustaining the product involves rigorous quality testing before every release, fixing internal or customer reported defects in a timely manner and ensuring consistent high-quality experience.
- Software Updates and Security: Regular software updates are crucial to address customer feedback on the device, efficacy of the clinical software, resolution of bugs and vulnerabilities, and maintain/improve the device performance. MedTech companies need to continually evaluate and mitigate vulnerabilities that could compromise the quality or security of the device. The security of the software is critical to prevent unauthorized access to the device and causing potential harm to patients.

- Adaptation to Market Needs: MedTech industry requirements and customer needs evolve
 over time. Sustaining a medical device involves gathering feedback from users and medical
 professionals (e.g., doctors, nurses, technicians, etc.) and aligning them to changing market
 demands. Regular updates and new features need to be added to make the product more
 competitive and compelling to users.
- Modernization: Software modernization plays a crucial role in the sustenance of medical
 devices and products. Technology evolves over time and new technologies rapidly emerge.
 Modernization enables the integration of these advancements into the medical device and keeps
 its software component relevant, secure and effective. This ensures that the product continues to
 perform optimally despite the changing technology landscape.
- Regulatory Compliance: Medical devices are subject to strict regulations and standards to
 ensure their effectiveness and safety. Product sustenance involves continuous monitoring and
 providing updates to hardware and software to comply with evolving regulatory requirements.
 Failure to meet compliance needs may result in product recalls, legal issues and damage to the
 company's reputation.
- Obsolescence Management: During the long lifecycle that mature products may have, component obsolescence can become a concern as certain parts or third-party software may no longer be supported. Sustaining the product involves managing obsolescence by finding suitable replacement components or updating the device's design.

4.

Towards a Smart Product Sustenance Approach

Medical device OEMs should undertake an objective review of their core competencies. What aspects of their product portfolio can they keep in-house? For which aspects can they engage with partners who can meet essential, but non-core needs? Are emerging technology skills (cloud, analytics, etc.) part of their core competencies? Where do they need external help to upgrade their products in today's digital healthcare era?

These are vital questions to answer. OEMs must seek partners with the required engineering expertise for sustaining projects at a lower cost—while maintaining the same level of quality achieved with their in-house engineering talent.

Outsourcing to a qualified provider creates immense possibilities. OEMs can move their top talent to innovation-focused projects. At the same time, they can maintain the high quality of existing products to retain customer trust and preserve the product's acceptance in demanding markets. The right partner also brings in enough experience to introduce other cost-saving strategies for better margins, while maintaining customer commitment schedules.

In summary, outsourcing product sustenance to partners in the MedTech industry can offer several advantages.

- Skilled resources utilization for critical innovation projects
- Focus on core competencies while outsourcing non-core activities

- Tap the expertise of external partners with a dedicated focus on sustenance
- Leverage cost-efficiency for sustenance projects
- Flexibility in scaling up or down of sustenance staff based on changes in the org. priorities
- Reduce risks associated with compliance and security through specialized providers



5.

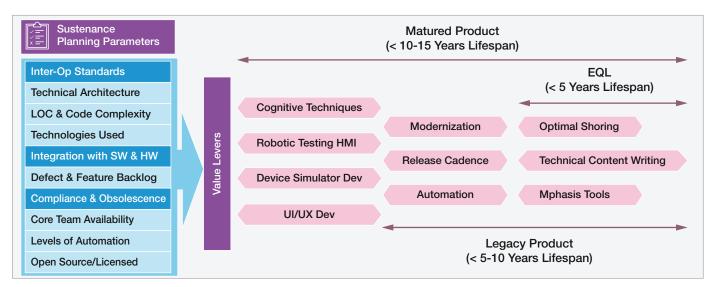
MedTech Product Sustenance Services – Why Mphasis?

With more than two decades of domain and technology expertise, Mphasis' products sustenance team helps companies to focus on innovation, customer acquisition, and new product development, while taking end-to-end ownership of products. We help OEMs to extend the life of their revenue-generating products through cost-saving sustenance solutions without compromising on customer SLAs. Our sustenance approach and proven transition process efficiently manage the entire product lifecycle with zero disruption.

Our robust Product Sustenance Engineering (M-PROSE) framework classifies product as mature, legacy and EOL, and applies the right set of solution levers.

Benefits of M-PROSE include:

- Risk-free transition
- Enabling Application Modernization to migrate to newer technologies
- Upgrading development and testing platforms
- Enhancing delivery processes
- Applying cognitive techniques to enhance end user experience
- Reduction of overall TCO



Successful implementation of this product sustenance framework is based on the following key tenets:

- Enable development platform e.g., Dev. Methodology, DevOps CI/CD pipelines, etc.
- Deploy test strategy e.g., type of testing, test automation, etc.
- · Implement defect fix and feature enhancements
- Maintain regulatory compliance (e.g., FDA/MDR) &
- · Ensure process update and alignment

Our enablers and differentiators are many. Key among them are:

- Wave-based transition framework to de-risk transition
- · Zero disruption during the transition and in end-client services
- Evidence-based design thinking workshops to enhance UX and product features
- Simulators to handle non-availability of instruments
- Client University model for knowledge retention and management

6.

Conclusion

Medical device companies must find ways to focus on their core competencies and work with a qualified partner with expertise in product sustenance solutions. This will effectively balance their product portfolio. Product sustenance involves a multitude of activities to deliver the highest levels of customer experience. It is therefore important to engage with the right partner who brings the perfect balance of MedTech domain capabilities and sustenance engineering skills. Mphasis, with its proven M-PROSE framework and risk-free transition model, is well positioned to help you in successfully balancing your product sustenance programs with NPI initiatives to save costs and ensure that your top talent is rightfully engaged.

7.

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Ranjeet Marawar has more than 20 years' experience in Product Engineering, R&D and Solutioning for the MedTech Industry and he is part of the MedTech solutioning group within Mphasis. His specializations include medical device software engineering, medical imaging, Al/Machine Learning, Generative Al, connected health and MedTech practice. He is responsible for MedTech industry new offerings/solution building, thought leadership and nurturing client engagements. Ranjeet holds a M.Tech. degree in Biomedical Engineering from Indian Institute of Technology (IIT), Mumbai.

About Mphasis

Mphasis' purpose is to be the "Driver in the Driverless Car" for Global Enterprises by applying next-generation design, architecture and engineering services, to deliver scalable and sustainable software and technology solutions. Customer centricity is foundational to Mphasis, and is reflected in the Mphasis' Front2Back™ Transformation approach. Front2Back™ uses the exponential power of cloud and cognitive to provide hyper-personalized (C = X2C³ = 1) digital experience to clients and their end customers. Mphasis' Service Transformation approach helps 'shrink the core' through the application of digital technologies across legacy environments within an enterprise, enabling businesses to stay ahead in a changing world. Mphasis' core reference architectures and tools, speed and innovation with domain expertise and specialization, combined with an integrated sustainability and purpose-led approach across its operations and solutions are key to building strong relationships with marquee clients. Click here to know more. (BSE: 526299; NSE: MPHASIS)

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