

PRODUCT ENGINEERING SERVICES

Research | Design | Deploy

Trending

The medical devices industry is going through a disruption due to the consumer interest in digital technologies, stringent focus on patient safety and data security, and rising need of innovation in the underlying technology of the device.

Miniaturization and integration of technologies are two of the leading innovation themes in the industry. The OEMs are increasingly focusing on launching holistic solutions with the medical device, which can be seamlessly integrated into the customer's workflow to enhance user experience and improve operational efficiency.

While regulatory bodies have become more receptive to innovations, they still require comprehensive risk management to ensure critical aspects such as patient safety, data security, device reliability, etc. to be thoroughly addressed.

Opportunities & Challenges

Launching superior products in the market

With the increasing burden on the healthcare service providers and escalating healthcare service cost, consumers are inclined towards solutions which reduce their workload and improve clinical outcomes.

Improving device reliability, performance, and safety

Patient safety is of prime importance to all stakeholder in the value chain. The OEMs are required to ensure that the device meets high-quality standards.

Sustaining products in the market

A substantial NRE cost is associated with introducing a new device in the market. However, the product lifecycle is highly dependent on the factors such as innovations, technology penetration, and regulatory requirement changes. OEMs are required to make their devices and solutions future ready to minimize the impact of changing market dynamics.



Benefits Sought by the OEMs

- High performance and technologically advanced devices significantly improve patient outcomes
- Cost-sensitive devices enable a reduction in the overall healthcare service cost
- Meaningful workflow solutions ease the patient burden on the healthcare service providers and further improves operational efficiency
- Consolidated platforms with additional applications and greater functionalities reduce multiple device dependencies

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Development Cycle



Segments



Differentiators

- 15+ years of Industry practice
- ISO 13485:2016 design facilities
- QMS aligned to meet ISO 14971, IEC 62366, IEC 62304, 21 CFR Part 820 and EU regulations
- Class II and III device development experience
- Flexible engagement models conducive for innovation & research-led product engineering
- COEs for digital technologies
- Strategic partnerships with a large group of suppliers
- In-house prototyping and testing facilities

Cases

A point-of-care diagnostic device for malaria and sickle cell disease screening

- Complete product development ownership
- Connected device with a portable design for mass screening
- Clinical validation support through ecosystem partners

High-power laser-based therapeutic device development

- Comprehensive Project Management leading to € 150,000 saving on R&D expenditure
- Future-ready product for up-coming compliance requirements
- Technical file documentation support