TATA ELXSI

PRODUCT ENGINEERING SERVICES

Research | Design | Deploy

Trending

The global medical device industry is expected to grow at a CAGR of over 5% between 2017-2024 to reach USD 600 billion*. This growth will be fueled by factors such as focus on value-based care, consumer interest in digital technologies with emphasis on patient safety and data security, and technological innovations leading to safer and effective devices.

Miniaturization and integration of technologies are two of the leading innovation themes in the industry. Companies are increasingly focusing on launching holistic solutions with medical devices, which can be seamlessly integrated into the consumer'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.

**PR Newswire-2019*

Opportunities & Challenges

Launching superior and differentiated products in the market

With the increasing burden on healthcare service providers and escalating healthcare service cost, medical device manufacturers are inclined towards launching solutions that reduce the workload and improve clinical outcomes for their consumers.

Improving device reliability, performance, and safety for better patient outcomes

Patient safety is of prime importance to all stakeholders in the value chain. Companies are required to ensure that the devices meet 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 factors such as innovations, technology penetration and regulatory requirement changes. Companies are required to make their devices and solutions future ready to minimize the impact of changing market dynamics.

Benefits for consumers

- High performance and technologically advanced devices to significantly improve patient outcomes
- Affordable devices with meaningful workflow solutions for reduced overall healthcare service cost to patient
- Post-market solutions for improved turnaround time and reduced device downtime
- Functionality-rich consolidated platforms to reduce multiple device dependencies

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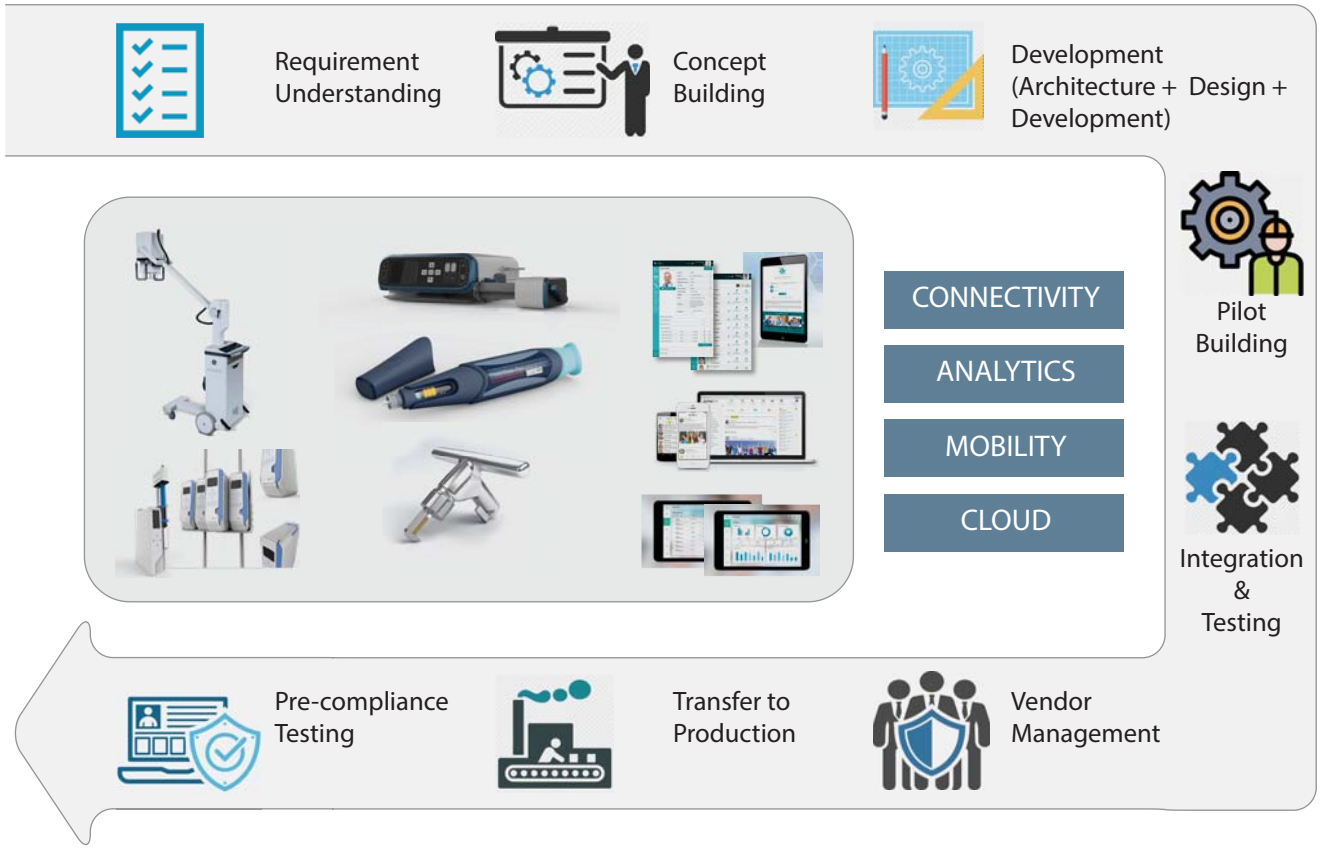
Development Cycle



Segments

Medical Imaging | In-vitro Diagnostics | Monitoring | Therapeutics | Surgicals & Disposables | Telehealth | Wearables | Software Solutions

Differentiators

- 15+ years of industry practice
- ISO 13485:2016 certified global 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
- COEs for digital technologies such as Artificial intelligence, Internet of Medical Things, and Augmented/ Virtual/ Mixed Reality
- Prototyping and testing facilities

Cases

A point-of-care in-vitro diagnostic device for malaria and sickle cell disease screening catering to the needs of emerging markets

- Complete product development ownership from market research to design transfer for manufacturing
- Connected device (WiFi, BLE) with a portable design for mass screening
- Clinical validation support through ecosystem partners

High power laser based therapeutic device reengineering

- End-to-end product lifecycle management and regulatory support
- Comprehensive project management leading to USD 165,000 saving on R&D expenditure
- Future ready product for upcoming compliance requirements

info@tataelxsi.com