TATA ELXSI

VERIFICATION & VALIDATION SERVICES

Design | Assess | Certify

Trending

The medical device industry spent over USD 28 billion on R&D in 2018, a 9-10% Y-o-Y growth.* Industry is focusing on R&D to develop new devices and improve functional and non-functional aspects. This has led to a rise in the complexity of medical devices. Companies are developing optimized test strategies, leveraging automation and DevOps to accelerate time-to-market amidst relentless competition.

Regulatory landscape is evolving to include stringent quality & regulatory requirements in the light of worldwide adverse events. Comprehensive and rigorous V&V plans are being implemented to satisfy new requirements set forth by the authorities.

Furthermore, in order to launch differentiated products in the market, businesses are developing holistic solutions for better clinical outcomes, by integrating digital technologies in their products. Enabling a seamless user experience across the value chain demands additional emphasis on tests such as compatibility testing, security testing, etc.

**Zinnov-2018*

Opportunities & Challenges

In a highly regulated and competitive industry, the key challenge for the manufacturers is to ensure product quality, reliability, and patient safety throughout the medical device lifecycle.

While an early launch of a medical device in the market could lead to significant market share and maximum ROI, manufacturers with ineffective testing strategies go through prolonged testing cycles. This may also potentially lead to product recalls, high cost of maintenance, and dwindling customer confidence.

In order to achieve product commercialization goals, companies are finding ways to accelerate product development through automation-based optimized V&V programs.

Benefits for consumers

- High-quality devices ensuring patient safety
- Patient data security across the healthcare service value chain
- Quick turnaround time for device maintenance and minimum downtime

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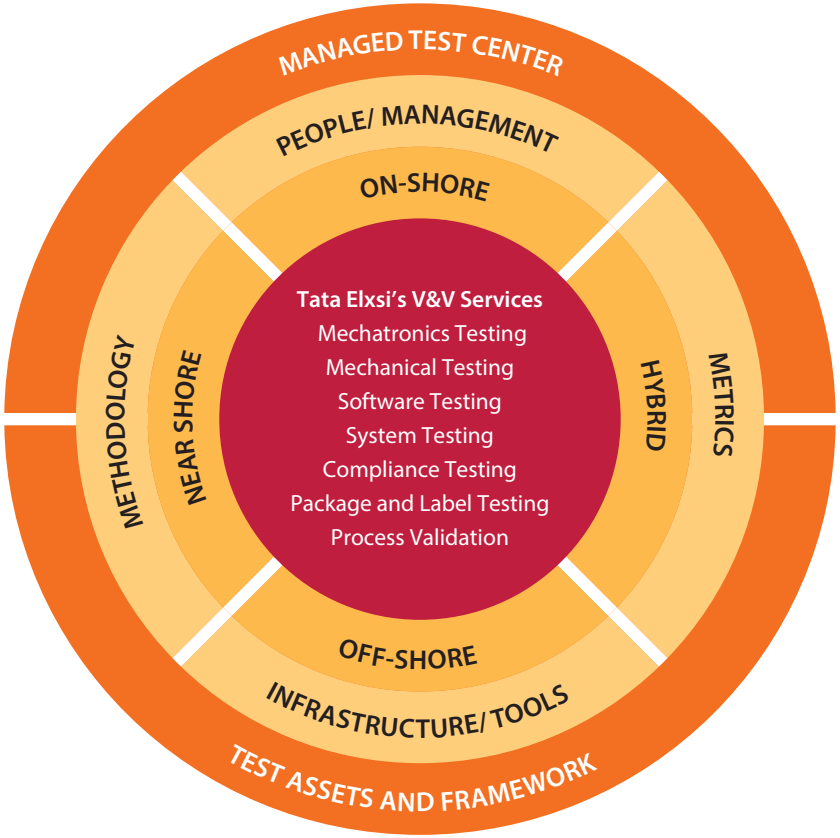
V&V Service Ecosystem



- Cost & Time Benefits
- Access to Experts
- Technology Know-how
- Domain Understanding
- Minimized Risk
- Workflow Optimization

Dedicated V&V center of excellence

Mature defect management process and KPI-based governance

Automation experience on multiple COTS & homegrown tools

Ecosystem of internationally accredited testing labs

Differentiators

- 15+ years of safety-critical device V&V experience
- ISO 13485 certified facilities with QMS aligned to meet ISO 14971, IEC 62366, IEC 62304, 21 CFR part 820, and EU regulations
- Team of industry trained biomedical and systems engineers with class II and III device experience
- Technical documentation expertise catering to regulatory requirements in major and emerging markets

Cases

Complete V&V of infusion pumps, leading to 20% reduction in time to market

- Test plan & protocol development
- Software and web application automation testing
- Test API enhancement
- Hardware and simulator APIs enhancement
- Pre-compliance testing (EMC/ EMI)

Automation testing of High Intensity Focused Ultrasound (HIFU) system application, resulting in a reduced overall cost of quality by 30%

- Test automation solution for 80% of existing manual test scenarios
- Regression testing for major and minor update releases
- Localization testing
- V&V documentation update

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