

VERIFICATION & VALIDATION SERVICES

Design | Assess | Certify

Trending

The growing complexity of medical devices and stringent quality & regulatory requirements have a direct impact on the efforts associated with test design, execution, and documentation.

Furthermore, the integration of digital technologies in medical devices demands patient data security. Additionally, the increasing competition requires the need to reduce the time to market.

Opportunities & Challenges

In a highly regulated and competitive industry, an early launch of a medical device in the market could lead to significant market share and maximum ROI.

However, the key challenges for the OEMs are to ensure product quality, reliability, and patient safety. Hence, OEMs need a comprehensive V&V program for new product introduction.

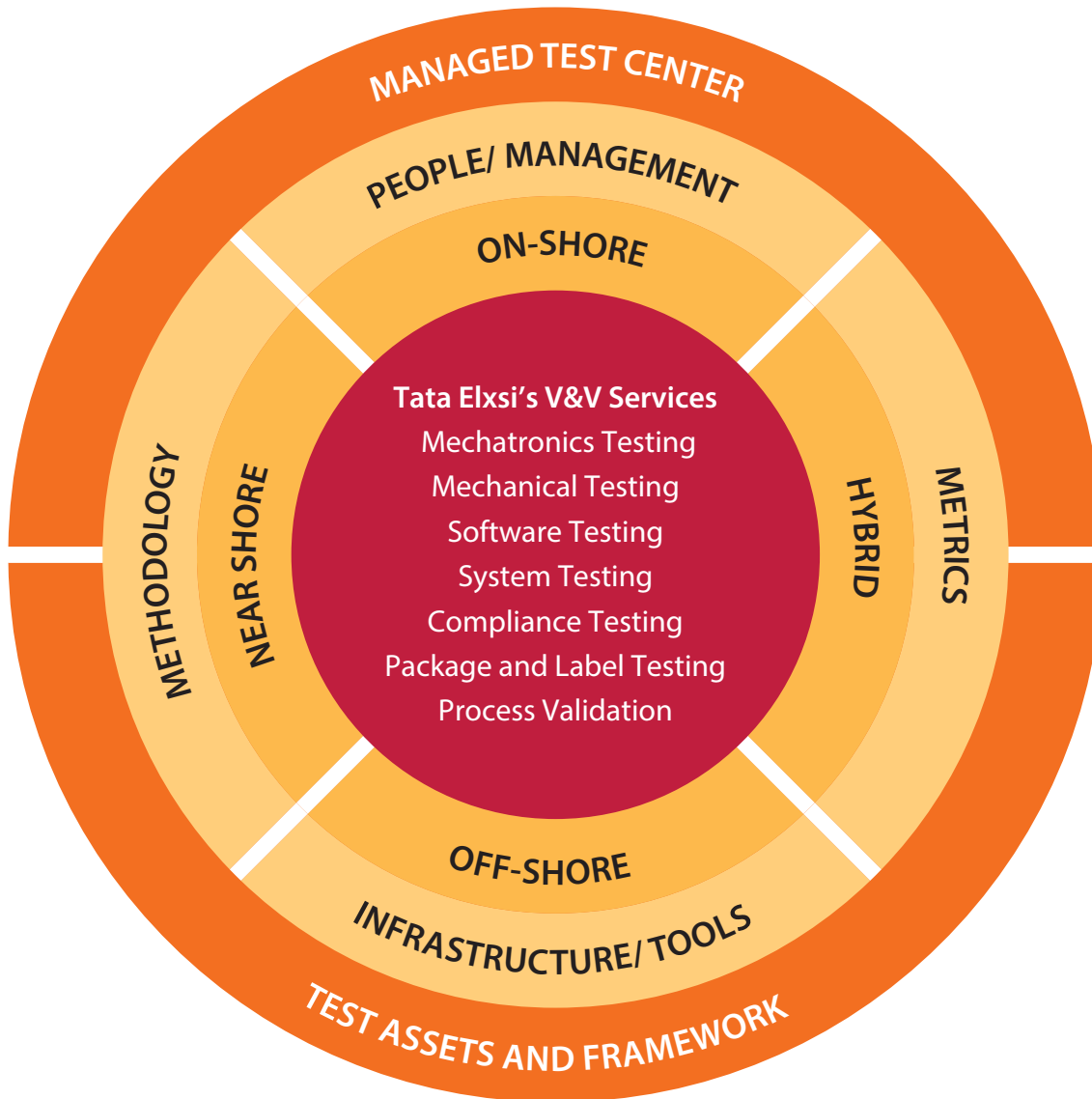
OEMs are finding ways to accelerate product development through optimized V&V programs without compromising on the quality of the end product.



Benefits Sought by the OEMs

- Comprehensive V&V program to ensure product quality throughout its lifecycle
- Advanced and automated V&V tools to facilitate error screening and thorough testing
- Reduced operating costs and time-to-market to achieve a competitive edge
- Dedicated test infrastructure and customized test environment
- Industry and domain understanding to develop an optimal testing plan

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Differentiators

- ISO 13485 certified facilities with QMS aligned to meet ISO 14971, IEC 62366, IEC 62304, 21 CFR part 820 and EU regulations
- Dedicated V&V Center of Excellence
- Automation experience with multiple COTS & open-source tools
- Expertise with 510(k) & PMA submissions
- Ecosystem of internationally accredited testing labs and in-house testing infrastructure

Cases

Complete IV&V activities for a pump-based therapeutic device, leading to a 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 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