

Lean approach in remediation leading to 24% reduction in lead time

A leading Europe based medical device maker with sterile and non-sterile packaging for the product

Major scope includes

- Defined a new approach to identify the Worst Case Products for testing and rationalizing the test results with similar products
- Prepared a lean approach gap analysis tool to be in compliance with ISO 11607- Part 1&2: 2019
- Performed gap closure activities for the identified gaps with testing and effective rationalizing
- Completely owned all the phases of the project including, requirement creation, testing (in-house and onsite), documentation and approval along with project management through change management

Future Scope

- Extending lean approach to other product segments



Team Size	Model	Performance	Business Impact	Project Duration
18	Fixed Price	Reduced lead time taken for the closure of gaps	Timely compliance with EU-MDR requirements for NB review	8 months