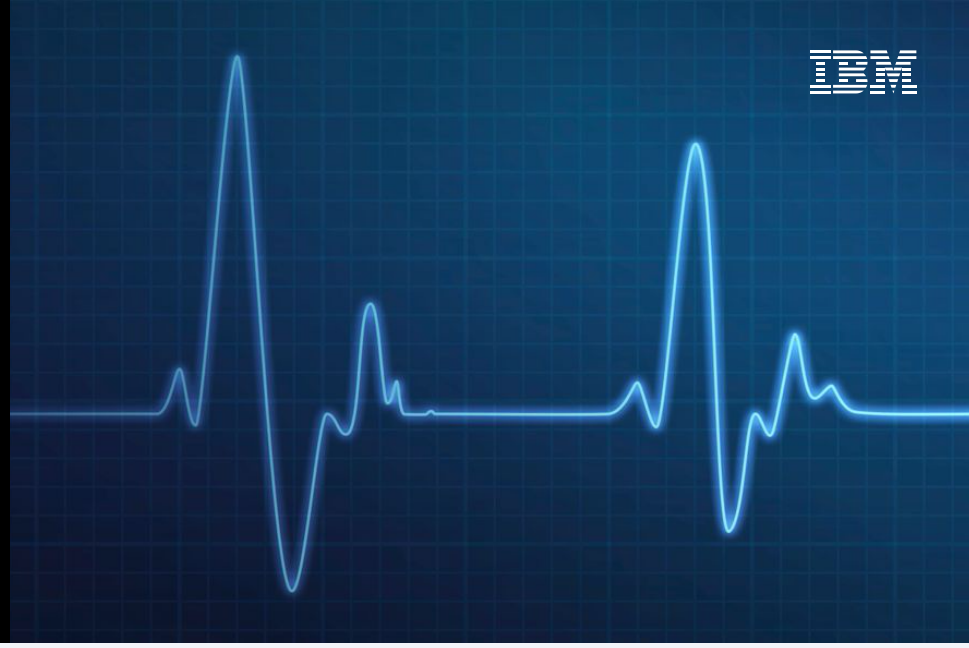
IBM **Engineering**

Streamlining Medical device design



Focus on innovation without compromising compliance by using IBM Engineering Lifecycle Management

Medical device manufactures must innovate to succeed. To grow, companies must deliver innovative, safe and fully compliant medical devices. This means adhering to increasingly rigorous regulatory standards like ISO 13485, IEC 82304-1, ISO 14971, IEC 60812, IEC 62304, ISO 60601, IEC 61508, 21 CFR 820.30 and 21 CFR 11 driven by both EU's MDR and the US FDA regulations.

According to industry analyst Ovum, IBM Engineering Lifecycle Management (ELM) is the industry leading portfolio for complex systems and software engineering. Capabilities to maintain transparency and traceability between requirements, system models, software, test cases, test results, changes and risks make it the ideal foundation to develop products that meet all quality and functionality requirements compliant. Key benefits:

- Drive collaboration for remote teams
- Ensure auditability and knowledge capture
- Establish a single source of truth for different roles in medical device engineering projects
- Develop and reuse system components to satisfy regional requirements with different variants
- Coordinate and track multiple teams of different pace

[1] Ovum Decision Matrix: Selecting an Application Lifecycle Management and DevOps Solution, 2019–20

Solve your engineering challenges faster with industry experience of Persistent Systems

Persistent Systems understands the daunting challenges of the medical device industry. With deep domain expertise, technology and efficient program management, Persistent can optimize the deployment of IBM ELM solutions.

- Persistent's medical device practice successfully develops and deploys Class I, Class II, and Class III devices
- **15+ Years of experience in the medical device industry** aligned with customer chosen engineering toolchain. Strong knowledge of regulatory and strategic frameworks that can support both simple and complex requirements, as a result, business benefits without affecting patient safety.
- Enabled our customers to experience **a reduction of BOM costs** leveraging our expertise, preventing product obsolescence a front runner for innovation while maintaining sustainability standards.
- **understand and comply to all relevant standards** which ensure your product meets the safety-critical product specifications.

Persistent

Learn more how Persistent can help you in medical engineering on **persistent.com**

Design medical device from requirements to tests

Model, simulate and test system and software design

Strategically reuse artifacts & changes between variants

Manage collaboration between engineering teams

IBM Engineering Lifecycle Management

Track project progress and process exceptions

Maintain end-to-end traceability across disciplines

Establish an integrated, traceable risk management

Electronically sign work items, test artifacts and design

Design Collaborate Stay compliant