IBM **Engineering**

Streamlining medical device design

Three key themes to setup your medical device design engineering for success

Medical device manufactures must innovate to succeed. To grow, manufacturers 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. IBM helps to:

Reduce time to innovation

- Adopt agility at scale that meets the needs of each part of your development team such as SAFe®
- Reduce time to market with strategic reuse by creating and managing product variants across multiple product lines

Improve quality

- Achieve transparency and traceability for design control as a by-product by creating work products in a controlled environment
- Use AI to validate quality of requirements

Reduce cost of compliance

- Understand status, responsibilities, audit trial and history for design control work products at every stage of the development
- Automatically generate high-quality documents from multiple sources to support compliance and audit requirements

Solve your engineering challenges faster with IBM Engineering Lifecycle Management

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 functional 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

Visit us to learn more about IBM Engineering Lifecycle Management and how you can benefit from it.

Design medical devices 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