

Each day, medical device companies face the realities and responsibilities of developing innovative products. To be successful, companies continually must balance cost, value, time-to-market and safety while complying with extensive regulations.

Challenges to Medical Device Development





Managing requirements and testing



Reusing artifacts



Project tracking & process exceptions



Managing variants



Collaborating between teams



Traceability across disciplines



Design process

Requirement management is essential. In a fast moving industry, it controls project scope, saving time and money. The goal is to digitally manage requirements across the entire version, variant and testing process with a shared dashboard with centralized storage.



Collaboration

Enabling effective collaboration in real time is critical for success across dispersed, multi-disciplined teams. Streamline engineering processes to enable global collaboration in real time — even while remote.



Staving compliant

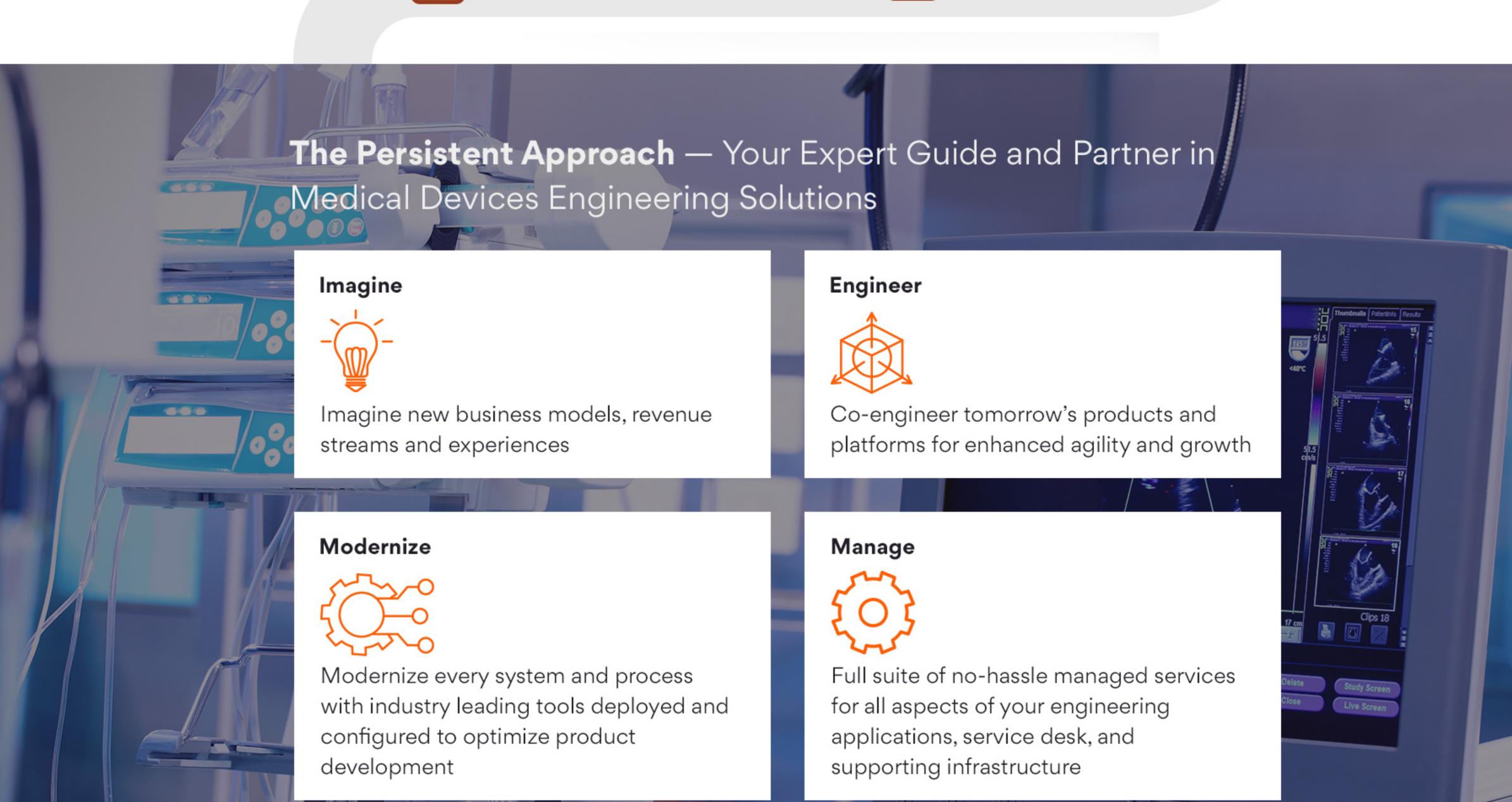
Staying compliant
Understand and comply
with all relevant standards
to ensure products meet
the safety-critical
regulations such as: ISO
13485, IEC 82304-1, ISO
14971, IEC 60812, IEC
62304, ISO 60601, IEC
61508, 21 CFR 820.30 and
21 CFR 11 as driven by
both EU's MDR and the US
FDA regulations.



Regulatory reporting



Risk management



Benefits



Better regulatory reporting



Increased product quality



Reduced safety costs



Shorter development cycles



Faster time to market



Transparency across development teams



Goal: Sustainable Innovation

Our Partners





Why Persistent

With more than 10,000 engineering experts and over 30 years of experience, Persistent is your knowledgeable guide and partner as you navigate the medical device development journey. We support you from quality assurance consulting and audits to implementation and testing via engineering application support that enhances your compliance and traceability reporting.

Go to persistent.com to learn more about how we can help you get from a great idea to a successful outcome.