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Accelerating Regulated Product Development

SUMMARY

A global medical device organization needed to modernize requirements management and product development workflows across multiple business units while maintaining FDA compliance. Legacy platforms, manual documentation, and disconnected workflows increased operational complexity and migration risk. The engagement prepared the organization for large-scale migration, improved process visibility, and established a scalable foundation for future development.

APPROACH

Our team partnered with stakeholders across multiple business units to document current workflows, define future-state requirements, and prepare the organization for migration to PTC Codebeamer and Modeler.

- **Discovery and Process Mapping:** Led value stream mapping, stakeholder interviews, and "day in the life" workshops to document workflows, pain points, and future-state needs.
- **Migration Planning:** Defined migration strategies, roadmaps, data requirements, and implementation plans for Polarion, DOORS, Excel, and document-based systems.
- **System Configuration:** Configured Codebeamer environments to support division-specific workflows, validation requirements, and user onboarding.
- **Platform Enablement:** Supported integrations, system administration, validation planning, and vendor collaboration to drive long-term adoption.

SOLUTION

The team configured PTC Codebeamer and Modeler environments, supported onboarding, and developed migration strategies for Polarion, DOORS, and manually maintained records. Additional work included integration planning, validation support, platform administration, and user enablement, establishing a scalable, compliant foundation for future development.

Results

>$1M

>$1M projected annual IT savings

>50%

>50% faster engineering process throughput

229

229 workflows and trackers configured

>40%

>40% fewer engineering process problem introduction points

35

35 legacy projects migrated