What Manufacturers Can Do

Key Digital Solutions for Regulatory and Clinical Efficiency

eQMS

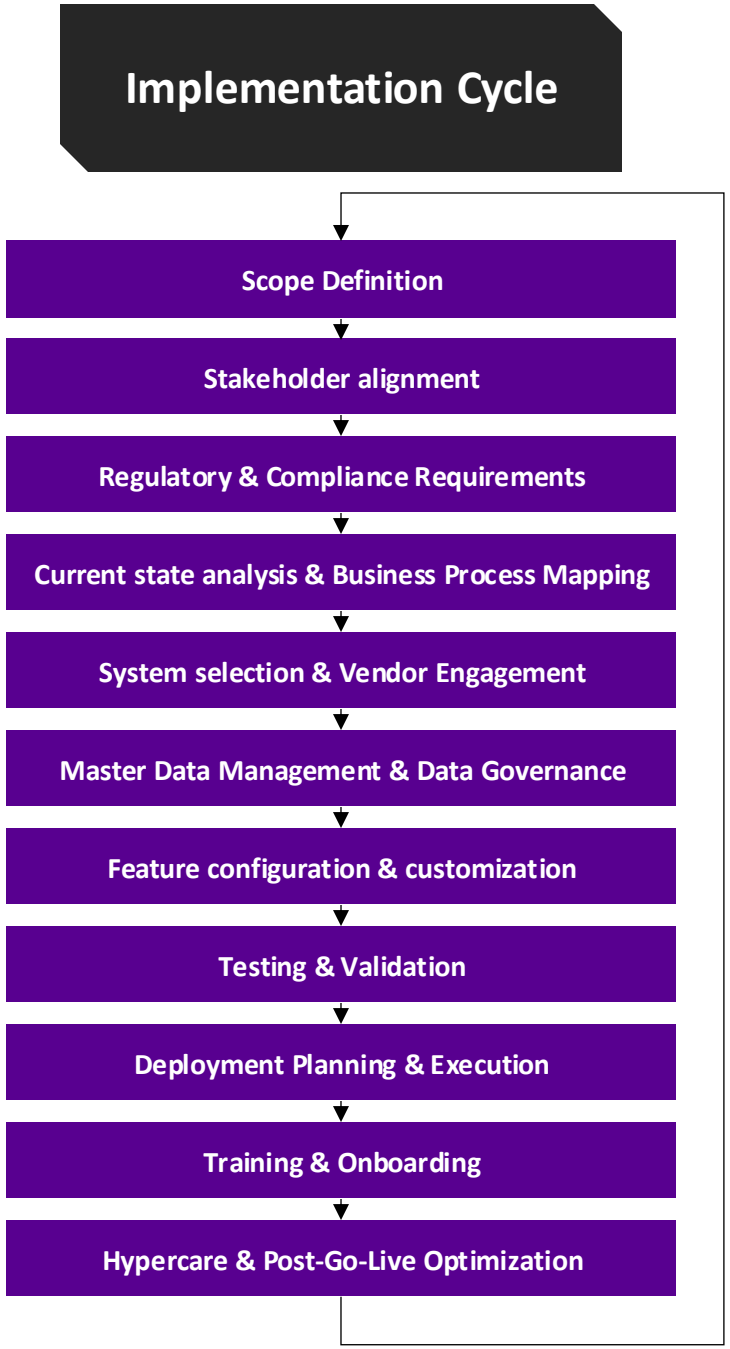
- Document Control
- CAPA, Change Controls, Deviation Mgmt
- Audits & Inspection Management
- Complaint Handling
- Trainings Management
- Risk Management
- Supplier Quality Management
- Control Plans & Quality Planning
- Product Lifecycle Management

RIMS

- Product Registration Tracking
- Submission Management
- Health Authority Interactions
- Regulatory Intelligence
- Regulatory Tracking
- Labelling Management
- Audit Readiness & Reporting

CTMS

- Study Planning
- Site Management
- Subject Tracking
- Monitoring Oversight
- Regulatory Document Management
- Issue & Risk Management
- Dashboards & Reporting



Regulatory Authorities Embracing Digital Transformation

Exploring how FDA and EMA are transforming Clinical and Regulatory Processes through Digital Tools, RWD, and eSubmissions

	FDA	EMA
Active Surveillance Platform	**NEST** **NEST (National Evaluation System for Health Technology)** is an initiative to use real-world data (RWD) and real-world evidence (RWE) to support regulatory decision-making across the medical device lifecycle.	**DARWIN EU** **DARWIN EU (Data Analysis and Real World Interrogation Network)** is network for accessing and analyzing real-world healthcare data across the EU to support regulatory decision-making.
	Improves post-market surveillance and accelerates evidence generation.	Facilitates evidence generation from RWD across Europe, supporting medicine monitoring, safety, and efficacy evaluations.
	Real-world data platforms, big data analytics, interoperability of health IT systems.	Federated data networks, real-world evidence analytics, data harmonization.
Digital Submission Platform	**eSTAR** **eSTAR (electronic Submission Template And Resource)** is an interactive PDF-based tool that helps prepare regulatory submissions in a structured, electronic format.	**eSubmission** A centralized platform for electronic submission of regulatory documents, supporting applications like CTD submissions, variations, and renewals.
	Streamlines submission preparation and review, reducing errors and improving communication between FDA and sponsors.	Increases efficiency and transparency in regulatory workflows through streamlined digital processes.
	Smart form automation, e-submissions, PDF templates with validation logic.	Web-based portals, secure document exchange, integration with national competent authorities (NCAs).

Driving transformation through intelligent innovation

Redefining quality, compliance and operational excellence with advanced technologies.

	Key Technologies	Automation Potential	Impact on Operations	Impact on Implementation Cycle
eQMS	**Generative AI (GenAI)** **Machine Learning (ML)** **Natural Language Processing (NLP)** **Large Language Model (LLM)** **Robotic Process Automation (RPA)** **Internet of Things (IoT)**	• SOP / Content Generation • Automated workflows (CAPA, NC, Change Control) • Automation supported Audits (Checklists, Fulfillment) • Real-Time KPI Reporting & Analytics • Automated complaint triage and vigilance report generation	• Significantly reduced manual effort • Faster issue resolution • Enhanced decision-making through real-time data • Enhanced data integrity	**Relevant regulatory implications** **Data Quality Assessment** **Performance monitoring for (AI) models** **Model retraining schedules**
RIMS		• GenAI supported Tech File authoring • Automated Regulatory Submission Tracking Compliance Workflow Automation • Document Categorization and Storage • RegIntel, Regulatory & Risk Alerts & Notifications	• Improved document retrieval & access • Highly consistent Tech Files • Reduced risk of compliance breaches • Enhanced regulatory alerts for proactive management	
CTMS		• Automated Study Planning • Site & Investigator Selection • Automated Monitoring, Reporting, and Enrollment • Data pattern recognition • Clinial Evaluation Report generation	• Increased trial efficiency • Enhanced patient recruitment & tracking • Improved Reporting & Analytics • Resource Allocation Optimization	

Future Opportunities with Advanced Technology Solutions

How Digital Solutions Are Shaping the Future of Quality and Compliance

Quality Audits	• Creation of checklists based on regulations / standards • Automated compliance checks of process documentation • Summary generation of (large) records including verification checks
Quality PMS	• Automated medical device monitoring & signal detection • Automated information completeness and consistency check enabling fully automated risk-based case triaging • Automated vigilance report generation based on external and internal data sources
RegIntel	• At scale identification of updates of regulatory requirements • Semi-automated interpretation of risk and impact • Fully automated process updates (redlining)