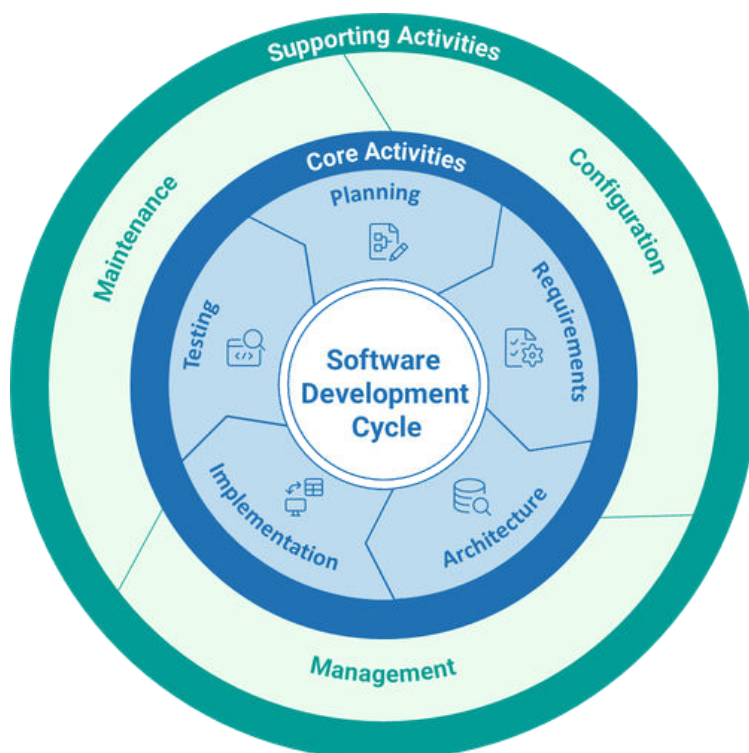


Medical Device Software Life Cycle Management

Software has become a cornerstone of modern medical technology, powering solutions ranging from diagnostic imaging systems to AI-based decision support tools. To ensure patient safety, product quality, and compliance with international regulations, medical device software must be developed, maintained, and decommissioned according to a structured, risk-based software life cycle process.

The international standard **IEC 62304** defines the framework of processes, activities, and tasks necessary to develop safe and effective medical device software. It requires integration into a quality management system (ISO 13485) and alignment with risk management (ISO 14971), usability engineering (IEC 62366-1), health software safety requirements (IEC 82304-1) and cybersecurity activities as part of the product life cycle (IEC 81001-5-1).

A structured life cycle ensures that software evolves safely with technology and clinical needs, while reducing business risks and facilitating regulatory approval in global markets.



Our Services Include:

Lifecycle Planning and Safety

Classification: We support lifecycle planning and safety classification according to IEC 62304 (A/B/C), including development and maintenance plans.

Process Implementation: We provide SOPs and templates integrating ISO 13485, ISO 14971 and IEC 62366-1 to streamline compliance.

Requirements, Traceability, and Architecture: Our services cover requirements management, traceability, and architecture, including SOUP control and tool qualification.

Configuration and Change Control: We help establish CI/CD-compatible configuration and change control, including impact assessments and re-validation rules.

Gap Assessments and Audits: We conduct gap assessments and audits against IEC 62304 and IEC 82304-1, and offer team training and workshops.

As your trusted partner, we tailor life-cycle controls to your product risk and regulatory pathway—delivering compliant, evidence-driven software that is safe to use and ready to scale.

