



Quality Excellence™

The next generation of the #1 enterprise
quality management system (QMS).

Qx

Quality

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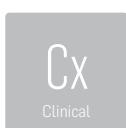
Quality changes everything.

Seven solutions. One platform.



Development Excellence

- Design control and specifications
- Design history file (DHF) management



Clinical Excellence

- Clinical quality management system (CQMS)
- Electronic trial master file (eTMF)



Regulatory Excellence

- Regulatory information management (RIM)
- 510(k), eCTD submissions and global registrations



Quality Excellence

- Quality management system (QMS)
- Product quality data analytics
- ✓ **Document Control and Change Management:** Automate quality processes throughout the product life cycle.
- ✓ **Comprehensive Training and Competency Management:** Manage all training tasks and activities throughout your enterprise.
- ✓ **Incident and Corrective Action Management:** Integrate corrective actions with all quality subsystems in the product life cycle.
- ✓ **Audit and Preventive Action Management:** Streamline audit planning, scheduling and execution activities from beginning to end.
- ✓ **Risk Management and Mitigation:** Unite all risk-related activities and documentation in one centralized repository.



Supplier Excellence

- Supplier management (SQM)
- Approved vendor lists (AVL)



Manufacturing Excellence

- Production records: EBR and recipe, eDHR and variant
- Equipment calibration and maintenance



Postmarket Excellence

- Postmarket surveillance (PMS)
- Medical Device Reporting (MDR)