

ORCANOS

Comprehensive Medical Device Solution

Leading manufacturers in automotive, aerospace, and medical device industries rely on database-driven development platforms to manage complex projects. Orcanos stands apart by uniting three typically separate systems in one integrated solution: electronic Quality Management System (eQMS), Document Management System (DMS), and Application Lifecycle Management (ALM). This integration creates a single source of truth for development processes, quality systems, and documentation.

AI-Assisted Development

We look forward to offering a platform that will harness artificial intelligence to accelerate development processes. In future releases, we anticipate the system will suggest risk analyses based on requirement patterns and generate test cases from specifications. We are developing natural language processing capabilities that will analyze requirements for consistency and compliance issues. Our planned AI engine will learn from historical data to provide predictive quality metrics and identify potential reuse opportunities across documentation. We expect to implement smart search capabilities to connect related information throughout the system, while pattern recognition will help maintain regulatory compliance. These exciting features are part of our development roadmap as we continue to enhance our platform.



The Digital Evolution: Beyond Files to Data

Traditional development processes rely heavily on Word documents, Excel sheets, and scattered network folders. Orcanos replaces this fragmented approach with a structural database that treats every element as interconnected data. Just as double-entry bookkeeping reveals accounting discrepancies through data relationships, Orcanos' interconnected structure unlocks new insights through multiple perspectives. Teams can instantly view all requirements affecting a single interface, analyze test results across specific variables, or identify similar test cases to optimize resource allocation. Documents build automatically from approved content, while changes track across the entire system. Teams collaborate in real time through shared data access, with automated workflow management ensuring consistency and compliance.



tecurat's Digital Medical Device Solution

Orcanos provides a comprehensive solution tailored for medical device manufacturers, and as an authorized system provider, tecurat brings specialized expertise to maximize its potential. Like Microsoft Gold Partners, tecurat's certified consultants are industry experts who help medical device companies optimize their Orcanos implementation. Our deep understanding of medical device standards like ISO 14971 and IEC 62366-1 enables us to configure the system for maximum efficiency and regulatory compliance. tecurat's consulting expertise ensures your Orcanos system is tailored to streamline MedTech processes while maintaining the flexibility to meet your organization's unique needs.



Unique Platform Development Innovation

Orcanos stands as the only known software solution capable of handling truly complex product platforms where components can be exchanged or updated. Similar to smartphone manufacturers releasing multiple variants, medical device companies can manage multiple product configurations from a single data core. The system automatically tracks component dependencies and maintains separate documentation for each variant while sharing common elements. When changes occur, they propagate intelligently across product families, maintaining regulatory compliance throughout.



Smart Content Management

Gone are the days of searching through network folders for the latest document version. The system maintains a complete history of every regulatory submission and interaction. Teams work with centralized content libraries that automatically track versions and maintain formatting consistency. Documents assemble in real time from approved components, while intelligent linking replaces traditional copy-and-paste approaches. Content validation happens automatically against regulatory requirements, with updates flowing seamlessly across document sets.



Database-Driven Quality Management

Quality processes transform from static documents into dynamic data points. The system captures every interaction in automated audit trails and integrates electronic signatures into approval workflows. CAPA and complaints link directly to affected products, while training records automatically connect to relevant procedures and versions. Quality metrics generate in real time, with risk management woven throughout the product lifecycle. The system continuously checks compliance against standards and provides comprehensive trend analysis.

Secure Collaborative Access

The platform's sophisticated access control system supports the entire development ecosystem. Internal teams work with customized views based on their roles. Suppliers submit documentation through secure portals. Customers access complaint systems, requirements, Test cases, Definitions and any other data object directly. Regulatory auditors review procedures with controlled access to required information. Quality teams manage approvals while project managers monitor progress. Every interaction remains secure and tracked.

Comprehensive Change Management

The database structure revolutionizes change management. When modifications occur, the system automatically identifies all affected data and documentation and analyzes impact across product variants. Updates flow through to related requirements while test cases adjust based on changes. Stakeholders receive targeted notifications based on their roles. The system tracks implementation, verifies regulatory compliance, updates training requirements, and maintains precise documentation control.

Agile Development Support

For organizations embracing agile methodologies, the system seamlessly integrates regulatory compliance into sprint cycles. Development tasks connect directly with requirements while documentation updates automatically. The platform supports continuous validation and provides robust release management tools. Teams can maintain compliance without sacrificing agility, with automated checks ensuring quality at every step.

