Ketryx

AI-powered compliance and Application Lifecycle Management (ALM) platform for MedTech, automating FDA, EU MDR, and ISO documentation and traceability.

https://www.ketryx.com/

Overview

Ketryx is an AI-native, connected Application Lifecycle Management (ALM) platform specifically designed for the life sciences and regulated industries, such as medical device manufacturers. It is trusted by major medical device manufacturers to bridge the gap between software development speed and regulatory compliance (FDA, EU MDR, and ISO standards).

Product Overview & Key Benefits Ketryx acts as a central orchestration layer, connecting existing, preferred development tools (like Jira, GitHub, GitLab, and AWS) into a single, traceable Software Development Lifecycle (SDLC). By embedding compliance into the modern development workflow, Ketryx eliminates the manual, error-prone burden of traditional compliance, reducing documentation time by up to 90% and helping teams release safer products faster.

Main Features and Capabilities

AI-Driven Documentation: Automatically generates Part 11–compliant documentation and audit-ready evidence, such as the Design History File (DHF), directly from development activities.
Real-Time Traceability: Creates a living traceability matrix, continuously mapping requirements, risks, tests, and code across connected systems.
AI-Driven QMS Enforcement: Acts as a quality enforcer, embedding compliance guardrails and enforcing Quality Management System (QMS) procedures directly within development tools to prevent process deviation.
Risk Management: Integrates IEC 62304 and ISO 14971-compliant risk management into the SDLC, enabling continuous tracking and mitigation of risks in tools like Jira.
Software Supply Chain Security: Automatically generates a Software Bill of Materials (SBOM) and provides continuous vulnerability monitoring.

Part 11-Compliant Signatures: Enables secure, legally binding electronic signatures within development tools like Jira to meet 21 CFR Part 11 requirements.
Target Users and Use Cases Ketryx is best suited for Quality Assurance/Regulatory Affairs (QA/RA) teams, R&D/Development teams, and AI/ML leaders in regulated industries. Primary use cases include developing FDA-regulated software (SaMD), achieving compliance with international standards (IEC 62304, ISO 13485), and accelerating the development and deployment of AI/ML-based medical devices.

Key Features

- AI-Driven Documentation (Part 11-compliant)
- Real-Time, End-to-End Traceability
- AI-Driven QMS Enforcement/Process Deviation Prevention
- Risk Management (ISO 14971-compliant)
- Automated Software Bill of Materials (SBOM) Generation
- Part 11-compliant Electronic Signatures in Jira

Pricing

Model: subscription

Free plan available for pre-market companies with less than $2M in funding. Multiple subscription options (Essentials, Enterprise) based on company size, stage, and products needed. Pricing is not publicly disclosed for paid tiers.

Target Company Size: startup, small, medium, enterprise

Integrations

Jira, GitHub, GitLab, AWS, Azure DevOps, TestRail, Google Workspace

Compliance & Certifications

IEC 62304, ISO 13485, ISO 14971, SOC 2 Type II, HIPAA, FDA 21 CFR Part 11, FDA 21 CFR Part 820