Kivo RIM

Regulatory Information Management (RIM) software for life sciences, offering a unified, compliant, and affordable platform for submissions, eTMF, and QMS.

https://kivo.io/rim

Overview

Kivo RIM is a cloud-based Regulatory Information Management (RIM) solution designed specifically for emerging and scaling pharmaceutical, biotech, and MedTech companies. It provides a unified, all-in-one platform that combines RIM, electronic Trial Master File (eTMF), Quality Management System (QMS), and Document Management System (DMS) capabilities.

The software is built to replace disconnected tools like spreadsheets and SharePoint with a centralized, compliant, and collaborative system, acting as a single source of regulatory truth. Key features focus on accelerating regulatory submission timelines and ensuring compliance. This includes a Submission Builder with pre-built structures for common submission types (INDs, CTAs, NDAs, etc.), an integrated eCTD viewer, and automatic export tracking for easy publishing handoff.

The platform supports the entire regulatory lifecycle, from document creation and review/approval (with Part 11 Compliant e-Signatures via DocuSign) to correspondence tracking and health authority commitments. Kivo is known for its ease of use, rapid deployment (in weeks), and affordable, transparent pricing model, making enterprise-grade RIM functionality accessible to smaller teams. It is fully validated and compliant with GxP standards, 21 CFR Part 11, SOC 2, and ISO 9001.

Key Features

- eCTD Submission Builder
- eCTD Viewer
- Part 11 Compliant e-Signatures (via DocuSign)

- Dossier Management
- Health Authority Correspondence Tracking
- Integrated QMS and eTMF Modules
- Automated Publishing Handoff Tracking
- Pre-formatted ICH Templates

Pricing

Model: subscription

Team plans starting under $1,000/month for 5 users. All-inclusive pricing covers access to DMS, RIM, QMS, eTMF, unlimited training, support, and lifetime continuous validation.

Starting at: USD $999

Target Company Size: startup, small, medium

Integrations

DocuSign, Office 365

Compliance & Certifications

FDA 21 CFR Part 11, SOC2, ISO 9001, GxP Standards, EDM Reference Model, TMF Reference Model