RAPS CONVERGENCE 2026

Regulatory Intelligence. Reimagined.

The only platform purpose-built for medical device regulatory professionals — from first market to global scale.

RAPS Convergence 2026

REGDESK.CO

Four Pillars of Regulatory Excellence

Plan

Map regulatory pathways across 120+ markets. AI-powered classification and submission strategy — before you commit resources.

Build

Compile compliant submissions with labeling requirements, UDI management, and automated document workflows.

Track

Monitor registrations, renewals, and approvals across your entire portfolio. Real-time dashboards and renewal alerts.

Maintain

Stay ahead of regulatory changes with automated impact assessments. Audit-ready documentation at every step.

INTELLIGENT RIM

AI-Powered Regulatory Intelligence Engine

01 Change Impact Assessment

Automatically detect regulatory changes and instantly assess impact across every product, SKU, and market in your portfolio. No manual monitoring needed.

02 Smart Classification

AI-driven device classification across 120+ markets. Instantly determine your regulatory pathway before committing engineering resources.

03 Automated Alerts

Never miss a renewal or regulatory update. Real-time monitoring with intelligent notifications mapped to your specific device portfolio.

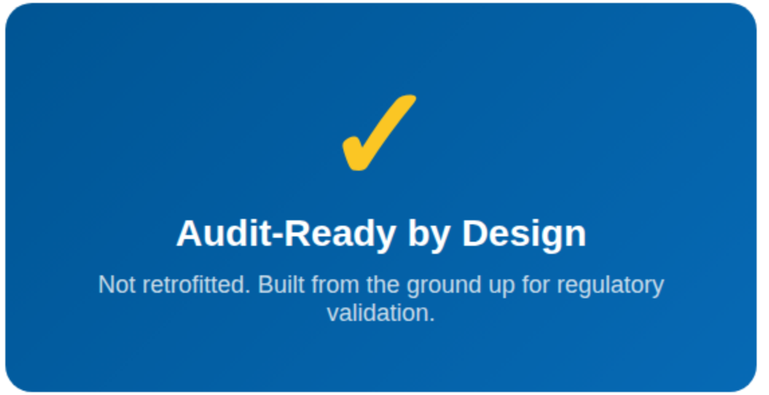
04 Regulatory Co-Pilot

AI-assisted labeling review, document summarization, and workflow automation — your regulatory team, supercharged.

ENTERPRISE-GRADE VALIDATION

Built for Audit. Ready for Review.

- **Full audit trails** — Every action, document, and approval automatically captured
- **GxP compliance** — Supports Good Practice guidelines including electronic records
- **21 CFR Part 11** — Electronic signature and records compliance built-in
- **Change management** — 4-stage validated workflow from assessment to approval
- **Role-based access control** — Enterprise identity and permissions management
- **SSO & multi-tenant workspaces** — Secure collaboration across your organization



TRUST & COMPLIANCE

Security You Can Count On.
Compliance You Can Prove.

Enterprise-grade security infrastructure protecting your most sensitive regulatory data — certified, validated, and auditable.

SOC 2 Type II

Independently audited security controls. Your data is protected by the gold standard in enterprise security.

ISO 27001

International standard for information security management systems — verified and maintained.

21 CFR Part 11

Electronic records and electronic signatures compliance for FDA-regulated environments.

GxP Compliant

Supports Good Practice guidelines including full audit trails and electronic records management.

GLOBAL SCALE

Trusted at Scale

120+
Markets Covered
Full regulatory depth, not just alerts

250K+
Products Managed
Across global portfolios

$2.2B
Market Size (2024)
Growing to $6.2B by 2034

11%
CAGR 2024–2034
Fastest-growing RIM segment

120+ Market Content Database

Deep regulatory guidance — not surface-level alerts. The only platform with this level of device-specific depth.

Device-Focused by Design

Purpose-built for medical device manufacturers — not repurposed pharma software. Every feature built for device regulatory teams.

Distributor Collaboration Tools

Unique in-platform distributor workflow management. A genuine differentiator no competitor has matched.

THE REGDESK DIFFERENCE

From First Market to Global Scale — In One Platform.

Most teams manage regulatory with spreadsheets, email threads, and outdated PDFs. RegDesk replaces all of it — with a system that scales with you.

WITHOUT REGDESK VS. WITH REGDESK

❌ Without	✅ With RegDesk
Manual tracking in spreadsheets — error-prone, not scalable	Real-time portfolio dashboard across all markets
Missed renewals discovered late — costly delays	Automated alerts months in advance, every time
Regulatory changes discovered months after the fact	AI impact assessment the moment a change is published

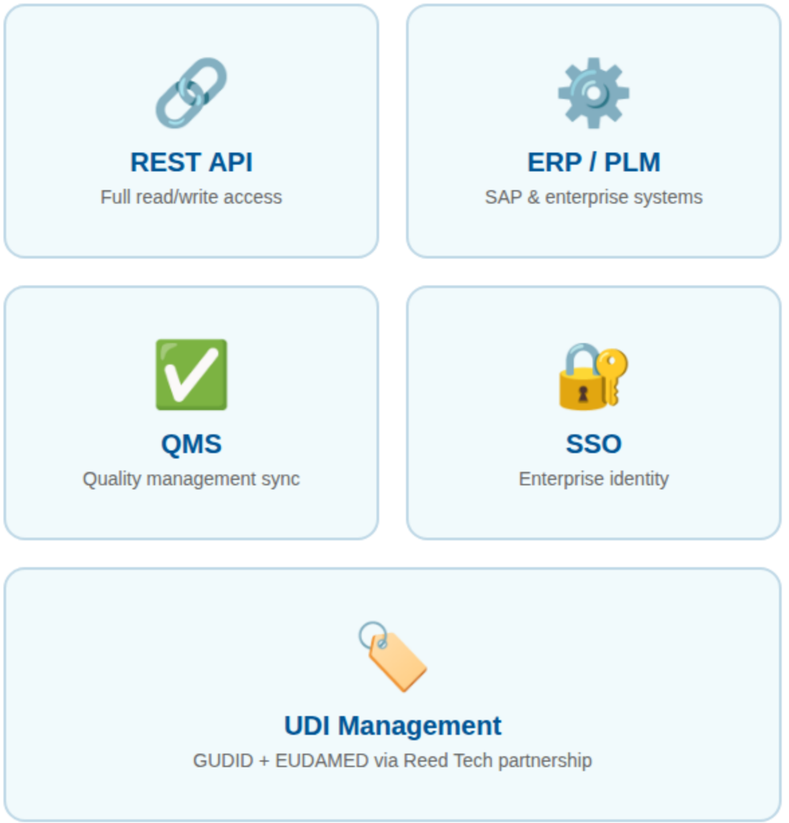
INTEGRATIONS & ECOSYSTEM

Fits Into Your Existing Stack.

- **API access** — Read/write API to integrate RegDesk into your existing tech stack
- **ERP / PLM integration** — SAP, PLM, eDMS, and enterprise systems
- **QMS / eQMS integration** — Bi-directional sync with quality management systems
- **SSO / enterprise auth** — SAML, OIDC, and enterprise identity providers
- **UDI management** — GUDID and EUDAMED via Reed Tech partnership

Self-Service Onboarding

No 6-month implementation. No dedicated consultant required. Get your team onboarded and productive in days — not quarters.



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Ready to Transform Your Regulatory Operations?

Speak with our regulatory intelligence experts today. See how RegDesk can help your team move faster, stay compliant, and scale globally.

regdesk.co
Schedule a Demo

120+ Markets
Full Regulatory Depth

SOC 2 · ISO 27001
Enterprise Security