

Coloplast RIM RFP

Key Requirements Analysis

Prepared by RegDesk · August 2026 · Confidential — Internal Use Only

62 User Stories

~95% Scored Highest Value (3-4)

\$332.8K Fixed Implementation Fee

\$3.5M Annual Subscription (Full Stack)

Coloplast is a Danish global medical device company seeking a full RIM platform to replace fragmented manual processes across registrations, submissions, change assessment, standards management, and licensing. This brief highlights the requirements most critical to emphasise in the demo.

 Deal-Critical System Integrations

MEP (Market Expansion Plan) — Coloplast's SharePoint-based commercial launch approval system. They require RIM objects to be auto-created after MEP commercial approval, with commercially required parameters syncing back to MEP. OoTB

STEP — Coloplast's master data management system. Must serve as single source of truth for RA hierarchy, regulatory attributes, labelling data, and UDI attributes flowing into RIM. OoTB

These two integrations appeared multiple times throughout the RFP and are likely the first questions Coloplast will raise in the demo. Demonstrate both explicitly.

 Suggested Demo Flow

Step	What to Show	Why It Matters
1 · Open with	MEP → RIM auto-creation flow	Their #1 pain: double maintenance
2 · Walk through	Change assessment: auto country impact list → local risk classification → task assignment	Most complex workflow, all scored 3-4
3 · Close with	AI content drafting with mandatory human review & source traceability	Specifically called out in user stories



 Top Functional Requirements — All Must-Have (Score 3-4)

Area	Requirement	Status
Registration & Lifecycle	Dynamic selling status + registration status by country in one view (no separate reports)	OoTB
	Full registration lifecycle states: draft → submitted → authority questions → approved / rejected / withdrawn	OoTB
	Licence-to-sell traceability — which approved document version obtained each licence	OoTB

Area	Requirement	Status
Change Assessment	Re-registration timeline intelligence with automatic expiry notifications	OoTB
	Re-registration forecast report by country and business area	OoTB
	Built-in RA change assessment workflow with auto-generated country impact list	OoTB
	Local risk classification per country as part of impact assessment	OoTB
	Task assignment to country RA stakeholders (replacing manual emails)	OoTB
	Compliance block: prevent active-selling status if registration incomplete	OoTB
Document & Submissions	Template-based document creation with auto-populated product + regulatory metadata	OoTB
	Structural templates for STED, 510(k), and other submission types	OoTB
	Country-specific local documentation derived from global templates	OoTB
	Submission assembly → QC → dispatch → archive in one traceable process	OoTB
Standards Management	Applicable standards linked to products at BUDI level; change notifications + gap analysis status	OoTB
	List of Applicable Standards (LoAS) generation with approval workflow	3rd Party
	Standards change notifications + gap analysis tracking	OoTB
Reg Intelligence	Country-level regulatory requirements by product risk class (stored, maintained, sourced)	OoTB
	Market entry effort + timeline evaluation for new market expansion	OoTB
AI Capabilities	Generative AI for regulatory content drafting — with mandatory human review + source traceability (explicitly called out in user stories #34)	OoTB



COLOPLAST RIM RFP — DEMO PREP BRIEF Technical & Commercial

Non-Negotiable Technical Requirements

Requirement	Detail	Status
Data Encryption	At rest and in transit	OoTB
RBAC + Row/Column Security	Full role-based, row-level, column-level, and user-group security	OoTB
Identity Management / SSO	Enterprise identity management integration	OoTB
SOC II + ISO 27001	SOC II  · ISO 27001 in final audit stages (est. Oct 2026)	OoTB
CFR Part 21 Part 11	Compliant access control + audit logging	OoTB
99%+ Uptime, 24/7/365	AWS cloud, disaster recovery SOP in place	OoTB
100+ Concurrent Users	Enterprise license — no per-seat or SKU charges	OoTB
Full Audit Trail	Object-level, row-level, user-level audit archive	OoTB

Gaps to Address Proactively

Item	Coloplast Requirement	RegDesk Position
Streaming Data Connectivity	Native streaming data processing integration	Via API — not native

Item	Coloplast Requirement	RegDesk Position
Mobile App Connectivity	Mobile OS/platform integration	Via API — not native
Custom SDK Connectors	Customer-buildable connectors via SDK	Via API
Internet Explorer 11	Must support IE11+	Not Fulfilled — deprecated browser
UDI Direct M2M Submission	Direct GUDID/EUDAMED machine-to-machine	3rd Party — lower priority (score 1-2)
LoAS Approval Workflow	List of Applicable Standards approval workflow	3rd Party

💰 Commercial Summary

\$332,800 Fixed-Price Implementation (No Overages)

\$3.52M Annual Subscription (Full Stack)

Incl. AI Costs — No Extra Consumption Fees

Module	Annual Fee
Tracking & Reporting	\$480,000
DCT Collaboration Tool	\$480,000
Change Assessment	\$480,000
Standards Management & AI Forms	\$480,000
EUDAMED Compliance Tool	\$160,000
AI Application Builder (Unlimited)	\$1,280,000
Regulatory Intelligence (126 countries) Included	
API Access & Support	\$160,000

Enterprise license includes distributors and third-party partners at no additional per-seat cost. No per-SKU charges. Optional Dev environment: +\$192K/yr.

