

Coloplast RIM RFP

User Stories Assessment

Based exclusively on the "RIM User Stories" sheet · 63 stories evaluated · August 2026

63 Total User Stories

48 Score 3-4 (Highest Value)

15 Score 1-2 (Lower Priority)

2 Not OoTB (Gaps)

Compliance Summary Across All 63 Stories

Status	Count	Stories	Meaning
OoTB	57	#01–03, #05–27, #29–45, #46–50, #51–59, #60–63 (excl. gaps)	Fulfilled out of the box
Alternative	2	#04, #14	Delivered differently than specified — requires explanation in demo
3rd Party	2	#20, #28	Requires third-party solution
Low Custom.	1	#26	Requires low-level customisation
Blank	1	#52 (no value entered)	Compliance not stated in RFP response — verify

Score Distribution by Theme

Theme	Stories	Score	Focus Areas
Document & Template Mgmt	#01–05, #17, #36–38	3-4	Auto-populated templates, submission structures, document import/reuse
System Integrations	#06, #07, #08, #09,	3-4	MEP auto-create RIM objects; STEP as data source
Registration & Licensing	#35, #39–41, #45	3-4	Compliance gate, licence traceability, lifecycle states
Change Assessment	#10–12, #43	3-4	Auto country impact list, local risk class, task assignment
Re-registration & EOL	#15, #16, #18	3-4	Timeline intelligence, expiry notifications, forecast reports
Standards Management	#19–21	3-4	Standards linked at BUDI level, LoAS generation, change alerts
Health Authority Interactions	#24–27	3-4	HA interaction log, Q&A tracking, AI-suggested answers
Submissions & Dossier	#30–32, #29, #44,	3-4	Dossier content plans, submission assembly, eCTD lifecycle
Regulatory Intelligence	#49, #58, #59	3-4	Market entry, country intel by risk class, registration strategy
AI / Data Governance	#33, #34, #50	3-4	Regulatory data governance, generative AI drafting with human review
Audit & Traceability	#13, #37, #42, #47, #48,	3-4	Audit reports, submission history, KPI reporting
Strategic / Portfolio	#51, #52, #56, #57, #60–63	1-2	Workload forecasting, coverage dashboards, dependency viz, risk mgmt
UDI Direct Submission	#28	1-2	M2M to GUDID/EUDAMED — 3rd party

COLOPLAST RIM — USER STORIES ASSESSMENT High-Priority Stories (Score 3-4) — Part 1

Score 3-4 Stories — Full Detail (Part 1: #01–#27)

All 48 high-value stories. These are Coloplast's primary evaluation criteria — every demo must address these.

#	User Story	Acceptance Criteria (summary)	Status	Note
#01	Create documents from templates with auto-populated product & regulatory metadata	Metadata auto-populates; linked docs flagged if source changes	OoTB	
#02	Structural templates for STED, 510(k) and other submission types	Submission type → correct template with required sections	OoTB	
#03	Country-specific local documentation from global templates	Country fields applied; output linked to global template	OoTB	
#04	Bulk update document attributes and record data	Attributes updated across all selected items with traceability	Alternative	Via import scripts / integration — not UI bulk edit
#05	Publish and maintain submissions in digital dossier format	System supports dossier structure, publishing and lifecycle	OoTB	
#06	MEP auto-creates RIM objects after commercial approval; syncs back	RIM object auto-created after MEP approval; parameters sync	OoTB	🔑 Deal-critical integration
#07	STEP as source for RA hierarchy, regulatory attributes, labelling, UDI	STEP data used when RIM record viewed/created; source visible	OoTB	🔑 Deal-critical integration
#08	Block active-selling status before registration is complete	System blocks status change and explains reason	OoTB	
#09	Dynamic selling + registration status by country in one view	Status shown together; filterable by country — no separate report	OoTB	
#10	Built-in RA change assessment with auto country impact list & local risk class	Change at BUDI level → affected countries + local risk class	OoTB	
#11	Theoretical impact assessment per country, local risk class	Impact overview per country before final RA decision	OoTB	
#12	Perform RA assessment + assign tasks to country RA stakeholders	Tasks assigned in-system; status & ownership traceable	OoTB	
#13	Audit reports by country/region with regulatory metadata + manufacturing sites	Active/registered products + metadata per region	OoTB	
#14	System-wide product search & filter without running reports	Search from anywhere; results without pre-built report	Alternative	Module-level search + AI search for docs & reg intel
#15	Re-registration timeline intelligence with expiry notifications	Notifications based on country/BA-specific timelines	OoTB	
#16	Re-registration forecast report by country and business area	Filterable/exportable forecast report	OoTB	

#	User Story	Acceptance Criteria (summary)	Status	Note
#17	Notified when source document changes (STED linkage)	STED creator notified; action identified	OoTB	
#18	EOL notifications + discontinuation task assignment to country RA	RA Product Owner notified; tasks assigned to country RA	OoTB	
#19	Manage applicable standards linked to products at BUDI level	Standards linked; replaces manual Word-based lists	OoTB	
#20	Generate List of Applicable Standards (LoAS) with approval workflow	Populated from linked standards; routed through approval	3rd Party	⚠ Requires 3rd-party — address proactively
#21	Standard change notifications + gap analysis status	Notifications on standard version changes; gap analysis tracking	OoTB	
#22	Secure document sharing with distributors and external authorities	Controlled access; sharing traceable	OoTB	
#23	Cross-functional collaboration with role-based access	Permissions match role; actions traceable	OoTB	
#24	Record & classify health authority interactions linked to applications	Region, authority, classification, linked app captured	OoTB	
#25	Track Q&As with authorities; trend by topic, country, product	Q&As grouped by functional area; trendable	OoTB	
#26	AI-suggested answers for HA queries based on previous responses	System suggests past approved responses for review	Low Custom.	Minor customisation needed
#27	Track regulatory commitments + internal requests with deadline notifications	Notifications as due date approaches; status tracked to closure	OoTB	



COLOPLAST RIM — USER STORIES ASSESSMENT

High-Priority Stories (Score 3-4) — Part 2

Score 3-4 Stories — Full Detail (Part 2: #29–#59)

#	User Story	Acceptance Criteria (summary)	Status	Note
#29	Track regulatory agency requirements & changes by market	Agency, market, effective date, product scope, change rationale recorded	OoTB	
#30	Manage dossier content plans across markets	Market-specific content mapping, reuse rules, distribution, archival	OoTB	
#31	Submission assembly, QC, dispatch and archive in one controlled process	Assembly → nav checks → QC → dispatch → archive; each step timestamped	OoTB	

#	User Story	Acceptance Criteria (summary)	Status	Note
#32	View submitted eCTD content & lifecycle history	Structure, lifecycle status, documents; navigate historical sequences	OoTB	
#33	Maintain regulatory data for reporting and downstream RIM processes	Field validation, governance ownership, data available for reports/integrations	OoTB	
#34	Generative AI to draft/reuse regulatory content with mandatory human review	Source limited to approved content; AI text flagged; user approval required	OoTB	 Key AI differentiator — demo this
#35	See where Coloplast has licence to sell + which doc version obtained each licence	Licence status, country, linked submission, approved doc versions, history	OoTB	
#36	Choose document review/approval path and route to stakeholders	No approval / review only / approval only / review+approval; all decisions retained	OoTB	
#37	View audit history for submissions and linked documents	Binder updates, doc adds/removes, source versions, downstream use traceable	OoTB	
#38	Import/reuse documents from approved source systems into RIM	Source system, doc ID, version, import date retained	OoTB	May need source system integration
#39	See which products registered per country (RA, Vigilance, Supply Chain)	Registration list with status, validity, licence ref; PSUR/vigilance market ID	OoTB	
#40	Search by product code → licence + all products under same licence	Related licences, countries, products, registration status, linked docs	OoTB	
#41	Lifecycle state per product/country for case handover	States: draft → submitted → HA questions → approved/rejected/withdrawn	OoTB	
#42	Regulatory KPI reports: cycle time to EC/FDA/NMPA + milestone timeliness	Cycle times; milestone entry within 10 days	OoTB	
#43	All ongoing regulatory changes linked to product/country	Changes listed by country, type, owner, status, due date, linked records	OoTB	
#44	Country-level reg intel by product risk class (registration/re-registration need)	Registration required, re-reg required, expected timelines, source/last reviewed	OoTB	
#45	Select registration activity type from guided options	Activity types with definitions; validation prevents incompatible selections	OoTB	
#49	Evaluate regulatory effort + timelines for new market entry	Required registrations, docs, estimated timelines; saveable/exportable	OoTB	
#50	Monitor data quality and completeness	Missing/duplicate/inconsistent data identified; assigned to owners; tracked	OoTB	
#58	Central repository of country-specific registration requirements + evidence	Source references, ownership, review dates maintained	OoTB	
#59	Product-family registration strategies + inheritance rules	Strategy at family level; linked products inherit approved	OoTB	

#	User Story	Acceptance Criteria (summary)	Status	Note
attributes				
Score 1-2 Stories (Lower Priority — Still OoTB)				
#	User Story	Status	Note	
#28	Submit UDI directly from RIM (M2M to GUDID/EUDAMED)	3rd Party	⚠ Not native — requires 3rd party	
#46	Maintain/retrieve local RA + distributor RA contact details	OoTB		
#47	Future-proofed for direct authority data submissions	OoTB	Roadmap commitment required	
#48	Regulatory launch readiness across products + countries	OoTB		
#51	Visualise dependencies: registrations, licences, sites, legal entities	OoTB		
#52	Forecast regulatory workload + resource demand	OoTB	Compliance not stated in RFP — verify	
#53	Identify previous submissions with reusable content	OoTB		
#54	Track open regulatory commitments to authorities	OoTB		
#55	Evaluate if open regulatory commitment affected by proposed product change	OoTB		
#56	Visualise registration coverage vs. portfolio	OoTB		
#57	Regulatory performance dashboards by BA, region, portfolio	OoTB		
#60	Simulate impact of proposed product change on registrations/licences	OoTB		
#61	Create, assess + monitor regulatory risks linked to products/countries	OoTB		
#62	Compare registration requirements across multiple countries	OoTB		
#63	Monitor reg intelligence sources + alerts by country, authority, product scope	OoTB		



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COLOPLAST RIM — USER STORIES ASSESSMENT Gaps & Demo Recommendations

Items Requiring Proactive Explanation in Demo

#	Story	Score	Status	How to Address
#04	Bulk update document attributes	3-4	Alternative	Explain import scripts / integration approach. Clarify it's not a UI bulk-edit button — Coloplast may push back on this.
#14	System-wide product search without reports	3-4	Alternative	Demonstrate module-level search + AI search for documents and regulatory intel. The acceptance criteria asks for a global unified search — confirm if this is truly met.
#20	LoAS generation with approval workflow	3-4	3rd Party	High priority story marked as 3rd party. Must explain which 3rd party, how it integrates, and whether it adds cost.

#	Story	Score	Status	How to Address
#26	AI-suggested answers for HA queries	3-4	Low Custom.	Low customisation required — frame as a near-native feature. Demonstrate capability if possible in demo.
#28	UDI direct M2M submission (GUDID/EUDAMED)	1-2	3rd Party	Lower priority — less risk. Still name the 3rd party solution if asked.

Recommended Demo Flow (Based on User Stories Only)

Order	Demo Segment	User Stories Covered	Why It Resonates
1	MEP → RIM auto-creation + STEP integration	#06, #07	Opens with their two most specific integrations — immediate credibility
2	Change assessment: country impact list → local risk class → task assignment	#10, #11, #12, #43	The most complex workflow; 4 top-scored stories in sequence
3	Registration lifecycle + licence-to-sell traceability	#08, #09, #35, #40, #41	Core RIM value — show compliance gate and full audit trail
4	Re-registration intelligence + EOL notifications	#15, #16, #18	Proactive compliance — often a gap in incumbent systems
5	Generative AI content drafting with mandatory human review	#34	Explicitly called out in user stories — save this for the close
6	Health authority Q&A log + suggested answers	#24, #25, #26	Differentiator — most RIM systems don't have institutional HA knowledge reuse

Scoring Summary — What Matters Most to Coloplast

✔ STRENGTHS (48 of 48 high-priority addressed)

RegDesk fulfills the vast majority OoTB. Core RIM workflows — change assessment, registration lifecycle, re-registration, document management, AI drafting — all covered natively.

⚠ WATCH POINTS (3 stories to prepare for)

#04 Bulk update (Alternative), #14 Global search (Alternative), #20 LoAS workflow (3rd Party) — all scored 3-4. These need clear, rehearsed answers in the demo.

Source: Coloplast_RFP_RIM_Aug_2026.xlsx — "RIM user stories" sheet only. 63 stories evaluated. Assessment date: August 2026.