

Coloplast Demo Playbook

Strategic guide to impress Coloplast based on their 63 RIM User Stories · August 2026

8 Strategic Themes

48 Must-Impress Stories (Score 3-4)

2 Critical Integrations

3 Gaps to Prepare For

The 8 Strategic Themes — What Coloplast Really Cares About

These themes emerge from grouping all 63 user stories by underlying business need. Each theme has a "hidden pain" — the real problem beneath the requirement.

#	Theme	Stories	Priority	Hidden Pain / Underlying Need
	Ecosystem Integration MEP + STEP connectivity	#06, #07	Must Open With	Double maintenance between 3 systems (MEP, STEP, RIM) is killing efficiency. They named their own internal tools — they expect you to know them.
	Change Assessment Product change impact	#10, #11, #12, #43, #55, #60	Highest Priority	Manual country impact analysis is error-prone and slow. Spreadsheets and emails to country RA teams are the current state.
	Registration Lifecycle Status, licence, compliance gate	#08, #09, #35, #39, #40, #41, #45	Highest Priority	Products sometimes ship to markets without completed registration. They want a hard compliance gate and full licence traceability.
	Proactive Renewal Mgmt Re-registration + EOL	#15, #16, #18, #27, #54, #55	High Priority	Licences lapsing unnoticed is a recurring compliance risk. No system currently forecasts renewal workload by country + business area.
	Document & Submission Mgmt Templates, dossier, eCTD	#01–05, #17, #30–32, #36–38	High Priority	Documents are created from scratch in Word, disconnected from product data. Submission assembly is manual and hard to audit.
	Authority Intelligence HA interactions, Q&A, reg changes	#24–27, #29, #44, #49, #58, #63	High Priority	HA Q&As and commitments tracked in email. No institutional memory of past responses. Market intelligence in spreadsheets.
	Responsible AI Generative AI with governance	#34, #26, #14	Differentiator	They want AI — but with guardrails. Approved sources only, mandatory human review, source traceability. Sophisticated buyer.
	Strategic Visibility KPIs, dashboards, portfolio	#42, #48, #52, #56, #57, #62	Supporting	RA leadership lacks a real-time view of regulatory performance, launch readiness, and registration coverage gaps.

The Single Insight That Will Win the Room

Coloplast named **MEP** and **STEP** by name in their user stories. No generic RIM vendor does that. Open the demo by saying: "We've mapped your MEP → RIM → STEP workflow specifically." That signals you did the homework — and immediately differentiates RegDesk from every other vendor they're evaluating.



COLOPLAST DEMO PLAYBOOK — RIM USER STORIES Theme Deep Dives — Part 1

Theme Deep Dives — How to Impress on Each Theme



Theme 1 — Ecosystem Integration (MEP + STEP)

User stories: #06, #07 · Score: 3-4 on both

 Open Here

Their Pain

When MEP approves a market expansion, someone manually creates the RIM record. When STEP updates product data, someone manually updates RIM. This double maintenance is a daily friction for every RA Specialist.

How to Impress

Show the live MEP trigger → RIM object auto-creation. Then show a STEP attribute update flowing into RIM in real time. Say: *"This eliminates the copy-paste step your team does today."* Ask them: *"How many hours per week does your team spend on this sync?"*

WOW Moment

Demonstrate bi-directional sync — not just MEP → RIM, but a RIM parameter change syncing back to MEP. Story #06 explicitly asks for this. Most vendors only claim one direction.



Theme 2 — Change Assessment Workflow

User stories: #10, #11, #12, #43, #55, #60 · All scored 3-4

 Most Complex

Their Pain

A product change at the BUDI level can affect registrations in 50+ countries. Manually identifying which countries are impacted, their local risk classification, and sending tasks to each country RA via email takes days — and errors cause compliance failures.

How to Impress

Initiate a product change in the demo, show the system instantly generating the country impact list. Highlight local risk classification per country (#11). Then show task assignment flowing to country stakeholders (#12) — all in one workflow, no email.

WOW Moment

Show story #60 — the *simulation* of a proposed change before initiating it. "You can see the impact before committing." That's a risk management conversation, not just a features conversation.



Theme 3 — Registration Lifecycle & Licence Traceability

User stories: #08, #09, #35, #39, #40, #41, #45 · All scored 3-4

Core RIM Value

Their Pain

Products have been marketed in countries where registration was incomplete or expired. They want a hard compliance gate (#08) and need to know *which document version* obtained each licence (#35) — critical for inspections and change assessment.

How to Impress

Show the compliance gate blocking a product from going to active selling (#08). Then show licence-to-document traceability (#35) — for each country, display the licence, the linked submission, and the exact document version that obtained it. Frame it as audit-readiness.

WOW Moment

Story #40: enter a product code → show all licences, all countries, all products under the same licence. This is the "one source of truth" moment. Ask: *"Today, how would your team answer this question?"*



Theme 4 — Proactive Renewal & Lifecycle Management

User stories: #15, #16, #18, #27 · All scored 3-4

Recurring Risk

Their Pain

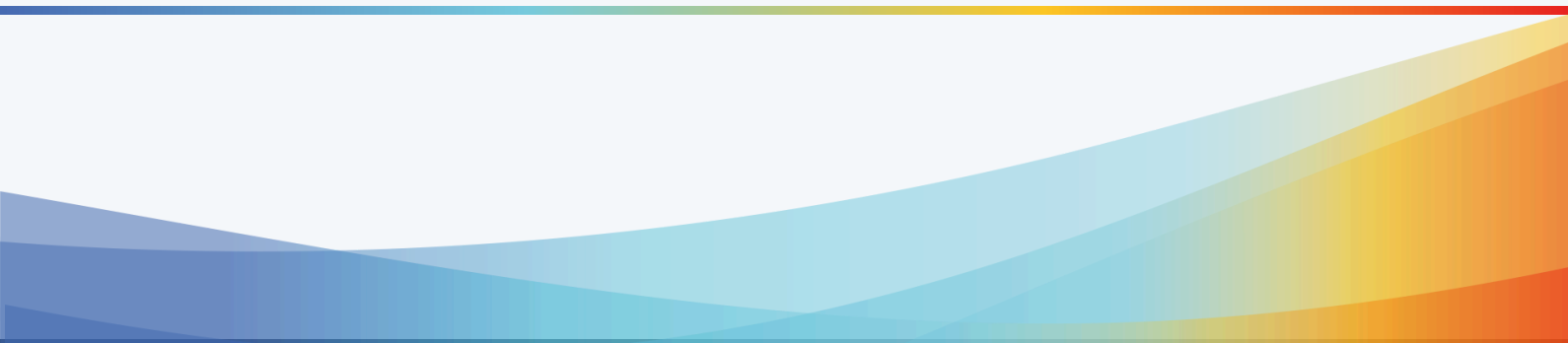
Re-registration deadlines and licence renewals are tracked in spreadsheets or calendar reminders. EOL product discontinuation tasks fall through the cracks. The RA team is reactive, not proactive.

How to Impress

Show the re-registration forecast report (#16) — a rolling view of which countries need renewal action and when, filterable by business area. Then show an automated notification (#15) arriving before a licence expiry window.

WOW Moment

Show story #18: EOL notification → RA Product Owner assigns discontinuation tasks to country RA directly in the system. The punchline: *"No spreadsheet, no email chain — the accountability is built in."*



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COLOPLAST DEMO PLAYBOOK — RIM USER STORIES Theme Deep Dives — Part 2

Theme Deep Dives Continued



Theme 5 — Document & Submission Management

User stories: #01–05, #17, #30–32, #36–38 · All scored 3-4

High Volume

Their Pain

Documents are re-created from scratch for every submission and every country. When a source document changes, linked STEDs are not automatically flagged. Submission assembly (QC → dispatch → archive) has no traceable controlled process.

How to Impress

Show template-based document creation with auto-populated product metadata (#01). Then show a source document change triggering a STED notification (#17). For submissions, walk through the assembly → QC → dispatch → archive sequence (#31) as a single auditable process.

WOW Moment

Story #03: create a country-specific document from a global template in one step, with country-specific fields pre-populated. Then show the linkage is maintained — if the global template updates, the local version is flagged. This kills a major manual workload.



Theme 6 — Authority Intelligence & Regulatory Commitments

User stories: #24–27, #29, #44, #49, #58 · All scored 3-4

Differentiator

Their Pain

Health authority interactions and commitments are tracked in email threads and personal notebooks. When an RA Specialist leaves, institutional knowledge of past HA conversations is lost. Market expansion decisions rely on individual expertise, not centralised data.

How to Impress

Show HA interaction recording (#24) with link to the application. Then demonstrate Q&A trend analysis by topic/country (#25). For market expansion, show story #49: select a target market → system displays required registrations, estimated timelines, and readiness score.

WOW Moment

Story #26: enter a new HA query → system surfaces suggested answers from previous approved responses. Frame it as: *"Your institutional regulatory knowledge stays in the system, not in someone's inbox."*

Theme 7 — Responsible AI

User stories: #34, #26, #14 · All scored 3-4 · Key differentiator

🏆 Close With This

Their Pain

They want AI to speed up regulatory drafting — but they're nervous about hallucinations and compliance liability. Story #34's acceptance criteria is highly specific: approved sources only, source references visible, AI text marked for review, human approval required before use.

How to Impress

Don't lead with "we have AI." Lead with: *"We built AI the way regulators think."* Show the guardrails first — source material is limited to approved content, every AI-assisted section is flagged for review, and the document cannot proceed without user approval.

WOW Moment

Demonstrate that source references are visible inline — the user can see exactly which approved document the AI drew from. This is the difference between "AI assistant" and "AI you can put in front of an FDA inspector."



Theme 8 — Strategic Visibility (RA Leadership)

User stories: #42, #48, #52, #56, #57, #62 · Scored 1-2 (supporting)

For Decision-Makers

Their Pain

RA leadership lacks a real-time view of regulatory performance. Launch readiness is assembled manually. Registration coverage gaps relative to commercial portfolio are invisible until a problem surfaces.

How to Impress

If a Coloplast RA Director is in the room, switch to the KPI dashboard (#42/#57) at this point. Show cycle times to EC/FDA/NMPA certification and registration coverage vs. active-selling markets (#56). This speaks to their language, not RA Specialist language.

WOW Moment

Story #48: regulatory launch readiness dashboard — blockers, outstanding tasks, and approvals for a product across all target markets. Frame it as: *"The single view your commercial and RA leadership have never had before."*

Recommended Demo Sequence (60-Minute Demo)

Time	Segment	Stories Covered	What to Say / Show	Audience
0–5 min	 MEP + STEP Integration	#06, #07	Open with: <i>"We mapped your MEP → RIM → STEP workflow specifically."</i> Show auto-creation + bi-directional sync.	All
5–18 min	 Change Assessment	#10, #11, #12, #43, #60	Initiate a BUDI-level change → auto country impact list → local risk class per country → task RA Specialists assignment → show pre-change simulation.	
18–28 min	 Registration + Licence Traceability	#08, #09, #35, #40, #41	Show compliance gate → single-view status → product code search to licence → all products under same licence → lifecycle states.	RA Specialists + Compliance
28–35 min	 Proactive Renewal Mgmt	#15, #16, #18	Forecast report by country + BA → expiry notification → EOL task assignment. Punchline: All no spreadsheets, built-in accountability.	
35–45 min	 Authority Intelligence	#24, #25, #26, #49	HA interaction log → Q&A trend analysis → AI-suggested answer from past responses → new market entry readiness assessment.	RA Specialists
45–55 min	 Responsible AI	#34	Lead with guardrails, not features. Show approved-source AI drafting → inline source reference → mandatory human review gate.	All + IT/Risk
55–60 min	 Leadership Dashboard	#42, #48, #57	KPI cycle times → launch readiness → registration coverage gap. Frame as: <i>"The view RA leadership has never had before."</i>	RA Directors

3 Gaps to Address Proactively — Don't Let Them Catch You

⚠️ **#04 — Bulk Update (Alternative)** Score 3-4. Bulk document attribute updates delivered via import scripts / integration, not a UI button. Prepare: explain the workflow, acknowledge the limitation, show the import path. If possible, show it on screen.

⚠️ **#14 — Global Search (Alternative)** Score 3-4. Module-level search + AI search for docs. Acceptance criteria asks for system-wide unified search. Be honest: demonstrate what exists, be clear on roadmap if global search is planned.

⚠️ **#20 — LoAS Workflow (3rd Party)** Score 3-4. List of Applicable Standards with approval workflow requires a 3rd-party solution. Name the partner, explain the integration, confirm it doesn't add friction to the user experience.

Discovery Questions to Ask Coloplast During the Demo

Question	What Their Answer Tells You
"How many hours per week does your RA team spend syncing data between MEP, STEP and your current RIM?"	Quantifies the MEP/STEP integration ROI in their own words
"When a product change is initiated today, how long does it take to identify all impacted countries?"	Establishes baseline for change assessment workflow value
"Have you ever had a licence lapse or a product marketed in a country without completed registration?"	Validates the compliance gate story — usually unlocks a real war story
"When an RA Specialist leaves, how does their knowledge of past HA interactions get transferred?"	Opens the door to the institutional knowledge / HA Q&A story
"What does your RA leadership currently use to track cycle times to EC, FDA, and NMPA approval?"	Positions the KPI dashboard as solving a real leadership gap

