Business Case Questionnaire

Helping RegDesk build your tailored cost savings estimate in Regulatory Information Management

The following questions help our team understand your current regulatory operations so we can estimate the potential cost savings from adopting a Regulatory Information Management (RIM) solution. All information is kept strictly confidential and used exclusively to build your personalized business case. Estimated completion time: 15–20 minutes.

COMPANY INFORMATION

COMPANY NAME

PRIMARY CONTACT

TITLE / ROLE

DATE COMPLETED

 # OF COUNTRIES (REGISTERED OR PENDING)

 # OF PRODUCTS IN PORTFOLIO

Confidentiality Notice: All information provided in this questionnaire is treated as strictly confidential. Data will be used exclusively to calculate your organization's personalized ROI estimate and will not be shared with any third parties.

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WHAT RIM FUNCTIONALITY IS OF MOST INTEREST TO YOUR TEAM?

Check all that apply

☐ **PLAN**

Regulatory Intelligence and Standards Monitoring
Monitor regulatory changes, create global regulatory plans, manage standards assessments.

☐ **BUILD**

Collaborating on Deliverables, AI Submission Building
Coordinate deliverables, build AI-assisted submissions, manage GSPRs and Declarations of Conformity.

☐ **TRACK**

Source of Truth for Submission and Task Status
Centralize registration status, report generation, stop-ship alerts, and audit-ready data.

☐ **MAINTAIN**

Change Control Workflow and Assessments Globally
Manage change control assessments across global markets with full traceability.

TOP REGULATORY PAIN POINTS

Describe up to 5 key pain points you are hoping a RIM solution can help improve.

#	PAIN POINT / CHALLENGE	IMPACT ON YOUR TEAM
1		
2		
3		
4		
5		

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PLAN *Regulatory intelligence, standards monitoring, and building global regulatory strategies.*

Section 1 — Regulatory Intelligence & Monitoring

Time and effort spent tracking regulatory changes, legislative updates, and building global regulatory plans.

QUESTION	UNIT	YOUR ANSWER
1. How many people in your RA team perform regulatory monitoring?	*# people*	
2. Average hours per week each person spends on monitoring?	*hrs/week*	
3. How many new product launch regulatory plans per year?	*plans/year*	
4. Average hours per new product launch plan?	*hours*	
5. How many existing-product-to-new-country regulatory plans per year?	*plans/year*	
6. Average hours per existing-product-to-new-country plan?	*hours*	

Section 2 — Standards & Legislation Monitoring

Monitoring standards, legislation, and guidances — and completing assessments when changes occur.

QUESTION	UNIT	YOUR ANSWER
7. How many people monitor standards, legislation, and guidances?	*# people*	
8. Average hours per week each person spends on standards monitoring?	*hrs/week*	
9. How many standards/legislations/guidances change per year requiring formal assessment?	*per year*	
10. Average hours per assessment process (including coordination)?	*hours*	

TRACK *Registration status, reporting, and stop-ship decision support.*

Section 3 — Registration Status & Reporting

Managing registration status, stop-ship decisions, and generating reports for internal stakeholders.

QUESTION	UNIT	YOUR ANSWER
11. How many regulatory status queries/reports per month?	*queries/month*	
12. Average hours per report?	*hours*	

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BUILD *Submissions, technical documentation, and managing deliverables with regional partners.*

Section 4 — Submissions Management

Creating country-specific regulatory submissions and coordinating deliverables with regional partners.

QUESTION	UNIT	YOUR ANSWER
13. How many global regulatory submissions per year?	*submissions/year*	
14. Average hours spent coordinating deliverables per submission?	*hours*	
15. Average monthly revenue per product per market?	*USD/month*	
16. Estimated months a RIM solution could accelerate your time to market?	*months*	

Section 5 — Technical Documentation & Compliance Forms

Time spent creating and revising GSPR/EPC checklists and Declarations of Conformity.

QUESTION	UNIT	YOUR ANSWER
17. How many GSPR/EPC created or revised per year?	*per year*	
18. Average hours per GSPR/EPC creation/revision?	*hours*	
19. How many Declarations of Conformity created or revised per year?	*per year*	
20. Average hours per DoC creation/revision?	*hours*	

MAINTAIN *Change control workflows and global assessments to keep registrations current.*

Section 6 — Change Control & Global Assessments

Coordinating and completing change control assessments across global markets.

QUESTION	UNIT	YOUR ANSWER
21. How many change control assessments per year?	*assessments/year*	
22. Average # of countries impacted per change?	*countries*	
23. Average hours per country-level assessment?	*hours*	

PLAN *RA team cost assumptions — used to calculate total cost of regulatory activities.*

Section 7 — RA Team & Cost Assumptions

Used to calculate the total cost of regulatory activities across your organization.

QUESTION	UNIT	YOUR ANSWER
24. Average fully-loaded annual cost of an RA team member? (salary × ~1.3)	*USD/year*	
25. Average productive working hours per year per FTE? (typical: 2,000–2,400)	*hours/year*	
26. How many RA employees (full-time) does your company have?	*# FTEs*	
27. How many RA contractors or consultants do you use?	*# FTEs*	

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ADDITIONAL NOTES

Use this space for any context that may help us build a more accurate picture of your regulatory operations.

What happens next?

1. **Analyze Responses**
   Our team reviews your answers and maps them to the ROI model
2. **Build Tailored Business Case**
   We calculate your projected time savings, cost reduction, and revenue impact
3. **Schedule 30-Min Walkthrough**
   We present your personalized ROI report and answer any questions

RETURN COMPLETED FORM TO

REGDESK ACCOUNT EXECUTIVE

EMAIL

PREFERRED MEETING DATE/TIME

PHONE / WHATSAPP

Thank you for taking the time to complete this questionnaire. We look forward to building your personalized RegDesk business case.

— RegDesk Sales Team

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