

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 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 is treated as strictly confidential and used exclusively to build your organization's personalized business case. Data will not be shared with any third parties.

WHAT RIM FUNCTIONALITY IS OF MOST INTEREST TO YOUR TEAM?

Check all that apply

☐ PLAN

Regulatory intelligence, standards monitoring, and building global regulatory strategies and plans.

Includes: regulatory change monitoring, standards assessments, new-country expansion plans

☐ BUILD

Creating regulatory submissions, technical documentation, and managing deliverables with regional partners.

Includes: submissions management, GSPR/EPC checklists, Declarations of Conformity

☐ TRACK

Centralizing registration status, reporting, stop-ship alerts, and providing audit-ready data.

Includes: status tracking, internal reports, stop-ship decision support

☐ MAINTAIN

Managing change control workflows and global assessments to keep registrations current.

Includes: change control assessments, global market impact analysis, renewal tracking

TOP REGULATORY PAIN POINTS

Describe up to 5 key challenges you are hoping a RIM solution can help address.

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

PLAN Planning activities: regulatory intelligence, standards monitoring, team costs, and building global regulatory strategies.

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	

Standards & Legislation Monitoring

Effort spent tracking standards, legislation, and guidances — and completing impact 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 change per year requiring formal assessment?	per year	
10. Average hours per assessment process (including coordination)?	hours	

RA Team & Cost Assumptions

Used to estimate the total cost of regulatory activities across your organization and calculate potential savings.

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

BUILD Build activities: creating submissions, technical documentation, and managing deliverables with regional partners.

Submissions Management

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

QUESTION	UNIT	YOUR ANSWER
15. How many global regulatory submissions per year?	submissions/year	
16. Average days to create a single submission?	days	
17. Average hours spent coordinating deliverables per submission?	hours	
18. Average monthly revenue per product per market?	USD/month	

Technical Documentation & Compliance Forms

Time spent creating and revising compliance documents such as GSPR/EPC checklists and Declarations of Conformity.

QUESTION	UNIT	YOUR ANSWER
19. How many GSPR/EPC checklists created or revised per year?	per year	
20. Average hours per GSPR/EPC creation/revision?	hours	
21. How many Declarations of Conformity created or revised per year?	per year	
22. Average hours per Declaration of Conformity creation/revision?	hours	

TRACK Track activities: maintaining a real-time source of truth for registration status, reporting, and stop-ship decision support.

Registration Status & Reporting

Effort spent managing registration status, generating reports for internal stakeholders, and supporting stop-ship decisions.

QUESTION	UNIT	YOUR ANSWER
23. How many regulatory status queries or reports generated per month?	queries/month	
24. Average hours spent per status report?	hours	
25. How many stop-ship decisions are reviewed per year?	per year	
26. Average hours spent investigating and resolving each stop-ship case?	hours	

MAINTAIN Maintain activities: change control workflows and assessments to keep global registrations current and traceable.

Change Control & Global Assessments

Coordinating and completing change control assessments across global markets with full traceability.

QUESTION	UNIT	YOUR ANSWER
27. How many change control assessments per year?	assessments/year	
28. Average # of countries impacted per change?	countries	
29. Average hours per country-level assessment?	hours	

ADDITIONAL NOTES

Use this space for any additional 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 cost savings model

2

Build Tailored Business Case

We calculate your projected time savings, cost reduction & revenue impact

3

Schedule 30-Min Walkthrough

We present your personalized business case report and answer any questions

RETURN COMPLETED FORM TO

REGDESK ACCOUNT EXECUTIVE

EMAIL

PREFERRED MEETING DATE / TIME

PHONE / WHATSAPP

Thank you for completing this questionnaire. We look forward to building your personalized RegDesk business case.

— RegDesk Sales Team