

CLIENT INFORMATION

COMPANY NAME	PRIMARY CONTACT
TITLE / ROLE	DATE

Cost Assumptions (from questionnaire — Section 7: RA Team & Cost)			
ASSUMPTION	CLIENT VALUE	UNIT	NOTES
Avg Fully-Loaded RA FTE Cost		USD/year	Salary × 1.3
Productive Hours / Year / FTE		hours	Typically 2,000–2,400
Total RA FTEs (employees)		# FTEs	From questionnaire
RA Contractors / Consultants		# FTEs	From questionnaire
Avg Monthly Revenue per Market		USD/month	Per product, one country

Savings Summary (auto-calculated — fill inputs on pages 2–3 first)		
MODULE	RECOVERABLE SAVINGS	FTE EQUIV.
PLAN Regulatory intelligence & standards monitoring		
Regulatory Intelligence & Monitoring		
Standards & Legislation Monitoring		
TRACK Registration status & reporting		
Registration Status & Reporting		
BUILD Submissions, documentation & deliverables		
Submissions Management		
Submissions & Time-to-Market		
Technical Documentation & Compliance Forms		
MAINTAIN Change control & global assessments		
Change Control & Global Assessments		
Speed-to-Market Revenue (Submissions Management)		
TOTAL PROJECTED SAVINGS		

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

Section 1 — Regulatory Intelligence & Monitoring

PLAN

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

QUESTION (FROM CLIENT QUESTIONNAIRE)	UNIT	CLIENT VALUE	SAVINGS %
1. # People performing regulatory monitoring	# people		100% saving
2. Hours/week per person on monitoring	hrs/week		100% saving
3. # NPD regulatory plans per year	plans/yr		50% saving
4. Avg hours per NPD regulatory plan	hours		50% saving
5. # Existing-product-to-new-country plans/year	plans/yr		50% saving
6. Avg hours per existing-product plan	hours		50% saving

Section 2 — Standards & Legislation Monitoring

PLAN

Effort spent tracking standards, legislation, and guidances — and completing impact assessments when changes occur.

QUESTION (FROM CLIENT QUESTIONNAIRE)	UNIT	CLIENT VALUE	SAVINGS %
7. # People monitoring standards/legislation	# people		100% saving
8. Avg hours/week per person on standards monitoring	hrs/week		100% saving
9. # Standards/legislations changing per year	per year		50% saving
10. Avg hours per assessment process	hours		50% saving

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

Section 3 — Registration Status & Reporting

TRACK

Effort spent managing registration status and generating reports for internal stakeholders.

QUESTION (FROM CLIENT QUESTIONNAIRE)	UNIT	CLIENT VALUE	SAVINGS %
11. # Regulatory status queries/reports per month	queries/mo		95% saving
12. Avg hours per report	hours		95% saving

BUILD

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

Section 4 — Submissions Management

BUILD

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

QUESTION (FROM CLIENT QUESTIONNAIRE)	UNIT	CLIENT VALUE	SAVINGS %
13. # Global regulatory submissions per year	subs/yr		85% saving
14. Avg hours coordinating deliverables per submission	hours		85% saving
15. Avg monthly revenue per product per market	USD/mo		

Section 5 — Submissions & Time-to-Market

BUILD

Effort and revenue impact of regulatory submission timelines.

QUESTION (FROM CLIENT QUESTIONNAIRE)	UNIT	CLIENT VALUE	SAVINGS %
16. # Global submissions per year	subs/yr		85% saving
17. Avg days to create one submission	days		85% saving
18. Avg monthly revenue per product per market	USD/mo		

Section 6 — Technical Documentation & Compliance Forms

BUILD

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

QUESTION (FROM CLIENT QUESTIONNAIRE)	UNIT	CLIENT VALUE	SAVINGS %
19. # GSPR/EPC created or revised per year	per year		85% saving
20. Avg hours per GSPR/EPC creation/revision	hours		85% saving
21. # Declarations of Conformity per year	per year		85% saving
22. Avg hours per DoC creation/revision	hours		85% saving

MAINTAIN

Change control workflows and global assessments to keep registrations current.

Section 7 — Change Control & Global Assessments

MAINTAIN

Coordinating and completing change control assessments across global markets.

QUESTION (FROM CLIENT QUESTIONNAIRE)	UNIT	CLIENT VALUE	SAVINGS %
23. # Change control assessments per year	assess/yr		75% saving
24. Avg # countries impacted per change	countries		75% saving
25. Avg hours per country-level assessment	hours		75% saving

FORMULA REFERENCE

Reg Intelligence Monitoring: $\text{people} \times \text{hrs_wk} \times \text{FTE_cost} \times 52 / \text{hrs_yr} \times 100\%$
Standards Monitoring: $\text{people} \times \text{hrs_wk} \times \text{FTE_cost} \times 52 / \text{hrs_yr} \times 100\%$
Registration & Reporting: $\text{queries_mo} \times \text{hrs} \times (\text{FTE_cost} / \text{hrs_yr}) \times 12 \times 95\%$
Technical Documentation: $(\text{gspr} \times \text{hrs} + \text{doc} \times \text{hrs}) \times (\text{FTE_cost} / \text{hrs_yr}) \times 85\%$
Change Control: $\text{assess} \times \text{countries} \times \text{hrs} \times (\text{FTE_cost} / \text{hrs_yr}) \times 75\%$

Reg Intelligence Plans: $\text{plans} \times \text{hrs} \times (\text{FTE_cost} / \text{hrs_yr}) \times 50\%$
Standards Assessment: $\text{changes} \times \text{hrs} \times (\text{FTE_cost} / \text{hrs_yr}) \times 50\%$
Submissions Management: $\text{subs} \times \text{hrs} \times (\text{FTE_cost} / \text{hrs_yr}) \times 85\%$
Time-to-Market: $\text{subs} \times \text{days} \times 8\text{hrs} \times (\text{FTE_cost} / \text{hrs_yr}) \times 85\%$
Speed-to-Market Revenue: $\text{monthly_rev} \times 3 \text{ months (Submissions)}$

► Calculate Savings — Click to Run All Calculations