## 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** | | |

Calculate Savings | Import Client F | > Export FD | xport Repo

**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:** people × hrs_wk × FTE_cost × 52 / hrs_yr × 100%

**Standards Monitoring:** people × hrs_wk × FTE_cost × 52 / hrs_yr × 100%

**Registration & Reporting:** queries_mo × hrs × (FTE_cost / hrs_yr) × 12 × 95%

**Technical Documentation:** (gspr × hrs + doc × hrs) × (FTE_cost / hrs_yr) × 85%

**Change Control:** assess × countries × hrs × (FTE_cost / hrs_yr) × 75%

**Reg Intelligence Plans:** plans × hrs × (FTE_cost / hrs_yr) × 50%

**Standards Assessment:** changes × hrs × (FTE_cost / hrs_yr) × 50%

**Submissions Management:** subs × hrs × (FTE_cost / hrs_yr) × 85%

**Time-to-Market:** subs × days × 8hrs × (FTE_cost / hrs_yr) × 85%

**Speed-to-Market Revenue:** monthly_rev × 3 months (Submissions)

Calculate Savings