

REGDESK REGULATORY INTELLIGENCE MANAGEMENT

ROI Report for Investment

Imricor Medical Systems — Regulatory Affairs Efficiency

PREPARED FOR

**Imricor — VP
Regulatory Affairs**

RA TEAM SIZE

**9 FTEs · \$150K Fully
Loaded**

MARKET FOOTPRINT

**18 Countries · 13 Product
Families**

DATE

**July
2026**

EXECUTIVE SUMMARY

Imricor Medical Systems operates across **18 countries** with a **9-FTE regulatory affairs team** managing 13 product families and 45 global submissions per year. The team faces a growing compliance and submission workload: 100 change control assessments per year each touching an average of 23 countries, 45 global submissions requiring 112 hours of coordination each, and 3 staff spending 4.5 hours per week on regulatory monitoring. Manual processes consume an estimated **9,892 hrs/yr** — 55% of total team capacity — in recoverable overhead.

This ROI report quantifies Imricor's efficiency savings case for RegDesk, derived entirely from **Imricor's own operational data**. At Full RIM pricing, RegDesk delivers **\$746,055/yr** in recoverable efficiency savings against a total Year 1 investment of \$266,250 — generating **\$1,499,415 net benefit over 3 years** and a payback period of approximately **5 months**.

\$146,250/yr

Full RIM License (Actual)
All modules · 18 countries · \$2,000/application (App Builder)

55%

Team Capacity in Manual Overhead
9,892 hrs/yr recoverable · 9 FTEs · 18,000 hrs available

45

Global Submissions/yr
112 hrs each · 85% overhead recoverable with App Builder

Bottom Line: Based on Imricor's own operational data, quantified efficiency savings total **\$2,238,165 over 3 years** against a \$738,750 total Full RIM investment — a **203% 3-year ROI** with payback in approximately **5 months**. The primary ROI driver is change control automation (\$258,750/yr) and AI-powered submission preparation (\$321,300/yr savings vs. \$90,000/yr App Builder fees).

IMRICOR'S OPERATIONAL REALITY

The following analysis is derived directly from Imricor's own operational data. Each line item represents time that is currently consumed by manual, cross-system processes — time that cannot be redirected to higher-value regulatory work.

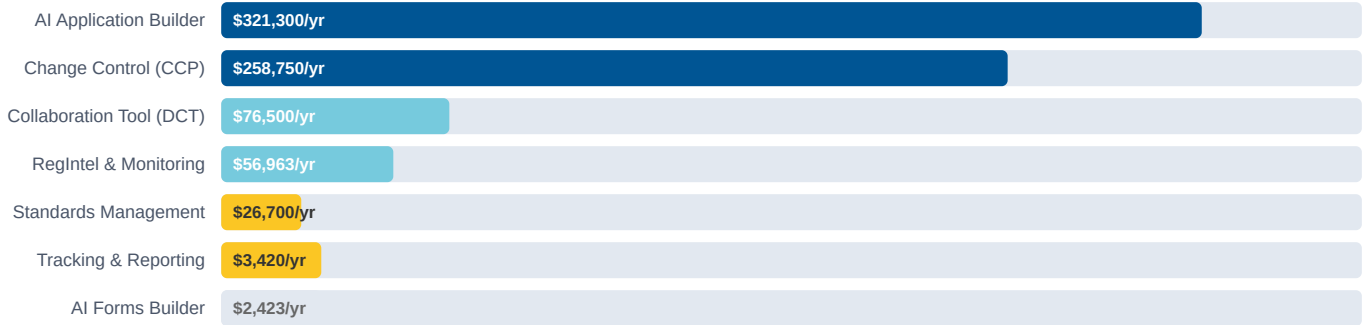
Cost Driver	Imricor Data Point	Annual Hours	Annual Cost*	Priority
Regulatory Monitoring	3 people × 4.5 hrs/wk · 100% savings	702 hrs/yr	\$52,650	HIGH
Submission Coordination	15 submissions × 80 hrs × 85% overhead	1,020 hrs/yr	\$76,500	HIGH
Standards Monitoring	3 people × 1 hr/wk · 100% savings	156 hrs/yr	\$11,700	MEDIUM
Standards Assessments	10 standards × 40 hrs × 50% overhead	200 hrs/yr	\$15,000	HIGH
Change Control (CCP)	100 assessments × 23 countries × 2 hrs × 75%	3,450 hrs/yr	\$258,750	HIGH
AI Submission Prep	45 submissions × 112 hrs × 85% overhead	4,284 hrs/yr	\$321,300	HIGH
GSPR & DOC Management	10 forms × various hrs × 85% overhead	34 hrs/yr	\$2,423	MEDIUM
Registration Reporting	4 reports/month × 1 hr × 95% savings	46 hrs/yr	\$3,420	MEDIUM
TOTAL (Recoverable)	Blended RA cost rate: \$75/hr	~9,892 hrs/yr	\$746,055/yr	ACTION

*Blended RA cost rate of \$75/hr applied (\$150K fully loaded ÷ 2,000 productive hrs/yr).

CAPACITY GAP: TEAM AT LIMIT

9 FTEs × 2,000 hrs = **18,000 hrs available annually**. Recoverable overhead consumes ~9,892 hrs = **55% of total team capacity** — before accounting for non-recoverable regulatory work. Change control alone (100 assessments × 23 countries) accounts for 4,600 country-assessments per year. AI Submission Prep at 45 submissions × 112 hrs = 5,040 hrs total workload before overhead reduction.

SAVINGS BY MODULE



TWO PATHS TO ROI — BASED ON IMRICOR'S OWN DATA

Actual RegDesk pricing applied. All savings derived from Imricor's operational data.

Base RIM
\$72,500/yr + \$21,600 one-time setup

Modules	RegIntel · DCT · Tracking
Annual Savings	\$136,883/yr
Year 1 Investment	\$94,100
Year 1 Net Benefit	+\$42,783
3-Yr Investment	\$239,100
3-Yr Total Savings	\$410,649
3-Yr Net Benefit	+\$171,549

72%

3-Year ROI · Payback ~8 months

Best for: Teams focused on regulatory intelligence, submission coordination and real-time status reporting.

Full RIM ★
\$146,250/yr + \$30,000 setup + \$2,000/application

Modules	All Base + Standards · CCP · App Builder · Forms
Annual Savings	\$746,055/yr
App Builder Fees (45 × \$2K)	\$90,000/yr
Year 1 Investment	\$266,250
Year 1 Net Benefit	+\$479,805
3-Yr Investment	\$738,750
3-Yr Total Savings	\$2,238,165
3-Yr Net Benefit	+\$1,499,415

203%

3-Year ROI · Payback ~5 months

Best for: Full automation of RA operations — change control at scale, AI-powered submissions, standards tracking, and compliance forms.

Primary CFO Argument: The App Builder costs \$90,000/yr in fees (45 submissions × \$2,000) but recovers \$321,300/yr in RA efficiency savings — a **3.6× return on the App Builder fee alone**. Change Control automation adds another \$258,750/yr. Combined, these two modules drive \$580,050/yr in savings against \$90,000/yr in incremental fees — making Full RIM the clear investment choice.

3-YEAR INVESTMENT VS. RETURN — ACTUAL REGDESK PRICING

BASE RIM — \$72,500/yr				
Item	Year 1	Year 2	Year 3	3-Yr Total
Platform License	\$72,500	\$72,500	\$72,500	\$217,500
Setup Fee	\$21,600	—	—	\$21,600
Total Investment	\$94,100	\$72,500	\$72,500	\$239,100
RegIntel & Monitoring	\$56,963	\$56,963	\$56,963	\$170,888
Tracking & Reporting	\$3,420	\$3,420	\$3,420	\$10,260
Collaboration Tool (DCT)	\$76,500	\$76,500	\$76,500	\$229,500
Total Savings	\$136,883	\$136,883	\$136,883	\$410,649
Net Benefit	+\$42,783	+\$64,383	+\$64,383	+\$171,549

FULL RIM — \$146,250/yr + \$2,000/application				
Item	Year 1	Year 2	Year 3	3-Yr Total
Platform License	\$146,250	\$146,250	\$146,250	\$438,750
App Builder Fees (45 × \$2,000)	\$90,000	\$90,000	\$90,000	\$270,000
Setup Fee	\$30,000	—	—	\$30,000
Total Investment	\$266,250	\$236,250	\$236,250	\$738,750
RegIntel & Monitoring	\$56,963	\$56,963	\$56,963	\$170,888
Tracking & Reporting	\$3,420	\$3,420	\$3,420	\$10,260
Collaboration Tool (DCT)	\$76,500	\$76,500	\$76,500	\$229,500
Standards Management	\$26,700	\$26,700	\$26,700	\$80,100
Change Control (CCP)	\$258,750	\$258,750	\$258,750	\$776,250
AI Application Builder	\$321,300	\$321,300	\$321,300	\$963,900
AI Forms Builder	\$2,423	\$2,423	\$2,423	\$7,269
Total Savings	\$746,055	\$746,055	\$746,055	\$2,238,165
Net Benefit	+\$479,805	+\$509,805	+\$509,805	+\$1,499,415

BASE RIM

72%

3-Year ROI · Payback ~8 months

FULL RIM

203%

3-Year ROI · Payback ~5 months

REGDESK DIRECTLY ADDRESSES IMRICOR'S CHALLENGES



Centralized Registration Tracking

Pain: Manual spreadsheet tracking of registration status across 18 markets

RegDesk provides real-time registration status visibility across all 18 active countries — replacing fragmented spreadsheets with a single source of truth accessible to RA, sales, and executive teams.



Change Control Automation

Pain: Coordinating 100 change assessments across 23 countries per year

100 assessments × 23 countries = 4,600 country-assessments/yr. RegDesk CCP automates impact scoping, routes to regional SMEs, and tracks completion — recovering 3,450 hrs/yr at \$258,750/yr value.



AI-Powered Submission Builder

Pain: 45 global submissions/yr at 112 hours each — manual, repetitive

RegDesk App Builder uses AI to pre-populate country-specific templates and leverage prior submissions — recovering \$321,300/yr in RA efficiency against a \$90,000/yr fee (3.6× return on the module cost).



Standards & GSPR Management

Pain: Manually maintaining GSPRs and declarations of conformity

RegDesk automatically monitors standard updates and triggers GSPR/DOC revision workflows — eliminating manual tracking of 10+ standard changes per year and recovering \$26,700/yr.



Global Regulatory Intelligence

Pain: 3 staff spending 4.5 hrs/week monitoring regulatory changes

RegDesk RegIntel delivers curated updates for all 18 Imricor markets and generates regulatory plans for new market entries — recovering 702 hrs/yr of monitoring overhead (\$52,650/yr).



Real-Time Reporting

Pain: 4 status report requests per month, 1 hr each

RegDesk's live dashboards eliminate manual report generation — any stakeholder (sales, finance, executive) can access current registration status, renewal deadlines, and portfolio health without RA involvement.

At **\$146,250/yr + \$2,000/application**, RegDesk Full RIM delivers a **203% 3-year ROI** and **\$1,499,415 net benefit** over 3 years — based entirely on Imricor's own operational data. The platform pays for itself in approximately **5 months**. Change control and AI submission automation alone recover \$580,050/yr against \$90,000/yr in App Builder fees.

Prepared by RegDesk · July 2026 · Confidential · regdesk.co · All figures based on Imricor's own operational data.