REGDESK REGULATORY INTELLIGENCE MANAGEMENT

ROI Report for Investment

Imricor Medical Systems — Regulatory Affairs Efficiency

PREPARED FOR	RA TEAM SIZE	MARKET FOOTPRINT	DATE
Imricor — VP Regulatory Affairs	9 FTEs · $150K Fully Loaded	18 Countries · 13 Product Families	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 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**.

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IMRICOR'S OPERATIONAL REALITY

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

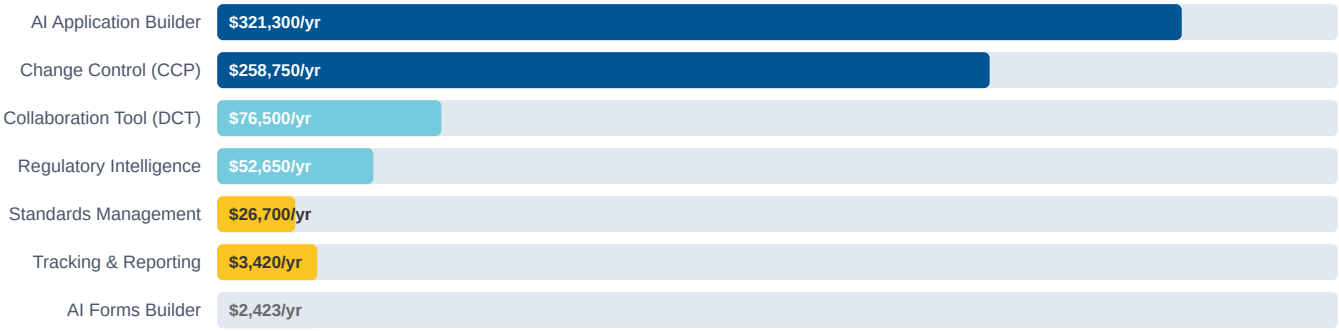
Cost Driver	Imricor Data Point	Annual Hours	Annual Cost*	Priority
Regulatory Intelligence	3 people × 4.5 hrs/wk · 100% savings	702 hrs/yr	$52,650	HIGH
Collaboration Tool (DCT)	15 submissions × 80 hrs × 85% overhead	1,020 hrs/yr	$76,500	HIGH
Standards Management	Monitoring (3 ppl × 1 hr/wk) + 10 assessments × 40 hrs × 50%	356 hrs/yr	$26,700	HIGH
Change Control (CCP)	100 assessments × 23 countries × 2 hrs × 75%	3,450 hrs/yr	$258,750	HIGH
AI Application Builder	45 submissions × 112 hrs × 85% overhead	4,284 hrs/yr	$321,300	HIGH
AI Forms Builder	10 forms × various hrs × 85% overhead	34 hrs/yr	$2,423	MEDIUM
Tracking & 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). Standards Management combines monitoring (156 hrs) and assessments (200 hrs).

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**. AI Application Builder (4,284 hrs) and Change Control (3,450 hrs) alone account for 43% of total available capacity.

SAVINGS BY MODULE



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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.

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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

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REGDESK DIRECTLY ADDRESSES IMRICOR'S CHALLENGES

Centralized Registration Tracking

Pain: Manual spreadsheet tracking across 18 markets

Real-time registration status visibility across all 18 active countries — replacing fragmented spreadsheets with a single source of truth for RA, sales, and executive teams.

Change Control Automation

Pain: 100 assessments × 23 countries/yr

4,600 country-assessments/yr automated. RegDesk CCP routes to regional SMEs and tracks completion — recovering 3,450 hrs/yr at $258,750/yr value.

AI Application Builder

Pain: 45 global submissions × 112 hrs each

AI pre-populates country-specific templates and leverages prior submissions — recovering $321,300/yr against a $90,000/yr fee (3.6× return on module cost).

Standards Management

Pain: Manual GSPR/DOC maintenance + standards monitoring

Automatic standard update monitoring triggers GSPR and DOC revision workflows. Recovers $26,700/yr across 10+ standard changes and 156 hrs/yr of standards monitoring.

Collaboration Tool (DCT)

Pain: Submission coordination across countries and partners

RegDesk DCT centralizes submission planning, document management, and distributor coordination — recovering 1,020 hrs/yr ($76,500) across 15 submissions/yr.

Global Regulatory Intelligence

Pain: 3 staff × 4.5 hrs/week monitoring 18 markets

Curated regulatory updates for all 18 markets + instant global regulatory plans for new market entries. Recovers 702 hrs/yr ($52,650) of monitoring overhead.

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**.

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

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