REGDESK REGULATORY INTELLIGENCE MANAGEMENT

RegDesk Business Case for Imricor Medical Systems

Benefits & ROI Analysis — July 2026

PREPARED FOR	RA TEAM	MARKETS	DATE
Imricor — Regulatory Affairs	9 FTEs · $150K Loaded	18 Countries	July 2026

ABOUT THIS REPORT

This document presents RegDesk's value proposition tailored specifically to Imricor Medical Systems — a pioneering interventional MRI medical device company operating across 18 countries with a growing portfolio of MRI-compatible cardiac devices. The figures in this report are derived entirely from Imricor's own operational data and current team structure, not from generic benchmarks.

The analysis covers two dimensions: (1) the specific benefits that each of RegDesk's platform modules delivers to Imricor's regulatory operations, and (2) a quantified ROI model showing exactly where and how those benefits translate into recoverable cost savings.

SOURCE DATA

All cost figures are computed from Imricor's own operational data, July 2026. FTE loaded cost assumed at $150,000/year ($75/hr · 2,000 hrs/yr). Savings percentages reflect RegDesk's efficiency methodology applied to Imricor's specific workflow data.

REPORT STRUCTURE

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Pg 3–4: Module-by-Module Benefits

Pg 5: ROI Business Case & Cost Model

Pg 6: Savings by Module

Pg 7: RA Team Context & Qualitative Benefits

Pg 8: Why RegDesk for Imricor & Next Steps

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IMRICOR MEDICAL SYSTEMS: A PIONEER IN INTERVENTIONAL MRI

Headquartered in Burnsville, MN · 104 employees · 18 countries · MRI-compatible cardiac devices

COMPANY SNAPSHOT

HQ: Burnsville, Minnesota
Employees: 104 globally
Markets: 18 active countries
Submissions: 45 global/year
Products: 13 families · NorthStar Mapping System, Vision-MR Catheters, Advance-MR EP Recorder
Focus: MRI-compatible interventional cardiac devices (iMR technology)
Exchange: ASX: IMR · Founded 2006

REGULATORY PROFILE

RA Team: 9 FTEs · $150K fully loaded
Annual Submissions: 45 global submissions (112 hrs each)
Change Assessments: 100/yr × 23 countries avg
Standards Activity: 10 standard changes/yr · 3 ppl monitoring
Compliance Forms: GSPR/EPC + DoC maintained for 13 product families
Current Tracking: Manual spreadsheets across 18 markets

THE REGULATORY CHALLENGE AT IMRICOR'S SCALE

🗂️

Fragmented Registration Tracking

18-country portfolio managed in manual spreadsheets. No single source of truth for registration status, renewal deadlines, or ship/no-ship decisions.

🔄

Change Control at Scale

100 change assessments/yr × 23 countries = 4,600 country-assessments managed manually, with coordination across regional SMEs and distributors.

🚀

Submission Overhead

45 global submissions/yr at 112 hrs each — built largely from scratch with minimal template reuse, consuming 4,284 hrs/yr of recoverable RA overhead.

🌍

Regulatory Intelligence Burden

3 staff spending 4.5 hrs/week monitoring regulatory changes across 18 markets — 702 hrs/yr of monitoring that RegDesk automates.

📐

GSPR & Standards Management

Manual maintenance of GSPRs and Declarations of Conformity, plus manual tracking of 10+ standard changes per year requiring individual assessments.

📊

No Management Visibility

4 status report requests/month each requiring 1 hr of manual data gathering. Leadership lacks real-time visibility into portfolio status across 18 markets.

Why RegDesk: RegDesk is an end-to-end regulatory operations platform purpose-built for global medical device manufacturers. Its four pillars — **Plan · Build · Track · Maintain** — address every challenge Imricor faces today: from intelligence monitoring across 18 markets, to AI-assisted submissions, centralized change control, and automated GSPR/DOC management. Imricor's 9-FTE RA team would be empowered to do more with less — freeing an estimated **4.97 FTE equivalents** for higher-value regulatory strategy.

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REGDESK PLATFORM MODULES: DELIVERED BENEFITS

Pain points addressed and capabilities delivered, mapped to Imricor's operational context

• PLAN PILLAR

RegIntel — Regulatory Intelligence

Human-curated regulatory intelligence across all 18 Imricor markets with real-time alerts. Integrated with workflows to operationalize intelligence automatically.

⚠ PAIN POINTS

- › 3 staff spending 4.5 hrs/week monitoring regulatory changes — 702 hrs/yr consumed
- › Ineffective reliance on distributors to flag regulatory changes in 18+ markets
- › Language barriers prevent timely understanding of local regulatory legislation
- › Difficulty operationalizing intelligence into regulatory strategy and submissions

✓ REGDESK BENEFITS

- ✓ All 18 markets monitored daily — eliminates 702 hrs/yr of manual monitoring
- ✓ Alerts pushed via multiple channels — immediate awareness of regulatory changes
- ✓ Integrated translation tools with original formatting preserved
- ✓ Intelligence auto-fed into change control, submission, and template workflows

Standards Management — Standards, Legislation & Guidance Monitoring

Centralized source of truth for standards and legislation globally, with integrated assessment workflows and product-level association across Imricor's 13 product families.

⚠ PAIN POINTS

- › No centralized location for standards lists, legislation, and guidances across 18 markets
- › No easy way to know which standards apply to specific products (13 families)
- › 10 standard changes/yr requiring manual 40-hr assessment processes each
- › Manual review of standards versions for all GSPR/EPC references

✓ REGDESK BENEFITS

- ✓ Centralized, RegDesk-maintained database — always current across all markets
- ✓ Associate products to each standard — instant portfolio impact reporting
- ✓ Streamlined assessment process with cross-functional collaboration — 50% time reduction
- ✓ Audit-ready reporting for management review or regulatory bodies

• BUILD PILLAR

Collaboration Tool (DCT) — Distributor/Deliverable Coordination

Project management for internal teams and external partners. Integrated with RegIntel. Full transparency on requirements, owners, and due dates across Imricor's 18-country network.

⚠ PAIN POINTS

- › Offline collaboration via email — no transparency to submission status or ownership
- › 15 global submissions/yr with 80 hrs of coordination overhead each
- › Difficult to find historical data for renewals across 18 country registrations
- › Coordination inefficiencies prolong submission prep — delayed market access

✓ REGDESK BENEFITS

- ✓ Seamless project management — regulatory intelligence auto-populates deliverables
- ✓ Full transparency on each requirement, owner, and due date with automated alerts
- ✓ Documents shared within tool — leveraged for future renewals across all markets
- ✓ Full audit history of all stakeholder and distributor activity

AI Application Builder — AI-Assisted Submissions

Custom submission templates per country and device class. AI auto-populates required elements. Seamlessly leverage one application across global markets — critical for Imricor's 45 submissions/yr.

⚠ PAIN POINTS

- › 45 submissions/yr built largely from scratch — 112 hrs each · 14-day process
- › Each country duplicates effort — bandwidth issues and inconsistency across 18 markets
- › No template reuse between submissions — gaps in data provided to regulators
- › Lengthy submission creation consumes 85% recoverable overhead per submission

✓ REGDESK BENEFITS

- ✓ Country-specific templates maintained by RegDesk — aligned with regulatory requirements
- ✓ AI significantly decreases preparation time — 85% overhead reduction applied
- ✓ Renewals and amendments easily leverage baseline submission content
- ✓ $321,300/yr recovered at 45 submissions × 112 hrs × 85% efficiency gain

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● BUILD PILLAR (CONTINUED)

AI Forms Builder — AI-Powered GSPR / EPC / DoC

Country-specific GSPR, Essential Principle Checklists, and Declaration of Conformity forms with AI autopopulation. Built-in flags for standard revision changes — critical for Imricor's 13 product families.

⚠ PAIN POINTS

› Manual creation of GSPR/EPC/DoC — time-intensive and error-prone across 13 product families

› Manual review of standards versions for all GSPR references

› Template maintenance requires internal RA resources with no cross-country reuse

› Limited ability to leverage forms created for one country across other markets

✓ REGDESK BENEFITS

✓ GSPR/EPC/DoC creation significantly improved through AI automation

✓ System flags outdated standard references — reduces compliance risk

✓ Automatically leverages information from forms created for one country to the next

✓ 85% overhead reduction on 10 form creates/revisions per year

● TRACK PILLAR

Tracking & Reporting — Portfolio Registration Status & Workflow Visibility

Real-time visibility to all in-flight RA workflows, registration status across 18 countries, and change controls. Integrated reporting eliminates manual status queries from leadership and sales.

⚠ PAIN POINTS

› Registration status managed in manual spreadsheets — often outdated across 18 markets

› 4 status report requests/month each consuming 1 hr of manual RA time

› No holistic portfolio view — metrics on time-to-approval rarely tracked

› Sales, finance, and leadership lack self-service access to regulatory status

✓ REGDESK BENEFITS

✓ Regulatory data centralized — real-time status for all 18 markets in one platform

✓ Flexible reporting by country, region, product, or full portfolio — self-service

✓ Audit-ready at any time — metrics easily extracted for management review

✓ 95% reduction in report generation time — 4 reports/month automated

● MAINTAIN PILLAR

Change Control (CCP) — End-to-End Change Management

Integrated workflow for change assessments across all 18 markets. Collaboration with regional SMEs. Decision trees maintained by RegDesk per country. Full audit trail — essential for Imricor's 100 assessments/yr × 23 countries.

⚠ PAIN POINTS

› 100 change assessments/yr × 23 countries = 4,600 country-assessments managed manually

› Tracking assessment status across countries and regional SMEs is inefficient

› Documenting how decisions were reached in each market is difficult to demonstrate

› Change communications to regional partners done via email — no audit trail

✓ REGDESK BENEFITS

✓ End-to-end change control — from RegIntel through assessment to regulatory activities

✓ Full transparency to internal and external stakeholders across all 18 markets

✓ RegDesk creates and maintains decision trees per market — 75% overhead reduction

✓ Full audit trail of all process steps and decisions — $258,750/yr recovered

QUANTIFIED VALUE: IMRICOR-SPECIFIC COST ANALYSIS

All figures derived from Imricor's own operational data — number of people performing each task, hours per week, and volume of work. This is not a generic benchmark. Each row reflects the actual cost of specific regulatory activities performed today by Imricor's 9 FTE RA team.

$746,055
Annual Recoverable Cost Savings

4.97 FTEs
Freed for Higher-Value Regulatory Work

11,937 hrs
Annual Hours Recovered

203%
3-Year ROI (Full RIM)

RegDesk Module	Task / Activity Studied	Annual Cost Savings	Savings Basis
AI Application Builder	Submission preparation — building global applications	**$321,300**	45 submissions/yr · 112 hrs each · 85% savings
Change Control (CCP)	Change assessment process across all 18 markets	**$258,750**	100 assessments × 23 countries × 2 hrs × 75% savings
Collaboration Tool (DCT)	Coordinating deliverables with distributors & partners	**$76,500**	15 submissions × 80 hrs × 85% savings
Regulatory Intelligence	Regulatory monitoring + global regulatory planning	**$56,963**	3 tasks: monitoring, new & existing product reg plans
Standards Management	Standards monitoring + completing assessments	**$26,700**	Two tasks: monitoring (3×1hr/wk) + 10 assessments (40 hrs × 50%)
Tracking & Reporting	Report generation & registration status visibility	**$3,420**	4 queries/month × 1 hr × 95% savings
AI Forms Builder	Creating and maintaining GSPR, EPC, and DoC forms	**$2,423**	Two form types; automation significantly reduces manual effort
TOTAL RECOVERABLE ANNUAL SAVINGS		**$746,055**	**= 4.97 FTE equivalents freed**

Source: Imricor operational data, July 2026 · FTE fully-loaded cost: $150,000/year ($75/hr)

3-YEAR INVESTMENT VS. RETURN SUMMARY

BASE RIM — $72,500/yr + $21,600 setup

Modules: RegIntel · Collaboration Tool · Tracking & Reporting

Annual Savings: $136,883 | Year 1 Net: +$42,783

3-Yr ROI: 72% | Payback: ~8 months

FULL RIM — $146,250/yr + $30,000 setup + $2,000/application

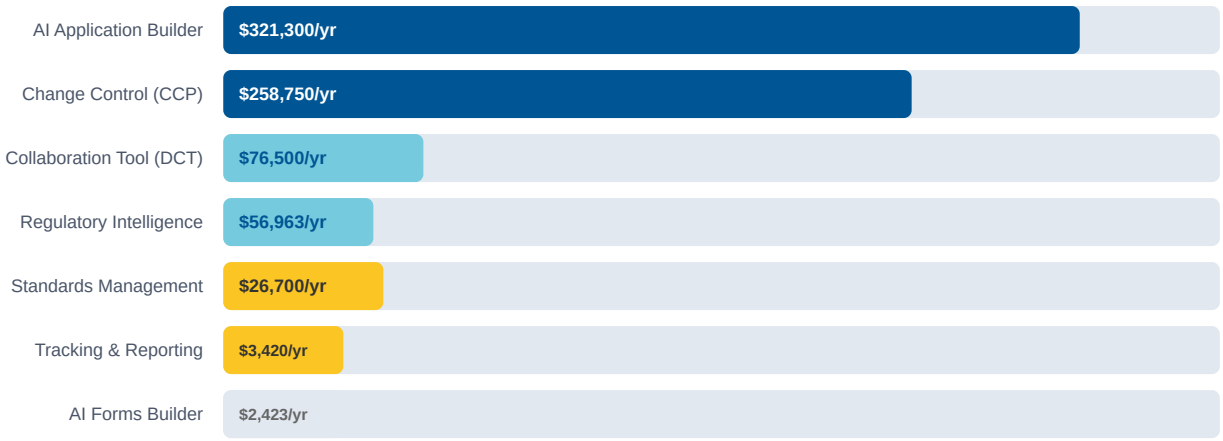
All modules including CCP, App Builder, Standards, Forms

Annual Savings: $746,055 | App Builder Fees: $90,000/yr

3-Yr ROI: 203% | Payback: ~5 months

COST SAVINGS BY MODULE

Annual recoverable savings across all 7 RegDesk modules — Imricor data, July 2026



TOTAL: $746,055/yr = 4.97 FTE equivalents

BASE RIM VS. FULL RIM — SAVINGS COMPOSITION

BASE RIM — $136,883/yr

Regulatory Intelligence: $56,963 (38%)

Collaboration Tool (DCT): $76,500 (56%)

Tracking & Reporting: $3,420 (2%)

Subtotal: $136,883/yr

FULL RIM ADDS — $609,173/yr

AI Application Builder: $321,300 (53%)

Change Control (CCP): $258,750 (42%)

Standards Management: $26,700 (4%)

AI Forms Builder: $2,423 (0.4%)

Full RIM Total: $746,055/yr

COMBINED VALUE

$746,055

per year

4.97 FTE equivalents

11,937 hrs/yr recovered

Note on App Builder ROI: The App Builder costs $90,000/yr in per-application fees (45 × $2,000) but recovers $321,300/yr in RA efficiency savings — a **3.6× return on the App Builder fee alone**. Combined with Change Control savings of $258,750/yr, these two modules recover $580,050/yr against $90,000/yr in incremental fees.

IMRICOR RA TEAM — CURRENT STRUCTURE

9 FTE regulatory affairs team managing cardiac device portfolio across 18 countries

CURRENT WORKLOAD BREAKDOWN

AI Application Builder overhead: **4,284 hrs/yr** (24% of team capacity)
Change Control (CCP) overhead: **3,450 hrs/yr** (19% of team capacity)
Regulatory Intelligence monitoring: **702 hrs/yr** (4% of team capacity)
Collaboration/submission coordination: **1,020 hrs/yr** (6% of team capacity)
Standards monitoring + assessments: **356 hrs/yr** (2% of team capacity)
Other recoverable overhead: **80 hrs/yr**
Total recoverable: 9,892 hrs/yr = 55% of team capacity

What 4.97 FTEs Freed Means for Imricor:

→ Expanding into new markets without headcount increase
→ Supporting PMA pathway clinical trial regulatory work (US ablation catheters)
→ Proactive regulatory strategy for Pulsed Field Ablation (PFA) development
→ Converting 40+ European hospital pipeline into fully operational commercial sites
→ Supporting strategic partnerships with Siemens, Philips, GE HealthCare

4.97
FTE EQUIVALENTS FREED
from low-value manual tasks

With RegDesk eliminating manual burden, 55% of current capacity is freed for higher-value RA work

QUALITATIVE BENEFITS — BEYOND THE NUMBERS

Strategic advantages that compound over time, derived from Imricor's own operational priorities

✓ More Compliant Work

RegDesk's daily monitoring and automated alerts mean Imricor's team is always working from the most current regulatory requirements — reducing compliance risk across all 18 markets. Integrated decision trees and audit trails ensure every regulatory decision is documented and defensible.

✓ More Registrations & More Markets

With 4.97 FTEs freed from manual overhead, Imricor can pursue more country registrations within the same headcount. The AI Application Builder's reusable templates accelerate the path from submission to approval — supporting Imricor's pipeline conversion across 40+ European hospital sites.

✓ Centralized Information for Strategic Planning

RegDesk's Tracking module provides leadership with real-time portfolio visibility — registration status, renewal timelines, and approval pipelines across all 18 markets in one place. Strategic decisions on market prioritization, PMA timing, and resource allocation become data-driven.

✓ Centralized Risk Abatement

Real-time intelligence across 18 markets allows Imricor to proactively address compliance gaps before they become commercial blockers. Change Control workflows ensure that product changes across the iMR portfolio are assessed systematically — critical as Imricor advances PFA and next-gen device development.

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5 REASONS REGDESK IS THE RIGHT FIT FOR IMRICOR

Tailored to Imricor's profile: pioneering iMR technology, global device portfolio, FDA & EU regulatory complexity

1 Change Control at Scale — Built for Imricor's Volume

Imricor performs 100 change assessments/yr × 23 countries = 4,600 country-assessments annually. The CCP Module is purpose-built to manage this volume — automated impact scoping, regional SME routing, and decision trees maintained by RegDesk per country. No other platform handles this at scale without a proportional increase in RA headcount.

2 AI Submission Builder — Purpose-Built for Volume Submissions

Imricor generates 45 global submissions per year. The Application Builder's AI functionality significantly reduces preparation time per submission, maintains country-specific templates, and enables content reuse across markets and renewal cycles. At Imricor's submission volume, this represents 4,284 hrs of annual savings — $321,300/yr against $90,000/yr in fees (3.6× ROI on the module).

3 Standards & GSPR Automation for Complex iMR Devices

Imricor's MRI-compatible cardiac devices require rigorous GSPR/EPC management and continuous standards monitoring. RegDesk AI Forms Builder automates GSPR/DoC creation and flags outdated standard references automatically — critical for a device company where standard changes directly impact CE marking and FDA submissions.

4 Distributor Collaboration at the Core

Imricor operates through distributor networks and hospital partnerships across 18 markets including 40+ European hospital pipeline sites. The Collaboration Tool is purpose-built for this model — bringing distributors and internal teams into a single workflow environment with transparent requirements, shared documents, and automated notifications.

5 Audit Readiness for FDA PMA & CE Mark Compliance

With active FDA PMA pathway submissions for ablation catheters and CE marking across 18 markets, Imricor's regulatory function requires audit-ready documentation at all times. RegDesk's integrated audit trails — from change control decisions to submission histories to standards assessments — provide the evidentiary record that auditors and notified bodies expect, across the entire portfolio, in a single platform. As Imricor advances PFA development and integrates Siemens/Philips/GE partnerships, this unified audit layer becomes strategically essential.

SUMMARY: THE BUSINESS CASE IN ONE VIEW

Value Driver	Annual Value	Primary Module(s)
Recoverable Cost Savings (Full RIM)	**$746,055**	App Builder, CCP, DCT, RegIntel, Standards, Tracking, Forms
Net 3-Year Benefit (Full RIM)	**$1,499,415**	After $738,750 total investment incl. App Builder fees
3-Year ROI / Payback	**203% / ~5 mo**	**Full RegDesk Platform · Based on Imricor's own data**

Ready to See RegDesk in Action?

Schedule a personalized demo tailored to Imricor's portfolio, team structure, and regulatory priorities. We'll walk through how each module maps to your specific markets, devices, and workflows — including live demonstrations of CCP automation, AI Application Builder, and real-time portfolio tracking.

📧 contact@regdesk.co 🌐 www.regdesk.co 📅 Schedule: regdesk.co/demo

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