SMEDTEC OS

EXECUTIVE BRIEF

Regulatory information management for small device teams

Five markets, three people and a spreadsheet: why the regulatory record breaks as a manufacturer grows, the dates that will not move, and what to put in place instead.

EU MDR and IVDR | UK, US, Canada, Australia | Every figure sourced

By Sherif Elkhadem, Founder, SMEDTEC Ltd

November 2026

In brief

Regulatory information management (RIM) is the work of keeping one answer current: which device is registered, certified or cleared where, who holds each registration, what it rests on, what falls due next and which evidence supports it. Large companies buy software for it. Small device and IVD teams mostly do it in Excel, SharePoint and their inboxes.

That works for one device in one market. It stops working at the second market or the first representative, because every market adds its own holder, identifier and recurring dates, and the record multiplies faster than the team does. Between now and the end of 2029 the EU's legacy-device deadlines, annual PSUR cycles and the changing UK position add dates that cannot be missed.

01

The record multiplies: devices × markets × holders, identifiers and dates. Three devices in five markets is already fifteen registrations.

02

The dates are fixed in law: EU legacy deadlines run to 2027, 2028 and 2029, and PSURs for higher-class devices are due at least annually.

03

The fix is a system of record, not more spreadsheet discipline: one record per device, dates that raise themselves, evidence attached and a log of every change.

01 What RIM is, and why small teams do it in Excel

In a large manufacturer, a regulatory information management system is the system of record for market access. In a small one, the system of record is usually a tracker that one person keeps.

RIM covers the facts about each product that regulators, notified bodies, distributors and auditors ask for: its classification in each market, the pathway it took, the certificate or clearance it holds, the registration and its number, the party holding it locally, the recurring obligations attached to it, and the documents that prove each one. Around those facts sit the dates: renewals, annual registrations and statements, post-market reports, certificate expiries and the end of transition periods.

RIM software grew up in pharmaceutical companies and large device groups, where it is typically bought as an enterprise project. A team of one to five people, selling a handful of devices into several markets, rarely has the budget or the time for that, so the work lands in the tools already open: a registration tracker in Excel, a folder tree in SharePoint, and email.

We call the same work **regulatory operations**: RIM, plus the pathway work, the post-market cycles and the people that keep the record true. It is the work SMEDTEC does for its own clients, and the reason we built SMEDTEC OS.

> The question is not whether your team does regulatory information management. It is whether the record lives in a system, or in one person's tracker and memory.

02 The multiplication problem

Every market adds the same kinds of facts under different rules: a different party holds the registration, a different identifier proves it, and a different recurring date keeps it alive. A tracker that records one device well does not record five markets well, because the same device now has five holders, five identifiers and five rhythms.

ILLUSTRATIVE EXAMPLE

A manufacturer with three devices sold in the EU, Great Britain, the US, Canada and Australia:

3 devices × **5** markets = **15** registrations × **4+** facts each = **60+** facts to keep true

Each registration has at least a holder, an identifier, a status and one recurring date. That is before certificates, representative agreements, post-market cycles and the evidence behind each one.

Who holds what, market by market

Market	Who holds it	What to record	Recurring item
European Union	Manufacturer, with an EU authorised representative if based outside the EU	EUDAMED actor registration (SRN), device registrations, certificates	Certificate expiry and surveillance audits; PSURs by class (section 3)
Great Britain	Manufacturer, with a UK Responsible Person if based outside the UK, who registers its devices with the MHRA	MHRA device registrations; the UK Responsible Person's details	Changes to registered devices and to the UK Responsible Person
United States	Manufacturer; a foreign establishment names one United States agent	FDA establishment registration and device listings	Annual registration and listing review, `1 Oct` to `31 Dec`
Canada	Manufacturer holding the Canadian medical device licence	Canadian licence numbers by device	Annual statement to Health Canada before `1 Nov`
Australia	Australian sponsor	ARTG entries	Annual obligations on each entry; check current TGA guidance

A planning summary, not a statement of every requirement. Sources in section 8.

None of these is difficult on its own. The difficulty is that they all live in different places, change on different schedules, and are usually remembered by one person.

03 The dates that will not move

EU legacy devices: Regulations (EU) 2023/607 and 2024/1860

Legacy devices can stay on the EU market until these dates only while the conditions hold: continued compliance with the directive, no significant change, no unacceptable risk, a quality system under the new regulation, and a notified body application and written agreement by the dates shown.

Regulation	Devices	May be placed on the market until	Notified body application / agreement
EU MDR	Class III; class IIb implantable (with listed exceptions)	31 Dec 2027	26 May 2024 / 26 Sep 2024
EU MDR	Other class IIb; class IIa; class I sterile or measuring; and devices that need a notified body for the first time	31 Dec 2028	26 May 2024 / 26 Sep 2024
EU IVDR	Certificate under the IVD Directive; or class D	31 Dec 2027	26 May 2025 / 26 Sep 2025
EU IVDR	Class C	31 Dec 2028	26 May 2026 / 26 Sep 2026
EU IVDR	Class B; class A sterile	31 Dec 2029	26 May 2027 / 26 Sep 2027

First-time notified body rows and IVDR class rows need a declaration of conformity dated before 26 May 2021 (MDR) or 26 May 2022 (IVDR).

> **Next in line.** For IVDR class B and sterile class A legacy devices, the notified body application is due by 26 May 2027 and the written agreement by 26 September 2027. Legacy devices already follow the new regulations' requirements on post-market surveillance, vigilance and registration (MDR Article 120(3d); IVDR Article 110(3d)). A targeted revision of both regulations, proposed by the Commission in December 2025, had not been adopted when this brief was written.

PSURs and PMS reports: MDR Articles 85–86, IVDR Articles 80–81

Regulation	Class	Document	Update
EU MDR	Class I	PMS report	When necessary
EU MDR	Class IIa	PSUR	When necessary, at least every two years
EU MDR	Class IIb and III	PSUR	At least annually
EU IVDR	Class A and B	PMS report	When necessary
EU IVDR	Class C and D	PSUR	At least annually

Great Britain. On 21 October 2026 the government confirmed it will keep accepting CE marked devices and IVDs long term, with UKCA as the domestic route; legislation is still to come. GB post-market surveillance rules have applied since 16 June 2025.

04 Six places a spreadsheet tracker breaks

Spreadsheets are not the problem; they are the right tool for one device in one market. These are the points where they stop being enough, in roughly the order teams meet them.

01
The record lives in three places

The tracker says what is registered, SharePoint holds the certificates, and the reasons for each decision are in email. Keeping them in step is manual, and they drift.

02
A date in a cell does not remind anyone

Renewals, annual statements and PSUR cycles sit in cells that someone has to check. The first missed date is usually found by a distributor or an auditor.

03
One device, recorded five ways

Names, versions and classifications drift between market tabs. When a device changes, the change has to be remembered in every row it touches.

04
No history of who changed what

File version history shows that a cell changed, not why, by whom or what it affected. A decision trail has to be rebuilt when someone asks for it.

05
Evidence is gathered when it is asked for

An audit or a notified body question starts a search through folders and inboxes, under time pressure, for documents that should already be attached to the obligation they support.

06
The logic leaves with the person

The tracker's structure, formulas and unwritten rules belong to whoever built it. When they leave, or an adviser changes, the context goes with them.

None of these is fixed by trying harder with the spreadsheet. Each is fixed by giving the record a structure that does the remembering.

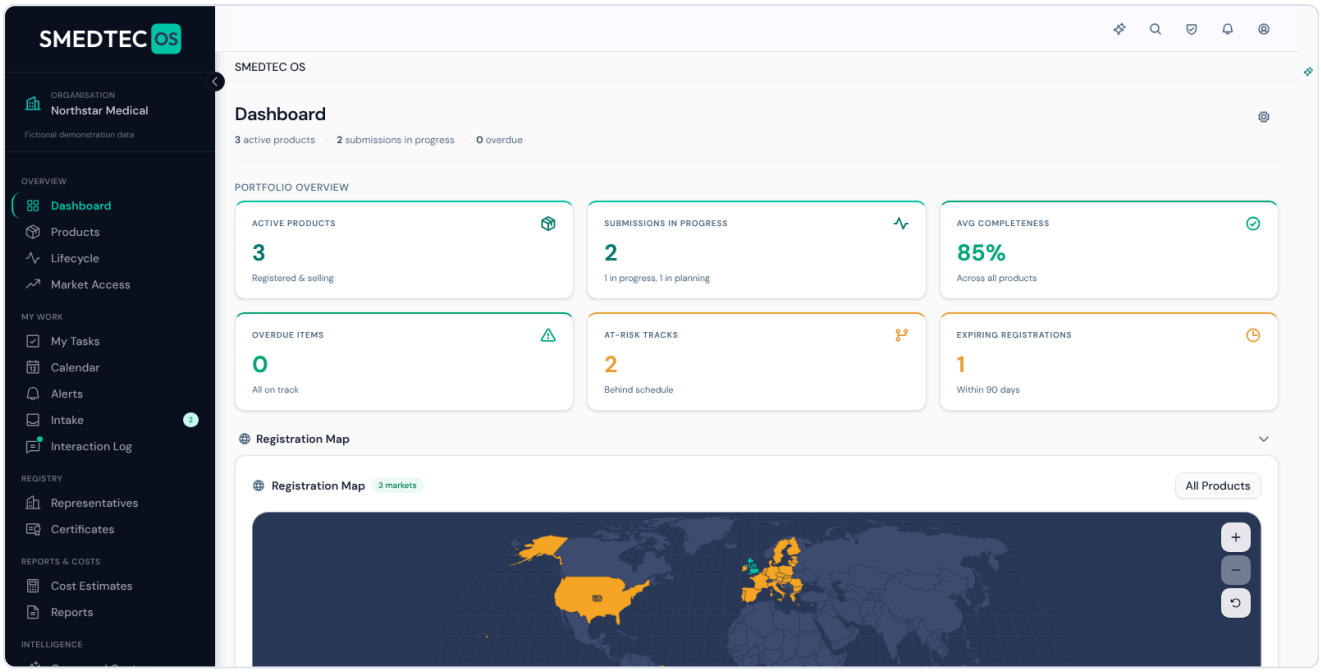
05 What a RIM system should do for a small team

Judge any tool against this list, ours included. For a team of one to five people the test is simple: does it remove remembering, without asking you to move your quality system?

- ✓ **One record per device,** with every market's registration, certificate and pathway hanging off it, so a change is made once.
- ✓ **Typed holders.** The EU authorised representative, UK Responsible Person, US agent, Australian sponsor or local representative recorded as a role, linked to the agreement behind it.
- ✓ **Dates that raise themselves:** on a dashboard and a calendar, with notifications before each one falls due and again when it is overdue.
- ✓ **Pathways as tracked work:** each submission broken into work items with owners, due dates and dependencies, so slippage shows early.
- ✓ **Post-market cycles that start on time:** PMS reports and PSURs scheduled per device, with the cycle's owner and evidence in one place.
- ✓ **Evidence attached to what it supports,** with versions, approvals and supersession, not a folder tree to search.
- ✓ **A log of every change** that application code cannot rewrite, and an export an auditor can verify.
- ✓ **Controlled access for advisers:** your consultant or representative sees the records you choose, read-only, and leaves without taking anything.
- ✓ **It sits alongside your eQMS.** Document control, CAPA and training stay where they are.
- ✓ **Weeks, not a project:** priced and set up for a small team, with your existing tracker as the starting point.

06 How SMEDTEC OS does it

SMEDTEC OS is the regulatory operations workspace we built for this work and use in our own consultancy. Each device has one record; its pathways, registrations, post-market cycles and documents hang off it.



The dashboard: submissions in progress, tracks behind schedule, registrations expiring within 90 days, and a registration map. Fictional demonstration data.

Registrations

A row per market with the registration number, status, certificate number and expiry, notified body, last renewal date and the responsible person, typed by role.

Representatives

Your authorised representatives, UK Responsible Person and agents in one register, with their agreements, expiry dates and the registrations they hold.

Pathways

A track for each market (EU MDR, IVDR, UKCA, 510(k), TGA, Health Canada and more) with work items, owners, target dates and evidence coverage.

Post-market

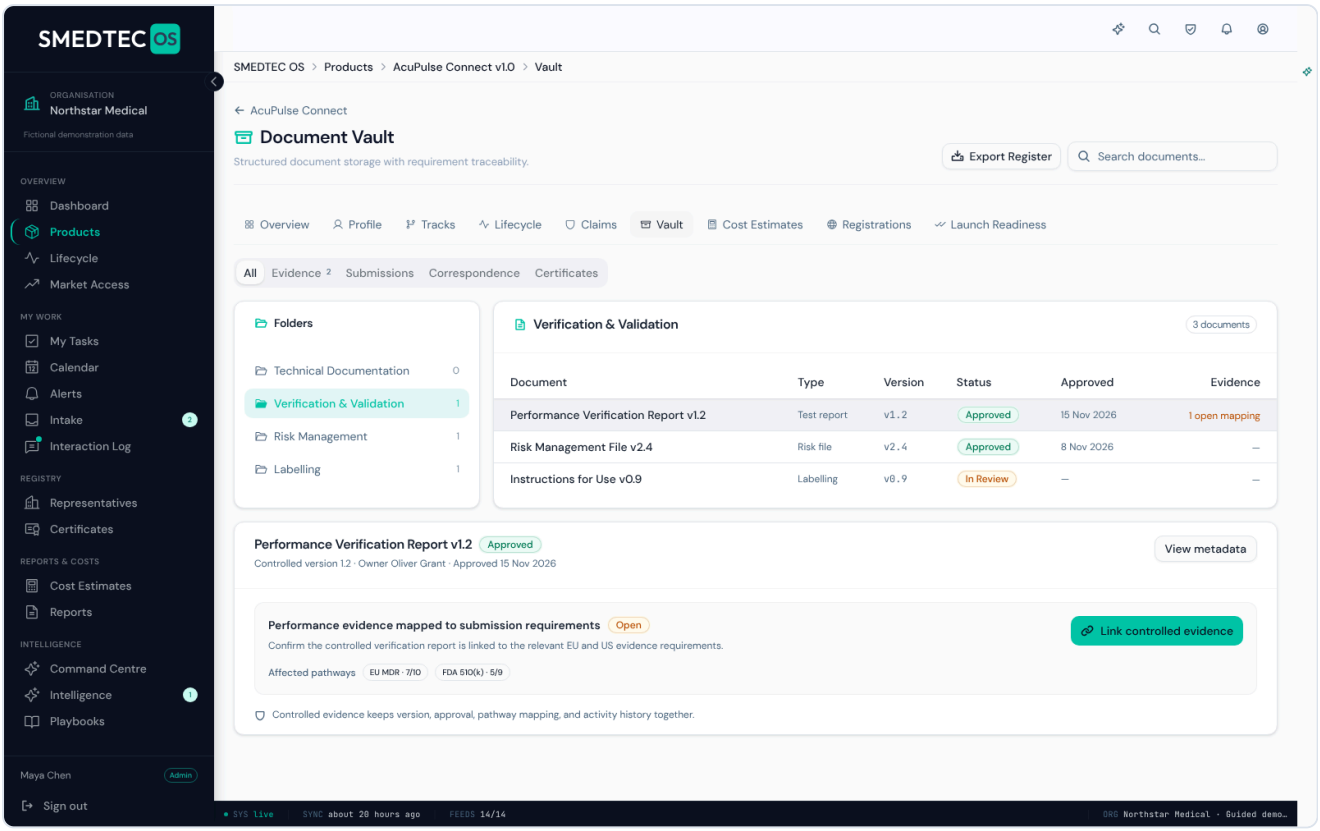
A post-market programme starts when a product goes on sale. You set each cycle's due date to the frequency that applies; reminders follow.

Documents and evidence

A vault with versions, approvals and supersession, evidence mapped to requirements, and audit packs exported with a SHA-256 manifest.

Advisers and audit trail

Advisers see what you share, read-only, until you remove them. Every upload, review and status change is in an immutable activity log.



The document vault for a fictional device: controlled versions, approval status, and evidence mapped to the EU MDR and FDA 510(k) requirements it supports.

What it does not do

- It does not file anything with an authority. Registrations and submissions are made in each authority's own system; SMEDTEC OS holds the record and the evidence afterwards.
- It does not decide classification, which transition date applies or how often a PSUR is due. Those are regulatory judgements for you and your adviser; the system holds the decision and its dates.
- It is not an eQMS. It sits alongside yours.

07 A 30-day plan

Whatever tool you choose, the first month looks the same. The aim is a record you trust, not a perfect one.

Week 1

Inventory

List every device and every market it is sold in. One row per device, one column per market.

Week 2

Holders

For each registration: who holds it, its identifier, and the agreement behind each representative.

Week 3

Dates and owners

Every recurring date, legacy deadline and PSUR cycle, each with a named owner.

Week 4

Evidence

Attach the certificate, registration and latest report to each item, and note what is missing.

Take the next step

Free health check	Send us your registration list. We load it into a workspace and send back a written review of renewals due, missing numbers, holders and dates. os.smedtec.co.uk/registration-health-check
Interactive demo	Walk through a fictional manufacturer's workspace in four minutes, no sign-up. os.smedtec.co.uk/demo
14-day trial	Your own workspace, no card needed. os.smedtec.co.uk

SMEDTEC OS

ABOUT SMEDTEC

A UK regulatory consultancy for medical device and IVD manufacturers, and the software it built for that work.

SMEDTEC Ltd provides classification, regulatory strategy, technical documentation and quality system work across the EU, UK, US and beyond. SMEDTEC OS is the regulatory operations workspace we use in that work and offer to manufacturers to run their own. Founder and CEO Sherif Elkhadem holds the RAPS Regulatory Affairs Certification (RAC, Devices) and is a member of BIVDA.

os.smedtec.co.uk · info@smedtec.co.uk · SMEDTEC Ltd, registered in England and Wales, company number 13308338

08 Sources

Read from the primary source between 19 and 21 November 2026.

1. Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and 2017/746 as regards transitional provisions (MDR Article 120(3a)–(3d) and (4)). EUR-Lex.
2. Regulation (EU) 2024/1860 amending Regulations (EU) 2017/745 and 2017/746 (IVDR Article 110(3a)–(3d)). EUR-Lex.
3. Regulation (EU) 2017/745, Articles 85 and 86; Regulation (EU) 2017/746, Articles 80 and 81. Consolidated text of 10 January 2025, EUR-Lex.
4. GOV.UK, "Regulating medical devices in the UK", updated 20 February 2026; and "Government confirms indefinite recognition of CE marked medical devices", 21 October 2026.
5. 21 CFR 807.22(b) (annual registration and listing, 1 October to 31 December) and 21 CFR 807.40(b) (United States agent). Code of Federal Regulations, 1 April 2025 edition, govinfo.gov.
6. Medical Devices Regulations SOR/98-282, section 43(1) (annual statement before 1 November). Justice Laws Website, Canada.
7. European Commission proposal for a targeted revision of the MDR and IVDR, December 2025; legislative status as reported in October 2026.

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