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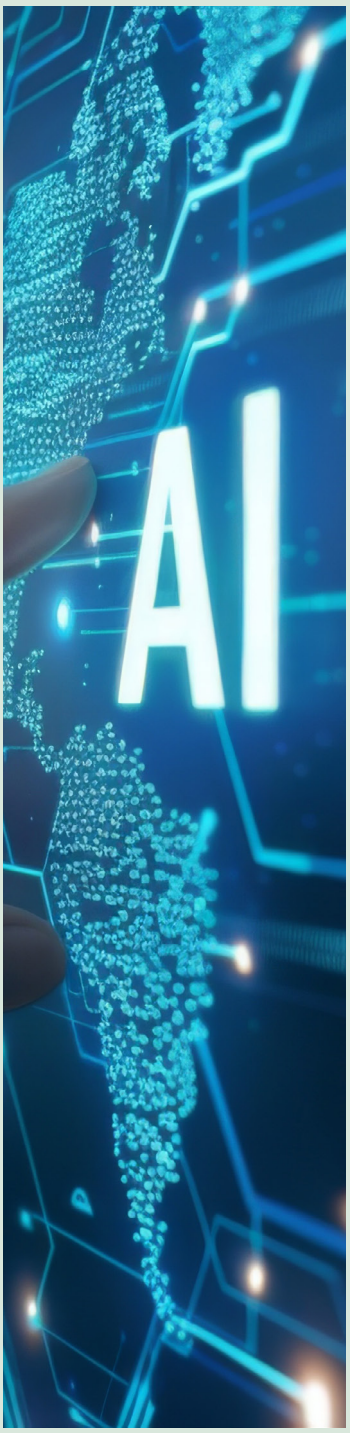


AI FRAMEWORK FOR PFAS COMPLIANCE IN MEDTECH

AN AI-ENABLED OPERATING MODEL TO ACHIEVE PFAS COMPLIANCE AT PORTFOLIO SCALE

Infosys
Navigate your next

Executive Summary

PFAS (per and polyfluoroalkyl substances) provide critical device performance—lubricity, heat and chemical resistance, and hydrophobicity—across tubing, coatings, seals, and packaging. At the same time, these "forever chemicals" face accelerating global scrutiny for their persistence and potential health impacts, prompting convergent actions under U.S. TSCA and EU REACH/MDR. PFAS readiness has therefore shifted from a onetime declaration to an enterprise operating model spanning design, supply chain, QARA, and ESG.

Infosys proposes a sixphase operating model—**Discover → Validate → Engage → Comply → Innovate → Sustain**—underpinned by AIassisted BOM screening, structured supplier outreach, targeted laboratory validation, and lifecycle governance. This approach reduces regulatory and recall risks, protects U.S. and EU market access, improves supplier throughput at scale, supports ESG reporting, and enables PFASreduced or PFASfree devices without compromising clinical performance.

The PFAS Reckoning Has Arrived

PFAS offer unique performance in MedTech but are environmentally persistent. Regulators have responded decisively with mandatory reporting and evolving restrictions, raising the bar for materials transparency and lifecycle accountability.

Key regulatory anchors:

- **United States (EPA / TSCA Section 8(a)(7)):** Onetime retrospective PFAS reporting for substances manufactured or imported between 2011–2022. The submission window runs **April 13, 2026, to October 13, 2026**; small manufacturers reporting exclusively as article importers have until **April 13, 2027**.
- European Union (REACH / MDR): A broad PFAS restriction is progressing through ECHA's scientific committees (RAC opinion adopted; SEAC draft expected in 2026). MDR Annex I require chemical risk considerations—including CMR/ED substances—with justification and labeling above relevant thresholds.
- APAC: Japan, South Korea, and Australia continue to strengthen PFAS oversight and disclosure, increasing pressure on supplier transparency.

What the Industry Isn't Saying (but lives with daily)

- Material substitution is not a simple swap; it impacts lubricity, sterilization compatibility, durability, kink resistance, and usability.
- Validated supply chains can be disrupted when supplier disclosures are incomplete or alternatives are immature.
- Biocompatibility may require retesting (e.g., ISO 10993 extractables/leachables) when materials change.
- Documentation and regulatory files often require updates; audits may be triggered depending on change scope.

A Smarter Path Forward: AI-Enabled Operating Model

PFAS offer unique performance in MedTech but are environmentally persistent. Regulators have responded decisively with mandatory reporting and evolving restrictions, raising the bar for materials transparency and lifecycle accountability.

Key regulatory anchors:

1

Discover — Inventory & Risk Identification

- AI/ML BOM screening across SDS/TDS/Declarations
- PFAS substance library with synonyms and CAS crosswalks
- Supplier risk heatmaps.

2

Validate — Confirm with Science

- Targeted LC-MS/MS and GC-MS testing
- Supplier reconciliation
- Prioritization of extractables/leachables as appropriate.

3

Engage — Supplier-Scale Alignment

- Education packages
- IPC-1752A XML/Excel templates
- FAQs and structured cadence with reminders/escalations
- Optional partner data networks for broad outreach.

4

Comply — Global Regulatory Readiness

- Live matrices for TSCA, REACH, MDR, APAC
- Audit-ready documentation
- Integration with QMS/PLM/DHF.

5

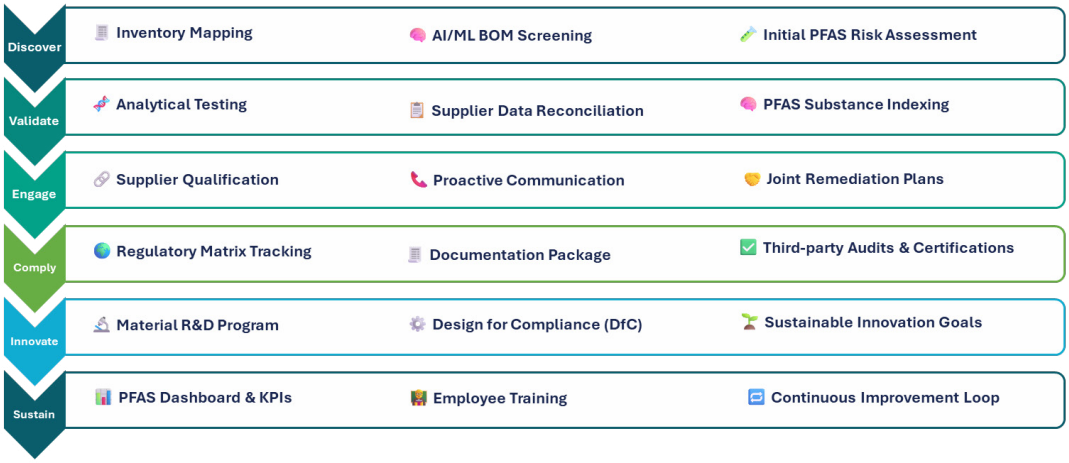
Innovate — Design for Compliance (DfC)

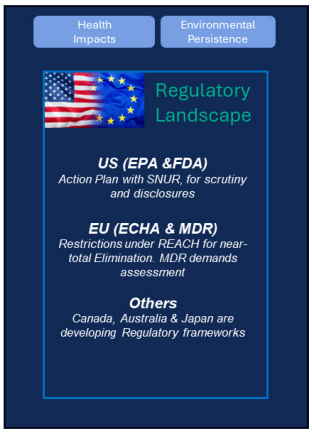
- Material R&D sprints to maintain performance while removing PFAS
- Decision logs and justification aligned with MDR Annex I expectations

6

Sustain — Operate & Improve

- KPI dashboards
- Quarterly regulatory updates
- Supplier scorecards
- Targeted training across R&D, Quality/Regulatory, and Sourcing





Risk Reduction
Avoid regulatory penalties and product recalls

Market Access
Stay compliant with EU MDR, REACH, and EPA rules

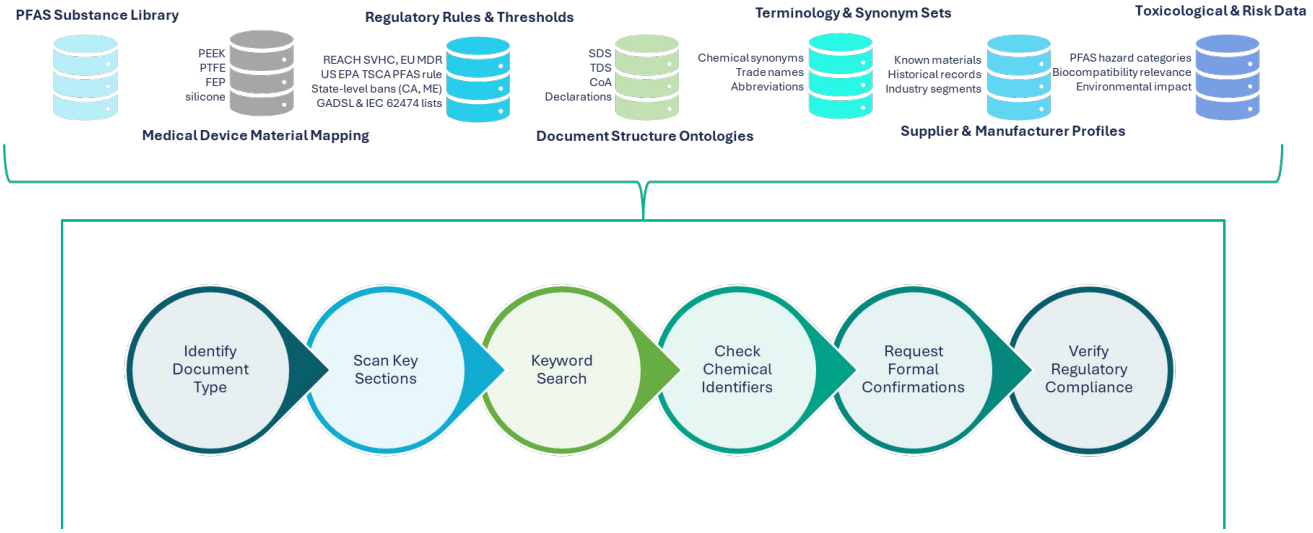
Brand Reputation
Demonstrate proactive stewardship on chemical safety

Operational Efficiency
Streamline supplier engagement and material controls

ESG Alignment
Support sustainability mandates and investor expectations

AI/ML-Powered BOM Screening

The screening pipeline integrates a PFAS substance library, medical material mapping, regulatory thresholds (REACH SVHC, TSCA reporting scope, MDR chemical expectations), document ontologies, and terminology/synonym sets. Retrievalaugmented generation (RAG) and knowledgegraph reasoning enable explainable triage, supplier confirmation triggers, and auditready traceability.



Supplier Outreach at Scale

A programmatic playbook supports outreach to hundreds or thousands of suppliers with consistent artifacts and cadence.

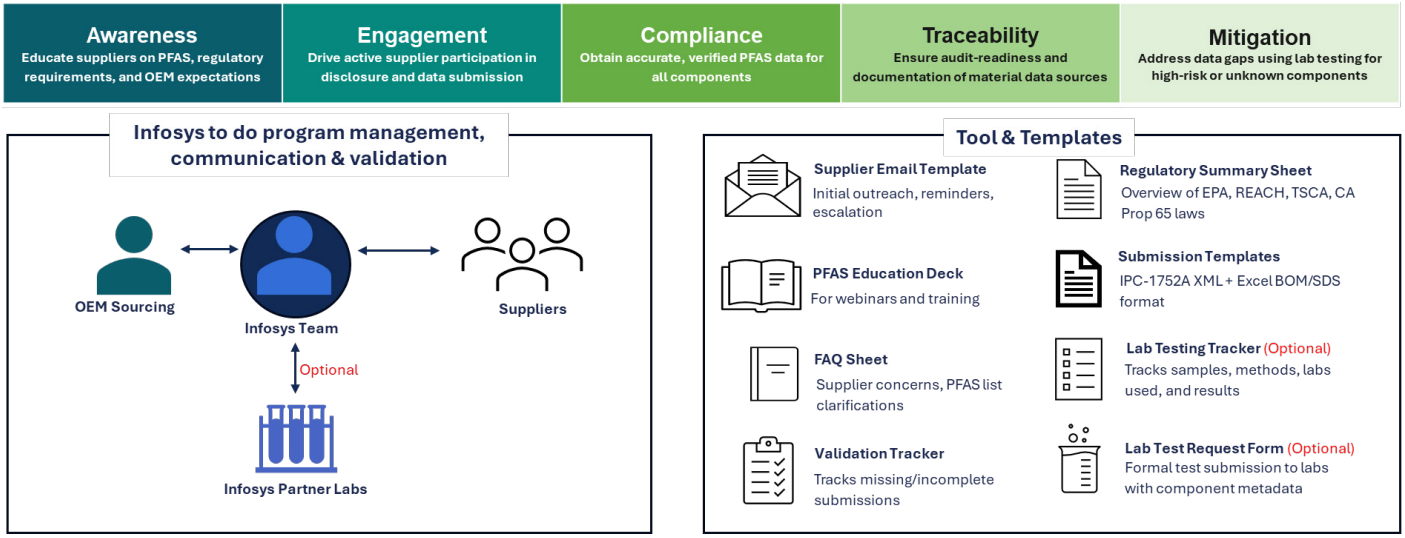
Toolkit includes:

Supplier education decks	Regulatory summaries	Email templates	XML/Excel declaration forms	FAQs	Validation and labtesting trackers

Segmentation prioritizes suppliers by spend tier, component criticality, PFAS risk, and geography.

Phases include:

Preparation → Initial Communication → Followups → Validation & Lab Mitigation → Closeout & Reporting → Futureproofing (contract clauses, SDS parsing automation).



Governance, KPIs, and Outcomes

Governance Model

Crossfunctional steering committee (Engineering, QARA/Regulatory, Sourcing, ESG) with working groups for Supplier PMO, Regulatory Ops, and Materials R&D.

Core KPIs:

- BOM coverage by disclosure status
- Time to validate high-risk parts
- Count of PFAS-containing materials removed or replaced
- Supplier response SLAs
- Audit-readiness index

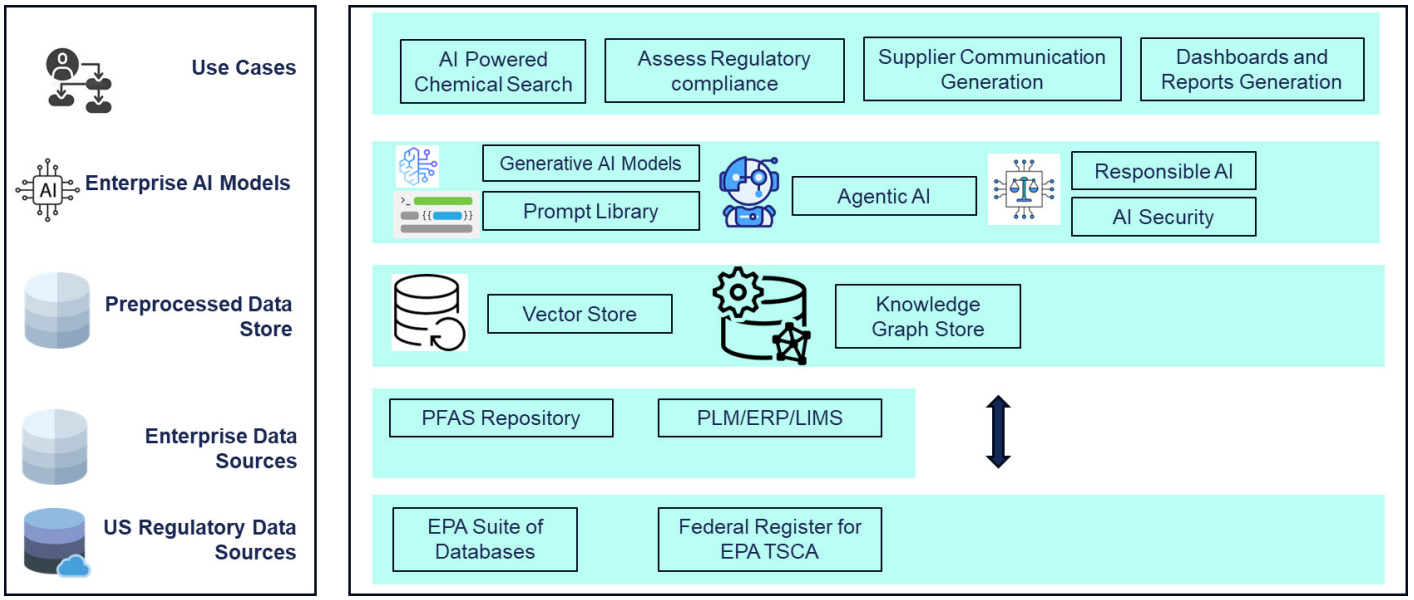
Expected outcomes:

- Reduced penalty and recall exposure
- Protected EU/US market access
- Faster supplier throughput
- Measurable ESG progress with decision-grade dashboards

Architecture at a Glance

Data flows from regulatory sources (EPA/EU lists) and enterprise systems (PLM/ERP/LIMS, PFAS repository) into vector/knowledgegraph stores, orchestrated by generative and agentic AI with managed prompts and ResponsibleAI overlays.

Use cases: chemical search, compliance assessment, supplier communications, dashboarding.



Business Value & the Case for Action

Risk & Cost: Reduce noncompliance events and avoid costly recalls.

Revenue & Access: Maintain readiness for MDR/REACH/TSCA to safeguard global distribution.

Efficiency: AI triage and programmatic supplier outreach reduce manual effort.

ESG & Brand: Demonstrate proactive environmental stewardship with measurable outcomes.

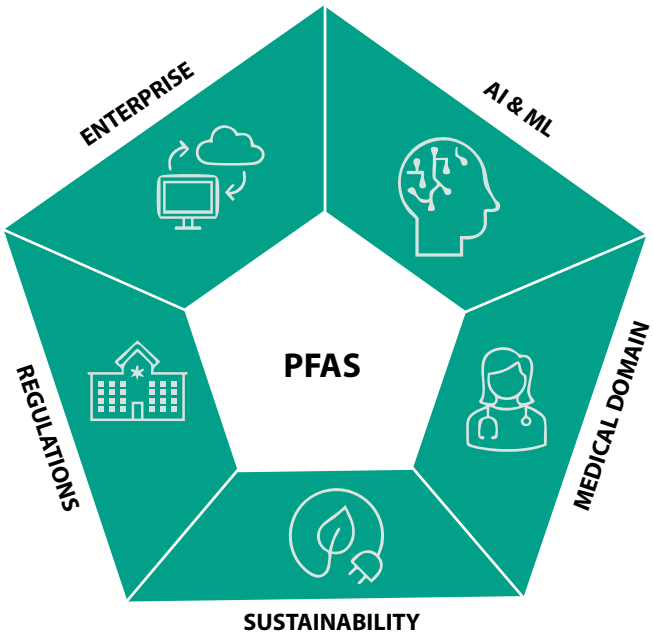
Why Infosys

Enterprise AI & scale: Document AI, RAG, knowledge graphs, responsibleAI controls, supplierscale execution.

Lifecycle rigor: Continuous, auditable controls aligned with evolving regulations.

Industrialization cadence: Proven playbooks enabling rapid standup and scale across portfolios.

Enterprise IT Excellence



Pioneering AI Enablement

Expert in Medical QARA

Deep Domain Knowledge

Championing Sustainability Through Action and Innovation

Actionable Recommendations

Establish PFAS as a continuous lifecycle program—not a onetime activity.

Begin with one device family; complete Discover → Sustain in 90 days and publish KPIs.

Institutionalize AI document intelligence for auditability and efficiency.

Segment suppliers; formalize cadence and SLAs; reserve lab testing for unresolved or highrisk cases.

Integrate DfC into engineering gates and fund PFASfree material R&D.

Voices from the Ecosystem

Regulatory & Quality: PFAS risks require coordinated global responses; MedTech must adjust design and compliance practices accordingly. (RQM+)

Sustainability & Supply Chain: Overreliance on "essential use" exemptions increases liability and supply risks; MedTech remains a notable PFAS source. (Assent / MedTech Intelligence)

Legal & Regulatory Impact: PFASfree substitution may trigger retesting, requalification, and updated marketing authorizations—planning is essential. (Hogan Lovells)

Environmental Programs: Expect increasing costs across testing, certification, redesign, and potential reputational exposure if delayed. (Battelle)

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