RESEARCH PAPER

From Safety Signals to Accountable Decisions: A Regulatory Governance Framework for Advanced Drug Delivery Systems

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Abstract

Advanced drug delivery systems such as autoinjectors, infusion pumps and software-enabled dosing devices sit at the boundary between medicinal-product and medical-device regulation. Regulators govern them largely through firms' own quality, risk and reporting systems. This article asks how, and at which organisational interfaces, safety signals about such systems are translated into accountable decisions under United States, European Union and Australian law. Combining doctrinal and comparative analysis with a descriptive analysis of 1,193 FDA recall records for drug delivery devices, it finds that all three jurisdictions require firms to generate safety information and that corporate law makes internal information systems relevant to directors and officers, but that the translation from signal to decision is left unspecified. Recall root causes for these devices are attributed disproportionately to design, change-control and software decisions. Drawing on the distinction between syntactic, semantic and pragmatic knowledge boundaries, the article develops the Integrated Lifecycle Accountability Framework, which specifies five translation interfaces with their decision rules, evidence trails and failure conditions, applies it to the documented EpiPen autoinjector record, and states six testable propositions. The framework is conceptual and has not been empirically validated.

Keywords: accountability; combination products; management-based regulation; medical devices; pharmaceutical regulation; risk governance

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Introduction

Advanced drug delivery systems (ADDS) — modified-release and long-acting formulations, prefilled syringes, autoinjectors, inhalers, infusion and insulin pumps, and software-enabled dosing devices — change where, when and how much of an active substance reaches its target (Vargason et al., 2021; Mitragotri et al., 2014). In doing so they relocate risk. A medicine that is well characterised as a molecule can fail a patient because a spring does not fire, a line occludes, a user misreads an instruction, or a wireless link is compromised. These failures are partly pharmaceutical, partly mechanical, partly behavioural and increasingly digital, and they fall across the legal boundary between medicinal-product and medical-device regulation.

Pharmaceutical regulation governs this terrain largely through firms' own management systems. Manufacturers must operate quality systems, apply quality risk management, investigate complaints and deviations, report adverse events and device incidents, control changes and take corrective action (21 C.F.R. pt. 211; 21 C.F.R. pt. 4; Regulation (EU) 2017/745; ICH, 2023). In the vocabulary of regulatory governance these are process-oriented or management-based requirements: the regulator prescribes the planning, analysis and review that firms must perform rather than the outcomes they must achieve (Coglianese & Lazer, 2003; Gilad, 2010). Corporate law adds a second layer. Directors and, in Delaware, officers owe duties of oversight that make the existence and use of internal information systems legally relevant (In re Caremark, 1996; Marchand v. Barnhill, 2019; In re McDonald's, 2023), and in Australia directors who cause or permit contraventions exposing the company to foreseeable harm may breach the statutory duty of care and diligence (ASIC v Cassimatis (No 8), 2016; Cassimatis v ASIC, 2020, paras. 77–79).

The difficulty is that the information regulators require firms to generate and the decisions on which accountability turns sit in different places. A complaint about an autoinjector that fails to activate is logged in a quality system; whether the complaint is linked to a known component defect, whether a lot is withdrawn, and who is answerable for the decision not to withdraw it are determined elsewhere, by different people applying different concepts of risk. The U.S. Food and Drug Administration's (FDA) 2017 warning letter to the manufacturer of EpiPen autoinjectors records a sequence of this kind: a component defect identified on receipt testing in February 2016, a complaint investigation in May 2016 that found the same defect, closure of that investigation in June 2016 with a determination that no market action would be taken, and a recall of 13 U.S. lots only after an FDA inspection in 2017 (FDA, 2017b). The letter records regulatory findings, not adjudicated facts, and the firm disputed any causal link between the complaints and patient deaths. It nevertheless illustrates the problem this article addresses: safety signals may be generated, recorded and even

investigated without being translated into accountable organisational decisions.

Existing frameworks each address part of this problem. Harmonised pharmaceutical guidance specifies how to assess and control quality risk and assigns quality-system responsibility to senior management (ICH, 2023; ICH, 2008). Enterprise risk management (ERM) standards connect risk to objectives and governance (ISO, 2018; COSO, 2017). Integrated governance, risk and compliance (GRC) models propose that the three functions be coordinated (Racz et al., 2010). Regulatory-governance scholarship explains why regulators rely on internal systems and why such reliance can produce symbolic rather than substantive compliance (Parker, 2002; Edelman, 1992; Krawiec, 2003). What remains under-specified is the mechanism by which a signal recorded under one regime becomes a decision for which an identifiable actor can be held to account before regulators, boards and courts — and why that mechanism is particularly fragile for products that straddle the drug–device boundary.

The article therefore asks: **How, and at which organisational interfaces, are safety signals concerning advanced drug delivery systems translated into accountable decisions under the regulatory regimes of the United States, the European Union and Australia, and what conceptual framework can make those interfaces analytically visible and empirically testable?**

The approach is conceptual, doctrinal and comparative. The article analyses binding law, judicial decisions and regulator guidance in three jurisdictions; conducts a descriptive analysis of FDA device recall records to locate where, in the product lifecycle, recall root causes for drug delivery devices are attributed; and applies the resulting framework to the documented EpiPen record. Its central contribution is the Integrated Lifecycle Accountability Framework (ILAF), which reframes integration as a problem of translation across knowledge boundaries rather than structural consolidation. Drawing on Carlile's distinction between syntactic, semantic and pragmatic boundaries (Carlile, 2004), ILAF specifies five translation interfaces at which signals, decision rights, obligations, assurance evidence and lifecycle learning must cross between functions, and states the failure condition and observable implication of each. The article contributes to regulatory-governance scholarship by identifying a mechanism through which management-based regulation can generate compliance records without generating accountability, and by showing how product classification determines where those records sit.

Section 2 reviews the relevant theory and compares established frameworks. Section 3 describes the method. Section 4 presents the comparative regulatory analysis and the recall-record analysis. Section 5 specifies ILAF. Section 6 applies it to the EpiPen record, and Section 7 states six propositions. Sections 8 to 10 discuss the contribution, implications and limitations, and Section 11 concludes.

2. Theoretical background

2.1 Process-oriented regulation and the internalisation of accountability

Regulatory scholarship has long recognised that regulators of complex, heterogeneous industries delegate much of the work of control to the regulated. Enforced self-regulation proposed that firms write and enforce their own rules under public oversight (Braithwaite, 1982); responsive regulation located such arrangements within an enforcement pyramid (Ayres & Braithwaite, 1992); and meta-regulation described regulators' attempts to make firms' internal governance systems themselves the object of regulation (Parker, 2002). Coglianese and Lazer (2003) showed that management-based regulation is attractive where outcomes are hard to measure and regulated activities heterogeneous — conditions that describe pharmaceutical quality and post-market safety well. Gilad (2010) grouped these approaches as process-oriented regulation and found that their effects on organisational performance are positive but uneven, depending on firms' commitment and on regulators' capacity.

Two lines of critique are central to this article. The first concerns symbolic compliance. Edelman (1992) showed that organisations respond to ambiguous legal mandates by building formal structures whose existence signals compliance without necessarily changing outcomes, and Krawiec (2003) argued that internal compliance structures can be cosmetic while shielding firms from liability. Power (2007) similarly warns that the expansion of risk management may produce defensible documentation rather than better decisions. The second concerns accountability in polycentric regimes. Black (2008) shows that where regulatory authority is dispersed among public and private actors, accountability relationships multiply and compete. ADDS manufacturers answer simultaneously to medicines regulators, device regulators, notified bodies acting as regulatory intermediaries (Abbott et al., 2017), boards, auditors and courts.

2.2 Two concepts of risk

ICH Q9(R1) defines risk as the combination of the probability of occurrence of harm and the severity of that harm, and frames quality risk management as the assessment, control, communication and review of risks to product quality across the lifecycle (ICH, 2023). The 2023 revision added guidance on managing subjectivity, on the formality of risk management, on risk-based decision-making and on product-availability risks (ICH, 2023). ISO 14971 applies a materially similar

harm-based concept to devices (ISO, 2019). ISO 31000 instead defines risk as the effect of uncertainty on objectives, and COSO links risk to strategy and performance (ISO, 2018; COSO, 2017). The two concepts answer different questions: whether a product is acceptably safe for its intended use, and whether the organisation will achieve what it set out to do.

Accounting research shows that the relationship between such concepts is not technical but organisational. Mikes (2009) identified distinct calculative cultures in risk functions, and Mikes (2011) described how risk managers perform boundary-work to make quantified risks count in decision-making. The ERM literature finds implementation heterogeneous and evidence of value contingent (Bromiley et al., 2015; Hoyt & Liebenberg, 2011; Mikes & Kaplan, 2015). Kaplan and Mikes (2012) distinguish preventable risks, which call for rules and controls, from strategy and external risks, which call for discussion and scenario analysis. Most quality failures in ADDS are preventable risks; many software, supplier and regulatory-change risks are not.

2.3 Knowledge boundaries and translation

Carlile (2004) distinguishes three kinds of knowledge boundary. At a syntactic boundary, actors share meanings and need only a common lexicon to transfer information. At a semantic boundary, the same terms mean different things, and knowledge must be translated. At a pragmatic boundary, actors have different interests, and knowledge must be transformed because acting on it imposes costs on one party. Boundary objects — artefacts that are shared but interpreted differently by different communities — enable coordination across such boundaries without requiring consensus (Star & Griesemer, 1989). Information-processing theory adds that organisations reduce the need for such coordination by creating slack or self-contained units, or increase their capacity for it through vertical information systems and lateral relations (Galbraith, 1974).

This framework fits the ADDS problem closely. A device complaint code and a pharmacovigilance case report describe the same event in incompatible lexicons (a syntactic boundary). A quality engineer's judgement that a defect is "infrequent" and an executive's judgement that residual risk is within appetite use the word "risk" in different senses (a semantic boundary). A decision to recall imposes costs on supply, revenue and reputation that the quality function does not bear (a pragmatic boundary).

2.4 Signal loss, escalation and the problem of many hands

Organisational-accident research shows that serious failures typically emerge from an incubation period in which warning signs are misread, discounted or not passed on (Turner, 1976; Reason, 1997), and that deviations can become normalised when each is judged acceptable in isolation (Vaughan, 1996). Research on organisational silence explains why information that is unwelcome to superiors is often withheld (Morrison & Milliken, 2000). When outcomes depend on the contributions of many officials, it becomes difficult to identify anyone who can be held responsible — the problem of many hands (Thompson, 1980). Accountability, understood as a relationship in which an actor is obliged to explain and justify conduct to a forum that can pass judgement and impose consequences (Bovens, 2007), requires that this difficulty be overcome.

Corporate law has addressed the same problem through oversight doctrine. Directors may be liable where they utterly fail to implement a reporting system or consciously fail to monitor one (In re Caremark, 1996; Stone v. Ritter, 2006). Where a company's mission-critical operations are subject to external regulation, Delaware courts have required a good-faith effort to oversee compliance with that regulation, including in food safety, clinical-trial and aircraft-safety contexts (Marchand v. Barnhill, 2019; In re Clovis Oncology, 2019; In re Boeing, 2021). In 2023 the Court of Chancery held that officers also owe a duty of oversight within their areas of responsibility (In re McDonald's, 2023). In Australia, the Full Federal Court upheld findings that directors breached s 180(1) of the *Corporations Act 2001* (Cth) by causing contraventions that exposed the company to a foreseeable risk of serious harm, including loss of its licence and investor claims (Cassimatis v ASIC, 2020, paras. 77–79). U.S. food and drug law also recognises criminal liability for responsible corporate officers without proof of awareness of wrongdoing (United States v. Park, 1975).

2.5 Established frameworks and the remaining gap

Table 1 compares the frameworks most relevant to ADDS governance. Each is well suited to its purpose, but none specifies how a signal recorded under one regime becomes a decision accountable to multiple forums. Quality guidelines assign responsibility to "senior management" and require management review (ICH, 2008; European Commission, 2013); ERM standards assign responsibility to the board and management for risk in general (ISO, 2018; COSO, 2017); GRC models and the Three Lines Model allocate roles but are not tied to product classification or to the specific legal obligations of medicinal-product and device law (Racz et al., 2010; Institute of Internal Auditors, 2020); and oversight doctrine sets a legal threshold for directors' and officers' conduct without prescribing organisational design. Process-oriented regulation theory explains why regulators rely on these systems and why they may fail (Gilad, 2010; Parker, 2002), but it does not specify where, within

the firm, the translation from signal to decision is most likely to break.

Table 1. Comparison of established approaches relevant to ADDS governance

Approach	Purpose	Unit of analysis	Core mechanism	Accountability allocation	Lifecycle coverage	Principal limitation for ADDS
ICH Q9(R1) quality risk management	Protect patients through control of quality risk	Product and process risk	Risk assessment, control, communication, review; managing subjectivity	Decision-makers in QRM; not linked to board	Development to discontinuation	Harm-based; silent on enterprise translation and legal forums
ICH Q10 pharmaceutical quality system	Lifecycle quality system and continual improvement	Pharmaceutical quality system	Management responsibility; management review; CAPA; change management	Senior management	Full lifecycle	Guidance; "senior management" not equated with board; drug-side only
ISO 14971 / ISO 13485 (devices)	Device risk management and QMS	Device and QMS	Risk analysis, evaluation, control; management review	Top management	Full lifecycle	Device-side only; combination interfaces left to firm
ISO 31000 / COSO ERM	Integrate risk with objectives and strategy	Enterprise objectives	Risk identification, appetite, reporting, integration with governance	Board and management	Not product-specific	Objective-based; no guidance on translating patient-harm judgements
Integrated GRC; Three Lines Model	Coordinate governance, risk and compliance roles	Enterprise functions	Role allocation; assurance lines	Management, risk/compliance, internal audit	Not product-specific	Generic; not tied to product classification or forum-specific obligations
Process-oriented regulation (management-based, meta-regulation)	Explain regulatory reliance on internal systems	Regulator–firm relationship	Prescribed planning and review; regulatory supervision of systems	Firm, supervised by regulator	Depends on regime	Explains reliance and failure in general; does not locate intra-firm breakpoints

Approach	Purpose	Unit of analysis	Core mechanism	Accountability allocation	Lifecycle coverage	Principal limitation for ADDS
Corporate oversight doctrine (Caremark line; s 180(1))	Set legal standard for directors' and officers' oversight	Individual fiduciary or statutory conduct	Information systems; response to red flags; foreseeable harm	Directors; officers (Delaware)	Not product-specific	Ex post legal threshold; not a design specification
ILAF (this article)	Make signal-to-decision translation visible and testable	Interfaces between functions across the lifecycle	Five translation interfaces, each with trigger, decision rule, evidence and failure condition	Named decision-maker at each interface	Full lifecycle, classification-sensitive	Conceptual; requires empirical testing

Sources: ICH (2008, 2023); ISO (2016, 2018, 2019); COSO (2017); Racz et al. (2010); Institute of Internal Auditors (2020); Coglianese and Lazer (2003); Gilad (2010); Parker (2002); case law as cited in the text.

The gap, stated precisely, is the absence of a framework that (a) treats the interfaces between quality, safety, enterprise risk, legal and governance functions as the primary unit of analysis, (b) distinguishes the kinds of boundary that signals must cross, (c) ties each interface to the classification-dependent obligations of medicinal-product and device law, and (d) specifies observable failure conditions. ILAF does not replace the frameworks in Table 1; it is an analytical overlay that identifies where they must connect.

3. Methodology

3.1 Design

The study combines doctrinal legal analysis (Hutchinson & Duncan, 2012), structured document analysis of regulator guidance and enforcement records (Bowen, 2009), a descriptive analysis of public FDA recall data, and conceptual theory-building using the model approach to conceptual articles, which specifies constructs and their relationships (Jaakkola, 2020; Whetten, 1989). The study did not involve interviews, surveys, experiments or confidential company data, and it does not claim to have validated the framework.

3.2 Jurisdictions and temporal scope

The United States, the European Union and Australia were selected because they represent three distinct architectures for products at the drug–device boundary: assignment to a lead agency centre by primary mode of action with combination-specific regulations (21 C.F.R. pt. 3; 21 C.F.R. pt. 4); separate medicinal-product and device legislation linked by a notified-body opinion for integral products (Directive 2001/83/EC; Regulation (EU) 2017/745); and a single regulator applying principal-therapeutic-effect and primary-mode-of-action criteria under one Act (Therapeutic Goods Act 1989 (Cth); TGA, 2023). They also differ in corporate-law oversight doctrine. The analysis addresses federal and EU-level law and does not examine state, Member State or territory variation except where noted. Law is stated as at 26 October 2026.

3.3 Source identification and selection

Source selection was purposive and iterative rather than systematic. An initial set of legal, regulatory and scholarly sources was assembled in October 2026 by targeted searching of official sources — the electronic Code of Federal Regulations and Federal Register, FDA, EMA, European Commission and Council of the EU websites, the Australian Federal Register of Legislation and TGA website, and the websites of the Delaware courts and the Federal Court of Australia — supplemented by general web searches, publisher pages and citation chaining. A supplementary targeted search was conducted on 26 October 2026 to verify the currency of each legal proposition, to confirm bibliographic details and to locate scholarship on process-oriented regulation, knowledge boundaries and organisational accountability. Search terms combined product terms ("combination product", "drug-device combination", "autoinjector", "infusion pump") with governance terms ("oversight", "management review", "risk acceptance", "warning letter", "recall"). Search strings, result counts and screening decisions were not recorded in a form that would permit replication, so the study does not claim to be a systematic review.

Inclusion required that a source (a) be a primary legal or official regulatory source in force or formally adopted at the cut-off date, or a judicial decision of a superior court in a selected jurisdiction; or (b) be peer-reviewed scholarship or a recognised standard bearing directly on a construct used in the framework. Proposals not yet adopted were included

only to describe regulatory change and were not treated as law. Each source was coded by normative status, distinguishing binding legislation, judicial decisions, instruments given legal force by incorporation (for example, ISO 13485:2016 through the FDA Quality Management System Regulation, and the PIC/S Guide to GMP through the TGA Manufacturing Principles), regulator guidance and harmonised guidelines, voluntary standards, and scholarship. A verification register recording each principal legal proposition, its supporting authority and its verification status is provided as supplementary material.

3.4 Comparative dimensions

Each jurisdiction was analysed along seven dimensions derived from the product lifecycle: classification and lead pathway; quality system and management responsibility; safety reporting; change control; corrective action and recall; individual accountability; and civil liability. For each dimension the analysis asked who bears the obligation, what triggers it, who must receive and act on the relevant information, and what records would evidence compliance. Accountability gaps identified in the analysis were classified as established (demonstrated by a primary source or documented regulatory finding), inferred (following from the structure of the legal obligations but not documented as having occurred), or hypothesised (theoretically plausible and proposed for testing).

3.5 Recall-record analysis

To examine where in the lifecycle recall root causes for drug delivery devices are attributed, the openFDA device recall endpoint was queried on 26 October 2026 (data last updated 22 October 2026) (FDA, 2026b). Drug delivery devices were defined by FDA product code using the openFDA device classification endpoint: infusion pumps (FRN), insulin infusion pumps (LZG, OYC, OPP, QFG), patient-controlled analgesia pumps (MEA), elastomeric pumps (MEB), drug-specific pharmacy-filled infusion pumps (QJY), implanted programmable pumps (LKK), pen injectors (NSC), on-body injectors (QLF) and non-electrically powered fluid injectors (KZE). Counts of FDA-assigned root-cause categories were retrieved for this set and, as a baseline, for all device recalls, for two periods by date of recall initiation (2002–2018 and 2019 to the data cut-off). The 43 FDA root-cause categories were grouped into seven analytic categories by lifecycle stage; the mapping, query strings and counts are provided as supplementary data. The unit of analysis is the FDA product recall record, of which one recall event may contain several; records are therefore not independent, and the 95 per cent Wilson intervals reported are approximate. FDA notes that root-cause determinations may be revised until a recall is terminated. CDER-led combination products, such as many autoinjectors, are recalled as drugs and are not captured in this endpoint. The analysis is descriptive and is used to locate where root causes are attributed, not to estimate effects.

3.6 Framework derivation and worked application

The framework was derived abductively. The comparative analysis identified recurring dependency points at which an obligation in one dimension depends on information or decisions generated in another — for example, a reporting obligation depends on complaint information, and a recall depends on a risk-acceptance judgement. Each dependency point was then classified using Carlile's boundary typology (Carlile, 2004) and examined through the lenses in Section 2 to identify the actor accountable for the translation, the evidence that it occurred and the condition under which it fails. Five recurring dependency points became the five interfaces. The five domains were retained from the initial framing because they correspond to distinct sources of obligation and expertise. Propositions were derived by stating, for each interface, the expected consequence of its failure, and by adding one proposition derived from the symbolic-compliance critique. The worked application (Section 6) uses the FDA warning letter and recall communication concerning EpiPen autoinjectors because the letter provides a dated, primary-source chronology of decisions at several interfaces (FDA, 2017b; FDA, 2017a). Competing interpretations were considered by asking, for each interface, whether an established framework would explain the same facts equally well.

4. Comparative regulatory analysis

4.1 Classification as the gateway

Classification determines which quality system, reporting regime and liability exposure apply to an ADDS, and therefore which internal function owns each obligation. In the United States a combination product is assigned to a lead centre according to its primary mode of action, defined as the single mode of action that provides the most important therapeutic action (21 C.F.R. pt. 3). Manufacturers must comply with the current good manufacturing practice requirements applicable to each constituent part, with a streamlined option for drug-led products, and with combination-specific postmarketing safety-reporting requirements (21 C.F.R. pt. 4). When the FDA replaced the device Quality System Regulation with the Quality Management System Regulation (QMSR), effective 2 February 2026, it made conforming amendments to Part 4 (Medical Devices; Quality System Regulation Amendments, 2024; FDA, 2026a).

The European Union has no unified legal category of combination product. Where a device and a medicinal product form a single integral product intended exclusively for use in that combination and not reusable, and the medicinal action is principal, the product is governed by medicinal-product legislation, but the device part

must meet the relevant general safety and performance requirements of the Medical Device Regulation; under Article 117 the marketing authorisation dossier must include the EU declaration of conformity or relevant certificate for the device part or, where the device part is not CE-marked but would require notified-body involvement if marketed separately, a notified-body opinion on its conformity (Regulation (EU) 2017/745, arts. 1(9), 117; Directive 2001/83/EC). Devices that are not integral are regulated as devices (Regulation (EU) 2017/745). In Australia, the TGA determines the pathway by considering the principal therapeutic effect and the primary mode of action in relation to the statutory definitions of medicine, biological and medical device (TGA, 2023). Software that controls dosing may itself be a device; in the United States, manufacturers of "cyber devices" must also meet statutory premarket cybersecurity requirements, including plans to monitor and address post-market vulnerabilities (21 U.S.C. § 360n-2). The 2019 recall of certain insulin pumps that could not be updated to remedy a wireless vulnerability shows how a risk originating in connectivity, rather than in formulation or manufacturing, can require field action (FDA, 2019).

4.2 Obligations, triggers and evidence

Table 2 summarises, for each comparative dimension, who bears the obligation, what triggers it and what records would evidence compliance. Three features matter for accountability. First, safety-reporting clocks run from the obligation-holder's awareness. In the European Union, marketing authorisation holders must submit serious suspected adverse reactions within 15 days and non-serious reactions within 90 days of gaining knowledge of them (Directive 2001/83/EC, art. 107(3)), through a pharmacovigilance system meeting implementing rules and guidance (Implementing Regulation (EU) No 520/2012; European Medicines Agency, 2017), and device manufacturers must report serious incidents within 15 days of awareness, within 2 days for a serious public-health threat and within 10 days for a death or unanticipated serious deterioration (Regulation (EU) 2017/745, art. 87). In the United States, device manufacturers report deaths, serious injuries and certain malfunctions under the medical device reporting regulation (21 C.F.R. pt. 803), and combination-product applicants must submit reports appropriate to their application type and additional constituent-part reports, including malfunction and five-day reports for device constituents and 15-day reports for drug constituents (21 C.F.R. pt. 4, § 4.102); correction and removal reports are due within ten working days of initiating the action (21 C.F.R. § 806.10). In Australia, medicine sponsors must report serious adverse reactions within 15 calendar days (TGA, n.d.-b), and device sponsors must report within 2 days for a serious threat to public health, 10 days for a death or serious deterioration and 30 days where recurrence might cause death or serious deterioration (Therapeutic Goods (Medical Devices) Regulations 2002 (Cth), reg. 5.7; TGA, n.d.-c). Because awareness can be attributed when information reaches persons within the organisation, information that sits in one system while another function owns the clock creates exposure before any decision-maker has considered it.

Second, quality-system obligations are increasingly harmonised and records of management deliberation increasingly inspectable. The QMSR incorporates ISO 13485:2016 by reference (Medical Devices; Quality System Regulation Amendments, 2024; ISO, 2016), and Australia's Manufacturing Principles have applied the PIC/S Guide to GMP PE009-17 since 1 September 2025 (TGA, n.d.-a). The FDA has stated that from the QMSR effective date it intends to review management-review reports, internal audits and supplier audits that were previously exempt from inspection (FDA, 2026a). Third, individual accountability is allocated differently: through fiduciary oversight duties and responsible-corporate-officer liability in the United States (In re Caremark, 1996; In re McDonald's, 2023; United States v. Park, 1975); through statutory role-holders such as the qualified person responsible for pharmacovigilance and the device person responsible for regulatory compliance in the European Union (Directive 2001/83/EC; Regulation (EU) 2017/745, art. 15); and through the directors' duty of care and diligence and executive-officer liability provisions in Australia (Corporations Act 2001 (Cth); Therapeutic Goods Act 1989 (Cth); Personal Liability for Corporate Fault Reform Act 2012 (Cth)).

Table 2. Comparative allocation of obligations for ADDS: holder, trigger and evidence

Dimension	United States	European Union	Australia
Classification	Holder: sponsor/applicant. Trigger: product design and claims. Lead centre by primary mode of action (21 C.F.R. pt. 3).	Holder: MAH or device manufacturer. Integral products under medicines law with device-part evidence (MDR art. 117).	Holder: sponsor. Principal therapeutic effect and primary mode of action (TGA guidance).

Dimension	United States	European Union	Australia
Quality system	Drug CGMP (pt. 211); QMSR incorporating ISO 13485 (pt. 820); pt. 4 for combination products. Evidence: investigations, complaint files, management review (now inspectable).	EU GMP (senior management responsible for PQS); MDR QMS and post-market surveillance (arts. 10, 83). Evidence: PQS and QMS records.	Manufacturing Principles adopting PIC/S PE009-17 from 1 Sept 2025; device conformity assessment. Evidence: GMP and QMS records.
Safety reporting	Trigger: awareness. 15-day drug reports; device MDRs; pt. 4 constituent-part reports (§ 4.102).	Trigger: knowledge/awareness. ADRs 15/90 days (Dir. 2001/83 art. 107(3)); serious incidents 2/10/15 days (MDR art. 87).	Trigger: awareness. Serious ADRs ≤15 calendar days; device events 2/10/30 days (reg. 5.7).
Change control	Supplements and reports by risk of change (§ 314.70); device change requirements.	Variations Regulation; reassessment of device-part evidence for integral products.	Variations to ARTG entries; device change notification.
Corrective action and recall	Recall guidance (pt. 7); corrections and removals reported within 10 working days (§ 806.10).	Field safety corrective actions reported in advance save urgency (MDR art. 87).	Recall and public-notification provisions of the Act.
Individual accountability	Directors' and officers' oversight duties (Caremark; McDonald's); responsible corporate officer (Park).	QPPV; person responsible for regulatory compliance (MDR art. 15); national company law.	Corporations Act s 180(1); executive-officer liability (TG Act ss 54B–54BA).
Civil liability	State tort law, subject to pre-emption (Riegel; Wyeth).	Directive (EU) 2024/2853 for products placed on the market after 9 Dec 2026, including software and disclosure.	Australian Consumer Law pt. 3-5; negligence (e.g., Gill).

Abbreviations: MAH, marketing authorisation holder; PQS, pharmaceutical quality system; QMS, quality management system; ADR, adverse drug reaction; ARTG, Australian Register of Therapeutic Goods; QPPV, qualified person responsible for pharmacovigilance. Summary only; obligations are subject to the detailed conditions of the cited instruments.

4.3 Change control, liability and the evidentiary function of records

Changes to an authorised product are themselves regulated (21 C.F.R. pt. 314; Regulation (EC) No 1234/2008), and harmonised guidance offers tools to make post-approval change more predictable (ICH, 2019). For ADDS, changes to device components, suppliers, software versions or cybersecurity controls may engage drug-side and device-side procedures simultaneously, and in the European Union may require reconsideration of device-part evidence (European Medicines Agency, 2021). Change control is therefore where commercial decisions, such as a change of component supplier, meet regulatory obligations and patient risk most directly. Corrective action is the corresponding point after a problem emerges: U.S. recall provisions are framed largely as guidance on voluntary action, supported by mandatory reporting and enforcement powers (21 C.F.R. pt. 7, subpt. C; 21 C.F.R. § 806.10), whereas the European device framework requires field safety corrective actions to be reported in advance save in cases of urgency (Regulation (EU) 2017/745, art. 87).

Civil liability converts internal records into evidence. In the United States, state-law claims against devices approved through premarket approval are substantially pre-empted where they

would impose requirements different from or additional to federal requirements (Riegel v. Medtronic, 2008), whereas failure-to-warn claims against drug manufacturers are generally not pre-empted where the manufacturer could have strengthened its labelling (Wyeth v. Levine, 2009); the lead pathway of a combination product can therefore affect liability exposure. In the European Union, Directive (EU) 2024/2853 applies to products placed on the market or put into service after 9 December 2026. It treats software as a product, addresses defects arising from updates within the manufacturer's control and failures to supply security updates, and introduces disclosure obligations and rebuttable presumptions of defectiveness or causation in specified circumstances (Directive (EU) 2024/2853). In Australia, manufacturers are liable for goods with safety defects under Part 3-5 of the Australian Consumer Law (Competition and Consumer Act 2010 (Cth) sch. 2), and the pelvic-mesh litigation shows that internal knowledge of risk can be central to findings of defect and negligence (Ethicon Sàrl v Gill, 2021).

4.4 Regulatory change

The European Union's reform of general pharmaceutical legislation, comprising a new directive and regulation intended to replace Directive 2001/83/EC and Regulation (EC) No 726/2004, was adopted by the Council on 28 September 2026 and, at the time of writing, awaits adoption by the European Parliament and publication in the *Official Journal* (Council of the European Union, 2026). Until the new acts enter into force and their transitional provisions apply, the existing instruments remain the governing law (Directive 2001/83/EC; Regulation (EC) No 726/2004). Regulatory change of this kind is itself an enterprise risk, because obligation maps, role allocations and reporting procedures must be revised across products and markets.

4.5 Where recall root causes are attributed

The recall-record analysis identified 1,193 FDA product recall records for the drug delivery device codes (874 initiated in 2002–2018 and 319 from 2019 to October 2026), of which 895 had an assigned root cause other than "Other", "Under investigation by firm", "Unknown" or "Pending". Infusion pumps (FRN) accounted for 721 records; no records were found for pen injectors (NSC) or on-body injectors (QLF), which may reflect, among other things, the regulation of many prefilled pens and autoinjectors as drug-led combination products whose recalls are recorded as drug recalls. Figure 1 compares the most recent period with all device recalls. Among drug delivery device records with an assigned root cause in 2019–2026, 58.6 per cent were attributed to design causes (95 per cent interval 52.3–64.7) compared with 34.1 per cent for all devices; 14.8 per cent to change control (10.8–19.8) compared with 11.6 per cent; and 20.7 per cent to production and process execution (16.0–26.3) compared with 34.0 per cent. Software-related causes at any stage accounted for 27.0 per cent of drug delivery device records (21.8–33.0) compared with 9.8 per cent for all devices, and rose from 8.2 per cent in 2002–2018. Supplier and material nonconformity fell from 25.1 per cent of assigned drug delivery device records in 2002–2018 to 5.1 per cent in 2019–2026.

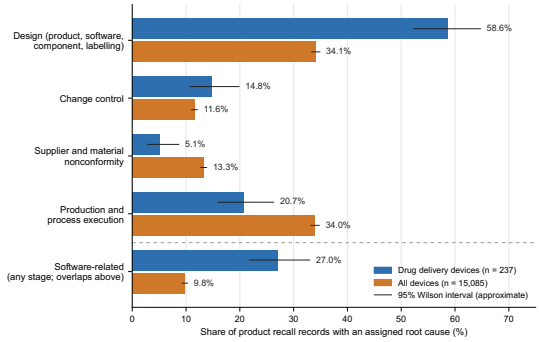


Figure 1. Attributed root causes of FDA product recall records, drug delivery devices and all devices, 2019 to October 2026. Shares are of records with an assigned root cause; software-related causes overlap the other categories. Intervals are approximate because records are clustered within recall events. Source: author's analysis of openFDA device recall data (FDA, 2026b), queried 26 October 2026.

Three cautions apply. Root-cause categories are assigned by FDA and may change; the use of "Other" fell sharply after 2018, which limits comparison across periods; and records cluster within events. The pattern is nonetheless informative for the argument. Recall root causes for drug delivery devices are attributed disproportionately to design and change-control decisions and to software, rather than to manufacturing execution. These are the points at which residual risk is accepted, changes are authorised and post-market learning should reopen earlier decisions — decisions made at the boundaries between engineering, quality, regulatory and enterprise functions. The data do not show that signals were mishandled; they show where in the lifecycle the decisions that FDA later associates with recalls are located.

4.6 Accountability gaps

Table 3 states the accountability gaps that follow from the analysis and classifies each by evidential status. Only the first is established by a documented regulatory record; the others are inferred from the structure of the obligations or hypothesised for testing.

Table 3. Accountability gaps identified in the analysis and their evidential status

Gap	Basis	Status	Interface
Signals recorded and investigated without escalation to field-action decision	FDA warning letter findings on complaint investigation, linkage to a known component defect and a June 2016 "no market action" determination (FDA, 2017b)	Established (regulatory finding, single case)	T1, T2
Reporting clock owned by one function while relevant information sits in another	Awareness-triggered clocks in all three jurisdictions; separate drug and device reporting streams for combination products (21 C.F.R. § 4.102; MDR art. 87; Dir. 2001/83 art. 107)	Inferred	T1, T3
Classification-dependent divergence in internal ownership of obligations across markets	Different classification architectures (Section 4.1); absence of pen- and on-body-injector records from device recall data	Inferred	T3
Technical risk acceptance without translation into enterprise consequences	Harm-based versus objective-based risk concepts; no guidance linking QRM acceptance to board appetite (ICH Q9(R1); ISO 31000)	Inferred	T2
Records adequate for inspection but not for board oversight or litigation	Inspectability of management review (FDA, 2026a); disclosure and presumptions under Directive (EU) 2024/2853; oversight doctrine	Hypothesised	T4
Post-market learning not reopening design and change decisions	Concentration of recall root causes in design, change control and software (Section 4.5)	Hypothesised (consistent with descriptive data)	T5

5. The Integrated Lifecycle Accountability Framework

5.1 Constructs

ILAF uses the following constructs. A **safety signal** is information suggesting a new or changed risk associated with a product, from any source: complaints, adverse-event and incident reports, supplier data, test results, use-error analyses or vulnerability disclosures. A **translation interface** is a recurring point at which information or decisions must cross a knowledge boundary between functions for an obligation to be discharged or a decision to be made. **Decision rights** are the authority to accept residual risk, close an investigation, authorise a change or initiate a field action. An **obligation map** is a product- and market-specific record linking each applicable legal obligation to an accountable role. **Assurance evidence** is a contemporaneous record showing who decided what, on what information

and against which criteria. Use-error and human-factors findings are treated as safety signals because delivery failures often arise from the interaction between device design and user (FDA, 2016). **Lifecycle learning** is the reopening of earlier design, risk-acceptance or change decisions in the light of post-market information. An **accountable decision** is one for which an identifiable actor can give an account to a relevant forum that is supported by contemporaneous evidence (Bovens, 2007).

5.2 Domains as sites of obligation and expertise

ILAF retains five domains: (A) corporate governance and accountability; (B) enterprise risk management; (C) legal accountability; (D) compliance assurance; and (E) patient safety and lifecycle learning. The domains are not organisational units or new management systems. They are analytical categories denoting distinct sources of obligation and expertise, each with its own vocabulary, records and forums. Domain E is where most new information about ADDS performance first appears; Domain C is where obligations are defined by classification and market; Domain B is where risks are aggregated against objectives; Domain D is where controls are tested; and Domain A is where decision rights are allocated and where oversight duties attach. Figure 2 shows the domains and the interfaces that connect them.

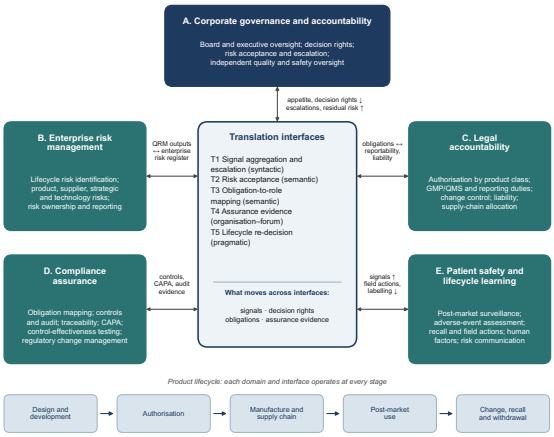


Figure 2. The Integrated Lifecycle Accountability Framework (ILAF). Five domains (A–E), understood as sites of obligation and expertise, exchange information, decision rights, obligations and assurance evidence through five translation interfaces (T1–T5) at every stage of the product lifecycle. Source: developed by the author.

5.3 The five translation interfaces

Tables 4a and 4b specify each interface. **T1 (signal aggregation and escalation)** crosses a syntactic boundary: drug-side and device-side records describe the same event in different lexicons, and the task is to transfer information by building a common product-level view and applying predefined escalation criteria. **T2 (risk acceptance)** crosses a semantic boundary: a harm-based judgement that residual risk is acceptable must be translated into its enterprise and legal significance, and the decision must be taken at the level whose authority matches its consequences. **T3 (obligation-to-role mapping)** crosses a semantic boundary between legal categories and organisational roles: classification and market determine obligations, which must be assigned to named owners, including statutory role-holders and, contractually, suppliers and software partners. **T4 (assurance evidence)** crosses the boundary between the organisation and its external forums: evidence must be capable of supporting accounts to a regulator, a board and a court. **T5 (lifecycle re-decision)** crosses a pragmatic boundary: post-market learning must reopen earlier design, risk-acceptance and change decisions even where doing so imposes costs on the functions that made them.

Table 4a. Specification of the ILAF translation interfaces: purpose, trigger, decision-maker and decision rule

Interface	Purpose and boundary type	Trigger or input	Responsible decision-maker	Decision rule
T1 Signal aggregation and escalation	Transfer signals across drug, device, supplier and software records into one product view (syntactic)	Complaint, ADR, incident, supplier nonconformity, test failure, use-error report, vulnerability disclosure	Head of quality or safety, with pharmacovigilance and device vigilance leads	Escalate when predefined criteria referring to patient harm, reportability or linkage to a known defect are met; record the criterion applied
T2 Risk acceptance	Translate harm-based residual-risk judgements into enterprise and legal consequences (semantic)	Proposal to close an investigation, accept residual risk, release or continue supply, or decline field action	Tiered: technical owner; executive risk owner; board committee above defined thresholds	Decision authority matches the severity and breadth of consequences; record harm-based and enterprise rationales side by side

Interface	Purpose and boundary type	Trigger or input	Responsible decision-maker	Decision rule
T3 Obligation-to-role mapping	Translate classification- and market-specific obligations into accountable roles (semantic)	New product, market, supplier, software version or legal change	Regulatory affairs and legal, approved by an accountable executive	Every reporting clock, change trigger and statutory role has a named owner per product and market
T4 Assurance evidence	Make decisions accountable to regulators, boards and courts (organisation–forum)	Decisions at T1, T2, T3 and T5; audits; management review	Compliance and internal audit; board committee as recipient	Evidence states decision-maker, information available, criteria and timing contemporaneously
T5 Lifecycle re-decision	Transform post-market learning into revisions of earlier decisions (pragmatic)	Trend, recurrence, field action, new vulnerability, change in use environment	Design and change authority, with quality and executive risk owner	Specified signals mandatorily reopen design risk files, residual-risk decisions and change approvals

ADR, adverse drug reaction.

Table 4b. Specification of the ILAF translation interfaces: outputs, relationships, failure conditions and observable implications

Interface	Output and evidence trail	Relationships and feedback	Failure condition	Observable implication
T1	Product-level signal log; escalation records; reportability assessments	Feeds T2 and T5; reportability depends on T3	Related signals remain in separate systems or are closed individually without linkage	Time from first related signal to escalation; whether field action precedes external intervention
T2	Tiered decision records with dual rationales	Constrained by appetite set in Domain A; evidenced through T4; reopened by T5	Consequential decisions taken at technical level on harm-based reasoning alone, or deferred indefinitely	Frequency with which “no action” decisions are reversed after external intervention
T3	Product-and-market obligation register; role assignments; contractual flow-down	Defines clocks used at T1 and change triggers at T5	Obligations unowned or owned by a function without access to the relevant information	Late or missed reports by market and product class

Interface	Output and evidence trail	Relationships and feedback	Failure condition	Observable implication
T4	Decision dossiers; control-test and audit results; management review records	Draws on T1–T3 and T5; reports to Domain A	Accounts must be reconstructed after the event, or diverge between forums	Consistency between accounts given to regulators, boards and courts
T5	Updated risk files; change records; labelling, training or software updates	Reopens T2 and T3; generates new T1 criteria	Risk files not updated after field experience; recurring causes in the same product family	Repeat recalls with the same attributed cause; age of design risk assessments

5.4 How the interfaces relate

The interfaces are not a sequence. They are triggered conditionally and reinforce one another. T1 is continuous; T2 is triggered when a signal, investigation or change requires a decision about residual risk; T3 is triggered by product, market, supplier, software or legal change and defines the clocks and triggers used by T1 and T5; T4 accompanies every decision; and T5 is triggered by recurrence or new information and reopens T2 and T3. Failures propagate: an unowned reporting obligation (T3) can leave a signal unescalated (T1), which leaves a risk-acceptance decision uninformed (T2), which leaves no evidence of oversight (T4) and no learning (T5). The interfaces therefore map onto the three mechanisms in Section 2: signal loss (T1), allocation of decision rights (T2) and translation of obligations into responsibilities (T3) determine whether information reaches an accountable decision; traceability (T4) determines whether the decision can be accounted for; and feedback (T5) determines whether the organisation learns.

5.5 Relationship to existing systems

ILAF supplements rather than replaces quality, risk and compliance systems. Its interfaces correspond to existing processes — complaint handling, CAPA, management review, change control, enterprise risk reporting and board reporting — and the framework asks whether each process carries information across the relevant boundary, to a decision-maker with matching authority, leaving evidence usable in other forums. An organisation whose management review already performs these translations needs no new structure. The framework adds analytical value where existing processes are organised by function or by regulatory regime, as is common for combination products whose drug and device constituents are governed by different quality systems and reporting streams.

5.6 Boundary conditions

ILAF is intended for organisations that hold, or act for holders of, authorisations for ADDS. It adds least where a single small organisation performs all functions through a few individuals with shared information, where products are not at the drug–device boundary, or where existing management review demonstrably performs the five translations. It may also fail in its own terms. Formalised interfaces can slow urgent decisions if escalation thresholds are poorly designed; tiered decision rights can diffuse rather than concentrate accountability if many actors sign off on each decision (Thompson, 1980); and interface records can become symbolic structures that signal compliance without changing decisions (Edelman, 1992; Krawiec, 2003). The framework does not alter the legal allocation of responsibility among manufacturers, sponsors, authorisation holders and statutory role-holders, and it does not resolve questions of classification.

6. Worked application: EpiPen autoinjectors

6.1 The documented record

EpiPen and EpiPen Jr are epinephrine autoinjectors regulated in the United States as combination products, and the warning letter cites violations of both drug CGMP and device quality-system requirements (FDA, 2017b). FDA inspected the manufacturing facility in October and November 2014 and cited CGMP violations; the firm proposed remediation in December 2015. On 1 February 2016 a failing unit was found during receipt testing of a lot of the Power Pak component; the firm rejected that lot and one associated lot without examining units from the associated lot, and continued manufacturing with other lots of the same component while the supplier's investigation remained open until October 2016. On 28 April 2016 a customer complaint reported that a unit from lot 5FA665 failed to activate. On 9 May 2016 the firm opened an investigation, confirmed the failure and found the same type of component defect. On 3 June 2016 it concluded that the defect was infrequent, closed the investigation and determined that no market action would be taken, without examining all reserve samples or extending the investigation to other lots. Between 2014 and 2017 the firm received 171 complaint samples for units that failed to activate when used correctly; the letter states that firm policy limited disassembly to cases approved by management and that the number disassembled was redacted. During the February–

March 2017 inspection, at FDA's urging, the firm reopened the lot 5FA665 investigation; after the inspection closed and multiple discussions with FDA, it recalled 13 U.S. lots (FDA, 2017b; FDA, 2017a). The letter cites 21 C.F.R. §§ 211.192, 211.198(a), 820.100(a)(1) and 820.30(f)–(g), notes that the product risk assessment had not been reviewed or updated since 2009, and states that the facility's "oversight and control over the manufacture of these products is inadequate" (FDA, 2017b).

6.2 Interface analysis

Table 5 applies the interfaces to the record. The analysis interprets documented facts; it does not establish what the firm's managers knew, intended or should have done, and it does not imply that ILAF has been validated or that it would have prevented the outcome.

Table 5. ILAF analysis of the documented EpiPen record

Interface	Documented facts (FDA, 2017b)	ILAF interpretation
T1 Signal aggregation	Component failure found on receipt testing (Feb 2016); complaint with same defect type (May 2016); 171 failure-to-activate complaint samples 2014–2017, with disassembly limited by policy	Signals from incoming inspection, supplier investigation and customer complaints existed in separate streams. The letter's finding that complaints were not linked to the known component defect is consistent with a T1 failure of the kind specified: related signals closed individually without linkage.
T2 Risk acceptance	Investigation closed as "infrequent" with no market action (Jun 2016); manufacturing continued with other component lots while supplier investigation open	Two consequential residual-risk decisions are documented. The record does not show at what level they were taken or on what enterprise reasoning. ILAF identifies this as the decision whose authority and rationale should be evidenced.
T3 Obligation-to-role mapping	Violations cited under both drug CGMP and device QS provisions; combination product	Drug-side investigation and complaint duties and device-side CAPA and design duties applied to the same events. The record does not show how these obligations were allocated internally; ILAF directs attention to whether one owner held both.
T4 Assurance evidence	Investigation reopened at FDA's urging; recall after inspection; FDA requested comprehensive review, revised complaint procedures and trend analysis	The account was ultimately given to the regulator after external intervention. ILAF predicts that where T4 is weak, accounts are reconstructed after the event — consistent with, but not proved by, this record.
T5 Lifecycle re-decision	No design validation testing reported; risk assessment not updated since 2009; repeat violations after 2014 inspection	Field experience did not reopen the design risk file. This corresponds directly to the T5 failure condition.

6.3 What the analysis adds and what it cannot show

An analysis based on quality-system requirements alone would classify the record as deficiencies in investigation, complaint handling, CAPA and design control — each a correct description. ILAF adds two things. First, it shows that the deficiencies sit at boundaries: between incoming inspection and complaint handling (T1), between technical investigation and the decision about market action (T2), and between field experience and the design risk file (T5). Second, it identifies the decisions on which accountability to a board or court would turn — the June 2016 decision to take no market action and the decision to continue production during the supplier investigation — and asks whether the organisation could evidence who took them and on what basis. The record cannot establish who made these decisions, what information they had, whether any patient harm was caused by the defect, or whether different interface

design would have changed the outcome. These limits are inherent in a single regulatory record and underline that the application illustrates rather than tests the framework.

7. Propositions

The framework yields six propositions. They are conceptual propositions stating expected relationships, not hypotheses that have been tested or findings. Table 6 states the mechanism, principal competing explanation, observable indicators and an appropriate research design for each.

Table 6. Propositions derived from ILAF

No.	Proposition	Mechanism	Competing explanation	Observable indicators	Possible design
P1	Where drug-side and device-side signals for the same product are reviewed in separate systems with separate escalation criteria, recurrent delivery failures are less likely to be linked to a known defect before external intervention.	Syntactic boundary prevents aggregation (T1).	Low signal volume or genuine rarity of failures.	Time from first related signal to escalation; field action before or after inspection.	Comparative analysis of warning letters and recall records; event-history analysis.
P2	Where authority to close investigations or decline field action rests at technical level without thresholds referring to enterprise consequences, "no action" decisions on recurrent defect signals are more likely to be reversed after external intervention.	Semantic boundary: harm-based judgement not translated into enterprise significance (T2).	Reversal reflects new information rather than decision level.	Reversals of closure decisions; decision level recorded.	Comparative case studies; vignette experiments with quality and risk professionals.

No.	Proposition	Mechanism	Competing explanation	Observable indicators	Possible design
P3	For the same delivery technology, differences in classification across markets are associated with differences in internal ownership of reporting and change obligations, and these with differences in reporting timeliness.	Classification determines obligations; ownership determines access to information (T3).	Differences in regulator practice or market size.	Ownership maps; report timeliness by market.	Multi-market case study of a single product family.
P4	Where interface decisions are recorded contemporaneously with decision-maker, information and criteria, accounts given to regulators, boards and courts are more consistent, and regulators less often characterise oversight as inadequate.	Traceability enables reuse of accounts across forums (T4).	Firms with better records may also have better substantive practices.	Language of enforcement records; consistency of disclosures.	Content analysis of enforcement records and litigation documents.
P5	Where specified post-market signals mandatorily reopen design risk files and change approvals, repeat recalls with the same attributed cause in a product family are less frequent.	Pragmatic boundary overcome by mandatory re-decision (T5).	Product maturity or exit of problematic products.	Repeat recalls by cause; age of risk files.	Panel analysis of recall records by firm and product family.
P6	Formalising interfaces improves escalation timeliness only where interface records are used in decisions; where they serve mainly external display, formalisation increases documentation without improving escalation.	Symbolic compliance moderates the effect of formalisation.	Formalisation effects may lag adoption.	Speak-up and quality-culture measures combined with process data.	Mixed methods: survey, document analysis and process data.

P1 to P5 each follow from the failure condition of one interface. P6 follows from the symbolic-compliance critique and qualifies the others: it predicts that ILAF-type formalisation will not by itself improve outcomes. The recall-record pattern in Section 4.5 is consistent with the premise of P5 that design and change decisions are where

many recall causes are attributed, but it does not test any proposition.

8. Discussion

8.1 Contribution

The article makes three contributions. First, it specifies a mechanism through which process-oriented regulation can produce compliance records without accountable decisions. Process-oriented regulation relies on firms to generate information about risk and to act on it (Coglianese & Lazer, 2003; Gilad, 2010). The analysis shows that for ADDS the generation and use of that information are separated by knowledge boundaries of different kinds, and that regulatory and corporate accountability attach to decisions taken across those boundaries. This extends the symbolic-compliance critique (Edelman, 1992; Krawiec, 2003; Power, 2007) by locating where symbolic structures are most likely to substitute for decisions: at semantic and pragmatic boundaries, where translation and transformation are costly, rather than at syntactic boundaries, where transfer is a technical matter.

Second, the article connects risk-work research to regulatory accountability. Studies of calculative cultures and boundary-work show how risk numbers come to count in organisations (Mikes, 2009; Mikes, 2011). ILAF shows that in regulated product safety the question is not only whether risk information counts but whether its translation is evidenced in a form that can be accounted for to several forums at once — a regulator inspecting management review, a board exercising oversight, and a court applying disclosure rules or oversight doctrine. This responds to Black's observation that accountability in polycentric regimes is multiple and contested (Black, 2008) by showing how a single internal record is reused across forums.

Third, the article shows that product classification, usually treated as a technical gateway, is also a governance variable. Classification determines which quality system and reporting stream an event enters, which function owns the clock, and where public recall data are recorded — as the absence of pen-injector and on-body-injector records from the device recall data illustrates. Comparative regulatory scholarship has paid less attention to this internal consequence of classification than to its external consequences for market access.

8.2 Counterarguments

Four objections deserve consideration. The first is that integration duplicates existing quality systems. Where management review already performs the five translations, this is correct, and ILAF requires nothing new; its claim is that for combination products organised by regime, the translations are often unspecified. The second is that formal interfaces create bureaucracy and slow urgent decisions. Escalation thresholds and tiered decision rights can indeed delay action if poorly designed; the framework therefore specifies that decision authority should match the consequences of a decision, which implies rapid escalation for severe signals rather than additional sign-off for routine ones. The third is that tiered decision rights may diffuse accountability among many signatories (Thompson, 1980). ILAF responds by requiring a single named decision-maker at each interface, but whether this works in practice is an empirical question. The fourth is that recording decisions creates legal exposure, particularly under disclosure mechanisms and presumptions of defect (Directive (EU) 2024/2853). The exposure is real, but the alternative — not recording known signals or decisions — is inconsistent with reporting obligations, inspectability of management review and oversight doctrine, and is itself a source of liability (FDA, 2026a; Marchand v. Barnhill, 2019). A further alternative explanation for the patterns discussed is resource constraint: firms may fail to aggregate signals because they lack investigative capacity rather than because of boundaries. The two explanations are not exclusive, and P1 is framed to allow them to be distinguished.

9. Practical and policy implications

For firms, the framework implies an audit of the five interfaces for each combination product: whether drug-side and device-side signals are reviewed together; whether decisions to close investigations or decline field action are taken at a level matching their consequences; whether every reporting clock and statutory role has a named owner in each market; whether decision records would support an account to a board or court; and whether field experience reopens design and change decisions. These are recommendations derived from the analysis, not legal requirements.

For regulators, the analysis suggests that inspection of interfaces may be as informative as inspection of functions. Risk-based regulators allocate attention according to their own models of where failure is likely (Black & Baldwin, 2010), and the recall-record pattern suggests that design and change-control decisions merit particular attention for drug delivery devices. The FDA's decision to review management-review records under the QMSR (FDA, 2026a) is one step in this direction. Regulators supervising combination products could ask firms to demonstrate how drug-side and device-side signals are aggregated and who decides on field action, and the European Union's pending pharmaceutical reform and new product liability regime offer occasions to align expectations about decision records across medicinal-product and device law (Council of the European Union, 2026; Directive (EU) 2024/2853). For boards, the Delaware and Australian decisions reviewed above indicate that oversight of mission-critical product safety requires information systems capable of surfacing red flags, and ILAF identifies the

decisions about which boards should expect to be informed.

10. Limitations and future research

The study has limitations, it has only used few datasets which includes FDAand The comparative analysis covers federal and EU-level law and omits state, Member State and territory variation and other major jurisdictions. The recall-record analysis covers only CDRH-regulated devices in one jurisdiction, relies on FDA-assigned and revisable root-cause categories, and treats clustered records as observations. The worked application relies on a single regulatory record that reports regulatory findings rather than adjudicated facts. The legal position is stated as at 26 October 2026 and will change, notably when the EU pharmaceutical reform is published. Future research could test the propositions using enforcement and recall records, comparative case studies and vignette experiments; extend the recall analysis to drug enforcement records for drug-led combination products; examine how small sponsors perform the translations through outsourced arrangements; and study how the new EU disclosure mechanisms affect internal documentation practices.

11. Conclusion

Advanced drug delivery systems distribute risk across formulations, devices, users, suppliers and software, and distribute obligations across medicinal-product and device regimes that classify the same technology differently. The United States, the European Union and Australia all require firms to generate information about safety and to act on it, and corporate law makes internal information systems relevant to directors and officers. The weak point lies at the boundaries where signals must be transferred, translated and transformed into decisions for which someone can be held to account. Recall root causes for drug delivery devices are attributed disproportionately to design, change-control and software decisions, which is where such boundaries are crossed. The Integrated Lifecycle Accountability Framework specifies five translation interfaces, their decision rules, evidence and failure conditions, and states six propositions for testing. Its central claim is modest but consequential: a firm can comply with each regime's requirements for generating safety information and still fail to produce accountable decisions, and regulatory governance should attend to the interfaces where that failure occurs.

Data availability statement

The recall data analysed are publicly available from the openFDA device recall endpoint (https://api.fda.gov/device/recall.json). The query strings, product-code list, root-cause counts and category mapping used in this study are provided as supplementary material. All legal and regulatory sources are publicly available and listed in the References.

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