

FROM COLD CHAIN TO PATIENT-CRITICAL CHAIN

Why Precision Therapies Need a
Dedicated Logistics Compliance
Framework

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I. Executive Summary

Precision therapies, including Advanced Therapy Medicinal Products (ATMPs), radioligand therapies (RLTs), and human organs and tissues, are increasingly transported through international logistics networks involving multiple parties. Unlike conventional pharmaceuticals, these products have highly specific transport requirements: they may be assigned to an individual patient, remain viable for only a short time, deteriorate without visible signs, and become unusable if a delivery window is missed.

Existing compliance frameworks were not designed around this reality. GDP, GMP, IATA CEIV Pharma, ISO 21973, dangerous goods regulations, and radiation-protection rules each address important elements such as temperature control, documentation, quality systems, and safe transport. However, they do not provide an integrated operating model for biological time limits, chain-of-identity verification at every handover, modality-specific handling, or the combined application of pharmaceutical-quality and dangerous-goods requirements.

This paper argues that precision therapy shipments should no longer be treated as a premium form of conventional cold chain. They require critical-chain governance, in which logistics controls are directly connected to critical usability and patient identity. Time should be treated as a critical quality attribute rather than only as a service level; chain of identity should be verified through common handover protocols; competency standards should reflect modality-specific requirements; and transport incidents should be captured through a harmonised data mechanism that enables cross-industry learning.

Two pathways are proposed. In the short term, GDP, CEIV Pharma, and ISO 21973 should be extended to address immediate precision-therapy risks. In the longer term, the industry should work towards a dedicated logistics compliance framework that integrates existing requirements through a common architecture and modality-specific annexes. The project recommends this dedicated framework as the long-term objective, with adaptation of existing frameworks serving as an interim bridge.



II. The Industry Has Reached an Inflection Point

For the purposes of this paper, precision therapies represent patient-specific or highly sensitive therapeutic modalities whose logistics are constrained by extreme time, temperature, identity, viability, or radiation requirements. This umbrella includes cell and gene therapies, RLTs, and organs and tissues for transplantation. The categories differ clinically and legally, but they share a logistics feature that conventional distribution models do not fully capture: product integrity cannot be separated from treatment continuity.

CONVENTIONAL PHARMACEUTICAL



Conventional pharmaceutical compliance is built around a recognisable set of assumptions. Medicines are manufactured in batches, released against specifications, held as inventory, distributed through qualified networks, and, in many cases, replaced if a shipment is lost. Precision therapies challenge each assumption. An autologous CAR-T product is made for one patient from that patient's own cells. A fresh unrelated donor stem cell product may have a viability window of approximately 72 hours. An RLT dose loses activity continuously through radioactive decay. A donor heart may have only four to five hours of cold ischaemia time. These products cannot be managed by adding more packaging and a premium courier to a conventional lane; the underlying unit of control has changed from a batch to a treatment episode¹.

AUTOLOGOUS CELL THERAPY



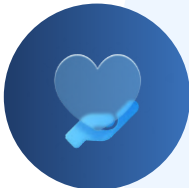
The complexity is especially visible in autologous cell therapy. The inbound leg may involve fresh leukapheresis material transported at 2–8°C, with only 24–72² hours available before manufacturing must begin. The outbound finished product may then be transported in a vapour-phase nitrogen dry shipper at approximately –160°C. Upon delivery to the treatment centre, the product can be unloaded and maintained frozen under validated storage conditions until it is required for administration. The highly time-critical period begins only after controlled thawing, when the product must be prepared and infused within a tightly defined timeframe; for some cryopreserved therapies, infusion must begin within 30 minutes after completion of thawing. A single therapy therefore moves through different physical states, temperature conditions and time constraints, while chain of identity must remain unbroken from collection through manufacturing, storage and final infusion³.

RLTs



RLTs expose a different mismatch. They are medicinal products and radioactive materials at the same time. Pharmaceutical quality requirements protect the therapy; dangerous goods and radiation-protection rules protect workers, the public, property, and the environment. Both regimes are necessary, but neither is designed to orchestrate the full patient-specific workflow from isotope production to administration. Delays do not simply create late delivery: they reduce the activity available to the patient and consume scarce production capacity⁴.

ORGANS AND TISSUES



Organs and tissues show why inventory-based thinking also has limits. Organ supply is donor-driven and non-bufferable. Each organ is matched to a recipient, and transport mode is selected around the fastest feasible route. Tissues can sometimes be preserved and stored, but their pre-processing stage remains time- and temperature-critical. Across these modalities, logistics performance is not adjacent to clinical performance. It is one of its determinants.

The relevant question is no longer only whether the shipment arrived intact. It is whether the correct patient received a usable therapy within its validated biological and regulatory window.

¹ Nan et al, 2022; Pruett et al, 2024; Rioufol & Wichmann, 2022

² There is no universal regulatory transport-time limit. Transport duration is product-, route- and validated-process-specific.

³ Navarro et al, 2025; Rioufol & Wichmann, 2022

⁴ Gonzalez et al, 2025; IAEA, 2018; Ostuni & Taylor, 2023

III. The Evidence Points to a Framework Problem, Not Merely a Process Problem

The master's thesis⁵ underlying this industry opinion paper used a qualitative, comparative approach to assess how existing regulations, standards, and guidance address the recurring risks of precision-therapy transport. It compared their intended obligations with documented therapy-specific requirements and classified coverage as full, partial, or absent.

The findings support a clear conclusion about framework design, but not a quantified industry-wide failure rate. Transport incidents are typically recorded within company quality systems, treatment-centre files, or modality-specific channels. Because there is no harmonised cross-industry database, the sector cannot reliably measure, or systematically learn from, identity errors, temperature excursions, and missed delivery windows.

Existing frameworks remain essential. GDP provides the legal baseline for medicinal-product distribution, including risk-based planning, temperature control, documentation, deviation management, and contractor oversight⁶. CEIV Pharma strengthens coordination across the air-cargo community, while ISO 21973 addresses the transport of therapeutic cells. Dangerous goods and radiation-protection rules provide critical safeguards for biological and radioactive materials⁷.

The problem is that these frameworks address different risks, scopes, and parts of the journey. GDP is high-level and designed primarily for conventional distribution. CEIV Pharma focuses on air cargo rather than the full critical route. ISO 21973 is limited to therapeutic cells and remains general on product-specific time and identity controls. Dangerous goods rules protect transport safety, not therapeutic efficacy. As a result, each party may comply within its own silo while critical handovers remain insufficiently governed.

Better training and execution are necessary, but they cannot close gaps that the frameworks do not define. Handlers cannot follow unspecified handover requirements, auditors cannot verify unrecognised biological time limits, and regulators cannot identify sector-wide patterns from fragmented private data. The central problem therefore lies at the interface between regulatory principles and end-to-end operational practice.

Table 1: Five recurring compliance blind spots

The blind spots synthesise the project risk categories and operational gap analysis. They are cross-modal, but the required controls must be applied through modality-specific specifications.

Blind Spot	What current frameworks generally provide	What precision-therapy compliance must add
Time sensitivity and coordination	Requirements to minimise transit time and meet agreed service levels	Validated end-to-end time limits; monitoring of remaining usable time; milestone alerts; clear contingency triggers linked to patient-critical use
Temperature and environmental control	Requirements to maintain specified conditions and investigate excursions	Therapy-specific limits; monitoring rules for cryogenic and shielded packages; sensor-placement requirements; validation of hidden failure risks
Chain of custody, identity and integrity	Traceability, documentation, security and record retention	A common handover protocol; required identity data; dual checks at critical handovers; standard exception and quarantine procedures
Handling and human factors	Generic requirements for trained and competent personnel	Role-based training for specific therapy types and handling environments, with regular reassessment
Scale, variability and personalisation	Quality systems designed around repeatable products and organisation-level controls	Therapy- and route-specific risk levels; facility-readiness criteria; capacity planning; interoperable data; harmonised incident reporting

⁵ Valentia, Tedesco & Espinosa, 2026 [Compliance Framework for Precision Therapies Logistics - Pharma.Aero](#)

⁶ European Commission, 2013

⁷ Council Directive 2013/59/Euratom; IAEA, 2018

IV. Five Blind Spots That Turn Logistics Deviations into Critical Events

01.

TIME MUST BECOME AN AUDITABLE QUALITY ATTRIBUTE

Existing frameworks tend to treat time as an operational variable: a route should minimise transit, a carrier should meet its service level, and a deviation should be investigated. Precision therapies require a different interpretation. Time is part of the product's usable condition. A stem cell shipment that remains within temperature but exceeds its validated viability window has not remained compliant. An RLT dose that reaches the hospital intact but after excessive dwell may no longer deliver the prescribed activity. A donor organ that arrives after its cold ischaemia ceiling has not merely arrived late.

The compliance implication is concrete. The product specification should include a validated end-to-end time budget, not only a target transit time. Each handover should record elapsed time and remaining viable time. In other words, every handover should show how much usable treatment time remains. Contingency decisions should be triggered against product-specific thresholds, with pre-authorised routes for escalation, rerouting, customs intervention, rescheduling, or controlled abandonment. Auditors should be able to test whether the network can execute within the biological window under normal and disrupted conditions. In other words, the clock should be governed with the same seriousness as temperature.

02.

ENVIRONMENTAL CONTROL MUST REFLECT INVISIBLE AND MODALITY-SPECIFIC FAILURE

Temperature control is the strongest area of existing pharmaceutical logistics, yet precision therapies expose the limits of generic cold-chain language. Cryogenic biological products may be compromised by warming above critical thresholds without any visible change. RLT packages may combine shielding, small product volumes, and product-specific temperature requirements that complicate conventional sensor placement. Organs can experience damage that becomes apparent only during surgical assessment. A compliant-looking package can therefore contain a clinically unusable product.

A precision-therapy framework should require modality-specific environmental profiles, packaging performance criteria, sensor-placement rules, and data-review procedures. The objective is not to put a universal temperature value into a global standard; product-specific specifications must remain decisive. The objective is to standardise how those specifications are translated into transport controls, how monitoring is validated, how data are linked to identity, and how invisible failure is ruled in or out at receipt.

03.

CHAIN OF IDENTITY MUST BE GOVERNED AT THE HANDOVER, NOT ONLY IN THE RECORD

Regulation and patient-critical standards clearly recognise traceability. The unresolved issue is operational: what must a courier, ground handler, airline, manufacturer, pharmacy, or treatment centre verify at the moment responsibility changes? In an autologous chain, an identity error is a wrong-patient event. In organ and tissue logistics, incompatible national procedures can undermine otherwise valid donor-recipient records. In RLT logistics, sealed packages and security-screening constraints increase reliance on accurate documentation and trusted-party status.

The sector needs a minimum handover data set and verification method that travels across organisations. At critical transitions, the protocol should specify which identifiers are matched, who performs the check, whether dual verification is required, how digital and physical labels are reconciled, what evidence is retained, and what happens when any element is inconsistent. A common exception pathway is just as important as the normal process: the product should be quarantined, the product owner notified, and the resolution documented in a record that remains accessible across the chain.

04.

COMPETENCE MUST CROSS ORGANISATIONAL AND REGULATORY SILOS

Every major framework requires training, but training content follows institutional boundaries. A person may be competent in pharmaceutical cold chain without understanding vapour-phase nitrogen dry shippers; competent in dangerous goods without understanding the therapeutic consequences of isotope decay; or competent in hospital pharmacy without being trained in the timed reception, identity checks, and post-thaw coordination required for CAR-T. Viral-vector handling adds biosafety knowledge that does not sit naturally inside conventional GDP or CEIV curricula⁸.

A dedicated framework should define role-based competence rather than a single generic course. Modules should correspond to the activity performed and the modality handled: cryogenic biologicals, fresh cells and tissues, viral vectors, radioactive medicinal products, organ transport, controlled handover, and clinical receipt. Competence should be demonstrable through practical assessment and recurrent qualification, and credentials should be portable enough to be recognised by participating organisations.

05.

SCALE REQUIRES INFRASTRUCTURE READINESS AND SHARED LEARNING

The bespoke white-glove model has compensated for missing standards by surrounding each shipment with product-specific expertise and direct communication. That model is valuable, but it is not a scalable substitute for compliance architecture. As volumes grow, more treatment centres, airports, couriers, regional packaging nodes, and customs interfaces enter the network. The probability of variation rises precisely when the products remain non-standard, patient-specific, or capacity-constrained.

Infrastructure must therefore be treated as part of readiness. A route is not fit for an RLT merely because the carrier accepts Class 7 cargo; the destination also needs appropriate clinical, radiation-safety, storage, and waste-management capability. A region is not ready for cell therapy merely because an airport is CEIV-certified; first mile, last mile, storage, and treatment-centre receipt must be aligned. The framework should combine organisation-level requirements with route- or community-level qualification.

Finally, the industry needs a transport-specific incident taxonomy and data layer. Today, temperature excursions, identity exceptions, time-window failures, customs holds, packaging failures, and handover errors are generally handled inside separate quality systems. A harmonised data set would allow benchmarking without exposing patient or commercially sensitive information. It would also support better packaging qualification, more realistic contingency planning, stronger pharmacovigilance interpretation, and evidence-based regulatory revision⁹.



⁸ Myles & Church, 2022; Pharma.Aero & Air Cargo Belgium, 2023

⁹ Gonzalez et al, 2025; OECD NEA, 2020

V. Adapt Existing Frameworks Now and Reconsider Future Standards

The fastest response, and a necessary bridge, is to extend the frameworks that already have authority, recognition, and audit infrastructure. GDP could explicitly recognise patient-specific and biologically time-critical products, require validated time windows in transport specifications, and clarify how distribution controls interact with release and import requirements. CEIV Pharma could add a precision-therapy tier covering chain-of-identity controls, time-window performance, modality-specific competency, and first/last-mile interfaces. ISO 21973 could be deepened through quantitative handover requirements and companion standards or annexes for other precision-therapy modalities.

These extensions would reduce immediate risk because operators and regulators already know how to implement and inspect the underlying systems. They would also create a shared vocabulary and evidence base for the longer-term framework. Existing institutional channels - including GDP revision processes, CEIV programme development, and ISO/TC 276 work - provide realistic entry points for action.

However, adaptation has a ceiling. GDP, CEIV Pharma, ISO, patient-critical accreditation, human tissue rules, and dangerous goods regulations are owned by different institutions. Extending each one independently may improve the nodes while leaving the route fragmented. A shipment could move through a GDP-compliant distributor, a CEIV-certified air-cargo community, an ISO-aligned courier, and an accredited treatment centre, yet still encounter incompatible handover protocols and unclear authority at the interfaces. Precision therapies are most exposed at exactly those interfaces.

The central risk of an adaptation-only strategy is therefore false reassurance. The sector may accumulate more certificates without achieving end-to-end control. A dedicated framework is needed not because existing standards are weak, but because none has the mandate to integrate the full patient-critical logistics chain. The dedicated framework should operate as an orchestration layer: a common core that maps existing obligations, closes the gaps between them, and adds modality-specific controls where no current framework is sufficient.

This position also acknowledges the limitations of the dedicated pathway. A new framework requires an institutional owner, stakeholder consultation, funding, maintenance, auditor competence, and regulatory recognition. Without endorsement from competent authorities and standards bodies, it could remain a voluntary badge. The right strategy is therefore dual-track: use adaptation to stabilise the present system while building governance and evidence for a dedicated end state.

VI. Minimum Architecture of a Dedicated Precision Therapy Transport Framework

A fit-for-purpose framework should not attempt to impose one operating specification on all precision therapies. The common need is an architecture, not a universal temperature or transit time. We propose one common set of rules, supplemented by requirements for individual therapy types, routes and jurisdictions. At minimum, the framework should contain the following eight design elements:

01.

MODALITY-SPECIFIC RISK TIERS.

Classify logistics requirements by product and treatment model, for example autologous cells, allogeneic cells and tissues, viral-vector gene therapies, RLTs, organs, and preserved tissues. The tier should determine the applicable controls, evidence, training, and contingency requirements.

02.

A VALIDATED END-TO-END CONTROL PLAN.

Define the treatment route from collection or production to product receipt and administration, including first mile, airport and airline interfaces, customs, storage in transit, last mile, and in-hospital handovers. Qualification should address the whole route, not only individual organisations.

03.

TIME-WINDOW COMPLIANCE.

Treat maximum elapsed time and remaining viable time as auditable parameters. The control plan should contain milestone budgets, alert thresholds, decision authority, and disruption scenarios. The relevant product owner must be linked to escalation when a time limit is threatened.

04.

OPERATIONAL CHAIN-OF-IDENTITY AND CUSTODY GOVERNANCE.

Specify mandatory identifiers, verification frequency, dual-check requirements, digital-record expectations, label reconciliation, tamper and security controls, exception handling, quarantine, and long-term record accessibility.

05.

ENVIRONMENTAL AND PACKAGING PERFORMANCE.

Translate product specifications into validated packaging, monitoring, sensor placement, data review, temporary storage, and excursion-assessment requirements. The framework should recognise cryogenic, refrigerated, controlled-room-temperature, deep-frozen, shielded, sterile, and organ-preservation conditions.

06.

COMPETENCY AND FACILITY READINESS.

Define role-based qualifications and recurrent assessment for personnel, together with minimum facility and equipment readiness for hubs, storage points, treatment centres, hot labs, tissue banks, and contingency locations.

07.

**MULTI-REGIME
INTEGRATION.**

Map how GDP/GMP, ATMP regulation, human tissue and organ rules, patient-critical accreditation, biosafety, security, dangerous goods, and radiation-protection requirements apply concurrently. The framework should identify the controlling requirement and decision owner when obligations overlap or conflict.

08.

**DATA, INCIDENT
REPORTING, AND
CONTINUOUS
IMPROVEMENT.**

Establish a minimum transport event record and a harmonised taxonomy for delays, excursions, identity discrepancies, packaging failures, customs interventions, route changes, and critical-window impacts. Aggregated reporting should support benchmarking and revisions while protecting patient and commercial confidentiality.

Certification should also reflect where risk actually resides. Organisation-level certification remains useful, but it is insufficient for a treatment chain defined by handovers. The framework should therefore support route, lane, or community qualification in which the participating manufacturer, logistics providers, airport actors, and treatment centre demonstrate a shared control plan and interoperable escalation process. This approach builds on the community logic of CEIV Pharma while extending it beyond air cargo and into the critical endpoints.

Governance should be neutral and multi-stakeholder. A practical model would separate technical ownership from legal authority: an industry and academic consortium could develop the standard, data model, and implementation guidance; existing institutions such as ISO, IATA, WHO, EMA, national authorities, and patient-critical accreditation bodies could provide recognition or incorporate relevant elements into their own instruments. Manufacturers, logistics providers, treatment centres, airports, airlines, and patient representatives should participate because each holds information or operational responsibility that the others do not.



VII. A Phased Industry Agenda

The absence of a perfect institutional solution should not delay practical risk reduction. The sector can move through a staged programme that produces immediate controls, generates evidence, and builds toward formal recognition.

Table 2. Proposed implementation roadmap

Timelines are indicative. The immediate priority is not to create a new badge, but to standardise the controls and evidence needed at the handover interfaces.

	PRIMARY OBJECTIVE	PRIORITY DELIVERABLES	INDICATIVE LEAD ACTORS
 0-18 MONTHS: BRIDGE AND MEASURE	Reduce the most critical handover risks using existing frameworks	Minimum handover data set; identity-verification protocol; time-window requirements; role-based training; common incident taxonomy; identify 2-4 pilot routes across different therapy types	Manufacturers, Pharma.Aero-type consortia, logistics providers, treatment centres, IATA/CEIV participants, ISO experts
 18-36 MONTHS: PILOT AND STANDARDISE	Turn pilot results into common, auditable requirements	Common framework and therapy-specific annexes; route/community audit method; data governance and interoperability guidance; proposal to align GDP, CEIV Pharma, ISO 21973 and patient-critical accreditation	Standards bodies, regulators, industry associations, auditors, researchers, patient and product representatives
 36+ MONTHS: RECOGNISE AND SCALE	Achieve formal recognition and support wider adoption	Certification or recognition scheme; trained auditor pool; cross-border pilots; anonymised benchmarking; regular updates based on incident and performance data	Competent authorities, ISO/IATA/WHO pathways, national regulators, industry governance body

Manufacturers should begin by expressing product criticality in a standard transport profile rather than relying on bespoke shipping instructions that only selected partners understand. The profile should state the validated environmental range, maximum time budget, identity elements, monitoring requirements, handling limitations, and escalation authority. Logistics providers should translate that profile into route controls and ensure that subcontractors receive the same requirements in a verifiable form.

Airports, airlines, and ground handlers should focus on predictable acceptance, priority handling, contingency routing, safe temporary storage, and trusted-party processes for products that cannot be opened or conventionally screened. Treatment centres should integrate logistics receipt with pharmacy, cell-bank, nuclear-medicine, surgical, and administration scheduling so that a shipment is not considered successfully delivered until the receiving pathway is ready to preserve its usable condition.

Regulators and standards bodies should use existing revision and work-item mechanisms to place precision therapy logistics explicitly within scope. Academic partners can support independent evaluation of pilot routes, human-factor performance, network resilience, and equity of access. The industry also needs patient and clinical perspectives when defining acceptable risk, because a technically efficient process may still be poorly aligned with the realities of treatment scheduling and patient readiness.

Success should be measured by more than on-time delivery and temperature compliance. A mature scorecard would include identity-verification performance, remaining viable time at receipt, handover completeness, exception frequency, time to operational escalation, route recovery success, data availability, and the proportion of incidents that produce cross-organisational corrective action. These measures would make visible the aspects of treatment continuity that current logistics dashboards are missing.

VIII. Implications for Industry, Regulation and Research

The question is not simply whether precision therapies need another standard. The more important question is whether today's supply chains can consistently protect a treatment from origin to patient as volumes grow, networks expand, and more organisations become involved.

At present, many companies manage this complexity through highly customised processes, experienced teams and close coordination between partners. That approach works, but it is difficult to scale. Different organisations may use different handover checks, escalation procedures, data requirements and definitions of what constitutes an incident. As a result, risks can remain hidden at the points where responsibility moves from one party to another.

For industry, the implication is practical: precision-therapy logistics will increasingly require shared ways of working across the entire treatment route, not simply stronger controls within individual organisations. Manufacturers, logistics providers, airports, treatment centres, regulators and standards bodies will all have a role in building that consistency.

01. The business case is about reducing risk and making growth possible

A stronger compliance approach should not be viewed simply as another layer of regulation or certification. For precision therapies, logistics failures can have consequences that go far beyond the cost of a delayed shipment.

WHAT DOES THIS MEAN FOR YOUR ORGANISATION?



For manufacturers, it means defining critical logistics requirements in a way that every partner can understand and apply consistently. For logistics providers, it means demonstrating not only transport capability, but also the ability to manage identity, time-critical handovers, exceptions and clinical interfaces.

For airports, airlines and ground handlers, it means understanding where precision therapies need different handling priorities, storage options, screening processes or escalation routes.

For treatment centres, it means treating receipt of the shipment as part of the treatment process rather than simply as the end of transportation.

It also means clearer accountability. When responsibilities, handover checks and decision rights are defined consistently, organisations can respond faster to deviations and more clearly establish what happened, who needed to act and what corrective action is required.

Finally, greater consistency can support market expansion. Precision therapies currently depend heavily on experienced routes, specialist providers and selected treatment centres. Common readiness requirements could help additional locations demonstrate that they can handle these products safely, supporting wider patient access without lowering product-specific standards.

02. Build the framework through real routes, not around a conference table

A future precision-therapy compliance framework should be developed from operational experience. It should not begin as a large rulebook designed in isolation from the people who will have to use it.

Organisations should expect to participate in joint route qualification rather than relying only on their own certification.

A manufacturer may be fully compliant internally, a logistics provider may hold the appropriate certifications, and a treatment centre may meet all clinical requirements. That does not automatically mean the complete route works effectively.

Companies should therefore be prepared to test interfaces with their partners: how information moves, how responsibility transfers, how an exception is escalated and how quickly the network can recover from disruption.

The organisations that participate early in these pilots will also be in a stronger position to influence practical industry requirements and ensure that future standards reflect real operating conditions.

WHAT DOES THIS MEAN FOR YOUR ORGANISATION?



03. The industry needs better evidence to know what actually works

One of the clearest findings of the project is that the sector still lacks a shared view of what goes wrong during precision-therapy transportation.

Most organisations already record deviations and incidents. The challenge is that the information remains spread across separate company systems, clinical records and quality processes. Different organisations may also describe similar events in different ways.

WHAT DOES THIS MEAN FOR YOUR ORGANISATION?

Companies should increasingly expect to measure more than traditional logistics KPIs.

Alongside on-time delivery and temperature performance, organisations may need to track measures such as:

- completeness of critical handovers;
- identity-verification performance;
- remaining usable time at receipt;
- frequency and type of exceptions;
- speed of escalation;
- recovery from disrupted routes; and
- whether lessons from incidents are shared across the organisations involved.

This will require closer collaboration between supply chain, quality, regulatory, clinical and data teams. It will also require a different approach to industry learning. Organisations should continue protecting patient information and commercially sensitive data, but those protections should not prevent the sector from identifying recurring risks and improving common practices.

Academic partners can support this work by independently evaluating pilots, testing whether new approaches actually improve performance and helping distinguish evidence from commercial claims. Industry participation remains essential, because the most useful operational data and experience sit within manufacturers, logistics providers and treatment centres.



04. From individual compliance to shared confidence

The longer-term challenge is not simply to publish a new framework. It is to create an approach that organisations can adopt, regulators can recognise and supply-chain partners can apply consistently.

That requires credible governance, practical requirements and evidence that the approach reduces risk in real operations.

For individual organisations, the direction of travel is clear. Precision-therapy logistics will require greater visibility across the complete route, clearer responsibilities at every handover, more consistent collaboration with partners and better evidence of how the network performs when something goes wrong.

The organisations that prepare for this shift now will be better positioned not only to manage compliance, but also to scale precision therapies safely into new routes, markets and treatment centres.



IX. Conclusion

Precision therapies have fundamentally changed what pharmaceutical logistics must protect. The sector is no longer moving only products whose quality can be safeguarded through conventional cold-chain, documentation and security controls. It is increasingly responsible for patient-specific and biologically time-limited treatment opportunities: therapies that may depend on an unbroken chain of identity, remain viable for only a matter of hours, lose therapeutic value continuously through radioactive decay, require cryogenic handling, or involve donor organs that cannot simply be replaced. In this environment, logistics performance is no longer separate from clinical performance but is part of it.

Existing frameworks such as GDP, CEIV Pharma, ISO 21973, dangerous goods requirements and other regulatory and patient-critical standards remain essential foundations. However, this project has shown that compliance within individual frameworks, organisations or transport nodes does not by itself guarantee control of the complete treatment journey. The greatest vulnerabilities often arise at the interfaces: when responsibility changes hands, when information must move between systems, when a time window is threatened, or when an exception requires several organisations to act as one network.

The appropriate response is therefore a dual-track strategy. In the near term, existing frameworks should be adapted to address the most urgent precision-therapy risks, including validated time windows, operational chain-of-identity controls, modality-specific competency requirements, harmonised handover protocols and common incident reporting.

At the same time, the sector should work toward a dedicated logistics compliance framework that connects these requirements across the full patient-critical chain. Such a framework should not replace established regulation or impose a single operating specification on fundamentally different therapies. It should provide the common architecture through which existing obligations can be integrated, gaps at organisational interfaces can be closed, and modality-specific controls can be applied consistently.

Importantly, that framework should be built through operational evidence rather than developed only as a theoretical standard. Joint route qualification, cross-modal pilot projects, shared performance measures and a harmonised incident taxonomy can demonstrate which controls work in practice and where further refinement is required. The immediate objective should therefore not be the creation of another certification badge, but the establishment of shared confidence: confidence that manufacturers, logistics providers, airports, treatment centres and regulators understand their responsibilities, can recognise when a treatment opportunity is at risk, and can respond through a coordinated and auditable process.

The industry's next compliance question should consequently go beyond whether a shipment arrived on time, remained within temperature range or passed through individually compliant organisations. It should ask whether the right therapy reached **the right patient in a clinically usable condition, within its validated biological and regulatory window, through a traceable and resilient chain in which every critical handover can be demonstrated to have protected the treatment opportunity.**

That is the transition from cold-chain compliance to patient-critical chain governance. Achieving it will require cooperation across regulatory, logistics, manufacturing and clinical boundaries, but the direction is clear. As precision therapies scale into more routes, markets and treatment centres, the industry cannot rely indefinitely on bespoke expertise and exceptional intervention to compensate for fragmented standards. The controls that protect treatment continuity must become systematic, interoperable and auditable across the entire route.

For precision therapies, the ultimate measure of logistics compliance is therefore not simply successful delivery. It is the preservation of the patient's opportunity to receive the intended treatment. **That is the standard the next generation of pharmaceutical logistics must be designed to protect.**

X. Acknowledgements

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This consortium reflects the strength of industry-academic collaboration, demonstrating how diverse expertise can be combined to produce rigorous, practice-relevant outcomes.

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