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Industry Opinion Paper

PACKAGING QUALIFICATION WITHOUT DUPLICATION

Why the Next Advance in Cold Chain Packaging Qualification Will Come from Trusted Evidence, Not New Technology.

NOVEMBER 2026

A PHARMA.AERO PROJECT | PACKAGING QUALIFICATION INTEGRATION (PQI)



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I. Executive Summary

Every temperature-sensitive medicine that moves within the global supply chain travels in a Temperature-Controlled Packaging Solution that has been qualified, usually more than once.

Suppliers of Temperature-Controlled Packaging Solutions (TCPS), whether passive or active, generate substantial qualification evidence for their products. Pharmaceutical, life science and biologics companies then generate their own, frequently repeating tests the supplier has already performed. Vendor approval cycles of 18 months to two years were reported during this project, and packaging providers described requalifying solutions they had already qualified to the same standard.[1]

What This Paper Is

This industry opinion paper sets out the position of the Pharma.Aero Packaging Qualification Integration project on the qualification of Temperature-Controlled Packaging Solutions (TCPS) and the use of supplier-generated qualification evidence. It draws on a survey of 29 respondents across four stakeholder groups, ten structured interviews, and a review of regulatory, pharmacopoeial and industry guidance. A detailed technical report is available to Pharma.Aero members. Participating organisations are not named; interviewees are identified by role only.

What This Project Examined

The Packaging Qualification Integration project set out to understand how TCPS qualification is performed today, where effort is duplicated, which parameters are genuinely comparable between organisations, and whether supplier generated evidence could be integrated into a pharmaceutical company's qualification process under appropriate governance.

The project did not assess the use of simulated or modelled qualification methods, because of the limited regulatory acceptance of those methods to date. This may be included in the next phase.

What the Project Found

The repetition is generally not caused by a lack of data. Three barriers emerged consistently across every stakeholder group, and none of them is technological: evidence generated by one organisation is not comparable with another's, the terms qualification and validation are not used consistently, and there is no agreed basis on which evidence generated by another party can be assessed and kept under control. These barriers are set out in Section IV.

Regulatory frameworks are moving towards risk-based lifecycle approaches that would accommodate the reuse of justified external evidence. Expectations for how performance is demonstrated, however, still differ significantly between markets, and that divergence is itself a barrier to any globally applicable model.

The conclusion of this paper is that the next advance in cold chain packaging qualification will not come from better packaging, better sensors or better technology. It will come from the industry agreeing how qualification evidence is generated, how it is interpreted and judged, and who remains accountable for the decision it supports.



The question is no longer whether supplier data can be trusted. It is: under what conditions can it be relied upon, and who remains accountable?

[1] *Pharma.Aero. Packaging Qualification Integration: stakeholder survey (29 respondents) and interview round (10 structured interviews), 2026.*

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II. Why Cold Chain Packaging Qualification Is Different

In most industries, packaging is qualified once by the organisation that designs it, and its customers rely on that work. In the pharmaceutical supply chain, the same solution is often qualified several times over: by the supplier that designs and manufactures it, by the company that ships product in it, and sometimes again by a contract manufacturer or a logistics provider.

This is not mistrust. It reflects the conditions under which the sector operates. A qualification decision is ultimately a patient safety decision, and it must be defensible to an inspector years after the shipment has been delivered. Good distribution and good manufacturing practice require that transport conditions are defined, that variation is considered, that risks are assessed and that critical conditions are monitored.[2] Accountability for the decision cannot be transferred to a supplier, no matter how capable and trustworthy that supplier is.[3]

The consequence is a system in which duplication is the safe choice. Repeating a test is easier to defend than explaining why someone else's test was sufficient. That calculation only changes when the industry agrees what sufficient evidence looks like.



[2] *European Commission. Guidelines on Good Distribution Practice of medicinal products for human use (2013/C 343/01), Chapter 9, Transportation. PIC/S. PE 011, Guide to Good Distribution Practice, Chapter 9.*

[3] *European Commission. Guidelines on Good Distribution Practice (2013/C 343/01), Chapter 7, Outsourced activities. The contract giver is responsible for assessing the competence of the contract acceptor and remains accountable for the outsourced activity.*

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III. What the Industry Told Us

Twenty-nine survey responses and ten structured interviews were gathered across four stakeholder groups: life science companies, packaging providers, freight forwarders and ground handling agents.

The picture was consistent, and unusually candid.[4]

01. Duplication Is Recognised by Everyone

Every group described the same pattern, and none defended it. Providers reported customers routinely repeating qualification work already performed; manufacturers described approval cycles measured in years; both sides described the cost as substantial and the benefit to the patient as negligible.

> "We are all repeating each other's work."
>
> *-Life science manufacturer*

02. Supplier Evidence Rarely Answers the Buyer's Question

Suppliers qualify to demonstrate how their solution performs, typically with a simple and reproducible thermal load in a single configuration. A pharmaceutical company needs evidence at the minimum and maximum payloads it ships, against the ambient conditions reflective of its own lanes. Where the evidence does not reach that question, it cannot be leveraged and the work is repeated.

> "Customers do not hesitate with our qualification data. They have their own processes that may require redundant testing. Each pharmaceutical company has its own quality management system and methodically reapproves every solution."
>
> *-Packaging provider*

03. Part of the Journey Is Still Unmeasured

Freight forwarders and ground handling agents described the airport transfer, between aircraft, tarmac and cool room or freezer, as the least instrumented part of the journey. Handlers also reported limited advance visibility of inbound temperature-controlled volumes. These are sources of both lane information and variability, and they argue for including logistics partners in a qualification conversation that has historically excluded them.

> "We have no visibility of the inside of the box. With passive packaging we are on the passenger seat, and we learn of an excursion only at destination."
>
> *-Ground handling agent*

[4] *Pharma.Aero. Packaging Qualification Integration: stakeholder survey and interview round, 2026. The findings are qualitative and are not presented as statistically representative of the industry.*

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IV. Why Evidence Is Not Reused Today

The project identified three barriers. None of them is technological, and all three are within the industry's power to remove.

01. COMPARABILITY

Three parameters determine whether qualification evidence generated by one organisation can be used by another: the ambient temperature profile it was tested against, the definition of the payload, and the placement of the temperature probes.

Each is set differently across the industry. Two organisations can qualify the same packaging solution, to the same procedural standard, and produce results that cannot be compared. The supplier data is sound; it does not necessarily answer the question the life science company has to answer.

02. TERMINOLOGY

'Qualification' and 'Validation' are used interchangeably across the industry, and the distinction matters.[5] Qualification of a solution demonstrates that it performs as designed under defined conditions, and can be performed once for the market.

Validation demonstrates that a specific product, on a specific route, under a specific procedure, arrives within specification, and can only be performed by the product owner as part of its transportation validation plan.

Much of what is described as duplication is in fact the validation process. It is legitimate, and no reuse model should attempt to remove it. Until the two activities are consistently defined and distinguished, organisations cannot agree on what is genuinely being duplicated and what can be streamlined.

03. GOVERNANCE

Organisations will not rely on data whose traceability and limitations they cannot see, or whose basis they cannot defend when questioned.

Interviewees were equally clear about what does not work: repositories owned or funded by a single commercial party. A custodian that is independent and industry-funded was described as workable by every group.



[5] *European Commission. EudraLex Volume 4, Annex 15: Qualification and Validation, 2015, Glossary; World Health Organization. TRS 961, Annex 9, Model guidance for the storage and transport of time and temperature sensitive pharmaceutical products.*

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V. The Direction the Industry Is Moving Toward

The regulatory environment is moving towards the position this paper advocates, though not uniformly. Good manufacturing and distribution practice in the European Union and across the authorities participating in the international inspection cooperation scheme allows packaging qualification and validation data obtained outside a manufacturer's own programmes to be used, where the approach is justified and the controls can be assured and defended.[6] The lifecycle model in the current process validation guidance of the United States, the quality risk management principles of ICH, and the science and risk based verification approach of ASTM all point the same way: effort proportionate to risk, and assurance maintained through continued verification rather than repetition.[7]

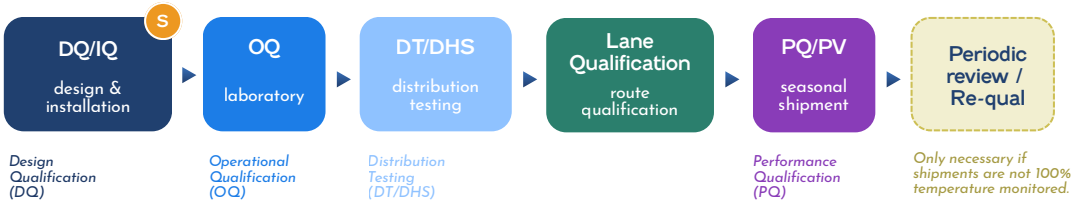
From Sequential Qualification to a Risk and Science Based Approach

The same qualification elements are required in both models. What changes is the order in which they are completed, whether existing evidence may be referenced, and how assurance is maintained after release.

SEQUENTIAL

TODAY

A fixed sequence, each stage released before the next begins. Common where shipments are not monitored, or monitored only in part.



Consequence. Supplier evidence is repeated rather than referenced, every stage sits on the critical path to first shipment, and assurance after release depends on a fixed interval rather than on what shipments actually show. Supplier evidence is in practice only ever supplementary here, and mainly for design and installation.

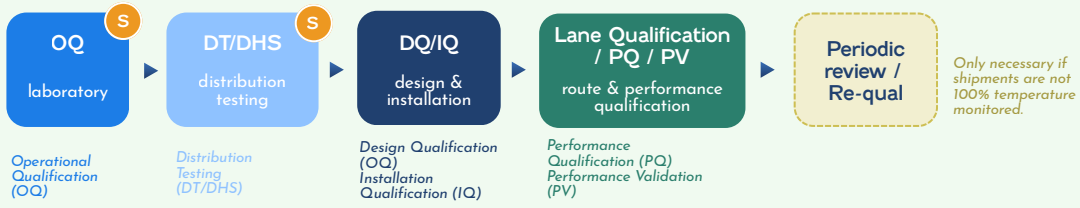
Available Today Where Every Shipment Is Temperature Monitored

Continuous monitoring evidences performance on each lane as it happens, and excursions are detected and dispositioned shipment by shipment. Much of the proposed approach can therefore be applied now, under existing rules. Monitoring does not replace laboratory qualification. A logger records an excursion; it does not prevent one, and it does not protect the product from loss. Qualification establishes the margin the solution holds at conditions a given shipment may not have encountered.

RISK & SCIENCE BASED

PROPOSED

A required suite, sequenced by risk, supply and business need.



Consequence. Lane Qualification and the formal performance qualification or verification are treated as one element rather than two sequential stages, with a formal performance qualification executed only where regulation requires it. Elements may overlap where risk assessment supports it, supplier evidence may be referenced where it is justified and controlled, and monitored shipments provide continued verification in place of requalification on a fixed interval. With an agreed framework in place, supplier evidence could support the laboratory thermal performance and distribution testing elements, which is where most duplication occurs today. Design verification is the step at which the supplier's design and installation data are checked, rather than an element that supplier evidence supplements.

Anchored by risk assessment

Product stability budget, lane conditions, criticality of the solution and the evidence available set the sequence and the interim controls.

Complete before the qualified state

Every element is completed or justified before the solution is declared qualified for routine use.

Assurance from real shipments

Where shipments are monitored, performance data support both interim control and continued verification.

S **Supplier evidence** may supplement the element. In the practices observed in this project, supplier evidence was mainly used to support design and installation. Under an agreed framework it could extend to laboratory thermal performance and distribution testing. Design verification, lane performance and the formal PQ remain the responsibility of the shipping organisation. | **Distribution testing (DT/DHS)** is not an automatic case. Whether supplier distribution testing can be referenced depends on the product type and on the testing the manufacturer already holds on file for that product. Where the product, its primary packaging or its hazard profile differ from what the supplier tested, supplementary testing is required.

Figure 1. The qualification elements required in both models are the same. What changes is sequence, the use of existing evidence, and how assurance is maintained after release.
Image provided as courtesy of Cold Chain Consult

[6] *European Commission. EudraLex Volume 4, Annex 15: Qualification and Validation, 2015, Principle: "Data supporting qualification and/or validation studies which were obtained from sources outside of the manufacturers own programmes may be used provided that this approach has been justified and that there is adequate assurance that controls were in place throughout the acquisition of such data." The same text appears in PIC/S PE009, Annex 15.*

[7] *US Food and Drug Administration. Process Validation: General Principles and Practices, 2011, in particular Stage 3, Continued Process Verification. ICH. Q9(R1) Quality Risk Management and Q10 Pharmaceutical Quality System. ASTM International. E2500, Standard Guide for Specification, Design, and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment.*

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Expectations for demonstrating performance on the lane, however, differ markedly. Some markets require a defined performance qualification (PQ) before routine use and periodic revalidation thereafter. Others expect qualification against the ambient extremes of the route, with periodic confirmation that the route and transportation processes have not changed. Others again do not have any specific cold chain packaging requirement, and expectations are inferred from marketing applications and inspection practice.[8] An organisation shipping globally must therefore satisfy several different interpretations of the same underlying objective.

Within a risk-based approach, qualification becomes a suite of elements rather than a fixed sequence. Design Verification (DV) only to verify the supplier test data, followed by real-world worst-case lane shipping conditions via a PQ or PV. A formal performance qualification is executed where a regulation or a marketing authorisation commitment requires it. Otherwise, performance on the lane can be demonstrated through lane qualification, route verification, performance qualification, or performance verification, supported by risk assessment and, increasingly, by the monitoring data that accompanies most shipments today.



[8] *Illustrative examples only, and not a substitute for local regulatory advice. National Medical Products Administration, Good Supply Practice, Appendix 5 (2016), requires cold and insulated boxes to be validated before use and revalidated periodically. Health Canada, GUI-0069, expects qualification against the ambient extremes of the route and the maximum transport time. See also Anvisa RDC 430/2020 and IN 138/2022, and PIC/S PE009-17 as applied by the Therapeutic Goods Administration from 1 September 2025.*

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VI. Five Conditions for Trusted Reuse

The project developed a conceptual framework for how supplier evidence could move into a pharmaceutical company's packaging qualification process, covering data flow, roles, responsibilities and governance. The framework is set out in full in the technical report. Its foundation is five conditions, and these are the industry positions this paper puts forward.

01.

Comparable

Evidence is generated against conventions the industry has agreed: ambient profiles, payload definitions and probe placement. Without this, every reuse decision is a bespoke technical comparison.

02.

Traceable

The origin, configuration, method, version and approval status of the evidence, and the link between the evidence and the conclusion drawn from it, are always recoverable.

03.

Transparent

Assumptions, known differences, unavailable information and the limitations of the evidence are stated, not implied. Transparency about what evidence does not show is what makes reliance defensible.

04.

Risk Based

Supplier and pharmaceutical qualification are never automatically equivalent. Evidence may inform a strategy, support a risk assessment or satisfy particular parameters, and the judgement is made case by case.

05.

Accountable

Supplier participation does not transfer accountability. The qualification decision, and responsibility for product quality and compliance, remain with the marketing authorisation holder.



AND ONE CONDITION FOR THE INDUSTRY

None of the above is achievable by a single organisation. Comparability requires agreed conventions, and trusted custodianship requires an independent body. This is collective work, which is why it has not happened yet.

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VII. Five Reframes for Industry Leaders

Five shifts in framing would change how qualification effort is spent, without weakening a single control.

FROM	TO
Repeating tests	Reusing evidence
Qualification as a document	Qualification as a lifecycle
Requalification on a calendar	Continued verification from shipments
Suppliers as vendors	Suppliers as evidence partners
Protecting data	Governing shared evidence

Each reframe is modest on its own. Together they describe an industry that spends its qualification effort on the questions that remain genuinely open, rather than on confirming what is already known.



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VIII. Conclusion: The Next Phase

Duplicated qualification of Temperature-Controlled Packaging Solutions (TCPS) is widely recognised, its causes are largely within the industry's control, and the conceptual work to address it is now done. What remains is alignment: among industry participants on common conventions, and with regulators on how performance may be demonstrated.

There is precedent for this. In bioprocessing, fragmented supplier testing was addressed through an industry-authored protocol that suppliers could execute once and customers could rely on, and the subject was subsequently taken up in a pharmacopoeial chapter. Air cargo itself has already accepted independent certification against a common standard.[9] Neither required new technology. Both required the industry to convene.



Industry Working Groups

- Harmonised conventions for ambient profiles, payload definition and probe placement across all TCPS types.
- A defined supplier evidence package, so that what is shared is consistent and usable.
- A risk and science-based qualification pathway, including the role of shipment monitoring.
- Governance and custodianship of shared evidence, hosted with existing standards bodies.



Regulatory Engagement

- Structured dialogue with subject matter experts and agencies across the major markets, on where formal performance qualification is required and where lane qualification or verification is sufficient.
- Engagement with standards and pharmacopoeial bodies, so that conventions agreed by industry can be carried into recognised guidance.



Pharma.Aero invites life science companies, packaging suppliers, freight forwarders, ground handling agents, standards bodies and regulators to join the next phase of the Packaging Qualification Integration project, and to help establish a streamlined, risk and science-based approach to qualification that reduces duplication while strengthening assurance for patients.

[9] *BioPhorum Operations Group. Standardised extractables testing protocol for single use systems in biomanufacturing; the subject was subsequently addressed in United States Pharmacopeia General Chapter <665>. IATA. CEIV Pharma certification programme.*

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IX. Acknowledgements

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