Whitepaper

Envirotainer

Quality You Can Prove:

A Practical Framework for Evaluating Supplier Certifications

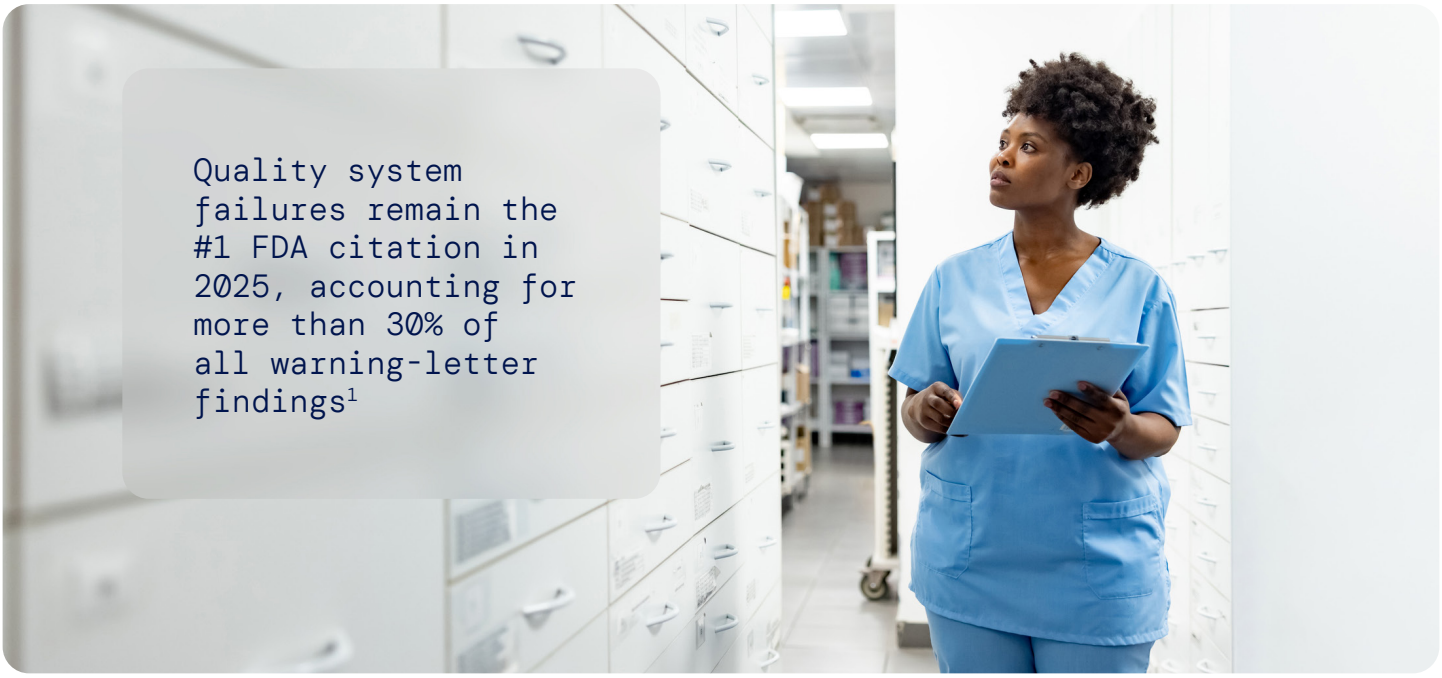
Contents

Executive Summary

Pharmaceutical logistics operate at the intersection of two of the world's most regulated industries: pharmaceuticals, where patient safety is paramount and aviation, where safety, standardization, and compliance are non-negotiable. In this environment, independent and accredited certifications can be powerful tools for reliability and trust when they are relevant, verifiable, and embedded in daily operations.

When misunderstood or misused, however, certifications risk becoming marketing ploys rather than mechanisms that prevent temperature excursions, data-integrity failures, and operational breakdowns.

This whitepaper examines what certifications truly represent, how they differ from self-declared compliance, where their value lies and where common misinterpretations arise. It also outlines how pharmaceutical manufacturers can verify supplier claims and assess whether certifications meaningfully support patient safety and product integrity.



Why Certifications Matter in Pharma Cold Chain Logistics

The global pharmaceutical supply chain is undergoing rapid transformation. Temperature-sensitive medicines have grown more than twice as fast as the overall pharmaceutical market, and approximately 45% of the top 20 global best-selling drugs now require refrigerated transport[2]. As biologics, vaccines, and advanced therapies continue to expand, cold chain integrity has become a core patient-safety concern rather than a logistical afterthought.

At the same time, temperature excursions remain a persistent and costly risk. Industry analysis estimates annual losses of USD 35 billion per year due to cold chain failures[3]. Air transport - critical for global reach - adds further complexity, with shipments exposed to environments ranging from sub-zero aircraft holds to extreme heat on airport tarmacs.

In this context, certifications are frequently cited as proof that companies, products, and services are fit for use in pharma transportation. Yet what certifications mean, and what they do not mean, is often misunderstood. As supply chains globalize and reliance on third-party providers increases, manufacturers must be able to distinguish between meaningful, independently verified certifications and claims that offer reassurance without reducing real risk.

What Is a Certification and What Is It Not?

A certification is a written assurance issued by an independent, accredited body confirming that a product, service, or management system meets specified requirements of a recognized standard.

Key characteristics of credible certification:

- **Independence:** Conducted by an accredited third party - not self-declared
- **Verification & documentation:** Issued following structured audits and ongoing evaluation
- **Standards-based:** Aligned to recognized international standards such as ISO 9001 (Quality Management Systems) or ISO 14001 (Environmental management systems)

Standards vs. regulations

Standards are voluntary frameworks that can form the basis for certification (e.g., ISO 9001).

Regulations are legal requirements (e.g., EU GDP, aviation regulations) with which companies must comply.

While standards and regulations may overlap in intent, they are not interchangeable. Certification to a standard does not replace regulatory compliance, but when relevant, it can strengthen and structure how compliance is achieved.

> "Certification - the provision by an independent body of written assurance (a certificate) that the product, service or system in question meets specific requirements."
>
> - ISO Organisation

The Value of Certifications When Applied with Purpose

Certifications deliver value in two distinct but connected area: internal operations and external assurance.

Internal value:

Strengthening operational discipline

Working toward and maintaining accredited certification requires organizations to:

- Define, document, and manage critical processes
- Clarify responsibilities, governance, and escalation paths
- Reduce variability and prevent repeat errors
- Strengthen deviation management, CAPA, and learning loops
- Embed risk-based thinking and continuous improvement

External value:

Trust, transparency, and efficiency

For pharmaceutical manufacturers and regulators, credible certifications can:

- Build confidence in supplier capability
- Reduce duplicated audits and qualification burden
- Demonstrate alignment with globally recognized expectations
- Support access to regulated markets
- Enable clearer, evidence-based supplier comparisons

These principles are foundational to ISO 9001. In the pharmaceutical cold chain where even small temperature deviations can degrade product efficacy, such discipline directly supports patient safety and product integrity.

As cold chain therapies continue to grow in both volume and value, the ability to rely on verifiable systems becomes increasingly important.

Where Certifications Go Wrong: Common Misconceptions

Despite their potential, certifications are often misunderstood or misapplied.

"More certifications mean better quality"

Quantity does not equal relevance. Certifications confirm that systems exist; they do not guarantee flawless execution. Excessive or irrelevant certifications can:

- Increase administrative burden
- Create conflicting processes
- Encourage "tick-box" quality behaviour
- Divert focus from actual cold chain risks

Risk-based guidance such as EU GDP and WHO frameworks emphasizes relevance and effectiveness over paperwork volume.

"Certification guarantees flawless operations"

False. Certification strengthens processes, but it does not eliminate human error or operational complexity. Temperature excursions still occur when controls fail - particularly at handover points and during last-mile activities. This is why operational frameworks such as IATA's Temperature Control Regulations (TCR) remain essential complements to quality management system standards.

"Certification as a marketing label"

Terms such as "ISO-based" or "aligned with ISO principles" are frequently used in the market. While such descriptions may reflect internal intentions, they are not equivalent to accredited certification and should not be interpreted as such. ISO emphasizes that certificates must be independently verifiable and issued by accredited bodies. Without transparency and verification, trust erodes.

Verifying Certification Claims

Certifications can, and should, be verified.

Pharmaceutical manufacturers can protect their supply chains by:

- Requesting official certificates from suppliers, including scope, sites, validity dates, and issuing bodies
- Validating certificates through accredited databases such as IAF CertSearch, US FDA databases, EU registries
- Mapping certificate scope to actual operational activities on relevant lanes

Verification is not about distrust - it is about risk management. Transparent verification strengthens the integrity of the entire healthcare supply chain.

Practical Tip!

Build verification into onboarding and periodic business reviews: require expiry dates, scope statements and surveillance schedules tied to the certificate scope.

Benefits of Choosing an ISO 9001-Certified Thermal Packaging Provider

For pharmaceutical manufacturers, engaging an ISO 9001-certified thermal packaging provider offers several tangible benefits:

- Independent verification of a structured quality management system
- Consistent, process-driven execution supported by risk-based thinking
- Improved deviation and CAPA discipline tied to measurable outcomes
- Streamlined supplier qualification through publicly verifiable certification
- Alignment with GDP and IATA TCR expectations through mature operational controls
- Global recognition and confidence in quality-sensitive partnerships

A valid, accredited certificate with clearly defined scope and sites provides meaningful differentiation from vague or unverified claims.

The Envirotainer Perspective

Envirotainer's approach to certifications is guided by four principles:

- **Certification with purpose:** We prioritize certifications and controls that demonstrably reduce risk and improve customer satisfaction
- **Operationalization:** Certification frameworks are embedded into SOPs, training, monitoring, and CAPA loops.
- **Transparency:** We provide certificates, scopes, and verification pathways and align with customer audits.
- **Continuous learning:** We link audit outcomes and deviation trends to design, process, and lane improvements.

In 2025, Envirotainer achieved company-wide ISO 9001:2015 certification, reflecting a commitment to consistent, verifiable quality management across its global operations. This certification is independently accredited, publicly traceable, and embedded in day-to-day execution - not treated as a marketing label.

We encourage pharmaceutical manufacturers to verify all suppliers' certification claims, including our own, using independent sources such as IAF CertSearch.

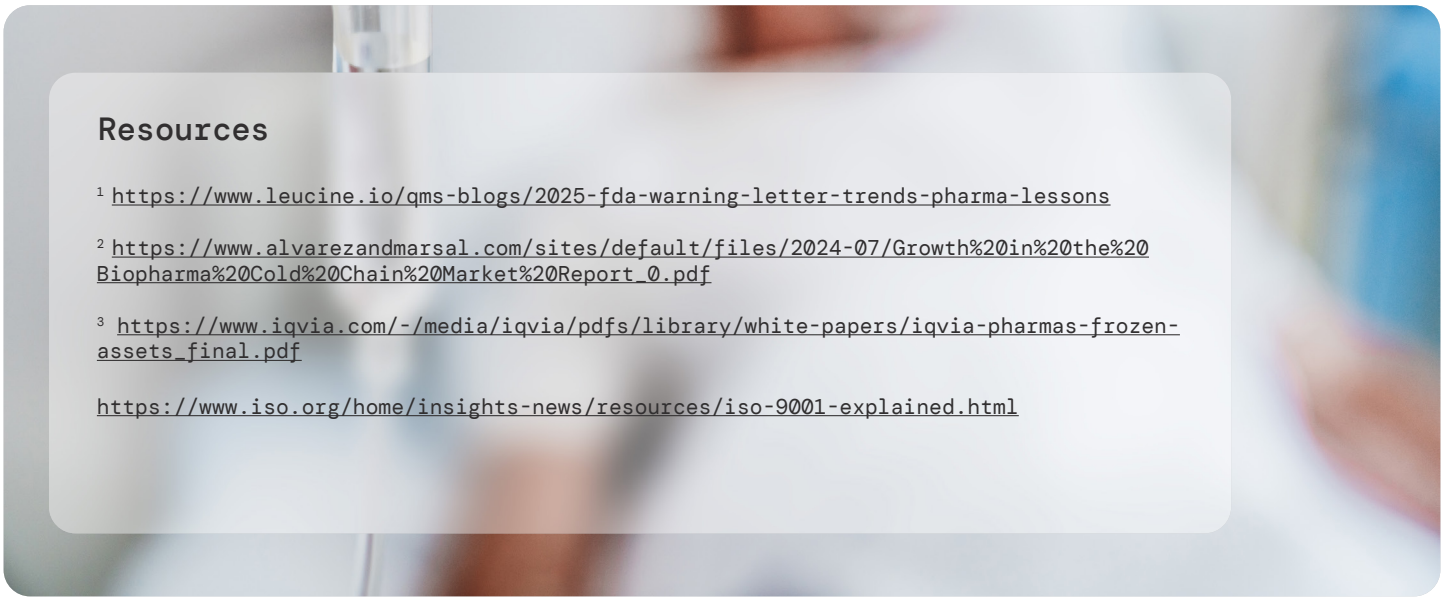
In Conclusion

Certifications can be powerful tools for strengthening organizational performance, credibility, and accountability, but only when applied with integrity and purpose.

When certifications are pursued merely as marketing labels, exaggerated beyond their scope, or used to substitute for real operational controls, trust is eroded and patient safety is put at risk.

In an industry where temperature deviations can destroy efficacy, cost billions, and impact lives, certification must reflect reality, not aspiration.

Envirotainer will continue to champion that standard.



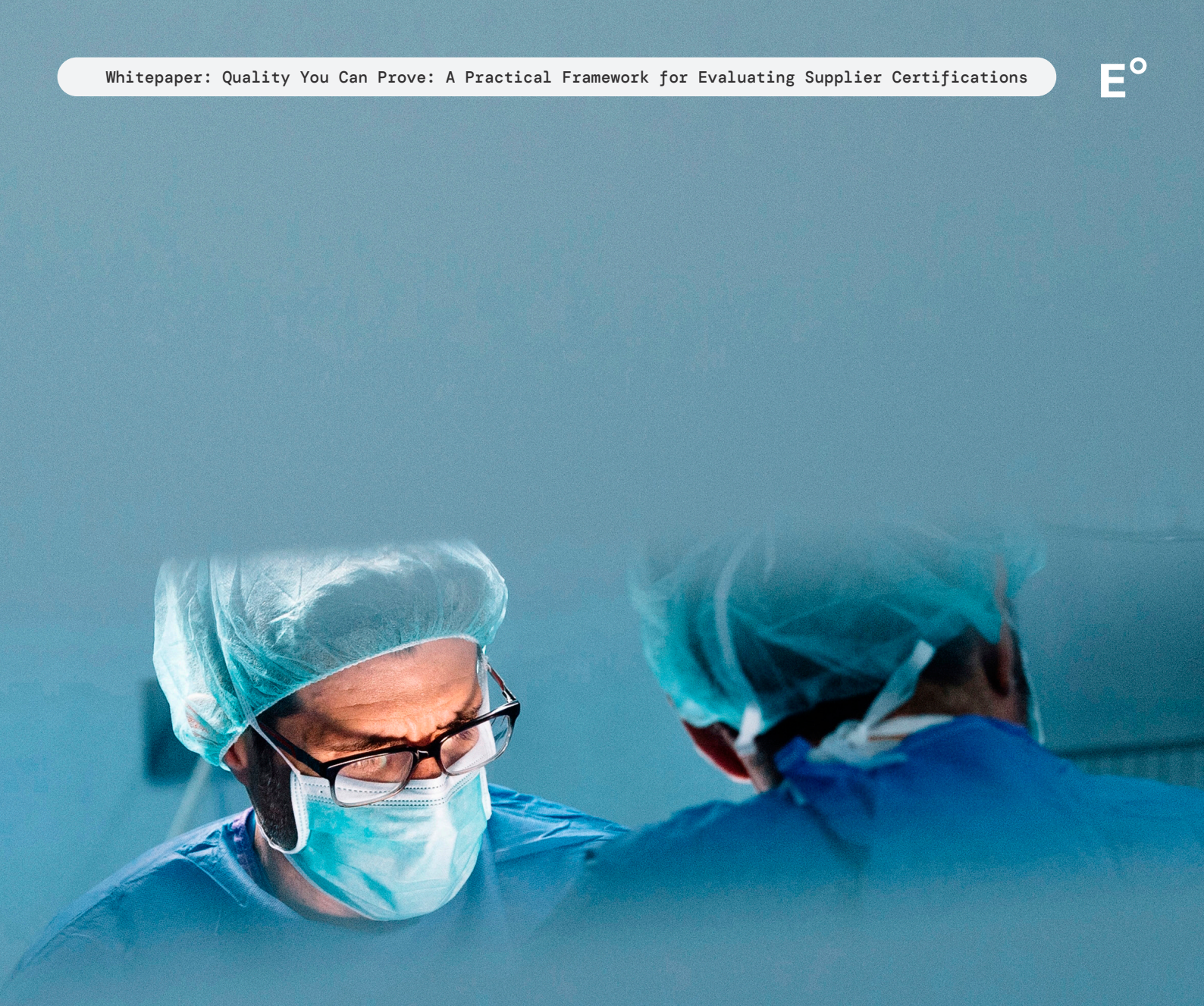
Resources

[1] https://www.leucine.io/qms-blogs/2025-fda-warning-letter-trends-pharma-lessons

[2] https://www.alvarezandmarsal.com/sites/default/files/2024-07/Growth%20in%20the%20Biopharma%20Cold%20Chain%20Market%20Report_0.pdf

[3] https://www.iqvia.com/-/media/iqvia/pdfs/library/white-papers/iqvia-pharmas-frozen-assets_final.pdf

https://www.iso.org/home/insights-news/resources/iso-9001-explained.html



About Envirotainer

Envirotainer transports life-saving pharmaceuticals around the world with innovative temperature-controlled solutions.

With 40 years leading the industry, the world's largest pharmaceutical companies trust us to deliver. We offer the widest choice of cold chain solutions with a range of shipment monitoring services, all backed by our extensive global network to get your product to where it needs to be, precisely when it needs to be there.

When it comes to sustainability, we lead by example. Our ambitious science-based targets guide us, so we can reduce not only our emissions but our customers', too. Our transparent reporting, data-driven approach, and precise CO2 calculations allow us to measure our environmental impact all the way down to emissions per vial.

From research and development all the way to commercial distribution, we can deliver large quantities down to single patient samples. So, no matter what the pharma industry produces, we can ensure the safety and efficacy of medicines for every phase of the pharmaceutical life cycle.