



CASE STUDY

Achieving Continuous Audit Readiness Across a Global Medical Information Program



Introduction

With experience supporting over 280 audit inspections across 25 countries in 2025, ProPharma is a trusted partner in regulatory compliance and inspection readiness. Our deep expertise is reinforced by our own inspection history, including six FDA inspections, with the latest in February 2023 concluding with zero Form 483 observations.*

We view audit readiness as more than a milestone; it is a state of being. Through proactive quality oversight, risk-based decision-making, and industry-leading quality systems, ProPharma helps organizations maintain continual compliance and confidently navigate regulatory scrutiny.

*As of July 2026, our last FDA inspection was in February 2023.

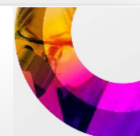
Challenge

Maintaining continuous audit readiness across a global Medical Information operation presents significant operational and regulatory challenges. Organizations operating across multiple countries and affiliates must navigate evolving regulatory requirements while ensuring consistent quality standards, compliant processes, and effective governance across diverse regional teams.

As organizations expand globally, they often face increasing complexity in maintaining standardized documentation, training, quality management processes, and oversight.

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Variations in local regulations, differing stakeholder expectations, and decentralized ways of working can make it difficult to achieve consistent compliance and demonstrate inspection readiness across all markets. Coordinating activities across numerous affiliates also requires clear governance, effective communication, and defined accountability to ensure that risks are identified and addressed proactively.

Companies often engage partners such as ProPharma to strengthen their quality and compliance capabilities, provide independent expertise, and establish sustainable frameworks that support ongoing inspection readiness rather than reactive audit preparation. By leveraging specialist regulatory knowledge and proven governance models, organizations can enhance consistency across their global operations while integrating improvements into their existing quality systems and business processes.

Without a structured, proactive approach to governance and compliance, organizations may be exposed to increased regulatory risk, inconsistent execution across regions, delayed issue resolution, and greater operational inefficiencies. These challenges can ultimately impact audit outcomes, increase the likelihood of regulatory observations, and divert valuable resources away from strategic business priorities.

Our Approach

This case study highlights a long-standing client partnership that has successfully operated for more than nine years. The engagement supports Medical Information services across 118 countries and 11 client affiliates, requiring a highly coordinated and scalable operating model to ensure consistency, compliance, and quality across all regions.

Recognizing that every organization has established systems, training platforms, and compliance processes, ProPharma tailored its approach to complement the client's existing operating environment rather than replace it. By integrating seamlessly with the client's quality framework, ProPharma strengthened governance while supporting continuous audit readiness across the global program.

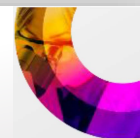
To streamline decision-making and ensure consistent direction, the client appointed a single lead representative to act on behalf of all affiliates, while ProPharma assigned a dedicated program lead responsible for central oversight, coordination, and delivery. This clear governance structure provided defined ownership, simplified communication across multiple stakeholders, and ensured issues were resolved efficiently.

“Achieving zero findings is a remarkable accomplishment.”

The program was supported by a robust governance framework, including biweekly governance meetings where both organizations reviewed operational performance, monitored quality metrics, discussed emerging risks, identified opportunities for continuous improvement, and assigned action items with clear ownership. This collaborative approach fostered transparency, accountability, and disciplined execution, enabling both organizations to maintain a state of continuous audit readiness while supporting consistent service delivery across the global network.

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Results

During the client's latest audit of ProPharma in Q2 2026, ProPharma achieved a successful outcome with zero findings, observations, or comments. The auditor recognized the robustness of ProPharma's Quality Management System and highlighted the strength of the collaborative partnership between ProPharma and the client, which was evident throughout the audit.

This successful outcome demonstrates the effectiveness of a proactive, governance-led approach to quality management and regulatory compliance. Through consistent execution, clear accountability, and continuous oversight, the partnership has enabled sustained audit readiness across a complex global operation.

Conclusion

This long-standing partnership demonstrates how a proactive, governance-driven approach to quality and compliance can deliver sustained audit readiness and exceptional client outcomes on a global scale. By aligning closely with the client's existing systems and processes, establishing clear ownership and accountability, and maintaining regular governance forums, ProPharma has helped ensure consistent execution across 118 countries and 11 affiliates throughout more than nine years of collaboration.

“...consistently upholding the high standards expected across Medical Information operations.”

The success of this approach is reflected not only in the audit outcome – zero findings, observations, or comments during the Q2 2026 client audit – but also in the strength and maturity of the partnership itself. The auditor's recognition of ProPharma's robust Quality Management System and the highly collaborative working relationship between both organizations reinforces the value of a shared commitment to quality, transparency, and continuous improvement.

Most importantly, the longevity of the relationship and the client's continued trust in ProPharma are strong indicators of client satisfaction. Through responsive service, effective governance, and a commitment to delivering consistent, compliant outcomes, ProPharma has become a trusted extension of the client's organization, helping maintain continuous audit readiness while supporting broader global business objectives.

Improve the Health and Safety of Patients

From early concept development through each clinical phase, product launch, and commercialization, we partner with pharmaceutical, biotechnology, and medical device clients to tackle complex challenges. We help to ensure regulatory goals are met, business objectives are achieved, and patient health and safety is improved.

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