



Inspection Challenges, Efficiencies, and Opportunities

October 2025



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Presentation Contents

This Session's Focus:

- Key inspection challenges for generics and biosimilars
- Opportunities for efficiency and collaboration
- Regulatory and industry perspectives

Objectives:

- Share real-world challenges
- Highlight innovative solutions
- Share considerations for future opportunities



Inspection Challenges



Resource Constraints

Increased volume and complexity of inspections, especially for global sites

Redundancy

Overlapping inspections by multiple regulators

Late-Cycle Inspections

Impact on approvals and supply chain plans, new launches

Regulatory Divergence

Navigating different global requirements; non-MRA countries

Emerging Risks

Adapting to new quality threats (Nitrosamines, PFAS)

Efficiencies & Opportunities

Reliance & Mutual Recognition: Leveraging MRAs to reduce duplication

Remote & Hybrid Inspections: Digital tools and virtual audits

Risk-Based Approaches: Prioritizing high-risk sites and processes

Collaboration: Pre-inspection planning and post-inspection feedback



Advancing Inspection Readiness

Background:

In 2025, our organization faced the challenge of preparing for a series of complex, multi-site inspections amid evolving regulatory expectations and increased scrutiny on data integrity, aseptic processing, risk management, and external manufacturing complexities.



Centralized Readiness

Establish a central support HyperSupport readiness team and Inspection Risk Register to help sites prepare for both scheduled and unannounced inspections, ensuring rapid remediation and compliance urgency.



Digital Transformation

Implement standard GxP IT Quality System and other digital tools to streamline investigations, CAPAs, and trending, improving cross-site visibility and lessons learned thereby reducing repeat occurrences.



Risk-Based Approach

Redesign Inspection Risk Register and adopted a tiered, Enterprise Integrated Risk Model—enabling us to escalate and address risks from site to cluster to global levels.



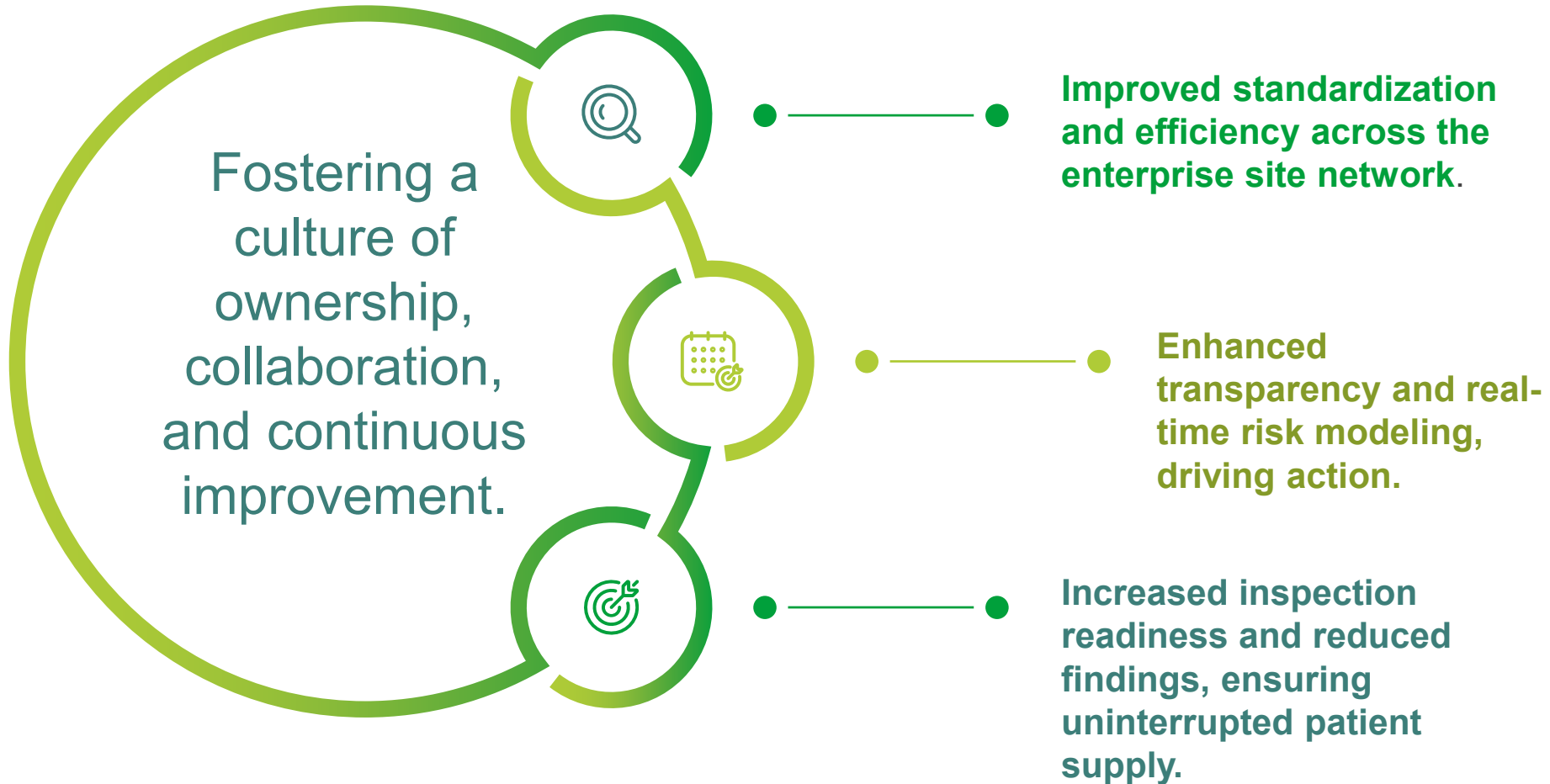
Training & Capability Building

Targeted training programs (Data Integrity Fundamentals, Quality Risk Management Tools). Created QMS SMEs CoP to share and learn best practices and standardize interpretation of regulations & requirements.

Governance & Continuous Improvement:

Strengthened governance through new forums, regular policy reviews, and independent audits

Advancing Inspection Readiness



Key Learning:

Establishing a global model
+
digital tools and data
+
empowered teams
=
driving sustainable quality excellence

Thank you.



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