

Inspection Readiness as a System:

Building Global Confidence for Compliance

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Agenda

- **Context & Philosophy**
 - **Global inspection landscape**
 - **Our readiness principles**
- **Operating System for Readiness**
 - **Global audit playbook**
 - **Gap assessments & KPIs**
- **Enablers**
 - **Technology for remote/virtual oversight**
 - **Knowledge transfer across sites**
- **Culture & Forward Look**
 - **Embed readiness every day**
 - **Continuous improvement & AI**
 - **Key takeaways & Q&A**

Global Inspection Landscape Shifts

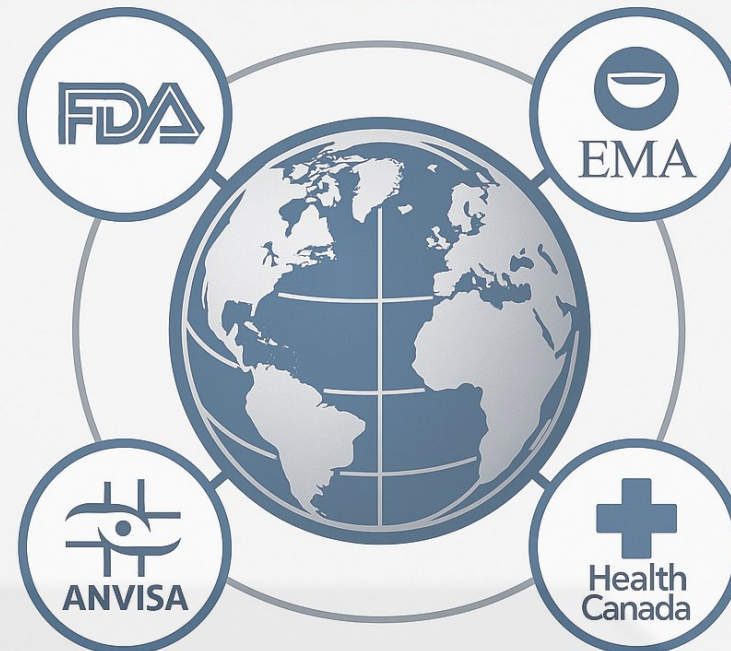


More Frequent, Deeper Inspections

Continuous State of Readiness Expected

Focus on Quality Culture and Data Integrity

GLOBAL REGULATORY AGENCIES



Global Oversight Challenges



Multiple local regulations and expectations



Different systems, Languages and maturity levels across regions



Global harmonization remains the ultimate goal

Inspection Readiness Philosophy



PROACTIVE: IDENTIFY AND
MANAGE RISKS EARLY



PREDICTIVE: USE DATA TO
ANTICIPATE AND PREVENT ISSUES



PREPARED: STANDARDIZED
PLAYBOOK AND CULTURE OF
CONSISTENCY

The Global Audit Playbook



Plan

- Standardized Framework
- Consistent Structure

Practice

- Mock Audits
- Identifies Gaps

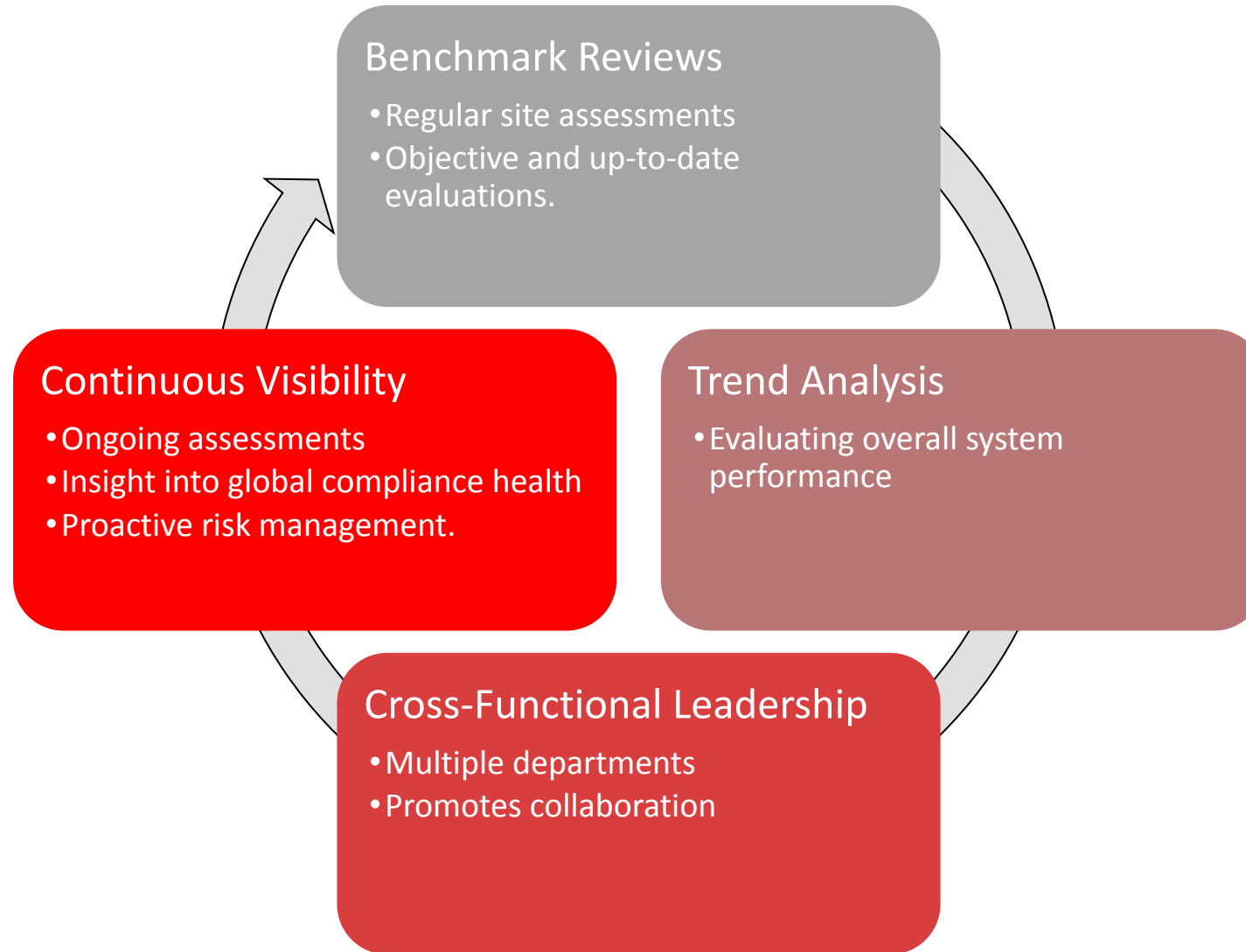
Perform

- Aligned communication during inspection
- Unified Response

Perfect

- Feedback and lessons learned

Regular Gap Assessments



Innovative Technology for Oversight

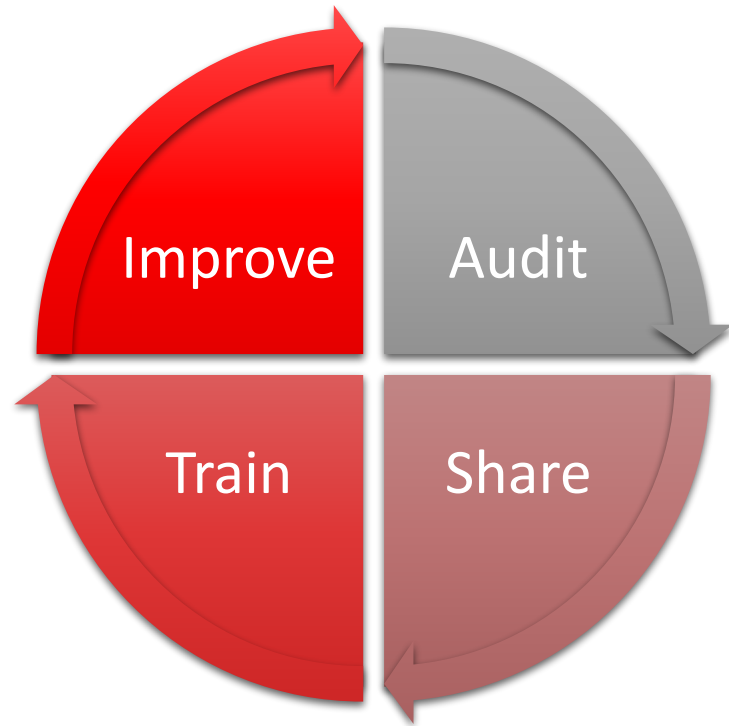
Virtual walkthroughs with
remote tools

Instant collaboration
between global experts.

Rapid coaching and
alignment post-review.



Global Knowledge Transfer



Compliance & Readiness KPIs



CAPA

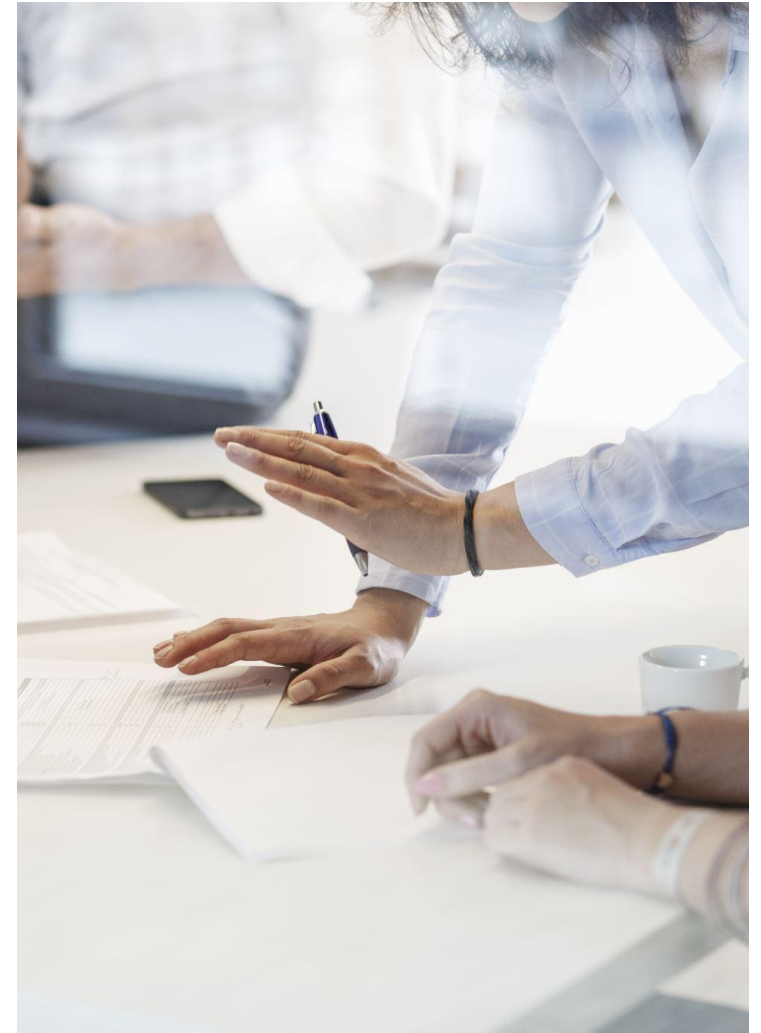
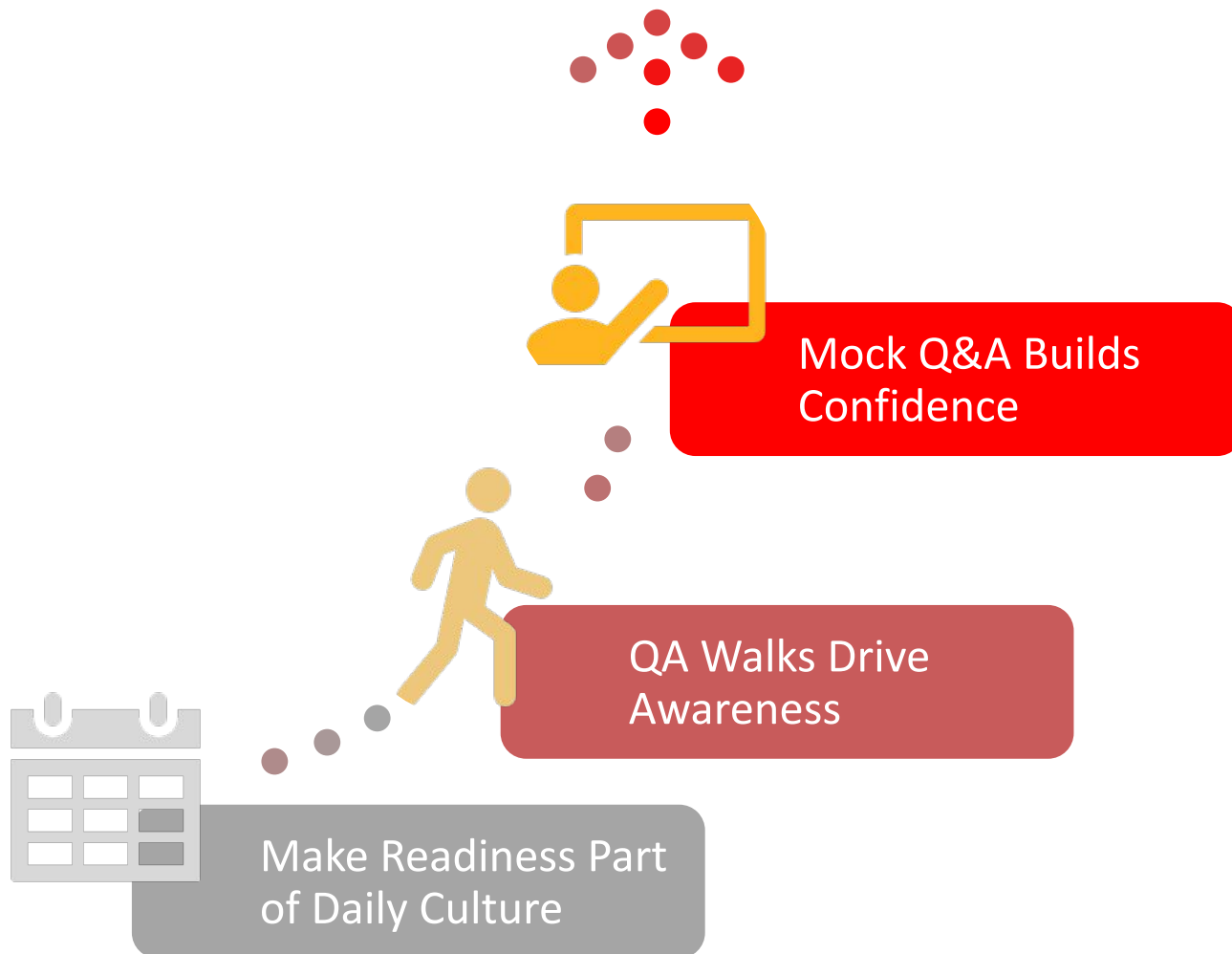
Deviations

Findings

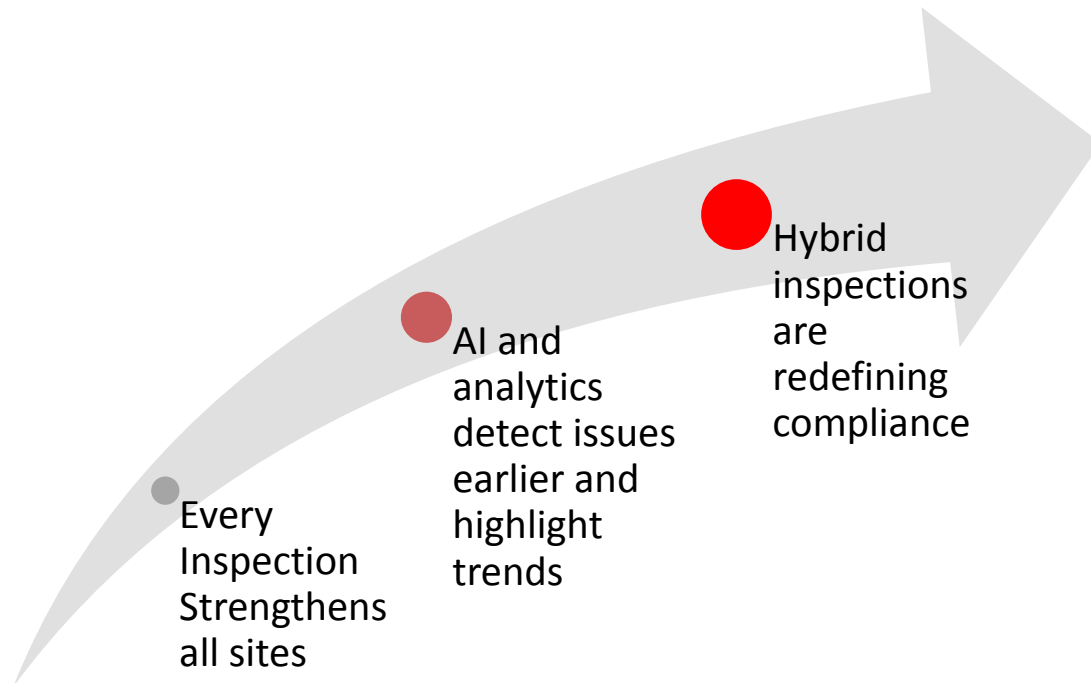
Self Inspections

Training

Embedding Readiness Every Day



Continuous Improvement & Future Vision



Closing and Key Takeaways

Harmonization
+ Technology +
Metrics =
Sustainable
Compliance

Culture Drives
Readiness, Not
Checklists

Control Is
Proven Daily,
Not Audited
Periodically

**THANK
YOU**