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Prepare for FDA's Evolving Inspection Approach

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Paige Sutton-Smith is Senior Quality & Regulatory Affairs Manager at Veranex with nearly 15 years in the medical device industry. Paige has a wide range of experience including US and EU regulatory strategy and approval, FDA and Notified Body interactions, product design and development, process validations, risk management, complaint handling, QMS deployment, and many others. Her track record includes numerous FDA approvals for active, invasive, and implantable products in areas such as organ preservation, orthopedics, insulin delivery, implantable neurostimulators, and cardiovascular implants.

Paige holds a BSc in Materials Science and Engineering from Lehigh University, has achieved a RAC-Devices certification, and is a certified auditor, Lean Six Sigma Black Belt, and ASQ Certified Quality Engineer. Paige assists clients with development and regulatory approval of medical devices, complex process control, and deployment/maintenance of QMS, including execution of audits and suppliers follow-up.

Today’s Objectives

Evaluate

Assess your current quality systems and inspection readiness against FDA’s evolving expectations, including data integrity, digital records, risk management, and post-market processes.

Apply

Use practical strategies to prepare for remote, hybrid, and on-site inspections, from documentation readiness to front-room and back-room response planning.

Recognize

Identify common compliance pitfalls tied to the revised inspection approach and understand how to reduce avoidable findings before they become regulatory risk.

FDA Inspections Have Changed

Beginning February 2, 2026:

- QMSR became effective
- FDA transitioned from QSIT to Risk-Based Inspections
- Inspection focus expanded beyond procedural compliance
- Greater emphasis on risk management and data-driven decision making

Key Takeaway:
Inspection readiness is now a continuous business process, not just a pre-inspection activity

FDA Inspections Have Changed

Where QSIT asked:

“Do you have a procedure for that?”

The new CP 7382.850 asks:

“Can you demonstrate that your system effectively identifies, evaluates, controls, and monitors risk?”

The New Inspection Model

QSIT	CP 7382.850
Subsystem-focused	Process-focused
Narrow process reviews	Lifecycle-focused
Heavy procedural emphasis	Assessment of decision-making across the QMS
Rigid format	Greater reliance on risk management documentation

Key Takeaway:
FDA investigators now review how risk information flows through quality, manufacturing, suppliers, complaints, CAPA, and management review.

Inspection Focus Areas

FDA organizes reviews into six QMS areas:

...plus the "OAFR"s

- Medical Device Reporting
- Unique Device Identification
- Corrections & Removals
- Device Tracking

Key Takeaway:

Inspectors will use risk information to determine which processes and records deserve deeper review rather than following a rigid sequence of review.

Common Readiness Gaps

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Risk Management Disconnects

- Risk files not linked to complaints
- CAPA not connected to risk evaluations
- Postmarket data not feeding risk reviews
- Limited evidence of risk-based decisions

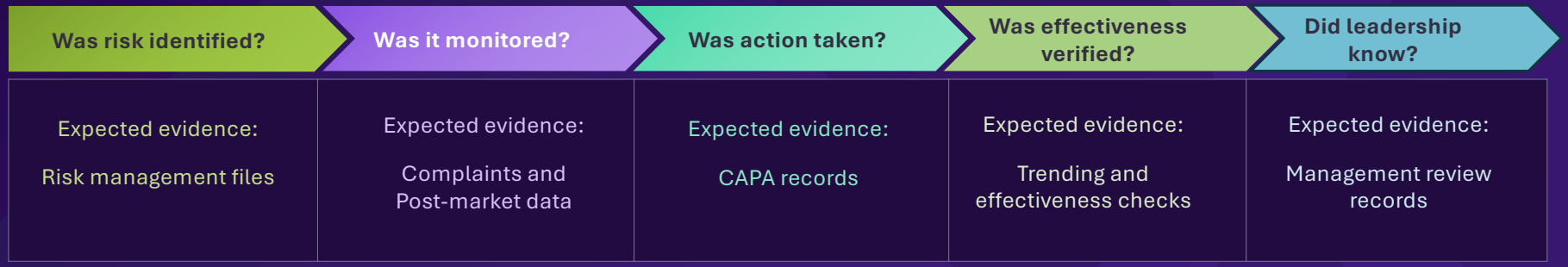
Data Integrity & Digital System Issues

- Inconsistent electronic records
- Poor traceability
- Lack of appropriate software validations

Supplier Controls

- Insufficient risk-based supplier oversight
- Weak monitoring of outsourced activities
- Lack of risk-based supplier classifications

Inspections Are More Data-Driven



Key Takeaway:

Instead of reviewing isolated records, inspectors increasingly look for evidence across multiple systems.

Actions To Take Now

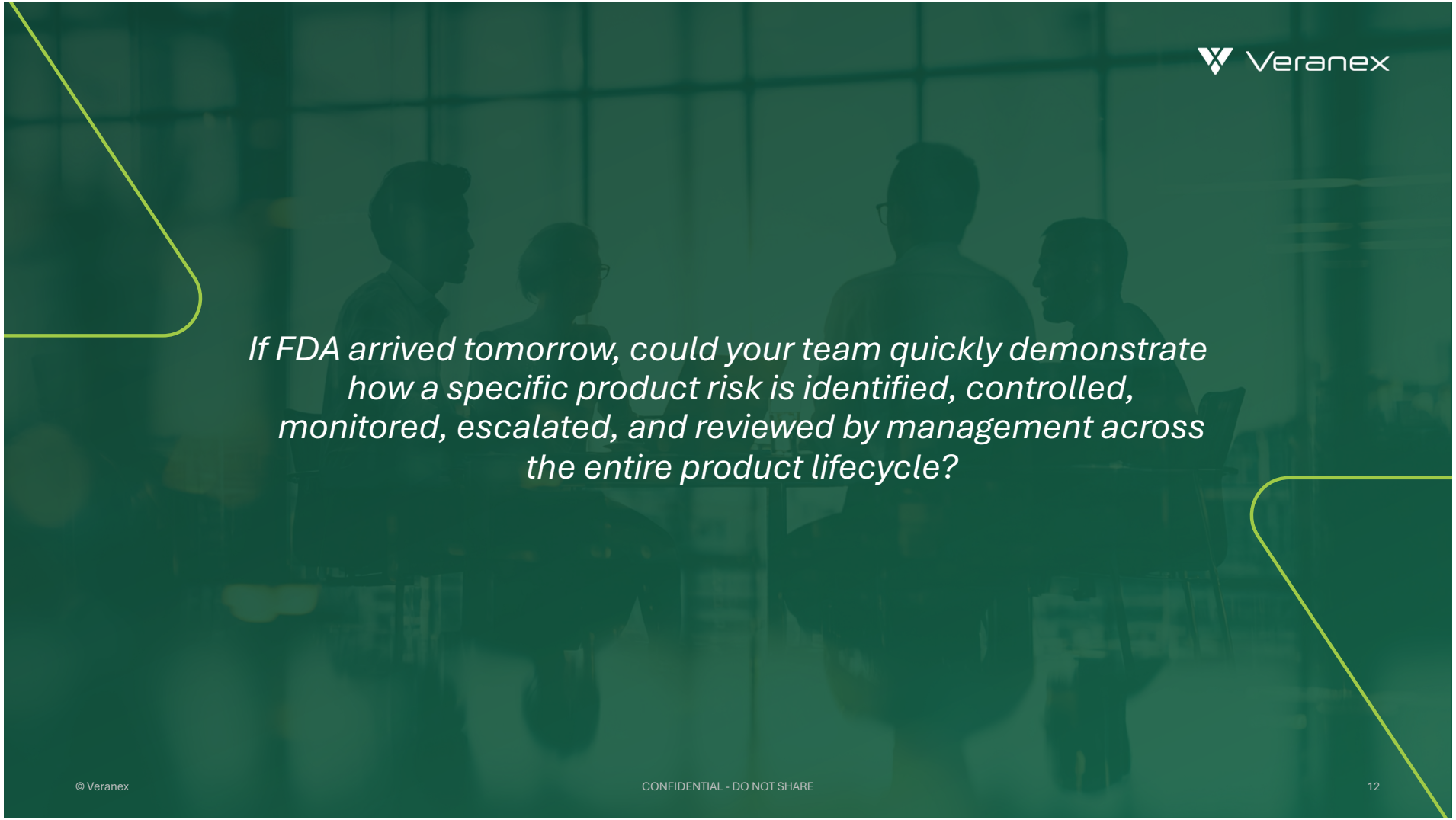
1. Perform a risk-based readiness assessment
2. Trace risk throughout the product life-cycle
3. Test retrieval of data from electronic systems
4. Conduct mock inspections
5. Strengthen inspection response teams and SMEs

Key Takeaways

Inspections are increasingly risk-based:
Risk management now sits at the center of FDA oversight.

Inspections are increasingly systems-focused:
FDA evaluates how processes work together, not in isolation.

Inspections are increasingly data-driven:
Organizations must demonstrate traceability, effectiveness, and evidence-based decision making.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If FDA arrived tomorrow, could your team quickly demonstrate how a specific product risk is identified, controlled, monitored, escalated, and reviewed by management across the entire product lifecycle?

Meet Us in Person | Upcoming Events

Georgia Life Sciences Summit
- August 25-26
- Atlanta, GA

MEDevice Boston (MD&M)
- August 26-27
- Boston, MA

AdvaMed Medtech Conference
- October 18-21
- Boston, MA

MedTech Strategist's Innovation Summit
- November 3-5
- San Diego, CA