To QSIT or Not To QSIT? That is not the Question!

Preparing for Medical Device Inspections

Julie Larsen, Principal and Director Inspection Readiness, BioTeknica

Braulio Ortiz, Principal and Co-founder, BioTeknica

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Introduction

Where I have been

- ASCP Certified Medical Technologist

- Rush St. Lukes's Presbyterian

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Introduction

Where I have been

- Over 20 years industry experience in quality roles in pharma, and medical devices, held internal audit positions at business and Corporate levels

  Worked on multiple FDA inspections, warning letters, Quality System remediations

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Introduction

Where I am now

- Principal Consultant and partner at BioTeknica

  Continue my work with auditing and assessments, FDA inspection preparation and support, 483 / WL responses, creating and remediating Quality Systems

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Introduction

What I have learned

- Companies who have an established program for inspection preparation are the most successful during inspections.

- Culture of self correction is key

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QSIT

- Quality System Inspection Technique
- In effect October 1999
- Used to assess a medical device manufacturer's compliance to the Quality System Regulation

Guide to Inspections of

Quality Systems

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QSIT Conversations

QSIT is outdated and incomplete

QSIT is supposed to save time but it doesn't

Investigators don't even follow QSIT

It's impossible to predict what will happen in a QSIT inspection

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What's a poor device manufacturer to do?

How do I even prepare for an inspection?

This isn't fair!

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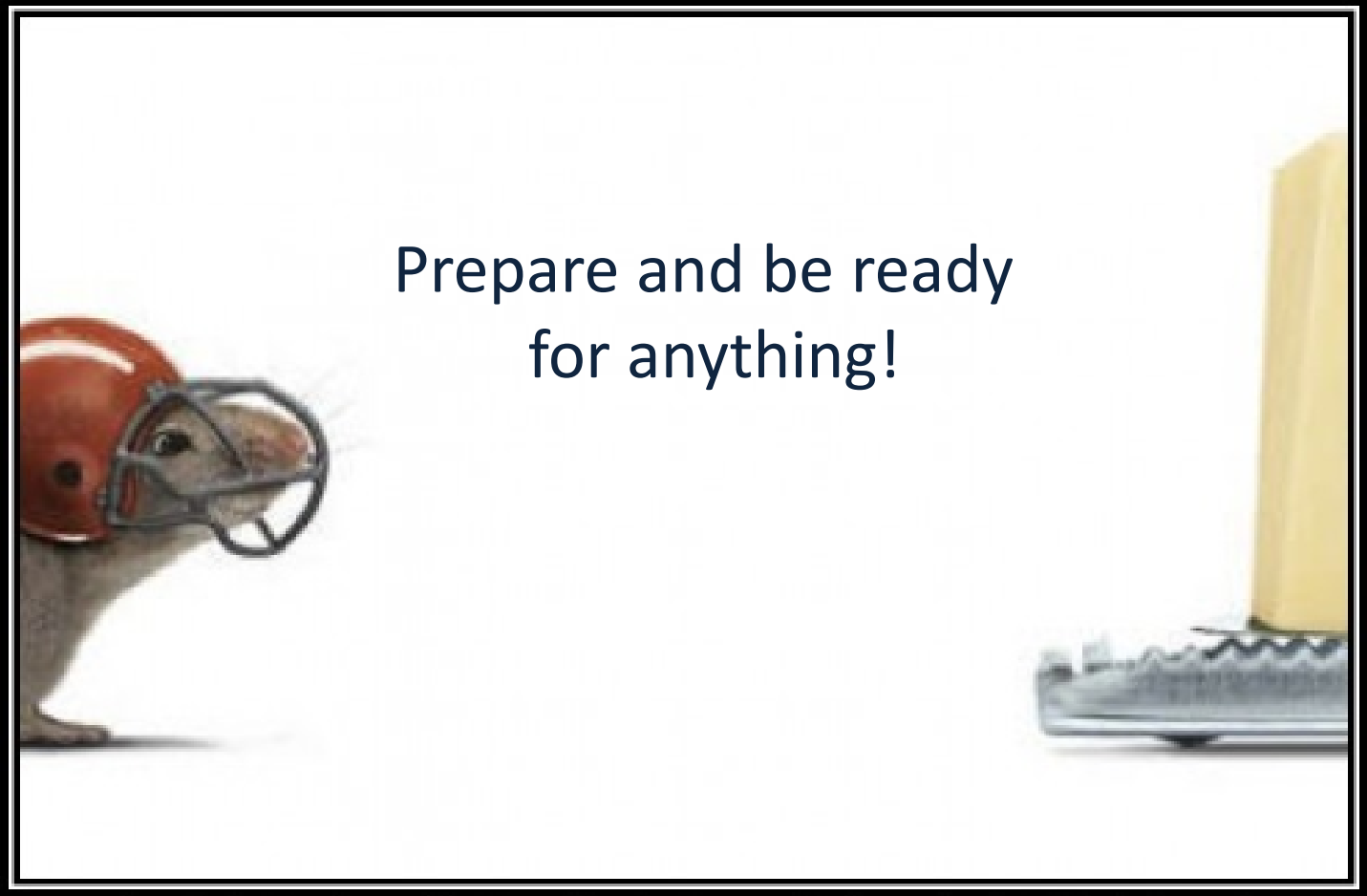
Prepare and be ready
for anything!
PREPARATION
"By failing to prepare you are preparing to fail."
Benjamin Franklin
DIY.DESPAIR.COM

Agenda

- QSIT Basics
- Applications of QSIT
- Three S for QSIT inspection success
- Case study breakout

10 Key Questions to Assess Inspection Readiness

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QSIT Basics

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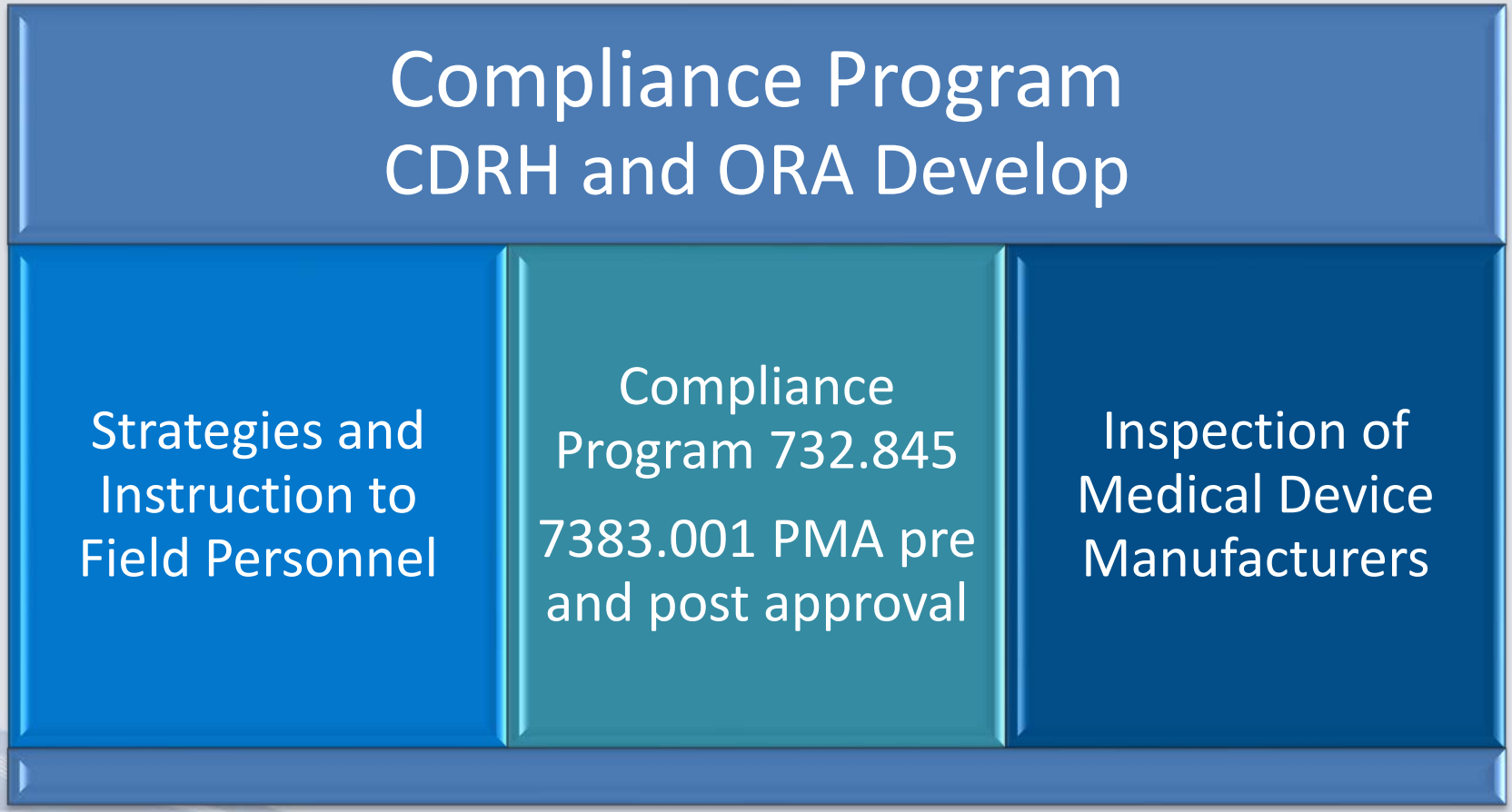
Inspection Approach



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Inspection Approach

Compliance program 7382.845
Inspection of medical Device Manufacturers

Quality System Regulation
21 CFR Part 820

Medical Device Reporting
21 CFR Part 803

Medical Device Tracking
21 CFR Part 821

Reports of Corrections and Removals 21 CFR Part 806

Registration and Listing
21 CFR Part 807

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QSIT

Quality System Inspection Technique

- Guidance for inspections
- Top down inspection process
- Utilizes a sub-system approach
- Compliance manual defines approaches

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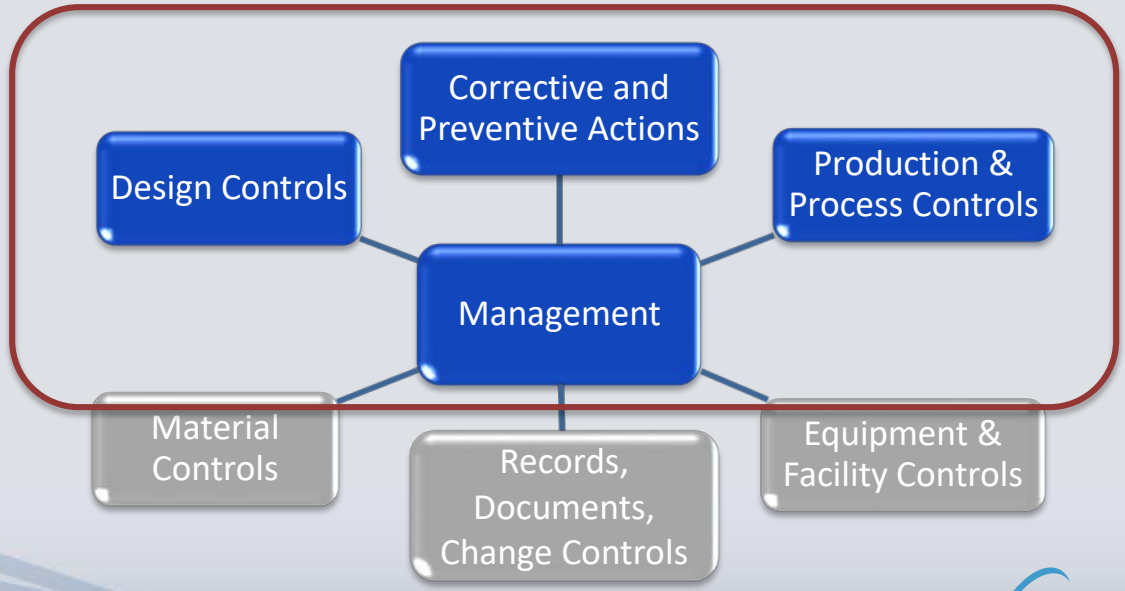
QSIT: Key Aspects

- Top down versus bottom up
- Four major subsystems
- Broad review
- Detailed review of records



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Inspection Approach

Who and When?

- Registration Database
- Device manufacturers in the United States

Prioritized by Risk

- Class II and III Devices – 2 years
- Recalls or field issues
- History of significant violations
- Warning Letter Follow Up

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QSIT: Types of Inspections

Level 1 Abbreviated	• CAPA plus one other subsystem (abbreviated) • Used for surveillance
Level 2 Comprehensive	• Baseline where no previous Level 2 • Covers all 4 major subsystems
Level 3 Compliance Follow-up	• Verify adequate correction of previous violations • May include elements of QSIT

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QSIT: Sampling

- Sample based on risk
- Binomial Sample plans
- Used to determine extent of a problem

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Applications of QSIT

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QSIT Application: Quality System

- Compliance expectations
- Procedure content
- Use when building, improving, revamping

FDA Guidance and Preamble

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QSIT Application: Internal Audit

- Requirement to audit all subsystems
- Check for implementation
- Expectation for thorough review of records

Internal Audit program demonstrates the manufacturers ability to be self correcting

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QSIT Application: Internal Audit

☑ **6. Verify that quality audits, including re-audits of deficient matters, of the quality system are being conducted.**

Review the firm's quality audit schedules to assure quality audits are being conducted with sufficient frequency. It is recommended that the time between quality audits not exceed a 12-month period. More frequent audits may be recommended if the firm has a serious Quality System Regulation problem.

Quality audits should consist of a formal, planned check of all elements in the quality system. They are **NOT** product audits. Quality audits must be conducted using adequate detailed written procedures by appropriately trained individuals. If conducted properly, a quality audit can detect system defects and, through isolation of unsatisfactory trends and correction of factors that cause defective products, prevent the production of unsafe or nonconforming devices. *Without an effective quality audit function the quality system is incomplete and there is no assurance the manufacturer is consistently in a state-of-control.*

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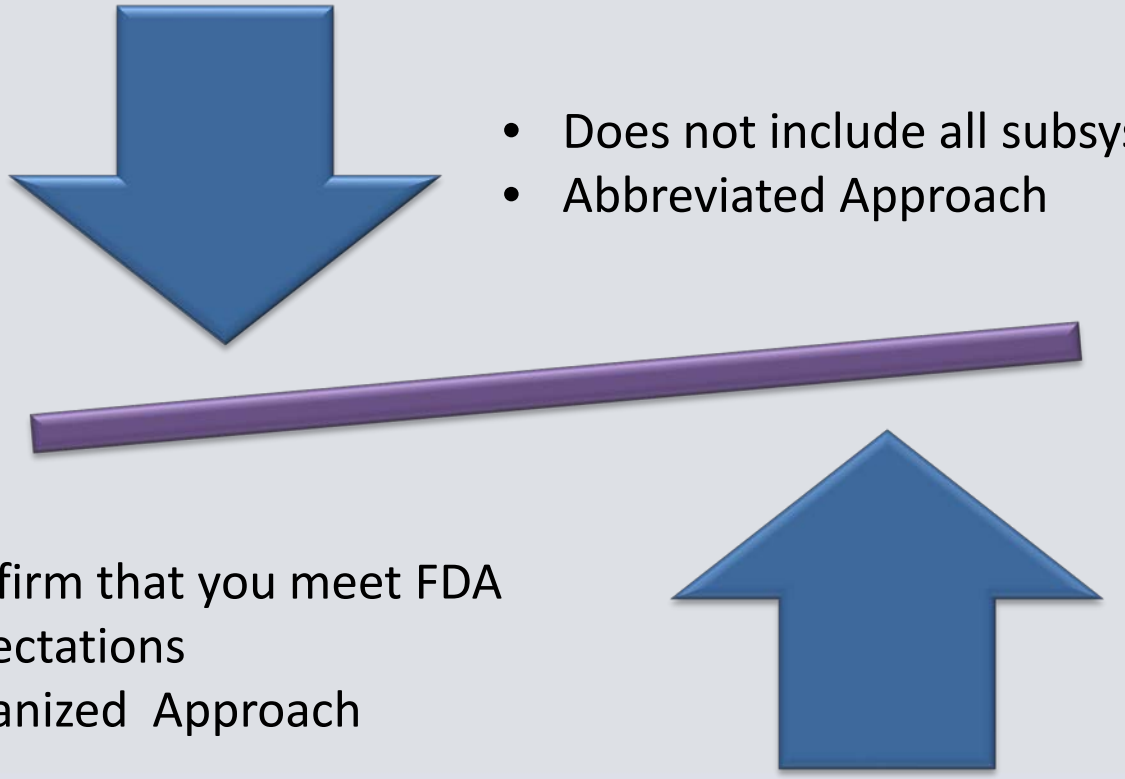
QSIT Application: Pros and Cons



- Does not include all subsystems
- Abbreviated Approach

- Confirm that you meet FDA expectations
- Organized Approach

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QSIT Application: FDA Use Pros and cons

- Abbreviated Approach
- Issues may not be visible

- More efficient inspections
- Focused approach
- Consistent approach

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Consider...

"The observations noted in this FORM FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements."

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Break Out: QSIT Application

- Read the scenario you have been given
- Prepare your answers to the question(s)
- Share your answers with the group

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QSIT for Inspection Readiness

The 3S for Success

Do you have strategies in place to handle potential compliance vulnerabilities during inspection?

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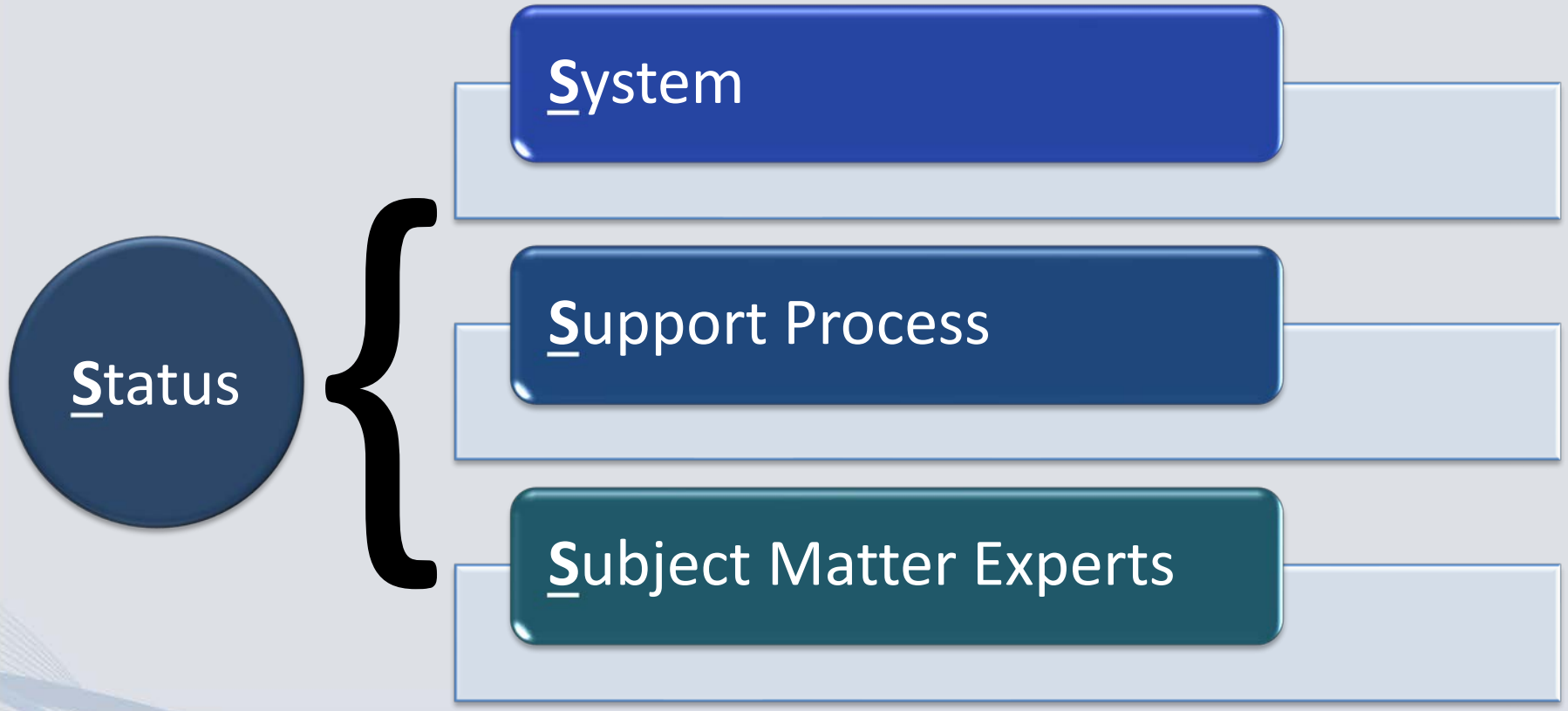
The three S for Inspection Success



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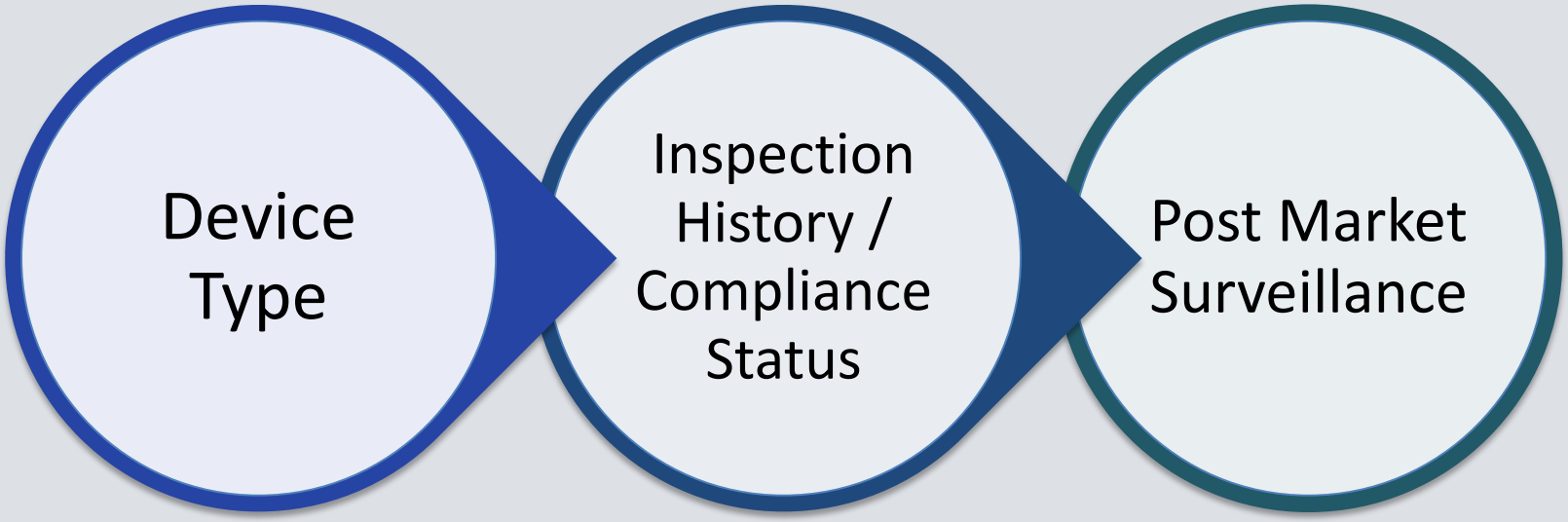
Status: Determination Factors



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Break Out

You have been given descriptions of fictional device companies. Based on the description, determine the following:

- What QSIT Level inspection is anticipated (Level 1, 2, or 3)
- What are the reasons for you selection?

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System

Factors to consider

Inspection Type	Internal	External
• Class • History	• Trending • Products	• Product Specific • Enforcement

Have you assessed and addressed all potential internal and external compliance risks?

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System: Inspection Type

What are the major subsystems that you need to prepare for in your inspection?

Three remaining subsystems

- Facilities and Equipment Controls
- Materials Controls
- Documents / Records/Change Controls

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System: Inspection Type

What are the major subsystems that you need to prepare for in your inspection?

Surveillance

- CAPA + PP&C or Design Controls
- EIR documents selection and rationale

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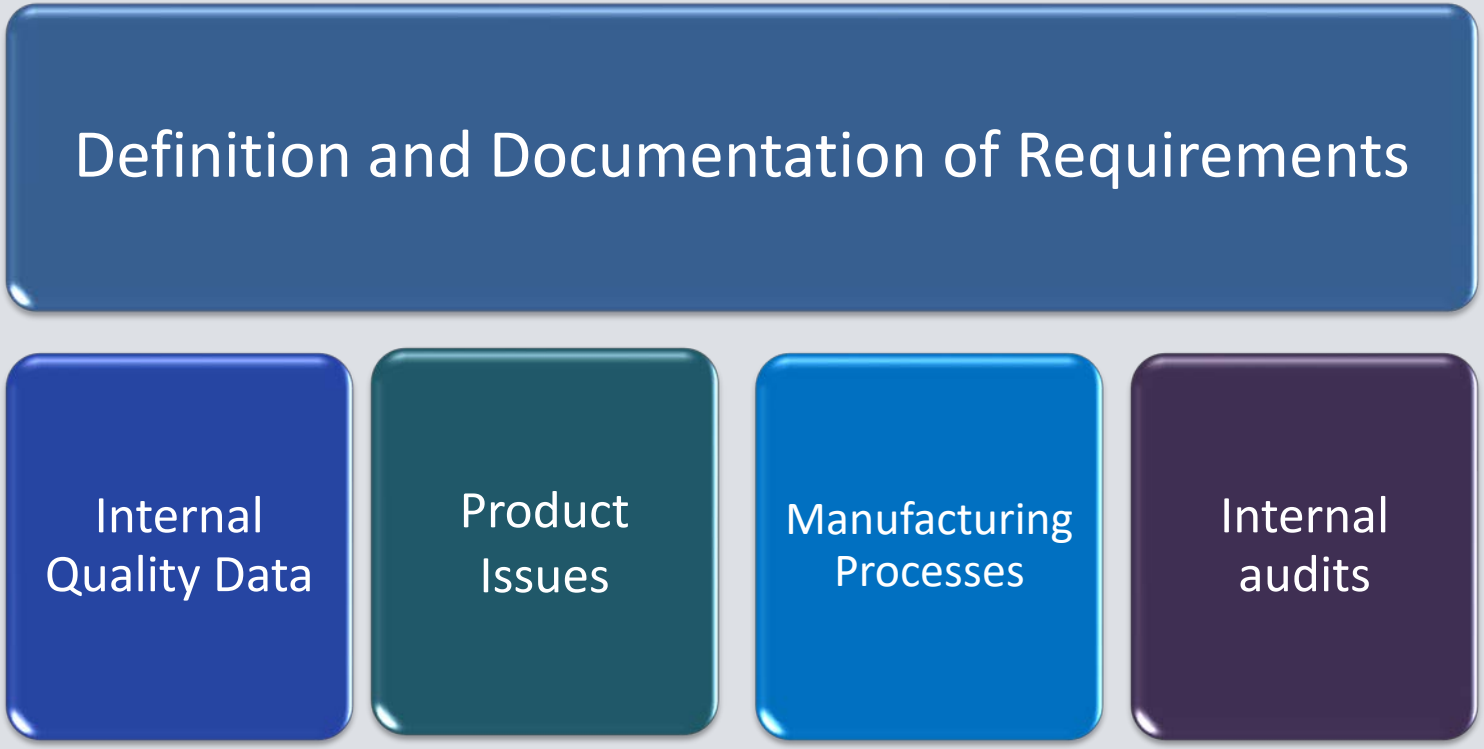
System: Internal Factors



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System: External Factors

Post Market	• Product performance in the field
Risk Decisions	• Where do you make risk decisions • Rationale for MDR, device correction
Enforcement Trends	• Where has the bar been raised • Understand how it applies • Where do you have similar findings

Are you aware of all the current trends as they specifically relate to your products?

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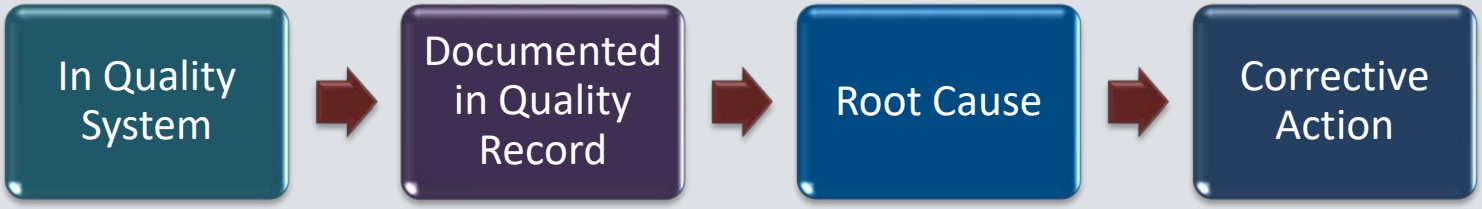
System: External Factors

- *What do I do if my company has a similar or same issue as recent 483 or warning letter?*



Demonstrate through objective evidence

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System: Outcomes

System review Outcomes

- Identified key QS areas for preparation
- List of targeted topics for each QS
- Product focus
- Identify needed actions

Have you reviewed your processes with a critical eye, viewing them from the FDAs perspective?

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Common Mistakes

Internal

- Empty CAPA
- Internal audit findings unaddressed
- Unaware of compliance gaps
- Actions do not match risk

External

- Companies are unaware
- Failure to keep up with new requirements
- An investigator cannot find this
- Complacency because of past success

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Support Process

Factors to consider

QS Requirements	Logistics	Records
• Procedures • Documents • Records	• Process defined • Team	• Record types • Format • Retrieval

Do you have an established process to fulfill the investigator's requests?

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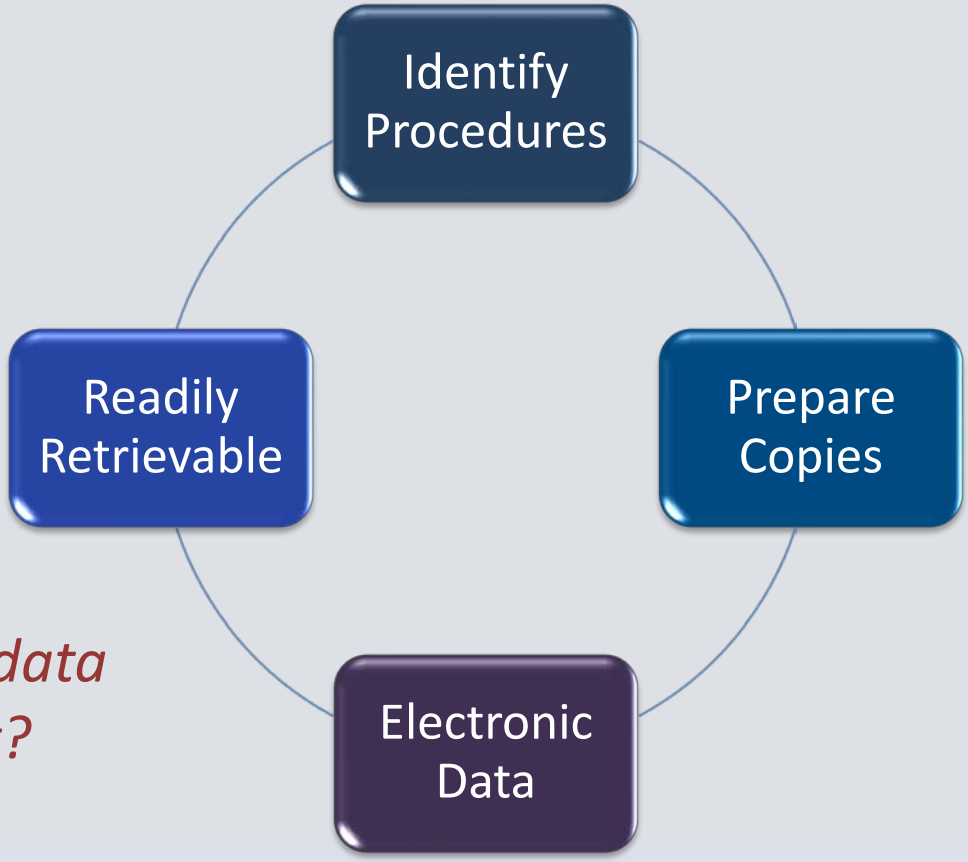
Support Process

- Quality System Requirements and records



Are you ready to provide data in an electronic format?

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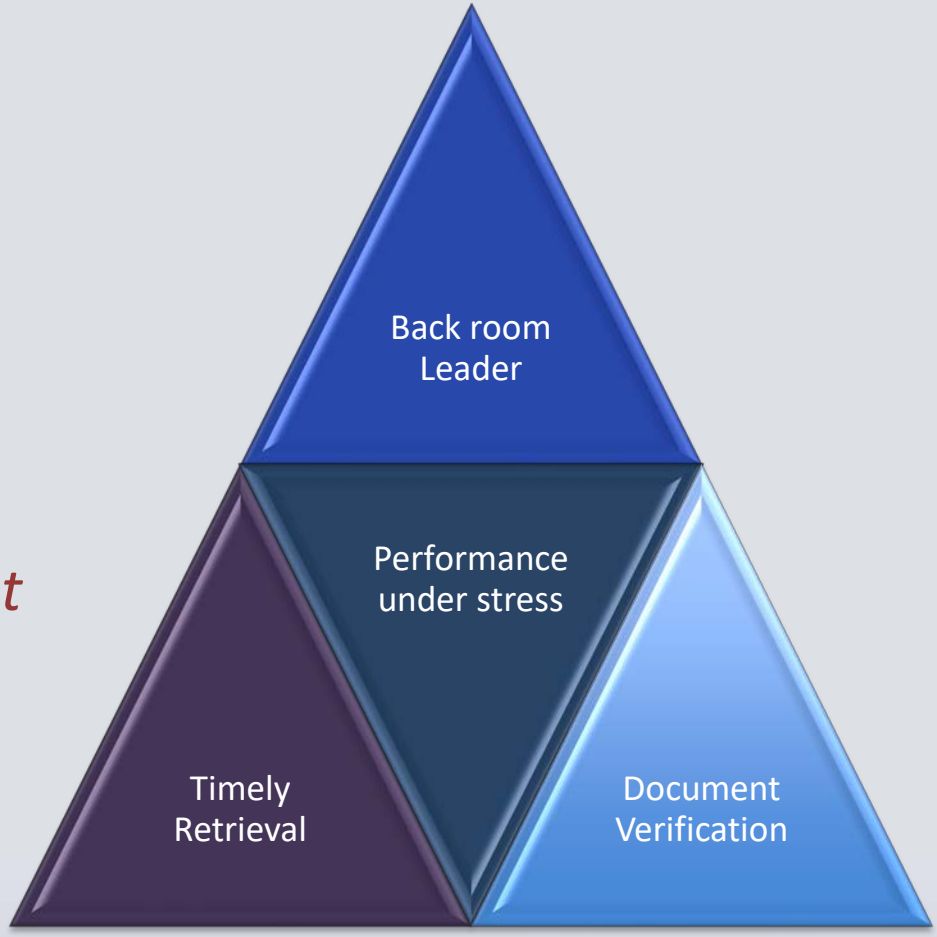
Support Process

- Logistics

Do you have a trained inspection support team in place and is your management team prepared?



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Support Process: Outcomes

- Procedure list
- Key records and documents list
- Back room lead identified
- Defined team roles
- Process for electronic data
- Challenge your process

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Common Pitfalls

- Failure to prepare documents
- Failure to control documents
- Lack of verification of requests
- Failure to review documentation during preparation
- Unable to provide data in electronic format
- Requests cannot be filled in a timely manner

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Subject Matter Experts

Factors to consider

Organization	Preparation	Skill Sets
• Key positions • Management Representative	• Identified SMEs • Align to QS • Simulated Inspections	• Competency • Performance under stress

Are you confident that all of your employees can competently answer the FDA's questions and provide clear explanations of your processes and quality records?

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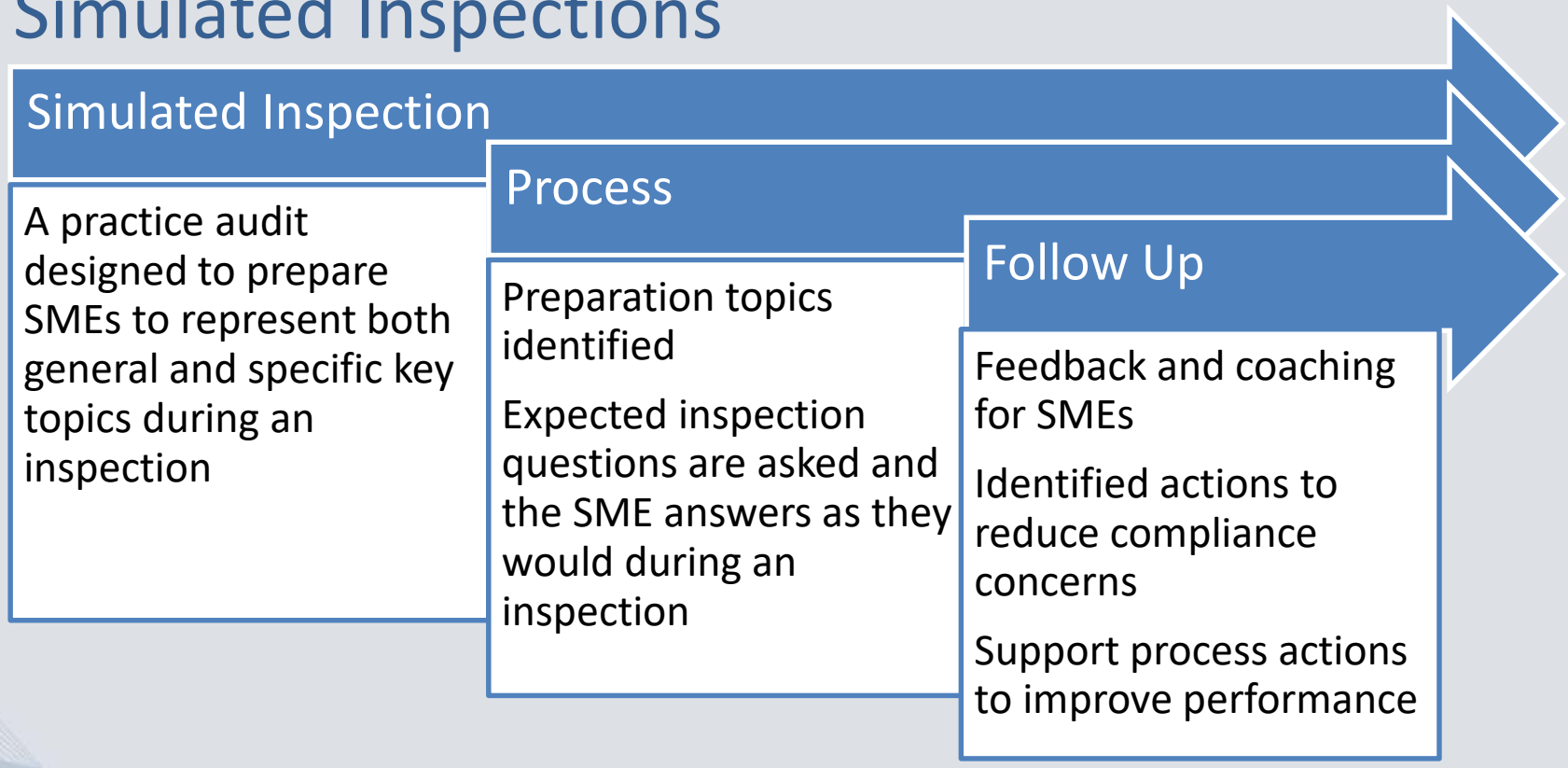
Subject Matter Experts

Simulated Inspections



Additional sessions are held until the topic is ready

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Subject Matter Experts

Outcomes

- SMEs aligned to topics
- Understanding of SME performance
- Practice sessions and follow up
- Track progress until ready

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Common Pitfalls

- Assumption SMEs are Prepared
- SME is the person who knows the most
- Job competence = SME competence

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The Three Ss: Plan

System Requirements

Support Plan

Subject Matter Experts

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The Three Ss: Plan

System Requirements

Sub System	Key Internal Factors / Actions	Key External Factors / Actions
Management Controls	Internal Factors: 1. 2. 3. 4. Actions 1. 2. 3.	External Factors: 1. 2. 3. Actions 1. 2. 3.
CAPA	Internal Factors: 1. 2. 3. Actions 1. 2. 3.	External Factors: 1. 2. 3. Actions 1. 2. 3.
Design Controls	Internal Factors: 1. 2. 3. Actions 1. 2. 3.	External Factors: 1. 2. 3. Actions 1. 2. 3.
Production and Process Controls	Internal Factors: 1. 2. 3. Actions 1. 2. 3.	External Factors: 1. 2. 3. Actions 1. 2. 3.

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The Three Ss: Plan

Support Process

Logistics	Support Team	Request Process

Subject Matter Experts

	Identify SMEs	Action Plan for Preparation
Organization gaps	1. 2. 3. 4.	1. 2. 3. 4.
Critical Topics	1. 2. 3. 4.	1. 2. 3. 4.

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Breakout: Three S Inspection Plan

Based on the device company descriptions, work with your team to develop a three S inspection plan

1. What is the inspection type?
2. Identify the sub-systems that will be focused on?
3. Develop Plan for each of the three Ss:
   - Quality **S**ystem
   - Support
   - SMEs

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Conclusions

If you were notified of an inspection today, would you be able to pass with flying colors?

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Conclusions

QSIT Preparation: The Benefits

- Organized approach aligned with FDAs approach
- Vulnerabilities are addressed and rehearsed
- Prevent unexpected issues
- Independent and unbiased review
- Experiential learning is more effective

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Are You Ready...10 Key Questions

1. Have you assessed and addressed ***all*** potential internal and external compliance risks?
2. Are you aware of ***all*** the current inspection trends as they ***specifically relate to your products***?
3. Have you reviewed your processes with a critical eye, viewing them from the ***FDA's perspective***?
4. Do you have a trained inspection readiness team in place and is your management team prepared?
5. Are you confident that all of your employees can competently answer the FDA's questions and provide clear explanations of your processes and quality records?

continued…

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Are You Ready...10 Key Questions

6. Do you have an established process to fulfill the investigator's request?
7. Has an independent third-party objectively assessed your vulnerabilities?
8. Are you ready to provide your data in an electronic format?
9. Do you have strategies in place to handle potential compliance vulnerabilities during an audit?
10. If you answered yes to all of the above, you are ready and would be able to pass with flying colors!

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References

- 2016 Annual FDA Medical Device Quality System Data: https://www.fda.gov/downloads/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cdrh/cdrhtransparency/ucm554548.pdf
- Other useful links on FDA website:
  - Inspection guides: http://www.fda.gov/ICECI/Inspections/InspectionGuides/default.htm
  - Investigation Operations Manual (IOM): http://www.fda.gov/ICECI/Inspections/IOM/default.htm
- BioTeknica Information:
  - Website: http://www.bioteknica.com/fda-irs/
  - Email: InspectionReadiness@Bioteknica.com
  - Phone: 305-764-3659

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Questions

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