Breakout: QSIT Application

Scenario

PDQ Medical Device Inc. has just completed a Level 1 QSIT inspection which covered CAPA and Production and Process Control. The design control subsystem was not covered and a significant gap in implementation of the design transfer procedure that multiple personnel at the company are aware of was not recognized during the inspection. This issue has been cited in repeat findings from the internal audit program, which have gone unaddressed. The inspection concludes with no 483s issued. The President of the business announces that the company is substantially compliant because there were no 483s.

Do you agree or disagree with the President's statement?

Should the company address the design transfer issue?

Discuss your rationale as a team. Select one Team member to document your rationale and share with the group.

Breakout: Determination of Inspection Type

- Company 1: The Company manufactures Class II orthopedic devices and is located in the United States. The last inspection was May 2016 and was a QSIT level 1 inspection that covered CAPA and Production and Process Controls. The company had several 483 findings, related to CAPA, MDR, and control of nonconforming material. The company responded to the findings and they received the EIR from their inspection in September 2016.

- Company 2: Company 2 manufactures Class II, III In-Vitro Diagnostic Device test reagent kits including HIV screening and associated instruments that read, and provide results in a hospital laboratory. They are located in the United States. The last inspection was a QSIT Level 1 in August of 2016. However, because of multiple findings and concerns the inspection expanded to a level 2 inspection which resulted in 10 findings across multiple subsystems and the company received a warning letter in October of 2016. The company responded to the warning letter and has been providing monthly updates on the progress of their corrective actions.

- Company 3: Company 3 manufactures Class I devices such as bandages, and wound dressings, and is Located in Ireland. The company has not yet had an FDA inspection.

Use the table below to document the anticipated QSIT inspection type for each company based on the descriptions above. Document the rationale for your decision.

	Company 1	**Company 2**	**Company 3**
Device Classification			
Compliance Status (NAI, VAI, OAI)			
Anticipated inspection class			
Rationale for inspection type selected			

Breakout: Develop QSIT Three S Inspection Readiness Plan

Instructions

For each of the three fictional medical device companies develop a three S inspection readiness plan.

1. Determine anticipated sub-systems that could be covered during the next QSIT inspection.
2. For the sub-systems selected, document key internal and external factors for preparation.
3. Determine key actions for the inspection support process
4. Develop plan for SME preaparation

Reference: Compliance Trends

Top 10 Most Frequent Quality System Warning Letter citations for Device Manufacturers CY 2016:

CAPA

- CAPA Procedures 820.100 (a) Procedures for corrective and preventive action have not been adequately established
- Complaint Procedures 820.198(a) Complaint handling procedures for [receiving] [reviewing] [evaluating] complaints have not been [established] [defined] [documented] [completed] [implemented].
- Nonconforming product 820.90(a) Procedures have not been [adequately] established to control product that does not conform to specified requirements.

Design Control

- 820.30(g) Procedures for design validation have not been [adequately] established.
- Design validation 820.30(i) Procedures for design validation have not been [adequately] established.

Management

- Quality Audits 820.22 Procedures for quality audits have not been [adequately] established.

Production and Process Control

- Calibration 820.72(a) Procedures to ensure equipment is routinely [calibrated] [inspected] [checked] [maintained] have not been [adequately] established.
- Purchasing Controls 820.50 Procedures to ensure that all purchased or otherwise received product and services conform to specified requirements have not been [adequately] established.

DOC

- Device History Record 820.184 A device history record has not been [adequately] maintained.

Company 1 Profile:
The Company manufactures Class II orthopedic devices and is located in the United States. The last inspection was May 2016 and was a QSIT level 1 inspection that covered CAPA and Production and Process Controls. The company had several 483 findings, related to CAPA, control of nonconforming material, MDR, and supplier control. The company responded to the findings and they received the EIR from their inspection in September 2016.

Internal Factors:

- Internal audits have been conducted according to schedule. There have been some findings related to design control with respect to Design Transfer. The company launched a new product, the Wonder Knee in 2013. During an internal audit it was discovered that specifications related to one of the manufacturing processes did not transfer according to the design validation.
- There have been some internal failures in Wonder Knee manufacturing based on incorrect dimensions.

External Factors:

- There have been no recalls and two device corrections, one reported, one not reported since the last inspection.
- The MDR procedure was updated in response to the 483, and there have been some late MDRs.

Support Process:
During the last inspection in 2016 Company 1's support room was run by the Director of Operations, who has moved on to another company. The new Director has been in the job for 6 months. The Director of Quality, who is the management representative, was in the inspection room with the investigator during most of the inspection in 2016, and remembers that there were some documents that were incorrect when they came into the room. She talks to the personnel who were in the support room during the last inspection to get their perspective on how things went. The information the support room team shared is as follows:

- It was difficult to pull an electronic list of all CAPA and complaints.
- The copier broke down
- The room was very small and it was hard to move around and keep track of the documents.
- The other Directors at the site came into the room and all were giving advice

The Director of Quality also remembered that at times there were decisions made that were different than what she and the previous Director of Operations had decided. It was not always clear how that happened and they were so busy, she did not have time to follow up on that.

Subject Matter Experts:

- The organization structure at the manufacturing site consists of a Site head, who all resources report to. There is a senior staff consisting of directors for each of the main areas (Operations, Quality, Research and Development, Field Service, and Human resources). Each of the directors has managers who report into them. The Director of Quality, who is the management representative reports in to the Vice President of Quality for the Business (located at headquarters).
- The Director of Operations reports directly to the site head, has been in the job for 6 months and was not present for the last inspection.

Company 2 Profile:

Company 2 manufactures Class II, III In-Vitro Diagnostic Device test reagent kits including HIV screening and associated instruments that read, and provide results in a hospital laboratory. They are located in the United States. The last inspection was a QSIT Level 1 in August of 2016. However, because of multiple findings and concerns the inspection expanded to a level 2 inspection which resulted in 10 findings across multiple subsystems and the company received a warning letter in October of 2016. The company responded to the warning letter and has been providing monthly updates on the progress of their corrective actions. The actions were all completed by September 30, 2017.

Internal Factors

- One of the findings in the 2013 inspection was the quality audit procedures did not include requirements that ensure auditors do not have direct responsibility for the matters being audited.
- There are some late CAPAs
- Process monitoring is performed for manufacturing processes. Processes are operating in a state of control with one exception. There is a trend the conjugation process related to adjustments.
- Manufacturing nonconformances are trended by area. There is a spike in nonconformances in the conjugation area.

External Factors:

- There was a device correction for the HIV assay for false positives. Product was removed from the field. The root cause was a change in raw material made by the vendor but not communicated to the company and resulted in false positives. A corrective action was made and implemented.
- There was a finding from the warning letter that the company was not reporting device corrections that had a risk to health (the above correction occurred after the inspection and was reported to FDA).

Support Process Factors:

During the last inspection, the support room was run by the Operations Quality Manager. The Director of Quality has been in his job for 6 months and was not present during the last inspection and neither was the current Site Senior Director. The Quality Director met with his Operations Quality Manager who was in charge of the support room during the last inspection to see how things were handled. The information provided by the Operations Quality Manager was as follows:

- They were able to keep up fairly well with the investigators requests
- They did have some problems with mistakes in some of the documentation that went into the room (a procedure had a missing page, and another document went in with pages out of order)
- They were able to easily pull the electronic lists requested for CAPA and nonconformances but there are new IT systems that were recently implemented and they are not sure how to pull data or generate reports from the new system yet.
- They had a problem with the copy paper in the last inspection, they ran out of paper and had to send someone to Staples to purchase some more, this delayed requests for about an hour.
- They have a data base that is used to document requests, and this is done directly from the inspection room.

- Many of the requests coming from the inspection room were difficult to understand, and were being sent by different people.

Subject Matter Experts:
The organization structure at the manufacturing site consists of a Site Senior Director who all resources report to. Most of the senior level managers have been in their positions less than one year, including the Site Director. The Director of Quality is the management representative, but was not present during the last inspection. There is a senior staff consisting of directors for each of the main areas (Operations, Warehouse and Distribution, Quality, Product Development, Human Resources). Each of the directors has managers who report into them.

Company 3 Profile:
Company 3 manufactures Class I devices such as bandages, and wound dressings, and is Located in Ireland. The company has not yet had an FDA inspection.

Internal Factors:
- The company has quality system procedures in place
- The company hired in a third party consultant to perform a QSIT assessment where some of the Quality procedures (CAPA, complaint handling) were found to be deficient in their requirements.
- There are internal audit findings related to not getting to root cause as well as some findings from their registrar.

External Factors:
- There have been no device corrections
- MDRs are reported, but there are a low number

Support Process Factors:
The Company has not used a support room during its EU related assessments. The company has an electronic system it uses for complaints and CAPAs, but has not had to extract or provide a listing electronically.

Subject Matter Experts:
The company has a Vice President of Operations that all employees report to. There is a senior staff with Directors of Quality, Operations, Product Development, and Human Resources. There is not a management representative identified. There are no personnel at the site who have been through an FDA inspection. The company is headquartered in the United States.