

# Case Study: Management Representative

- 3 different companies have appointed people in the following positions as management representatives:
  1. Vice President – Sales
  2. Vice President – Quality Assurance/Regulatory Affairs
  3. Vice President - Production
- What questions or concerns, if any, do you have about each appointment?

# Case Study: Component Change

- Superior Devices, Inc., just developed a specification for a new component for an existing device, using design controls. The change is necessary because there have been failures involving this component.
- What other documents, procedures, etc. might be affected by the changed specification?

# Changes to other documents?

- Design history file
- Device Master Record
- Device specifications
- Component specifications
- Purchasing documents
- Incoming inspection/test procedure
- Assembly procedure
- In-process inspection/test procedure
- Finished device inspection/test procedure
- Installation/servicing procedure

# Case Study: Component Change

- Superior Devices, Inc., is purchasing the same component from a new supplier because the old supplier is now out of business. The effective date of the change is “when the stock of old components has been used up.”
- Is the effective “date” acceptable? Why or why not?
- What if the component change was being made because the component was redesigned to address component failures that led to device failures?

# Case Study: Testing Later Rather Than Sooner

- Perfect Devices does not test in-process electronic assemblies because testing is time-consuming and expensive. Instead they conduct extensive finished device testing, which enables them to identify defective assemblies and replace them.
- Is Perfect Devices violating the Acceptance Activity requirements because they do not test in-process assemblies?
- Why or why not?

# Case Study: Models for Manufacturing

- Certain devices at Superior Devices, Inc., are assembled by hand. Many employees do not speak or read the local language. To help employees understand how to assemble the devices, models showing the components, the order of assembly and the finished assemblies are at each work station.
- When assembly procedures or components are changed, how should changes for the models be handled?

# Case Study: Personnel Requirements

- During an audit of Superior Devices, auditor Sleuth noticed a work station in the clean room with a box of tissue and a wastebasket filled with crumpled tissues.
- If you were auditor Sleuth what would you want to check into further regarding this situation?

# Case Study: Process Validation

- During an audit Sarah Sleuth reviewed the validation of a wave soldering process for a new device. There was no documentation of installation qualification for the wave soldering machine. When she raised this with the company, they told her they have been using a wave soldering machine for 5 years without problems and that should be adequate qualification of the wave soldering machine.
- Is 5 years of use an adequate installation qualification? Why or why not?

# Case Study: CAPA

- Sixteen customers have returned electronic monitors to OK Devices because the monitors did not work when they were taken out of the box and plugged in. OK immediately shipped replacement monitors to the customers with a note of apology, documented this action and closed the CAPA on this incident for the CAPA system.
- Has OK taken an adequate action? Explain why or why not.
- What should auditor Sleuth do?

# Case Study: Complaint Handling

- Perfect Devices, Inc. has received 10 complaints alleging that their device sparked several times before ceasing to function. PD investigated the first 3 complaints and identified the root cause of the problem. They are working on a redesign to eliminate the problem. They have not investigated the 7 remaining complaints.
- Is not investigating the 7 remaining complaints acceptable? Why or why not?

# Case Study: Complaint Handling

- Regarding the previous case study, Perfect Devices, Inc. identified the cause of sparking and failure to function after investigating 3 of 10 complaints, Mary Jones, who reviewed the complaints, documented the reason for not investigating 7 of the complaints with the statement: “Similar to complaints #XXX, XXY, and XXZ for which cause was identified. CAPA initiated 3/8/05.”
- Is this acceptable? Why or why not?

# Case Study: Purchasing Controls

- Perfect Devices, Inc. (PD) just found out their supplier of injection molded polystyrene plastic components is going out of business. They need a new supplier quickly. Two years ago they purchased latex components from Raja Rubber, Inc. Raja Rubber also makes injection molded polystyrene components.
- Can PD rely on their previous supplier evaluation of Raja Rubber, or should they perform a new evaluation?
- Explain your answer.

# Case Study: Maintaining Records

- Sleep Tite, Inc, makes hospital beds. During an audit, auditor Sarah Sleuth finds that Sleep Tite has destroyed all required records over 5 years old.
- Should auditor Sleuth write a non conformity for failure to maintain records for the required length of time?
- What else do you need to know about this situation?