The Case of the Missing Cavity

May 1, 2019

Phillip Pontikos, Ben Dastoli
Office of Regulatory Affairs
U.S. Food and Drug Administration

Steve Neidelman
King and Spalding

David Elder
Greenleaf Health

Adam Saltman
CDRH
Objectives

• To work as interactive teams on a case study to identify pertinent steps to take during complaint investigations.

• To discuss and review quality system decisions related to nonconforming product, complaints, and adverse events.
Case Study

• Each group will deliberate throughout this case study and will document their answers.

• A group discussion will occur for each question.
Case Study

• Your firm manufactures a single use Class III injectable device. This device has been manufactured for several years. The device consists of a drug component that is injected directly into the body to prevent death or serious injury
Case Study

• The device consists of an injection mechanism that is triggered by pushing a button that is spring loaded that injects a needle with drug product delivery into the human body.

• This product is under shortage and you are one of only two manufactures of this product. You manufacture approximately 60% of the available supply which is approximately 2 million units a year.
Case Study

• Over the last year, your firm has become aware of 15 complaints of the product not properly injecting. The complaints range from the needle not firing when the button is depressed, bent needles after the button is depressed but before injection into the patient, and difficulty in the device needle firing when the button is depressed. None of these complaints at this time have led to death or serious injury.
Case Study

• You become aware of complaint #16 which is a complaint of the needle not firing only this time, due to the failure, the patient was not able to receive the drug product and the patient subsequently died. The device is implicated due to this malfunction.

• The device was saved by the hospital and is available for examination.
Case Study Question #1

• What actions would you take at this time?
Case Study

• You receive the complaint product back for investigation. Your investigation finds that the device has a small partial occlusion at the firing end that the needle must pass through before exiting. This occlusion appears to be flash from the plastic component used. This occlusion can only be seen upon disassembly of the firing mechanism.

• The plastic component is manufactured by a contract manufacturer who also assembles the firing mechanism of the device for you.
Case Study Question #2

• What actions would you take at this time considering the facts you know at this time?
Case Study

• Your firm performed an audit of the component manufacturer. You find that the component is manufactured using injection molding. The component is made by using a mold that consists of 10 cavities each cavity manufacturing one component for a total of 10 components manufactured during each injection molding shot.
Case Study

• Each cavity molds the cavity number onto the component. You determine through examination of the complaint device that the component has the #5 molded on the product denoting it was molded in cavity #5.
Case Study

• At the same time you are performing the audit at the supplier, complaint #17 arrives at your firm. This complaint alleges that the device did not fire and subsequently the patient did not receive the drug product and died.

• The device was returned and your investigation found that there was a partial occlusion at the firing end that the needle must pass through before exiting. This occlusion appears to be flash from the plastic component that is used. You also find that the plastic part has a #5 molded onto that part.
Case Study Questions #3 and #4

• What actions would you take at this time?

• What challenges would you expect?
Case Study

• Since both complaint samples were from cavity #5 and because this product is under shortage, you elect to sort and reject parts made with cavity #5 until you can determine a cause. At this time, you have not determined a cause.

• Do you agree with this decision?
Case Study

• Within the next month, you receive an additional 10 complaints alleging the needle not firing and bent needles.

• Upon examination, you find that the suspect component in those devices come from cavities #1, #5, and #8. No death or serious injury occurred.

• How do the above facts impact your decisions? What steps would you take at this time?