FDA Mock Inspection

Featuring:

- Phillip Pontikos as: Director of RA/QA, VP at Spinal Tap
- Benjamin Dastoli: FDA Investigator
- Laureen Geniusz: FDA Investigator
- Narration/commentaries by: Steven Niedelman and Monica Wilkins
In response to two separate class I recalls initiated in the past year, CDRH has requested a for-cause inspection of Spinal Tap, a manufacturer of sterile, class II spinal implants. Each of the recalls was regarding reports of product contamination or sterility issues.

FDA Investigators Benjamin Dastoli and Laureen Geniusz are assigned to perform the Inspection.
Recalled Devices
Starting the Inspection

• FDA- 482 Issue to the most responsible person available at that time
• Collecting/reviewing paper and electronic records and databases
• Updates on FDARA
Tour / Inspecting the facility

- Understanding the products and the flow of the entire process for incoming to release

- Evaluating how the firm captures/manages non-conformances

- We speak with employees involved in the operations.

- We choose higher risk products and processes for review
Management Controls

• We review trending or analyses of quality data sources that go into the reviews
• Looking at how the data is reviewed and if meaningful data is being analyzed
• Along with the Quality System Regulations, we are evaluating employees knowledge, truthfulness, cooperation and commitment. Avoid telling Investigators what you think they want to hear, but focus on verifiable FACTS.
CAPA (corrective and preventive actions)

- We do not always randomly sample
- We have the authority to review quality data which is submitted to Management Reviews and the CAPAs which may result from the Reviews
- During review of quality systems, we routinely use linkages to other systems for review.
Design Controls

• We evaluate the adequacy of verification and or validation activities commensurate with the risk level for the associated potential hazards.

• When applicable, we attempt to link post market data, such as complaints or recalls back to possible issues with design and robustness of the design process
Production and Process Controls

• We review data across multiple data sources to try to “paint the picture”

• We are noting processes used during manufacturing such as gluing, cleaning or soldering which typically require validation

• We select processes for review based on CAPA indicators, risk, by assignment, not previously covered.

• Report recalls, MDRs as required by regulations, not as an “over-abundance of caution”. May send a message that the firm does not understand significance.
Purchasing Controls

- You as the owner of the device are ultimately responsible for the sterility of the device along with any other validated processes which are being performed by contract manufacturers.
- Your sterility assurance level (SAL) is based on the condition of the devices (bioburden, particles, etc.) supplied during validation. You should be able to provide documentation to show that current processes have not introduced additional challenges which may affect the sterilization process.
Collecting Affidavit/Shipping Records

• Typically collected when FDA is considering actions against the firm such as Warning Letter, Untitled Letters or Regulatory Meetings.

• To document interstate commerce of a component coming in or a finished product which was distributed. We regulate products which have been or will be distributed in interstate commerce. This is assumed in the FD and C act.
Closeout Meeting

Firm has the right to annotate, but we may not be able to use that annotation if we find it is not accurate.

Not necessary, but we may ask to send a copy of responses to the FDA-483 to the Investigators also.

Typically, contact with the firm stops once we leave the firm and compliance branch becomes the primary contact.
Conduct during the FDA Inspection

We understand that conduct during FDA inspections can be a sensitive subject. Our best advise and to avoid FDA leaving with misconceptions
Questions??