INVESTIGATOR INSIGHTS

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OBJECTIVE

- Categorize and address questions submitted by attendees
- Approximately 100 questions received

General Inspection Questions

- FDAs policy on record review/authority
- Selection of Investigators
- Investigator uniformity
- Observation consistency, 483 threshold
- Scheduling inspections: locations / priorities
- Requirement to disclose reason for inspections (directed/routine)

General Inspection Questions

- FDA authority
- Photographs- FDA policy
- Computerized systems review vs. hard copy
- General walk through on how FDA inspections are conducted

Contract Manufacturers

- Requirements for contract manufacturing and process validations
- Responsibility of risk management
- Responsibility for contract mfr and recall actions
- General requirements for contract manufacturer includes foreign sites

Quality System Regulations

- Design history file review during inspections.
- Finished medical devices in clinical trials which were used as samples and validation testing
- CAPA documentation: investigation of non-conformances, appropriate investigations, actions which do not result in a CAPA

Quality System Regulations

- Do fully verifiable processes require validation? (i.e. machining)
- Difference between Correction and removal (806) and CAPA (820.100)

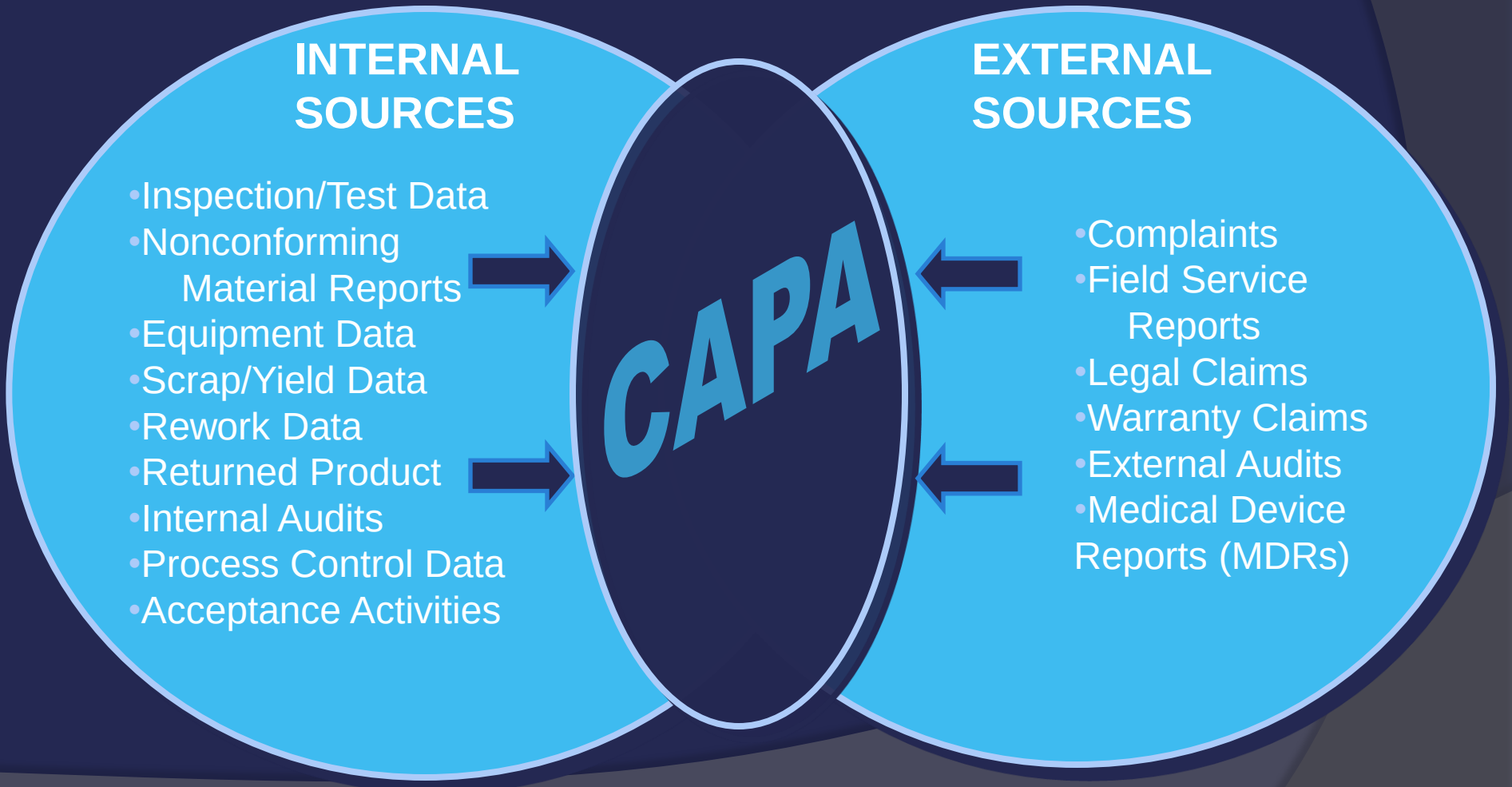
MDRs/Complaints

- General discussion on MDRs and inspectional coverage
- Returned product broken, is this a complaint even if no complaint received
- Difference between customer support and complaints
- Reporting requirements for US agents or non US manufacturer
- Combination products and reporting

Post Market Surveillance

- Monitoring medical device performance after a device is approved or cleared for marketing to identify problems and safety issues that occur during widespread clinical and home use
  - Detect and evaluate problems early
  - Minimize risk
  - Address those problems that may emerge with real-life use
  - Monitor known risks

Data Sources



Post Market Surveillance

What corrective actions (design and process) have been taken regarding this medical device?

Post Inspectional Activities

Establishment Inspection Report (EIR) reviewed by Investigation Branch Supervisor.

- If VAI (Voluntary Action Indicated) or NAI (No Action Indicated)

  - FMD letter sent

    FMD-145 , dated 3/1/1012, states “firm’s with inspectional results that fall with in the scope of this FMD will receive a first party redacted copy of EIR within 30 business days from the date of the “Final Classification” with the goal of 20 business days to be reached within 2 years.”

  - If there is a FDA-483 response, FDA sends a response/ acknowledgement letter per FMD-120.

Compliance Branch Review

- If violative , sent to the Compliance Branch for review.

- Compliance Officer reviews EIR, FDA-483, Documentary Sample, and firm's response, if there is one.

- Determines if the violations meet Situation I in Compliance Program and recommends action

Warning Letter Recommendation

- Direct Reference Warning Letter for 21 CFR Part 820 violations
- CDRH Office of Compliance concurrence with Warning Letter for premarket, MDR, and Correction and Removal violations

Warning Letter

- If the firm's response was received in 15 working days, the response is included in the Warning letter.
- Profiles are updated as Unacceptable.
- Inspection received a final classification as OAI (Official Action Indicated).

Remediation Expectations

- Systemic corrective actions
- Realistic timeframes
- Also need to assess the risk.

Medical Device Recalls

- Contact the Recall Coordinator in the District where the recall will be “controlled”.
- Recalls are classified by CDRH

Medical Device Recalls

- 21 CFR Part 806.10(a)
  - Each device manufacturer or importer shall submit a written report to your FDA district office of any correction or removal of a device initiated by such manufacturer or importer if the correction or removal was initiated:
    1. To reduce the risk of health posed by the device; or
    2. To remedy a violation of the Act caused by the device which may present a risk to health
- 21 CFR Part 806.10(b)
  - The manufacturer or importer shall submit any required report within 10-working days of initiating such correction or removal.

Medical Device Recalls

- 21 CFR Part 806.20
  - Each device manufacturer or importer who initiates a correction or removal of a device that is not required to be reported to FDA under 21 CFR Part 806.10 shall keep a record of such correction or removal.

Exports

- Obtaining Export Certificates
  - CDRH Export Certification and Tracking System (CECATS) http://www.fda.gov/medicaldevices/deviceregulationandguidance/importingandexportingdevices/ucm329896.htm
  - Guidance http://www.fda.gov/RegulatoryInformation/Guidances/ucm122048.htm

Exports

- The District Office becomes involved if a firm's profile is pending unacceptable or is unacceptable and sometimes for "export only" manufacturers.

Affidavits

- Investigations Operation Manual (IOM) section 4.4.8
  - "Statements on various affidavit forms may be obtained from persons who have dealt somehow with the goods sampled, know material facts related to the movement of goods, and/or events affecting their condition."
  - Example of when we obtain an affidavit.

TRANSFER OF OWNERSHIP OF A 510(k)

- A 510(k) may be bought, sold, or transferred. FDA is not involved in transfers of ownership. The new owner should maintain information documenting the transfer of ownership of a 510(k), including any legal transactions that took place, in its 510(k) files.

- The new owner should list the device according to 21 CFR part 807 and the previous owner should delete its device listing. Upon inspection of the firm or upon entry of glove shipments into the U.S., FDA may request a review of documentation of ownership. If the owner is not able to provide the information, FDA may request the owner to submit a 510(k). You may not distribute the gloves until FDA clears the new submission.

- Note that neither a registration nor a listing proves 510(k) ownership. The new owner of the 510(k) should maintain files with documentation proving ownership of the 510(k).

- To avoid problems when importing a device with a transferred 510(k) ownership, FDA recommends that a copy of the specific information relating to the ownership sale or transfer accompany all shipments to the United States. This could be a simple one-page document detailing the transfer transaction.

510(k) Continued

- Companies need to make sure they have all necessary paperwork to document compliance with Quality System Regulations

Questions