Interdependency of Post-Market Surveillance, Risk and CAPA

Presented by:
Phillip M. Pontikos
FDA/ORA/DDFI

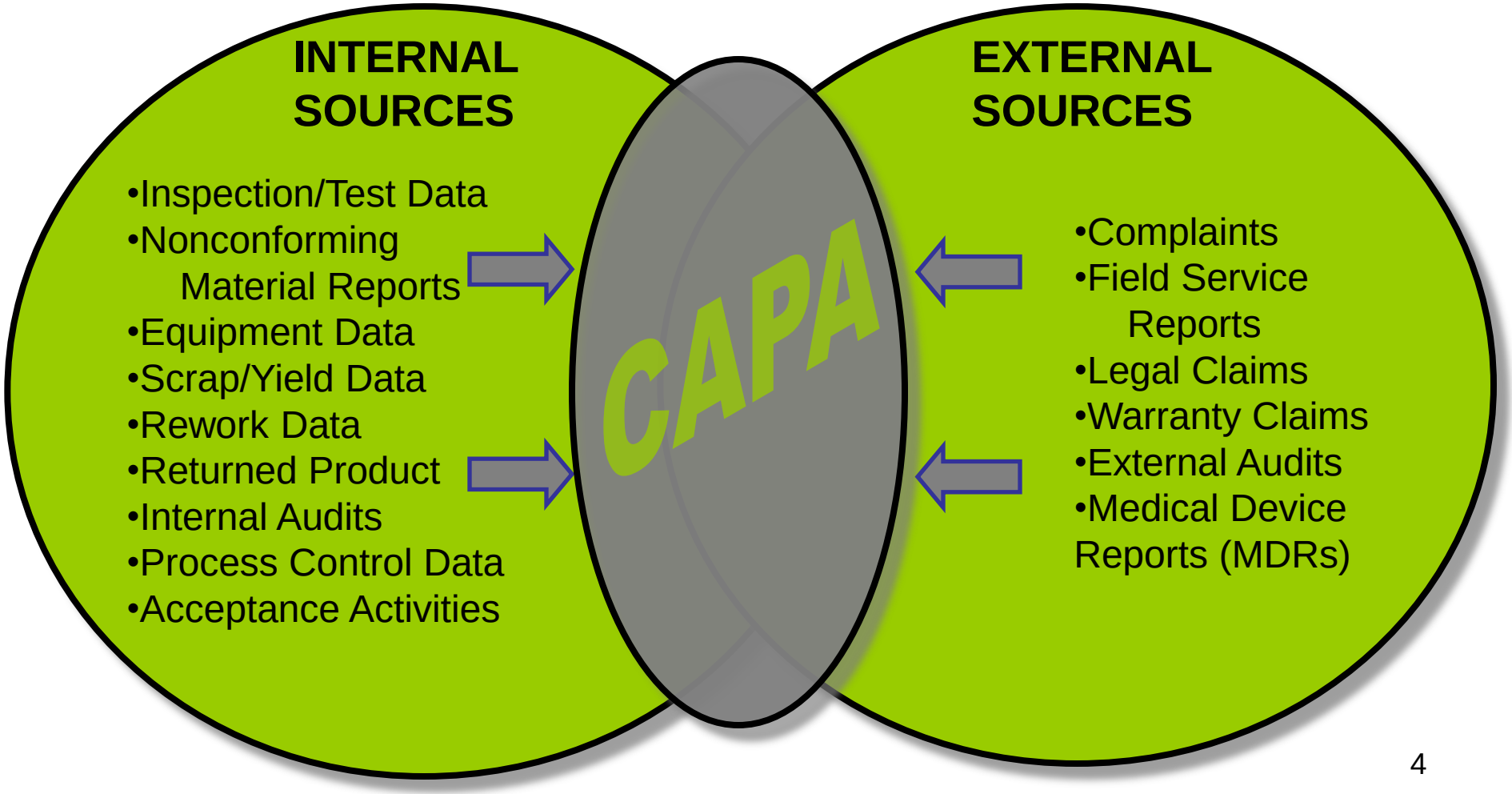
Presentation Objectives

- Discuss Quality System Regulation requirements for post-market surveillance
- Discuss linkages between post market surveillance data and product design
- Discuss data collection and data analysis

Presentation Objectives

- Discuss using risk management during evaluation of post-market data

Data Sources



The CAPA Process

INPUTS

Internal/
External
Sources

ELEMENTS

- Analyze Data, 820.100(a)(1)
- Investigate Cause, 820.100(a)(2)
- Identify Action, 820.100(a)(3)
- Verify/Validate Effectiveness, 820.100(a)(4)

OUTPUTS

Implement Changes, 820.100(a)(5)

Disseminating Information, 820.100(a)(6)

Submit for Management Review, 820.100(a)(7)

Document, 820.100(b)

CAPA Data Analysis – 21 CFR 820.100(a)(1)

Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other **sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems**. **Appropriate statistical methodology shall be employed** where necessary to detect recurring quality problems.

CAPA and Statistical Analysis

"FDA emphasizes that the appropriate statistical tools must be employed when it is necessary to utilize statistical methodology. FDA has seen far too often the misuse of statistics by manufacturers in an effort to minimize instead of address the problem. Such misuse of statistics would be a violation of this section."

61 Fed. Reg. at 52633-52634, Comment 159

CAPA and Risk Management

"FDA agrees that the degree of corrective and preventive action taken to eliminate or minimize actual or potential nonconformities must be appropriate to the magnitude of the problem and commensurate with the risks encountered…FDA does expect the manufacturer to develop procedures for assessing the risk, the actions that need to be taken for different levels of risk, and how to correct or prevent the problem from recurring, depending on that risk assessment."

61 Fed. Reg. at 52633-52634, Comment 159

CAPA and Risk Management

- Risk analysis allows a manufacturer to:
  - Determine priorities
  - Assign resources
  - Determine the severity of impact
  - Determine the depth of investigation

- Common tools
  - Hazard analysis
    - Used early for potential problems
  - Failure Mode Effects Analysis (FMEA)
    - Bottom up
  - Fault Tree Analysis (FTA)
    - Top down

CAPA Data Analysis – 21 CFR 820.100(a)(1)

- Investigators will verify all quality data sources including post-market data are defined and analyzed to identify existing product and quality problems

- Investigators will determine how the data is captured and maintained

CAPA Data Analysis – 21 CFR 820.100(a)(1)

- Investigators will review how the firm categorizes and groups data and performs their analysis
  - Verify the firm is using appropriate analysis techniques
  - Analysis of data should also include a comparison of the same problem type across different data sources

CAPA Data Analysis – 21 CFR 820.100(a)(1)

- Challenge the CAPA system by verifying data received by the CAPA system is complete and accurate
  - Select one or two data sources for review
    - Consider risk and other “indicators” when selecting

CAPA Data Analysis – 21 CFR 820.100(a)(1)

- There is no direct requirement to perform "trending" of data. Trend analysis is one type of data analysis

Complaint Handling – 21 CFR 820.198(a)

Each manufacturer shall **maintain complaint files**. Each manufacturer shall **establish and maintain procedures for receiving, reviewing, and evaluating complaints** by a formally designated unit.

"Evaluating" is determining if the information represents a complaint, and whether an investigation is necessary.

"Investigating" is determining the cause of the problem.

Complaint Handling – 21 CFR 820.198(a)(1) – (a)(3)

- 820.198(a)(1) All complaints are processed in a **uniform and timely** manner;
  - *Only place in 820 with a "timeliness" requirement*

- 820.198(a)(2) **Oral complaints are documented** upon receipt; and

- 820.198(a)(3) Complaints are **evaluated to determine whether the complaint represents an event which is required to be reported to FDA under part 803** of this chapter, Medical Device Reporting.

Review and Evaluation of Complaints 21 CFR 820.198(b)

Each manufacturer shall **review and evaluate all complaints to determine whether an investigation is necessary**. When **no investigation is made, the manufacturer shall maintain a record that includes the reason no investigation was made** and the name of the individual responsible for the decision not to investigate.

No investigation is an option, but MUST be justified!

Required Investigations – 21 CFR 820.198(c)

Any complaint involving the possible failure of a device, labeling, or packaging **to meet any of its specifications shall be reviewed, evaluated, and investigated**, unless such investigation has already been performed for a similar complaint and another investigation is not necessary.

Complaints that are Medical Device Reports (MDRs) – 21 CFR 820.198(d)

Any complaint that represents an **event which must be reported to FDA under Part 803** of this chapter shall be promptly reviewed, evaluated, and investigated by a designated individual(s) and **shall be maintained in a separate portion of the complaint files or otherwise clearly identified** ...

Investigation Record – 21 CFR 820.198(e)

When an investigation is made under this section, **a record of the investigation shall be maintained** by the formally designated unit identified in paragraph (a) of this section. The record of investigation shall include:

- Device Name
- Date Complaint Received
- Device ID/Control Number
- Name/Address/Phone Number of Complainant
- Nature/Details of Complaint
- Dates/Results of Investigation
- Any Corrective Action Taken
- Any Reply to Complainant

Integration of Risk Management

- Forms link between post-market surveillance data, design, production, CAPA
- Should be a fluid process that is integrated within the data sources
- Data and data analysis enable support of risk management decisions
- Awareness throughout organization

Questions?