Interdependency of Post Market Surveillance, Risk & CAPA

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Agenda

Post Market Surveillance

Post Market Surveillance and Product Design

Systematic Collection of Data

Risk Assessments and Investigations (CAPA)

Final Thoughts

Post Market Surveillance...

What Are the Expectations?

Any Requirements?

Post Market Surveillance

"Adverse Event Reporting Alone Cannot Capture All Risks Related to the Use of Medical Devices"

Post Market Surveillance...

- Activities carried out to gain information about the quality, safety, or performance of products placed in the market
- Proactive collection of information
- Distinct from enforcement
- Review of post-market studies
- Clinical trials required as a condition of market approval

Identification of Risks Begins at Design

Factors Important to Risk Assessment

- Device design and manufacture
- Materials
- Device users
- Human Factors
- Medical device systems

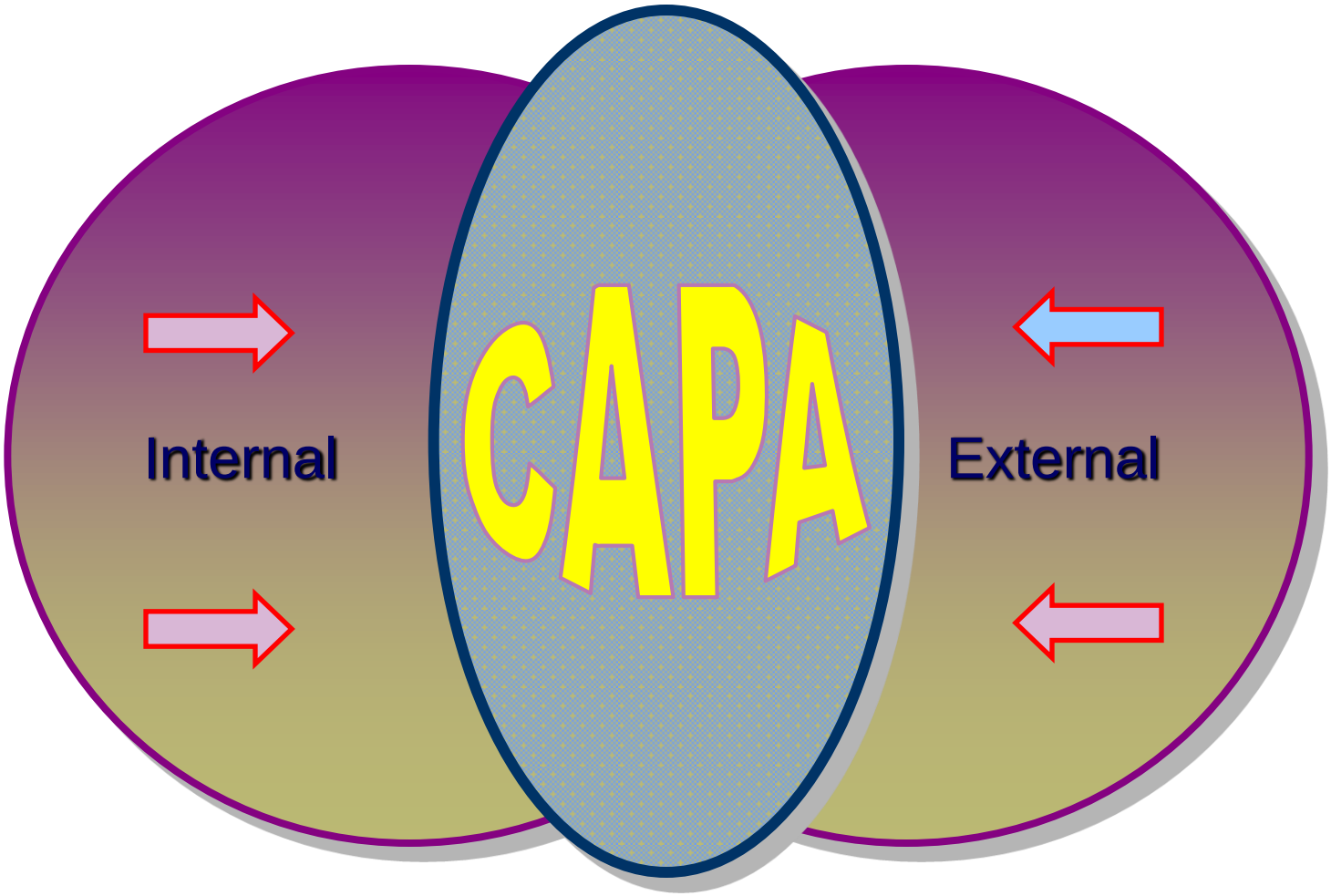
Tools for Risk Estimation

- Failure Mode and Effect Analysis
- Fault Tree Analysis
- Others

CAPA Process

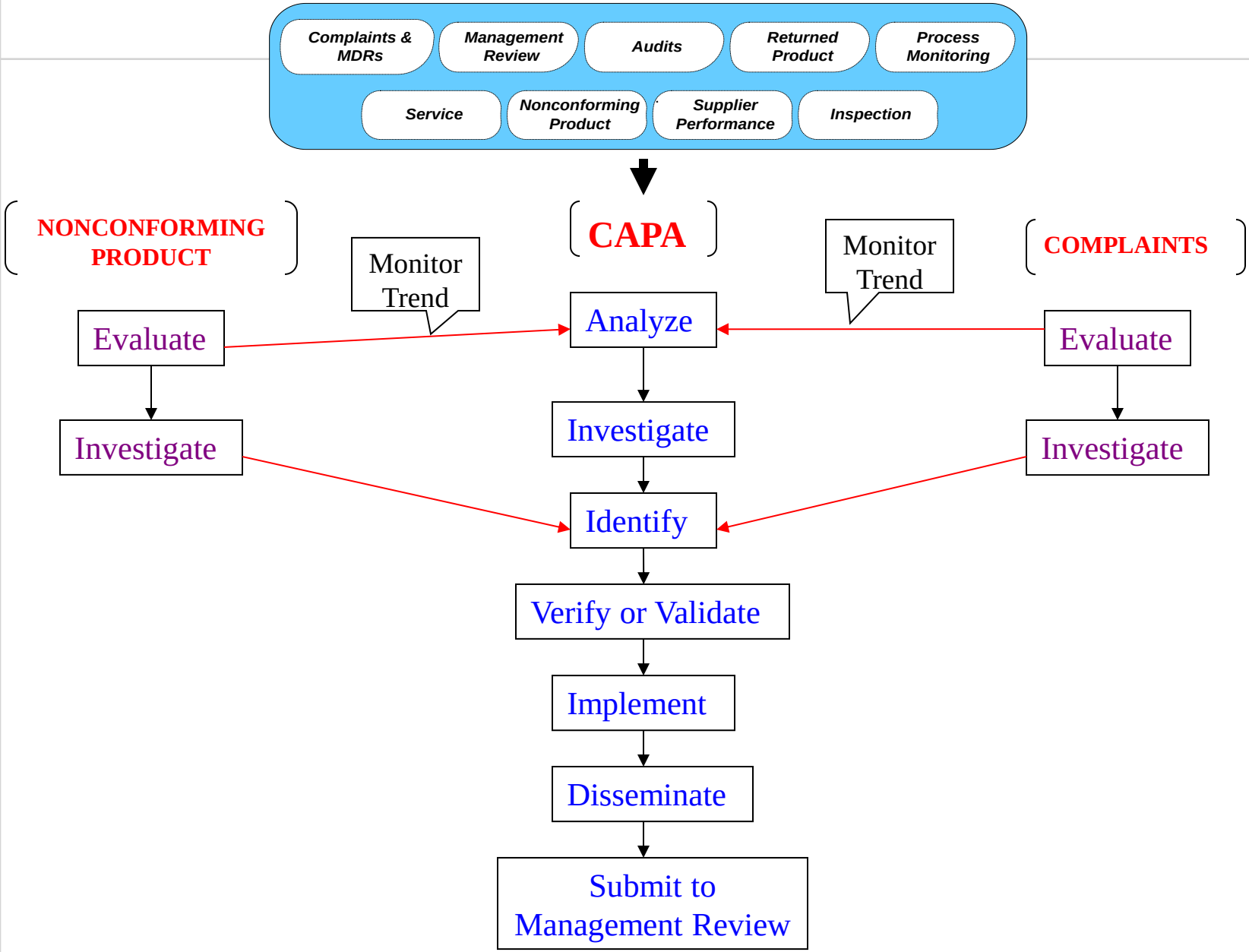
- Organization Structure
- Procedures
- Training
- Process & Systems
- Records & Data
- Maintenance
- Monitoring
- Analysis
- Modification
- Management
- Feedback
- Measured Improvement

Monitoring and Analysis



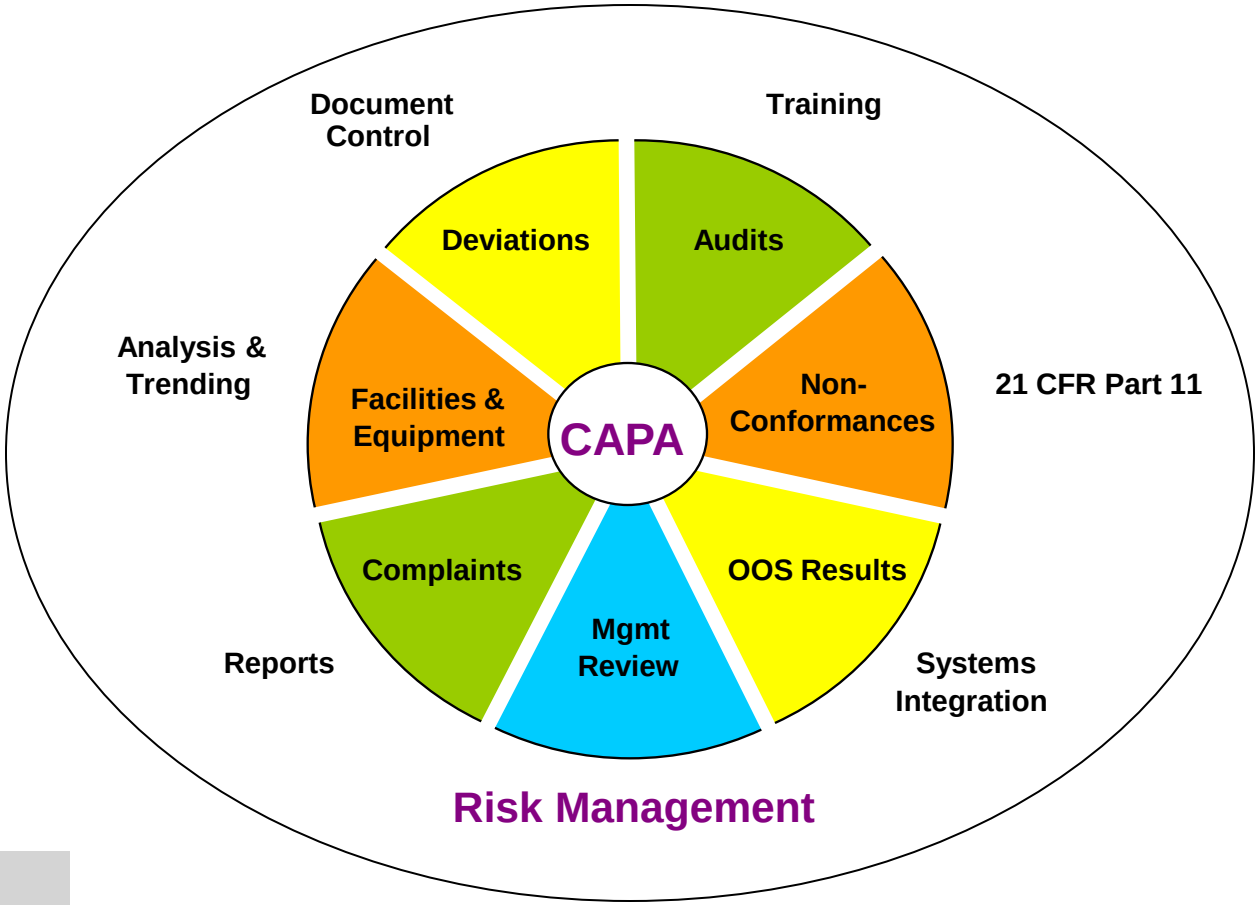
Post Launch Reviews

- Premarket Clinical Trials
  - Comparison
- Product Launch Learnings
  - Marketing and Sales
  - Complaints
- Postmarket Clinical Trials
- Product Performance
  - Investigated Concerns
  - MDRs
  - Complaints
  - Design Changes



Interlocked Concepts

CAPA and Risk Management are central to the implementation of an effective, closed loop, continuous improvement process that focuses on prevention and quality



Closed-loop process control

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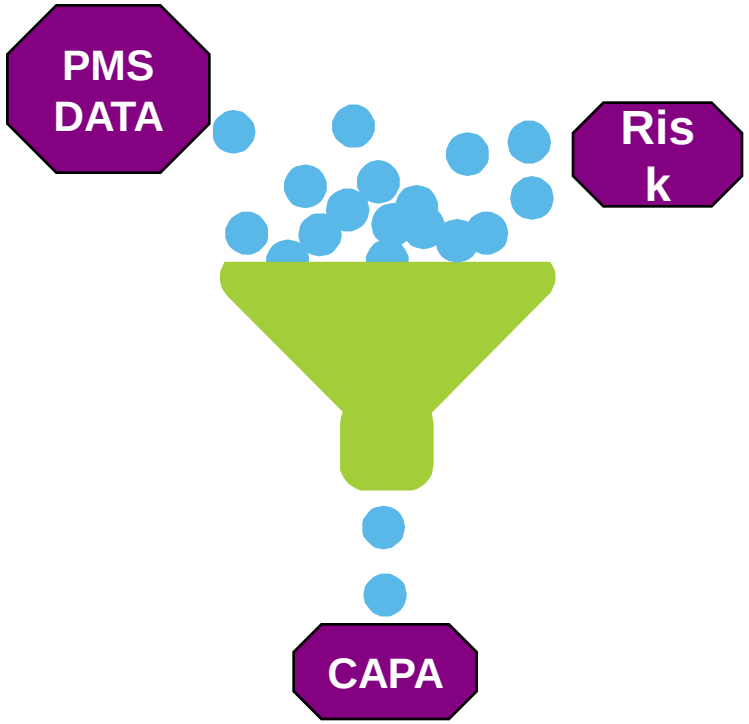

Final Thoughts

- Establish a risk management process
- Identify risks early, mitigate, and monitor
- Engage in postmarket surveillance monitoring as required by regulations
- Collect and analyze external data sources
- Use leading indicators to prevent product issues
- Act on lagging indicators such as complaints, product failures, and adverse events associated with product use
- Establish a PMS program that meets your needs

Questions

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