

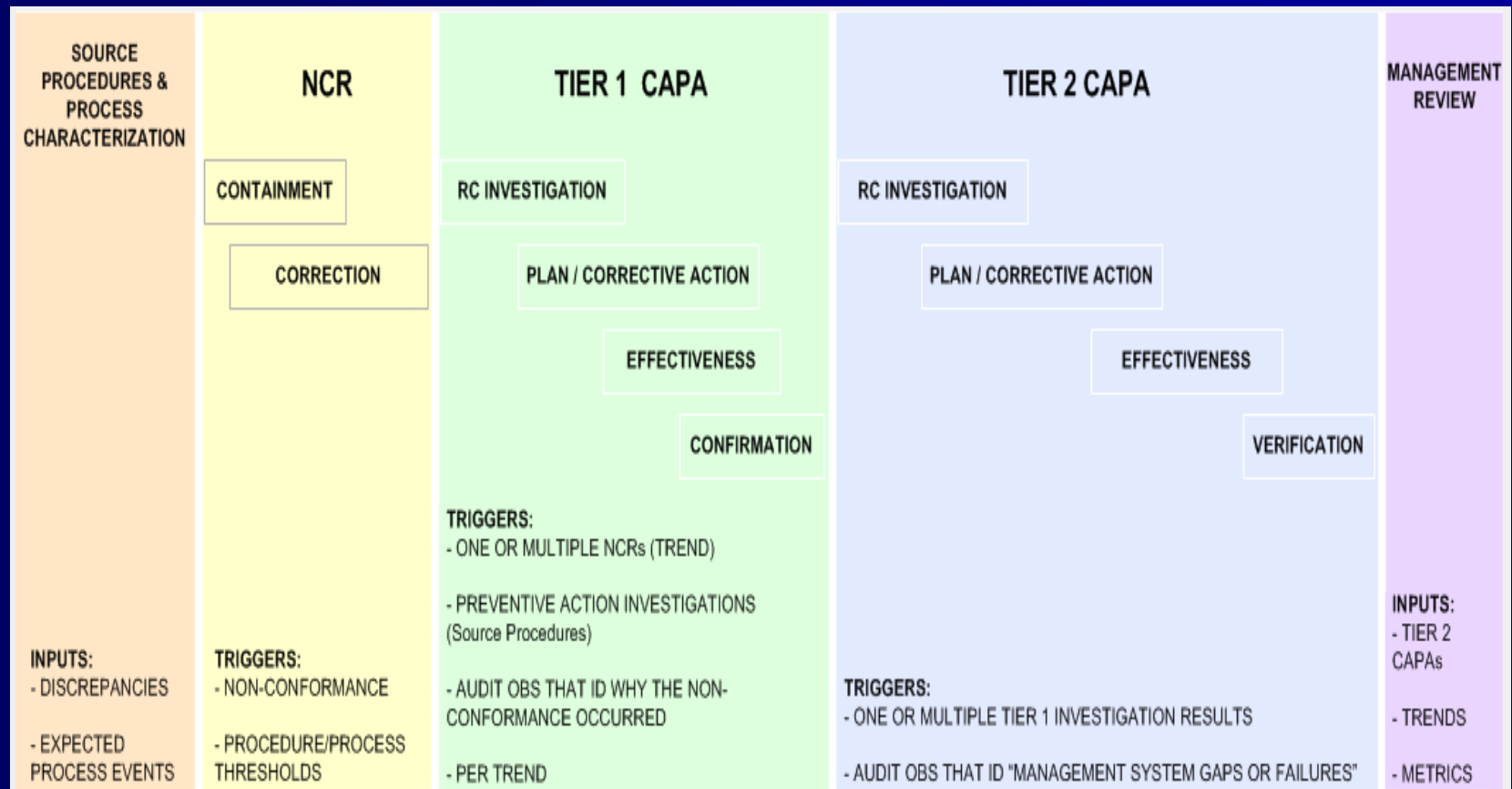
**Non-Conformance
Management**

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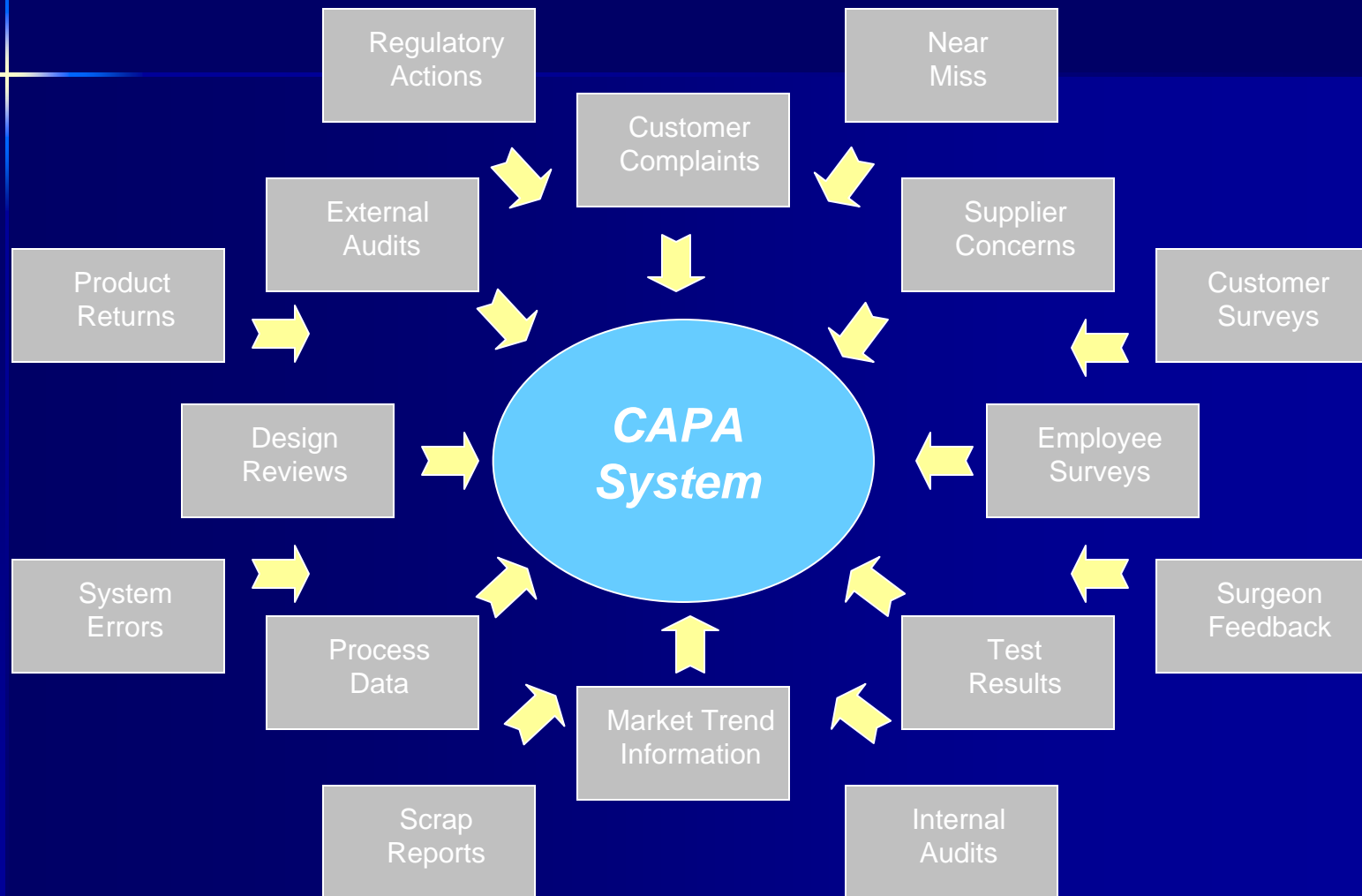
**Corrective and Preventive
Action**

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CAPA System Diagram



Feeds to NC Management



Definitions

Discrepant Event – Expected observation that is contrary to a standard or requirement or process outcome. i.e.: Pre-identified (Expected) Non-conformance with frequency within process capability.

Preventive Action: Action taken to eliminate the cause of a potential non-conformity, defect or other undesirable situation in order to prevent its occurrence.

Non-conformance – Unexpected observation that is contrary to a standard or requirement. Non-fulfillment of a requirement related to an intended or specified use.

Definitions

Correction – Action taken to eliminate a detected non-conformance. These actions may involve process or product changes, (e.g., rework or repair). Corrections typically are one time fixes

Corrective Action (CA) – Action taken to eliminate the causes of an existing non-conformance, defect, or other undesirable situation to prevent recurrence. The distinction between a correction and corrective action is that the former relates to the disposition of an existing non-conformance, whereas a corrective action relates to the elimination of its cause

Definitions

Effectivity/Effectiveness – The measure of the ability of the implemented Corrective Actions to objectively demonstrate successful elimination of the identified Root Cause(s). Effectiveness checks shall also be defined to establish that the original issue identified was eliminated or reduced to acceptable levels.

Detection by the customer (e.g. use of Complaint searches) shall not be the sole Effectiveness check. Effectiveness shall be detected at the earliest part of the process prior to arrival in the hands of the customer

Guidance

FDA Medical Device Inspection Guide

Determine if appropriate sources of product and quality problems have been identified. Confirm that data from these sources are analyzed to identify existing product and quality problems that may require corrective action.

Determine if sources of product and quality information that may show unfavorable trends have been identified. Confirm that data from these sources are analyzed to identify potential product and quality problems that may require preventive action

Guidance (continued)

FDA Medical Device Inspection Guide

Determine if failure investigation procedures are followed. Determine if the degree to which a quality problem or nonconforming product is investigated is commensurate with the significance and risk of the nonconformity.

Determine if failure investigations are conducted to determine root cause (where possible). Verify that there is control for preventing distribution of nonconforming product.

Guidance (continued)

FDA Medical Device Inspection Guide

Determine if appropriate actions have been taken for significant product and quality problems identified from data sources

Determine if corrective and preventive actions were effective and verified or validated prior to implementation. Confirm that corrective and preventive actions do not adversely affect the finished device.

Guidance (continued)

FDA Medical Device Inspection Guide

Verify that corrective and preventive actions for product and quality problems were implemented and documented.

Determine if information regarding nonconforming product and quality problems and corrective and preventive actions has been properly disseminated, including dissemination for management review

Discrepant Event Management

- All Discrepant Events should be captured and documented to allow for uniform categorization and tracking by process in a centralized fashion to facilitate process monitoring, reporting and decision making
- Discrepant Events should be reviewed using statistically valid methods to illustrate trends.
- Trends should be investigated and corrected using either a Preventive or Corrective Action depending on their status

Source Procedures

Define our expectations; they must:

1. Define the method for data collection & process monitoring
2. Define criteria for non-conformances vs. discrepant events.

Source Procedure Checklist

- ✓ Acceptance Criteria
- ✓ Discrepancy limit(s) (Alert Limit)
- ✓ Non-conformance limit(s) (Action Limit)
- ✓ Data collection methodology established

Source Procedure Checklist (continued)

- ✓ **Data analysis methodology** - Statistically valid method appropriate for the analysis and decisions to be made
- ✓ **Data analysis frequency** - Intervals adequate to support effective Preventive Actions to minimize product or process non-conformance
- ✓ **Data Analysis Responsibilities**

Source Procedure Checklist (continued)

- ✓ Data Analysis Defined Actions
- ✓ Data Reporting hierarchy for actions
- ✓ Data Reporting hierarchy for Management Review - Metrics

Process Monitoring

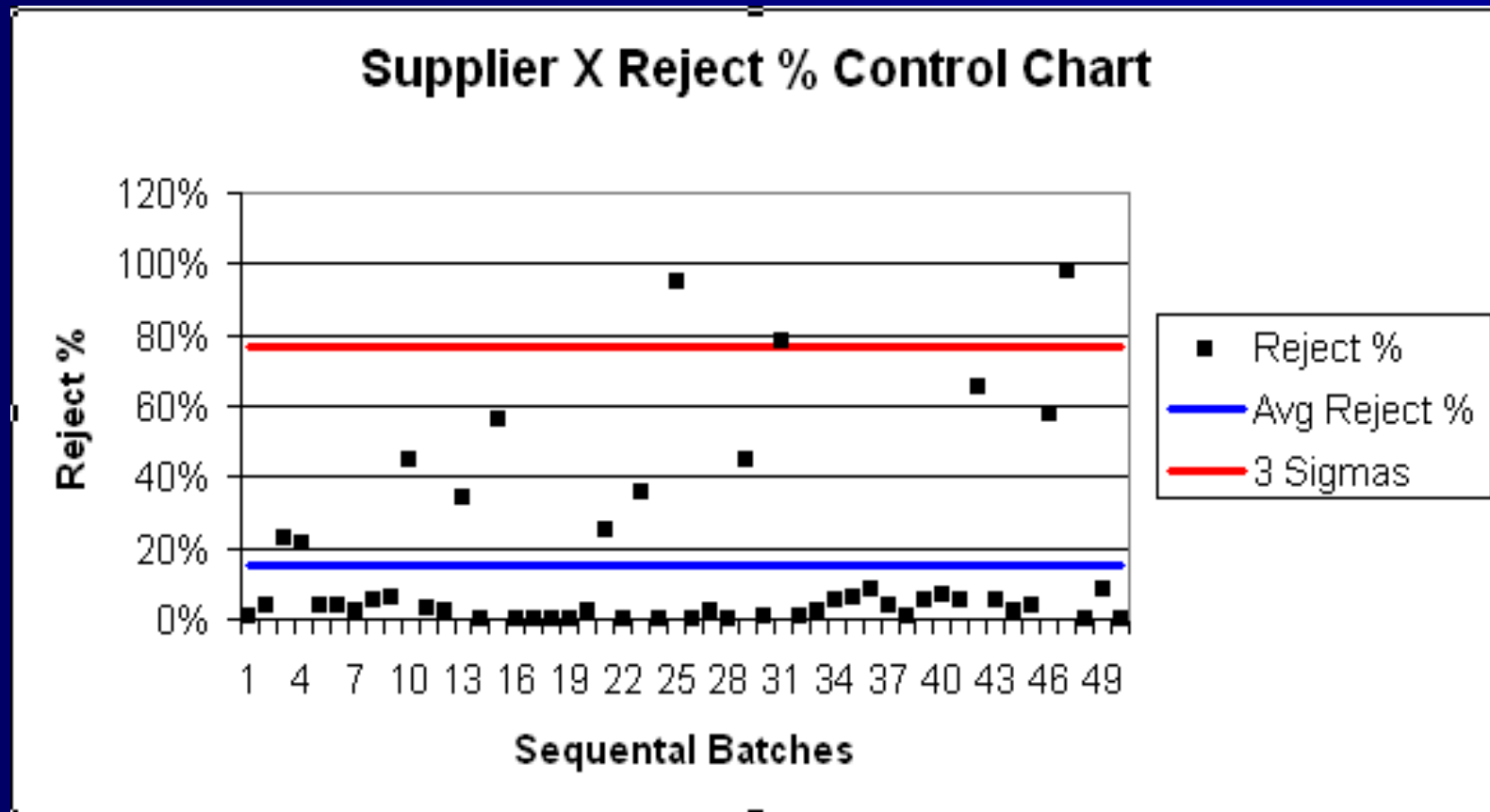
Define the technique or method you will use to measure the output from your process

The method must be able to record and detect Acceptable Results or Events, Discrepant Events, and Non-Conformances.

Data Reporting

- Data is to be reported at intervals adequate to support effective Preventive Actions to minimize product or process non-conformance
- Data is to be reported to demonstrate the state of Product and / or Process Performance at Management Review

Process Capability



Non-Conformances Management

All Non-Conformances must be documented and processed in accordance with a procedure purposed to Control and Correct Non-Conformances; inclusive of Containing the non-conforming process or product.

Formal Approach to Investigation

Why?

1. Can prevent us from seeing what is really happening
2. Can cause us to exclude data that does not fit our mental model (paradigm)
3. Can cause us to add data that is part of our model but not part of the current data set

Root Cause Generation

Tools

- Brainstorming
- Fishbone Analysis
- Cause and Effect Diagrams
- Logic Tree Analysis (Why/Why)

Investigation

- Research through Design History
- Research through Manufacturing Records
- Inspection / Test
- Experimentation

Investigation Examples

- Fishbone
- Cause and Effect Diagram

Questions & Discussion