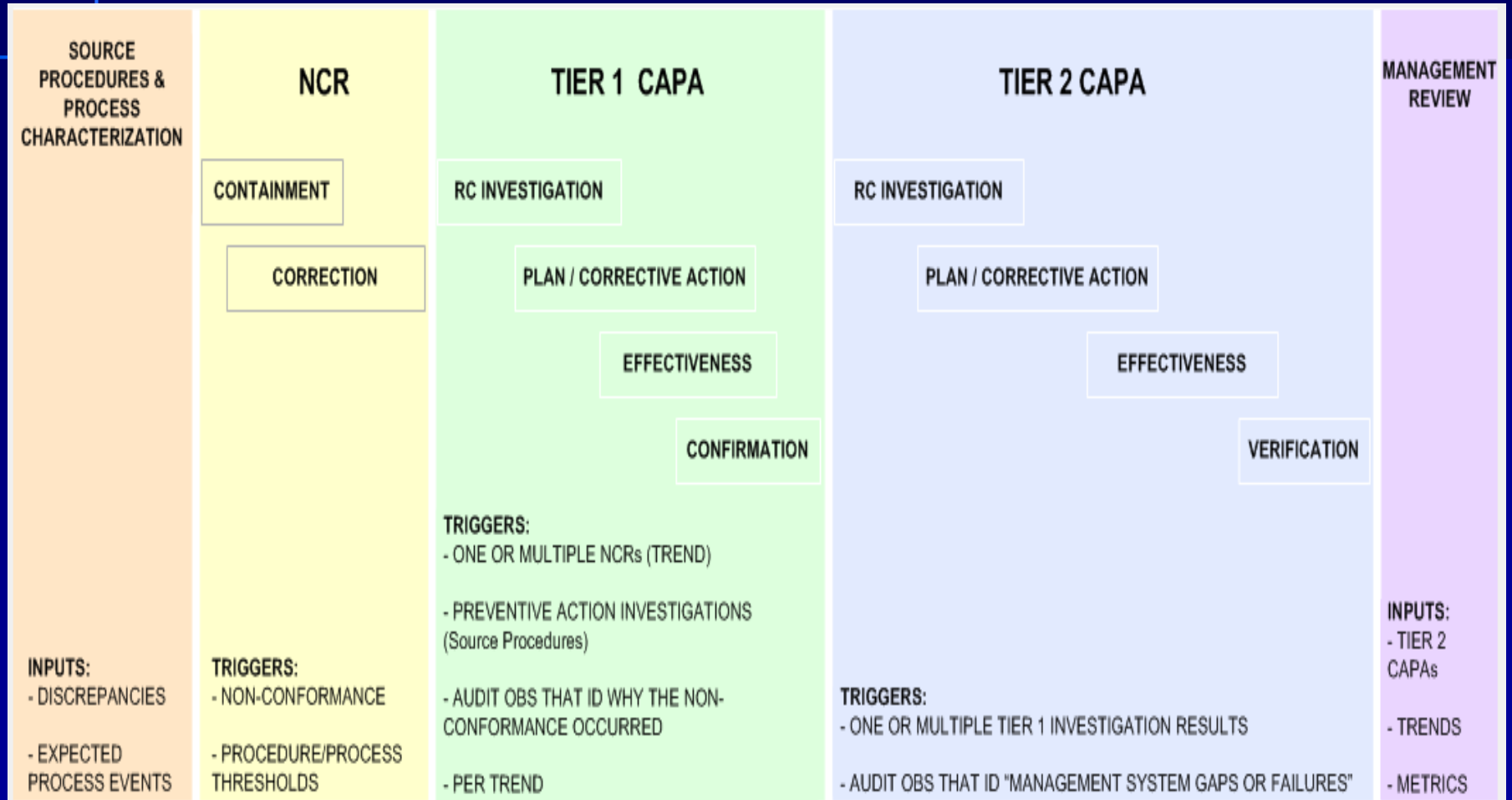


Non-Conformance Management & Corrective and Preventive Action

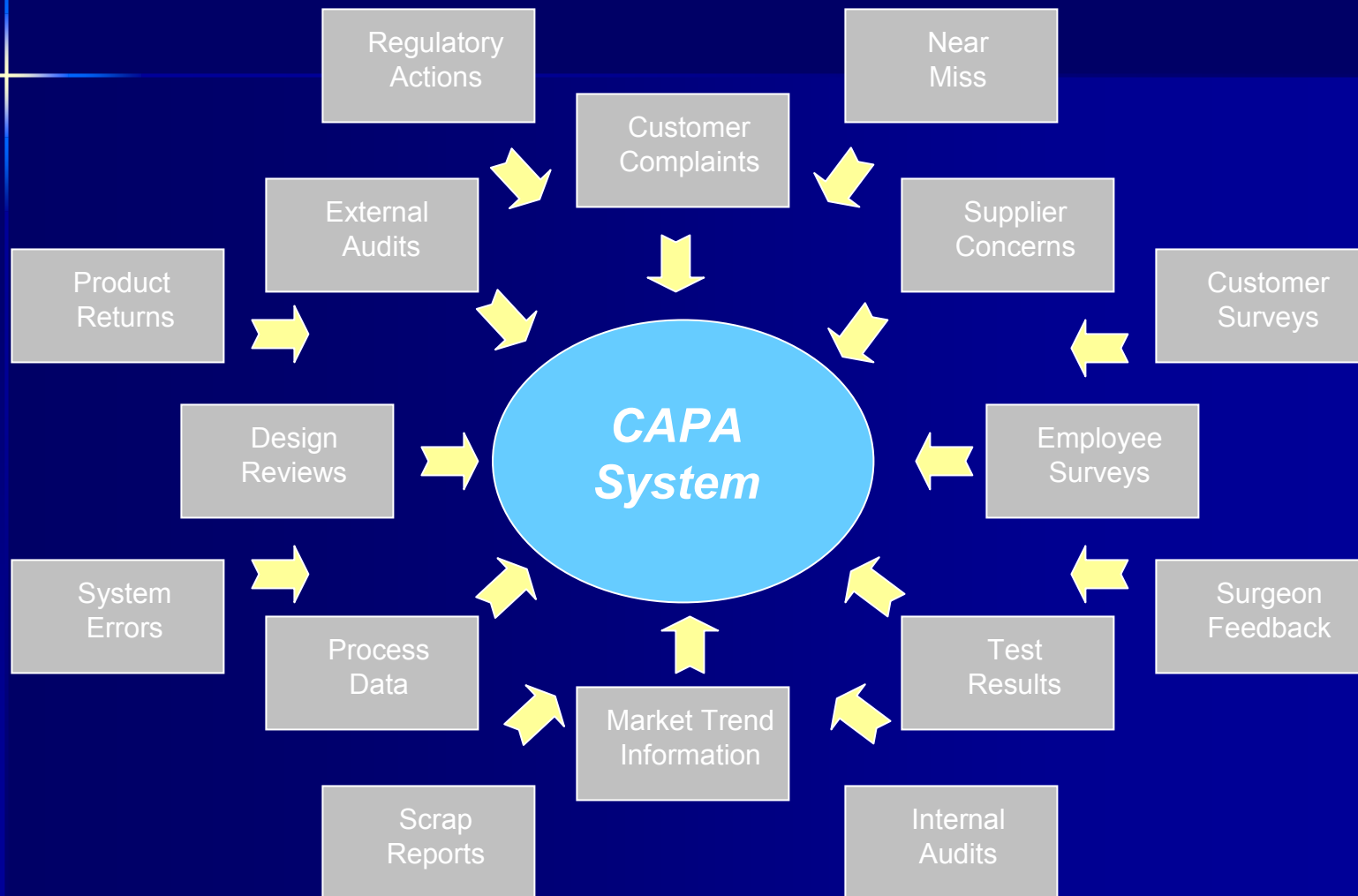
Part 1 – Definitions, Detection, Management & CAPA Escalation

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Elements of a CAPA System



Feeds to NC Management



Definitions

Conforming – An expected observation, event or characteristic. Fulfillment of a requirement.

Non-conformance – An unexpected observation or event. Non-fulfillment of a requirement.

Discrepancy– An expected observation not meeting a requirement.

i.e.: A Pre-identified (Expected) Non-conformance with frequency within process capability.

Definitions

Correction – Action taken to eliminate a detected non-conformance. These actions may involve process or product changes, (e.g., rework or repair). Corrections are fixes that correct the act that caused the non-conformance to exist.

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

Definitions

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

Root Cause – The factor associated with or relating to the reason for the observed symptom's existence.

Source Procedure – Any document that identifies a standard, requirement or expectation. Source procedures clearly identify the methods used to gather data on non-conformances and potential non-conformances and the threshold for initiation of a preventive action.

Definitions

Effectivity/Effectiveness – The measure of the ability of the implemented Corrective or Preventive 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 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.

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

Guidance (continued)

FDA Medical Device Inspection Guide

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

Expectations

Many Management System Regulations and Standards have similar requirements

For Example:

FDA 21 CFR Part 820

ISO 9001

ISO 13485

Expectations are similar among them

Discrepant Event Management

- All Discrepant Events are 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 are reviewed using statistically valid methods to illustrate trends.
- Adverse Trends are investigated and corrected using Corrective Action.
- Trends heading in a non-favorable direction are addressed using Preventive Action.

Source Procedures

Define our expectations; they must:

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

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

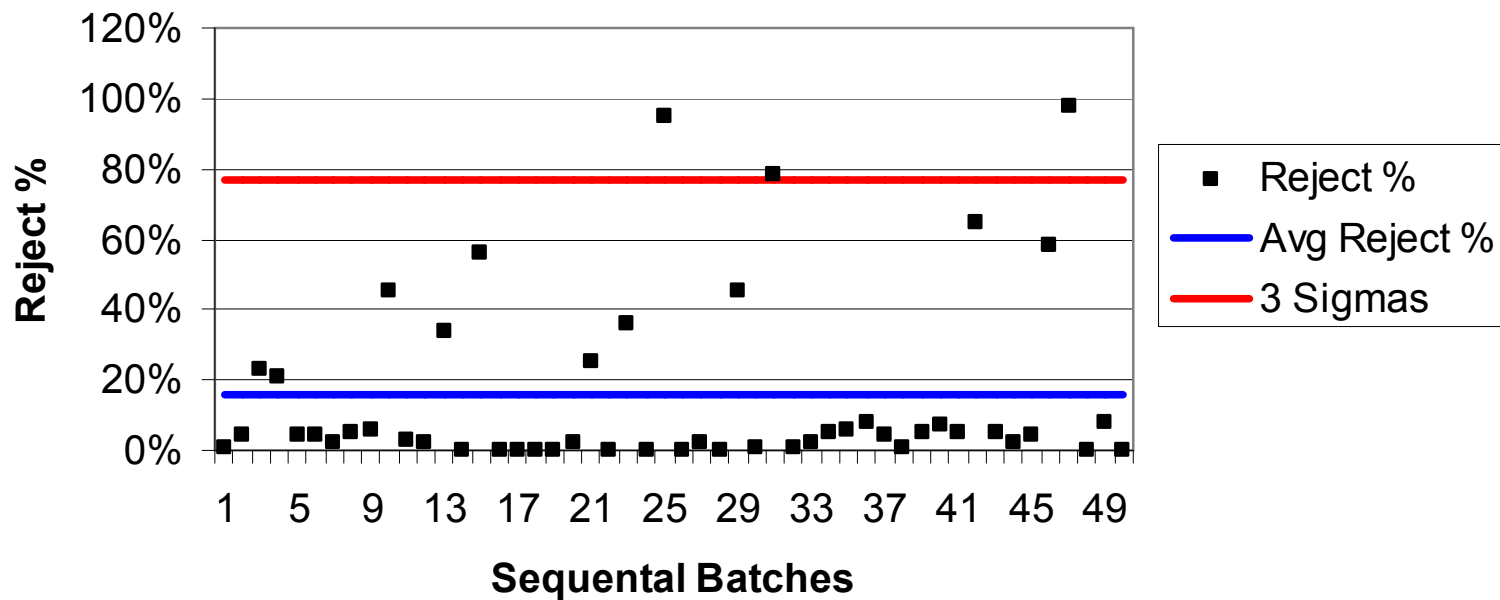
Process Monitoring

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.

Process Capability

Machine #5 Reject % Control Chart



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

Non-Conformances Management

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

Candidates for CAPA

Those Non-conformances that, through Prioritization / Risk Assessment, have been identified for investigation of Root Cause, Corrective or Preventive Action

Non-Conformance Management & Corrective and Preventive Action

- End of Part 1...
- Questions?

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