CAPA

DCVMN – Hyderabad, India

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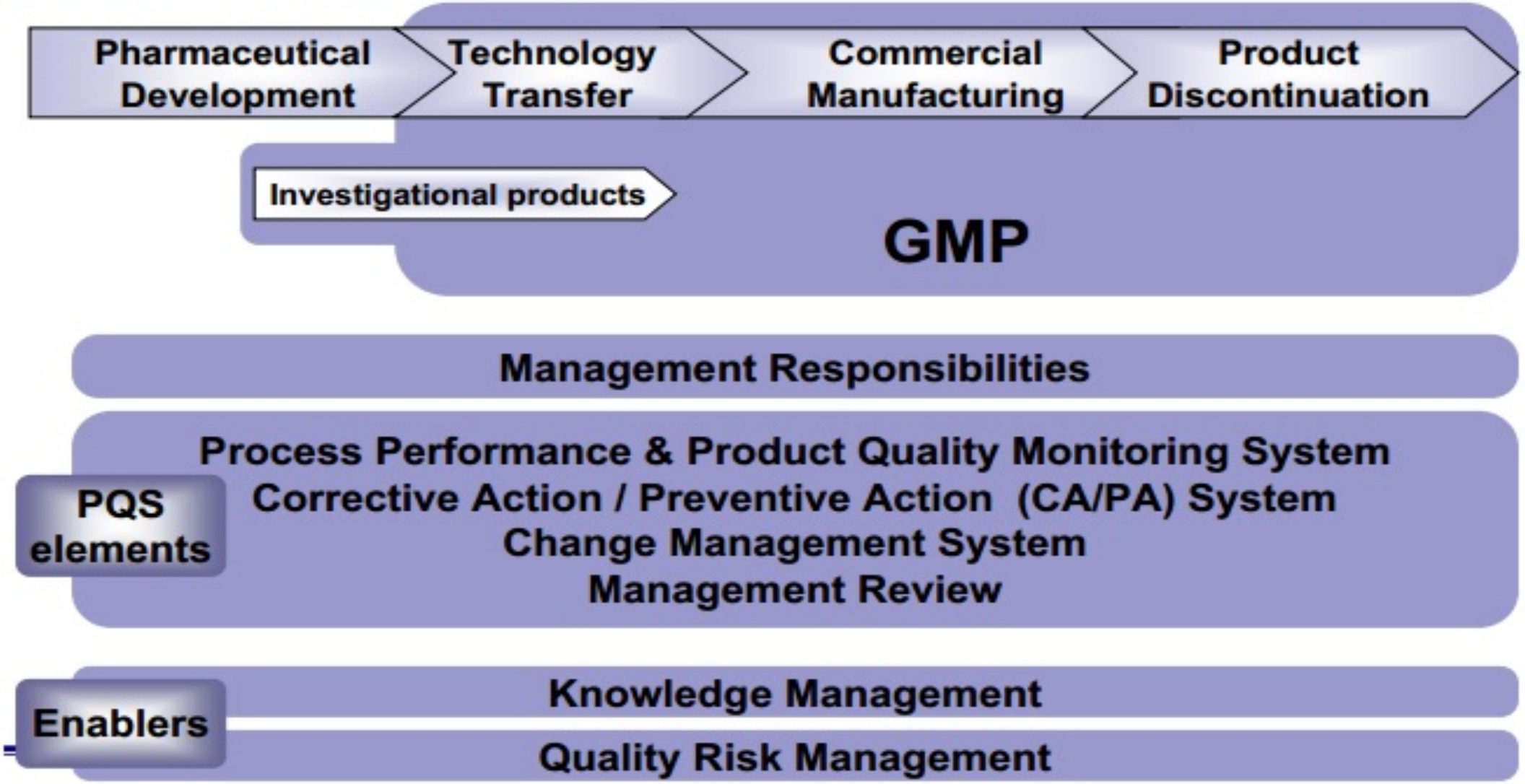
dcvmn
Developing Countries Vaccine Manufacturers Network

- What can we learn from deviations ?
- Why is it important to determine the root cause of deviations ?
- How can we implement an effective CAPA ?

ICH Q10 PQS


Pharmaceutical Development
Technology Transfer
Commercial Manufacturing
Product Discontinuation
Investigational products
GMP
Management Responsibilities
PQS elements
Process Performance & Product Quality Monitoring System
Corrective Action / Preventive Action (CA/PA) System
Change Management System
Management Review
Enablers
Knowledge Management
Quality Risk Management

State of control CONSISTENCY

Monitoring process performance
(quality management indicators & trend analysis)

Monitoring product quality
(product quality review or PQR)

Change management system

Internal & External Audit system

Corrective action and preventive action (CAPA) system

- Deviation: departure from an approved instruction or established standard (WHO TRS 957, 2010. Annex 2).
- There should be formal procedures to report, investigate and approve deviations.
- Deviations should be evaluated considering the likelihood of the risk to the product/ patient.
- Develop a policy on deviation management
- Determine a classification approach i.e. differentiation among various types of deviations
- Track deviations and analyze trends
- Database (software based or manual system) to assist in tracking and trending of deviations.

- Deviations should be investigated to understand if there is a serious impact in product quality
- Decision making process to follow any CAPA or batch release/rejection
- Investigation and its conclusions should be documented.
- Investigation of critical or major deviations should extend to other batches that may have been associated with the specific failure or deviation.

Purpose of CAPA

- "…collect information, analyze information, identify and investigate product and quality issues, and take appropriate and effective corrective and/or preventive action **to prevent recurrence of a problem."**

The **heart of an effective quality management system**

(key quality system element)

- ✓**Corrective action:** action taken to eliminate the **cause(s)** of a non- conformity, defect, or other undesirable situation to **prevent re-occurrence.**

- ✓ **Preventive action:** action taken to eliminate the cause of a **potential** nonconformity, defect, or other undesirable situation in order to **prevent occurrence.**

Preventive & corrective action

Corrective action example

- Investigate to determine the root cause of a packaging problem and take appropriate action to ensure that this problem does not re- occur.

Preventive action examples

- Trending of environmental monitoring indicates that the cleanroom is drifting toward alert limit.
- Investigation indicates that a small tear in a HEPA filter is the root cause of the drift.
- Replace the HEPA filter
- Verify/validate that the process meets specification.

Elements of a sound CAPA program (check list)

Documented procedure

- *Inputs (data sources)*
- *Method for analyzing inputs*
- *Method for prioritizing*
- *Investigation (determine root cause)*

Identify solutions (corrective or preventive)

- Verification or validation
- Impact assessment (risk analysis), where appropriate
- Corrective action plan
- Implement and Monitor
- Effectiveness verification
- Management review

Root cause analysis -

What do you think about the following situation:

Root cause analysis

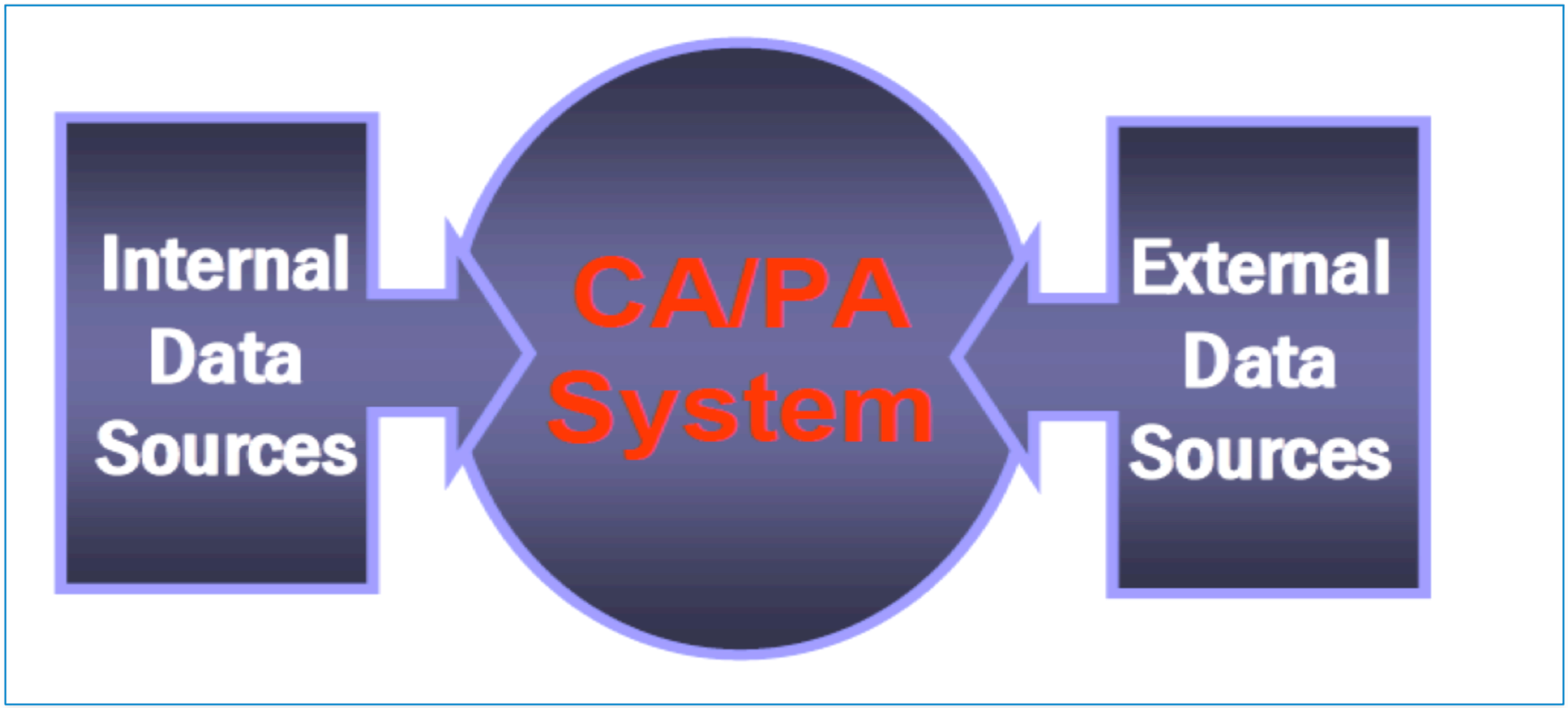
Root cause analysis tools:

- The “5 Whys”

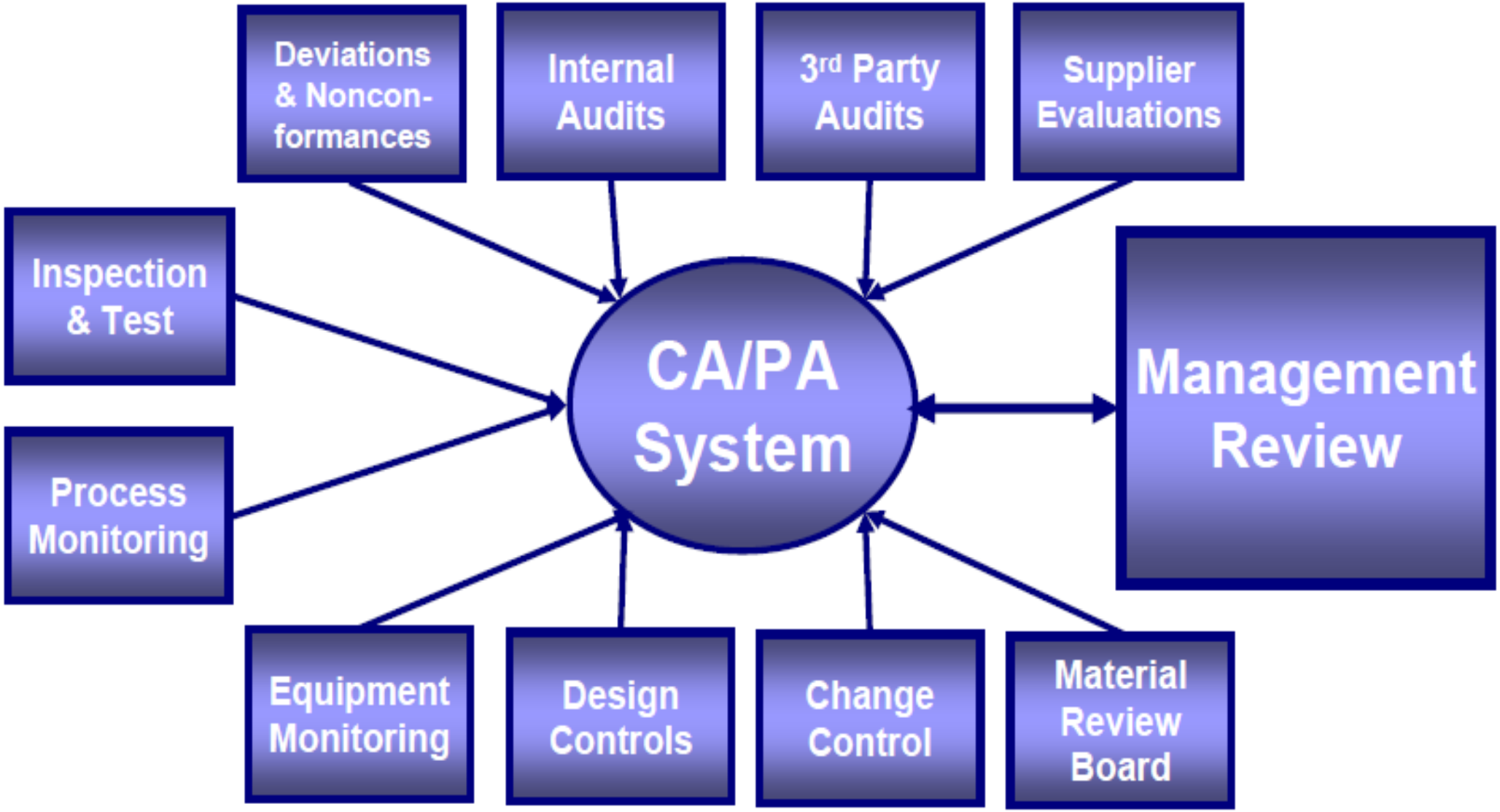
- Cause and effect diagrams (also called an Ishikawa diagram or fish bone diagram).

- QRM tools (e.g. Fault tree analysis or FTA).

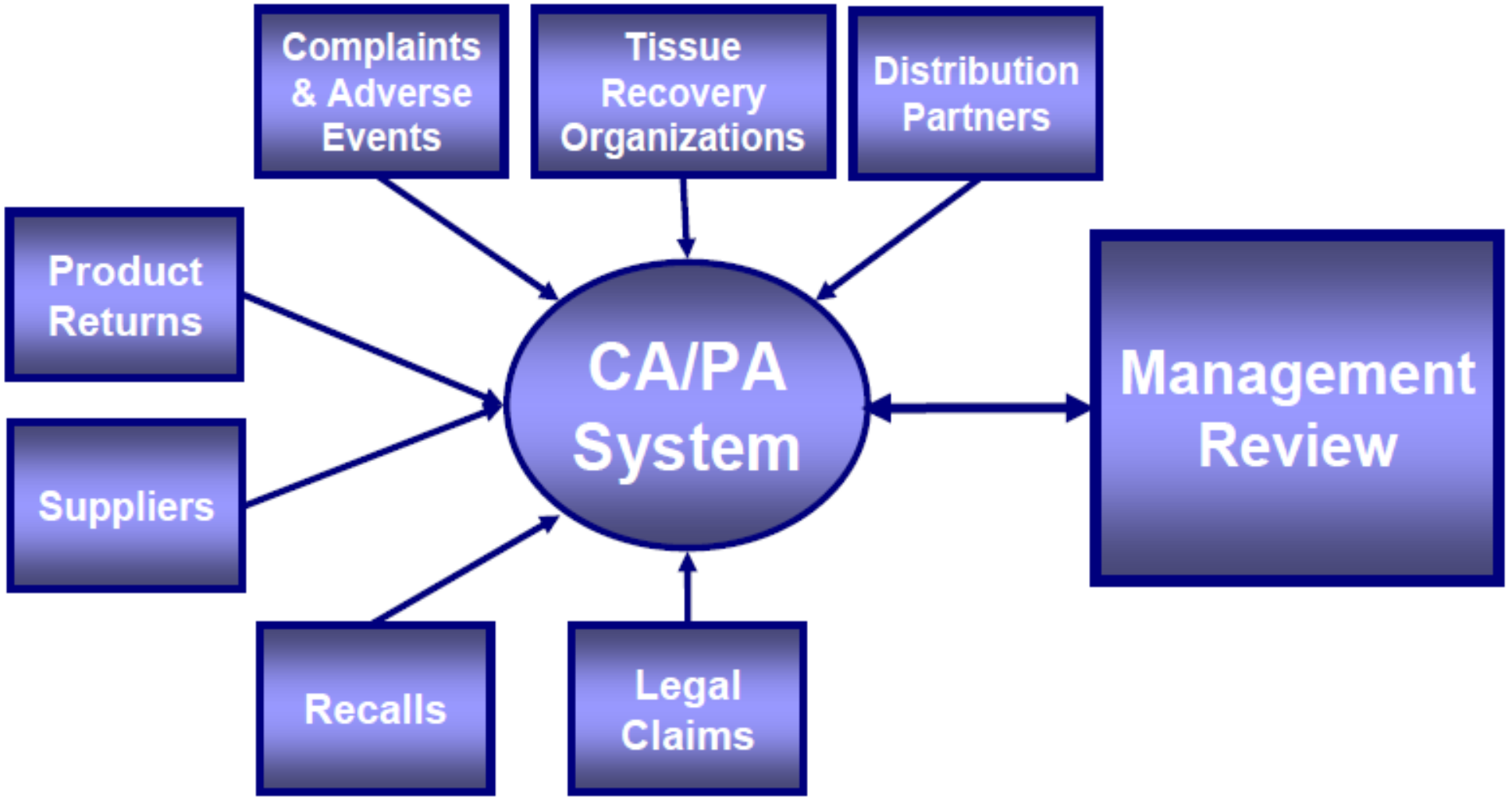
Quality data sources that should feed into CAPA



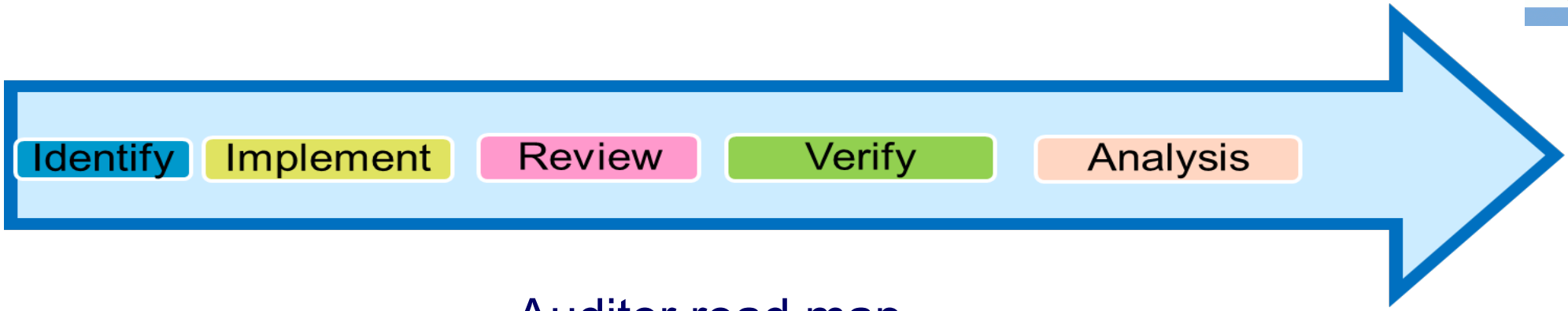
Internal data sources feeding into CAPA



External data sources feeding into CAPA



5 step CAPA approach



Auditor road map

- Is there objective evidence of action taken to prevent recurrence?
- Were quality data sources identified and analyzed?
- Was root cause identified?
- Were the actions effective, verified or validated?
- Was it controlled that the actions didn't adversely affect the product.
- Was CAPA information submitted for management review?

Summary

- Deviation management must assure prompt action, be based on quality investigations when required, and not to be repeated if CAPA is effective.

- Proper CAPA assures an effective learning process and prevents reoccurrence of deviations.


Namaste