

# AQS 200

## ROOT CAUSE INVESTIGATION

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*Any opinions, findings, and conclusions or recommendations expressed in this material are those of the author(s) and do not necessarily reflect the views of the National Science Foundation.*

# LECTURE 2 – MANUFACTURING (SERVICE) PROCESSES



# Manufacturing/Service Processes

What is a process?

# Manufacturing/Service Processes

What is a process?

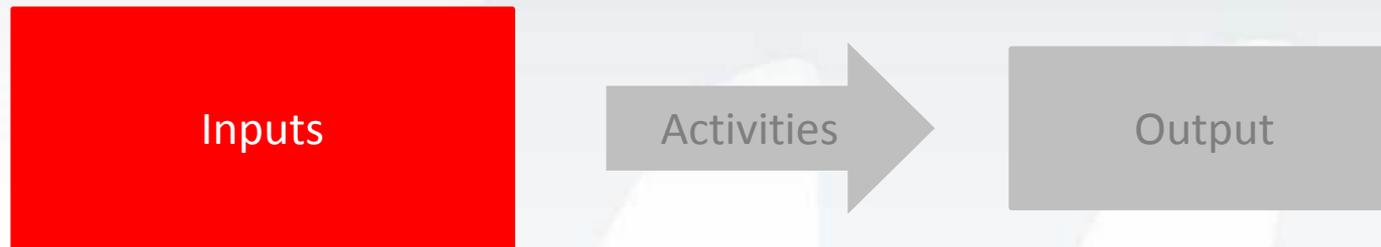
***A process is a chain of value-added activities that conclude in a product or service being delivered to a customer.***

\* The Memory Jogger™ 9001:2008

# Manufacturing/Service Processes



# Manufacturing/Service Processes



## *Examples:*

- **Materials:** raw material, components, parts
- **Resources:** employee time, equipment, energy, financial
- **Information:** instructions, procedures, specifications, drawings, acceptance criteria

# Manufacturing/Service Processes



## *Examples:*

- Assembling components into a finished device
- Reviewing information & requirements for an equipment installation and producing a validation protocol
- Requesting a bank withdrawal from a bank teller and receiving cash.

# Manufacturing/Service Processes



## *Examples:*

- Product
- Service
- Information
- Decision
- Records



products



medicines

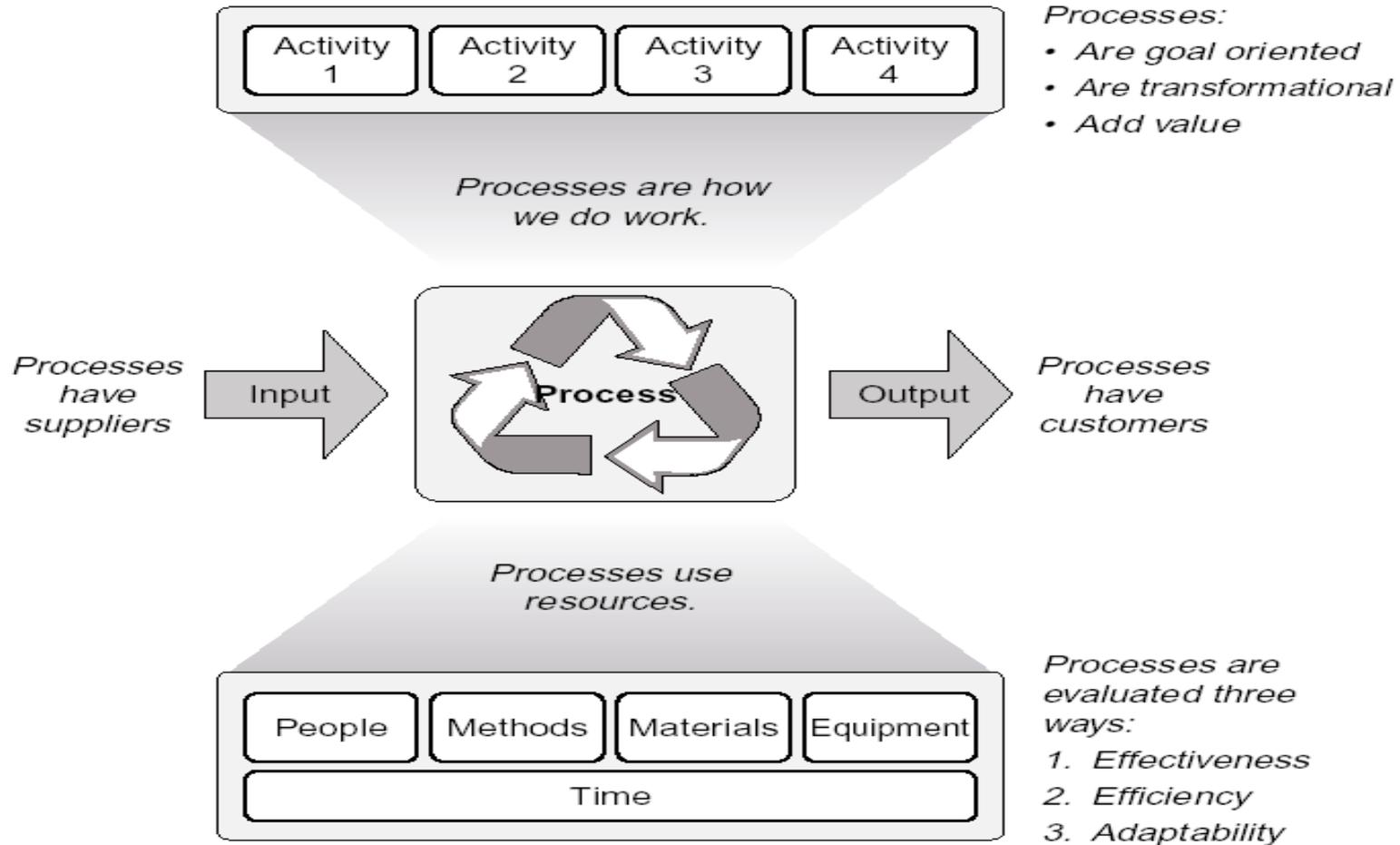


information



records

# Process Model Example



Excerpted from Robert A. Gardner's *The Process-Focused Organization: A Transition Strategy for Success*, ASQ Quality Press, 2004, pages 28-31.

# Processes

## Example



Filling the tank of gas in your car

# Processes

## Example – Filling the tank of gas

What are the **inputs**?

- Resources
- Information
- Materials

What are the **activities**?

What is the **output(s)**?

# Example – Filling the tank of gas

## Inputs

- Resources:
  - gas pump
  - cash or credit
  - person to fill the gas
  - time to stop at the gas station
  - electricity to pump the gas
- Information:
  - cost of gas
  - safety warnings
  - information displayed at the pump & on digital screen
- Materials:
  - car
  - gasoline (grade ?) vs diesel

## Activities

- Pull up to pump
- Shut car off
- Get out of the car
- Activate and pay at the pump
- Take fuel cap off
- Select grade of gas
- Obtain gas nozzle
- Insert gas nozzle into car
- Fill gas tank
- Put gas nozzle back
- Put fuel cap back on
- Get receipt

## Output(s)

- Full tank of gas
- Receipt
- Happy Customer(?)



# Processes

## Three Types of Processes

- Management
- Business
- Support

# Types of Processes

- **Management**

- Provide direction and governance for an organization.
  - organizational goals
  - develop and deploy strategy to attain goals
  - Establish/manage organization designs and performance goals.

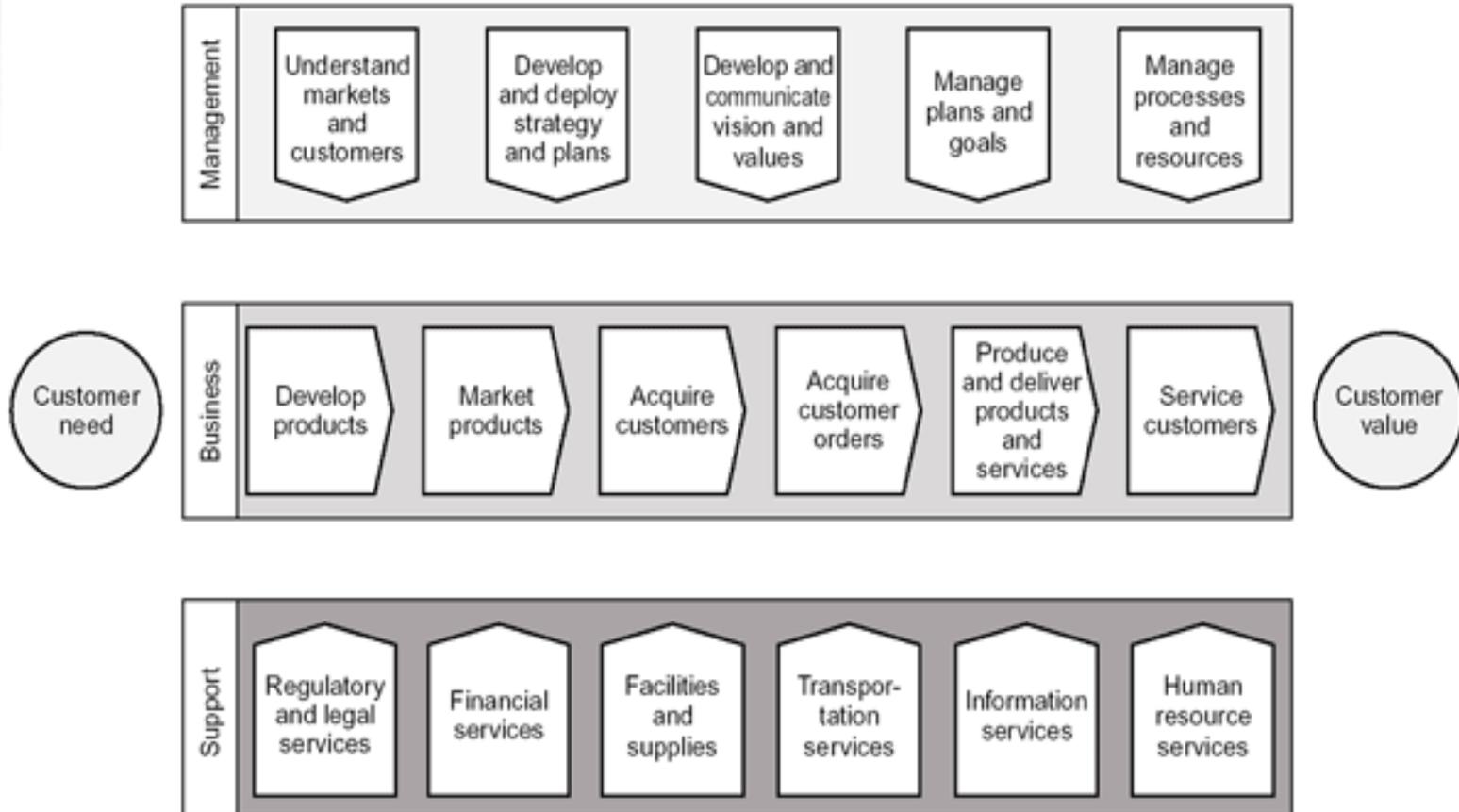
- **Business**

- Core Competencies as experienced by external customers
  - Value creating

- **Support**

- sustain the organization.
  - customers internal customers (within the organization)

# Types of Processes



Excerpted from Robert A. Gardner's *The Process-Focused Organization: A Transition Strategy for Success*, ASQ Quality Press, 2004

# Processes - Customers

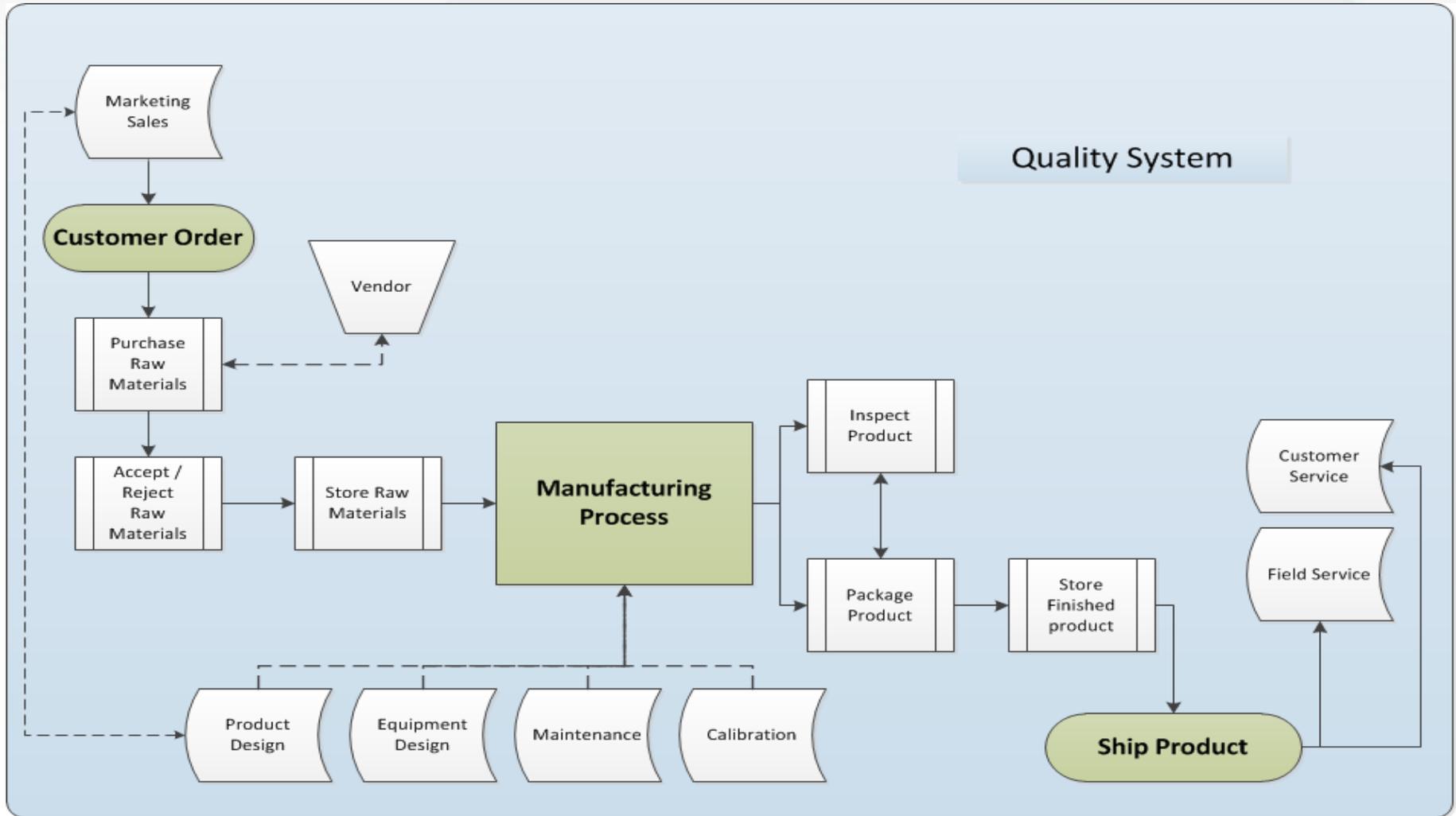
## Internal:

- Organizational staff

## External:

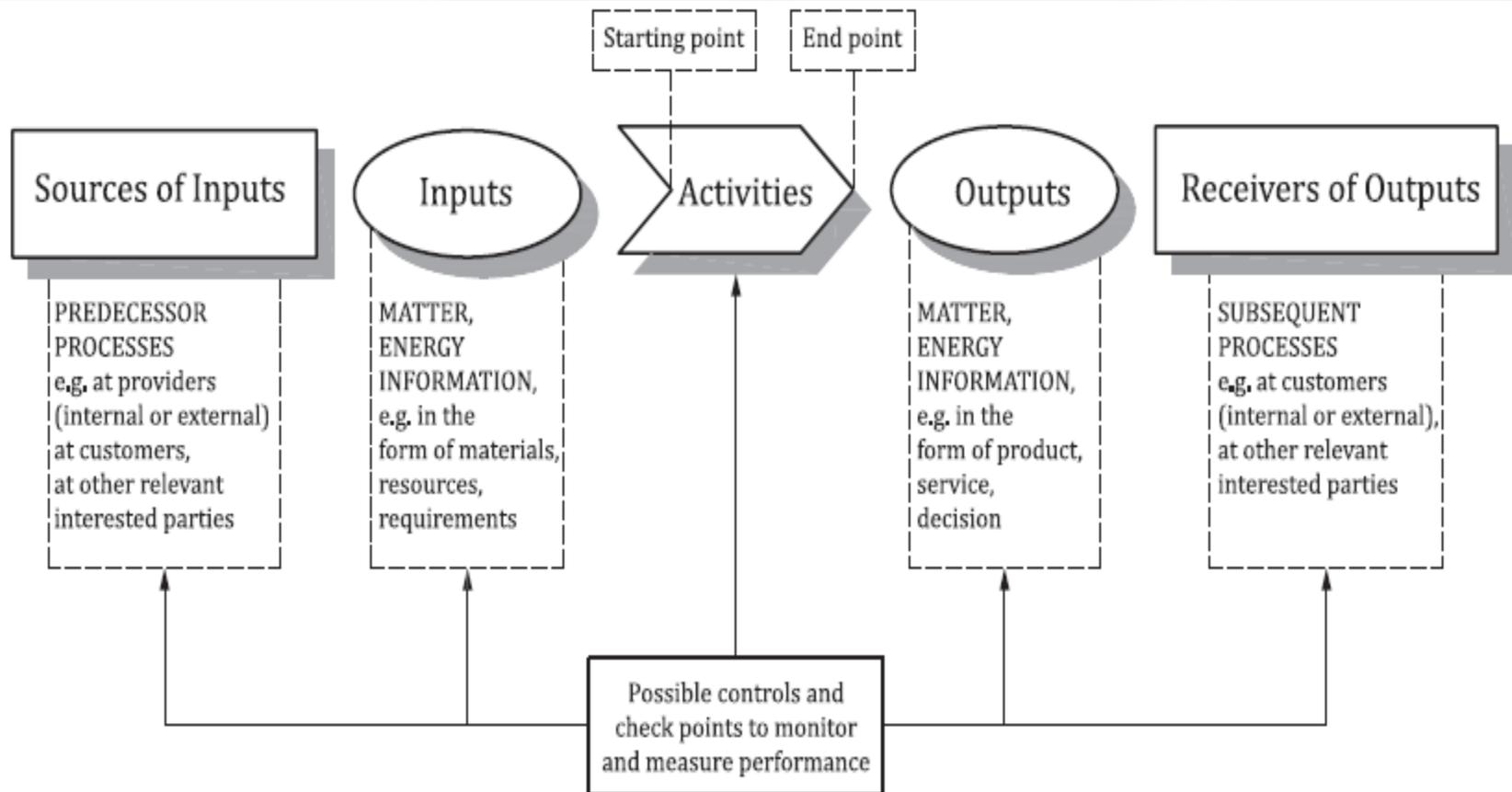
- Customer
- Supplier
- Consultant
- Contractor

# Processes - Customers



# Single Process Elements

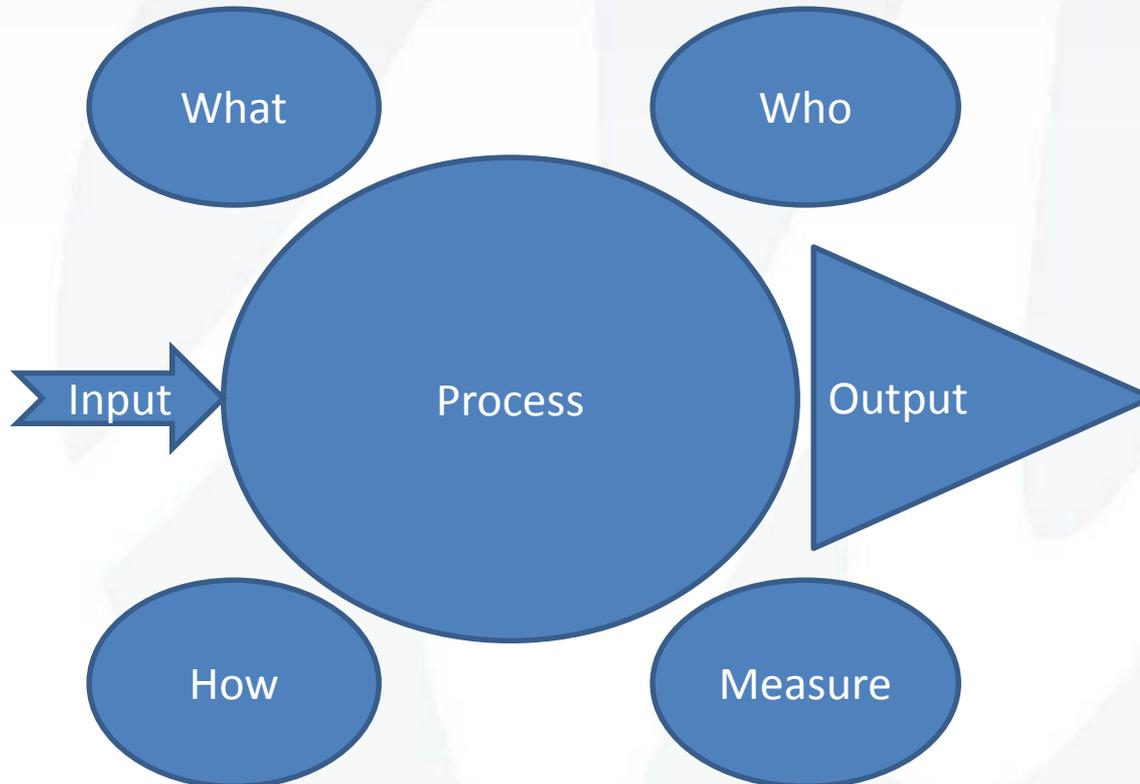
ISO 9001:2015



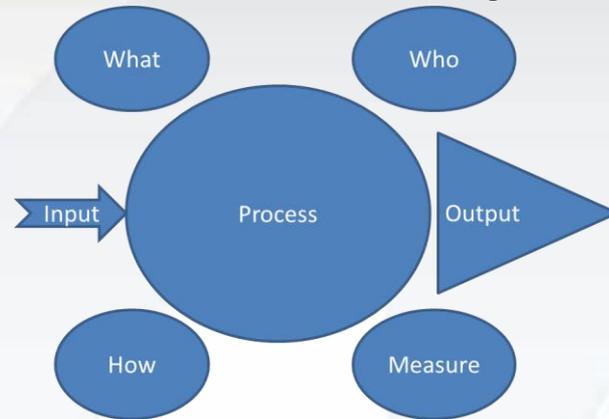
# Process – Depicting/Documenting

## Turtle Diagram\*

# Process – Depicting/Documenting



# Process - Depiction



- **What:** with what, materials, equipment
- **Who:** responsible persons, people doing the activities
- **How:** instructions, procedures, methods
- **Measure:** how much, how many, key measurables

# Process - Depiction



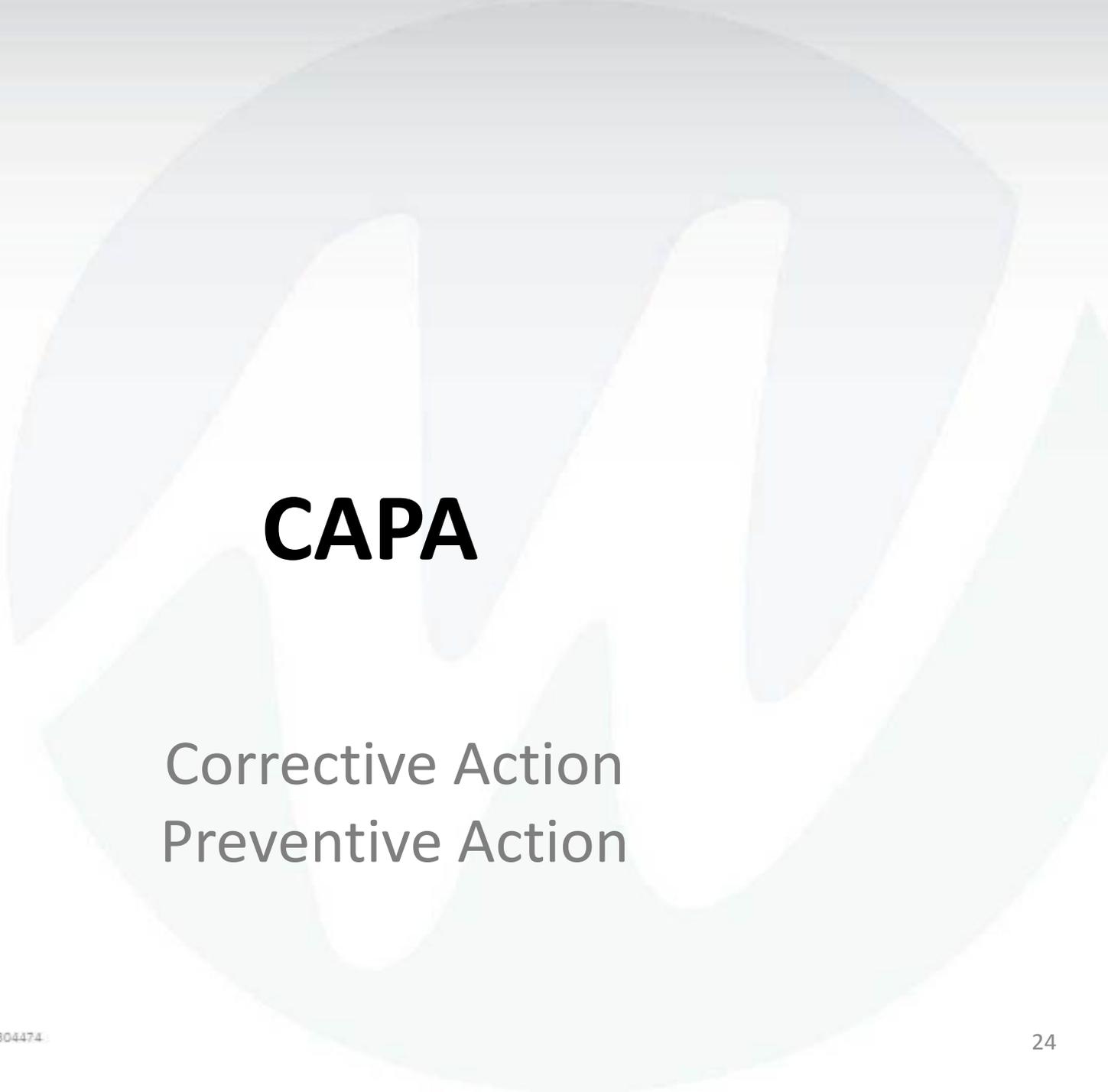
## Exercise

**Evaluate the process of making breakfast.**

identify inputs, activities, outputs

who, what, how, measures

- Two key organizational processes
  - Corrective Action / Preventive Action (CAPA)
  - Validation

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# **CAPA**

Corrective Action  
Preventive Action

# CAPA SYSTEM

- Quality Systems (ISO or FDA) require continuous improvement
- CAPA System
  - Captures corrective actions
  - Measures/verifies effectiveness
  - Take credit for preventive action

# CAPA SYSTEM

- Quality Systems (ISO or FDA) require continuous improvement  
“Act on the Difference”
- CAPA System
  - Captures corrective actions
  - Measures/verifies effectiveness
  - Take credit for preventive action

## New to ISO 9001:2015

Preventive action has been incorporated throughout the standard as “risk and opportunities”.

# CAPA SYSTEM

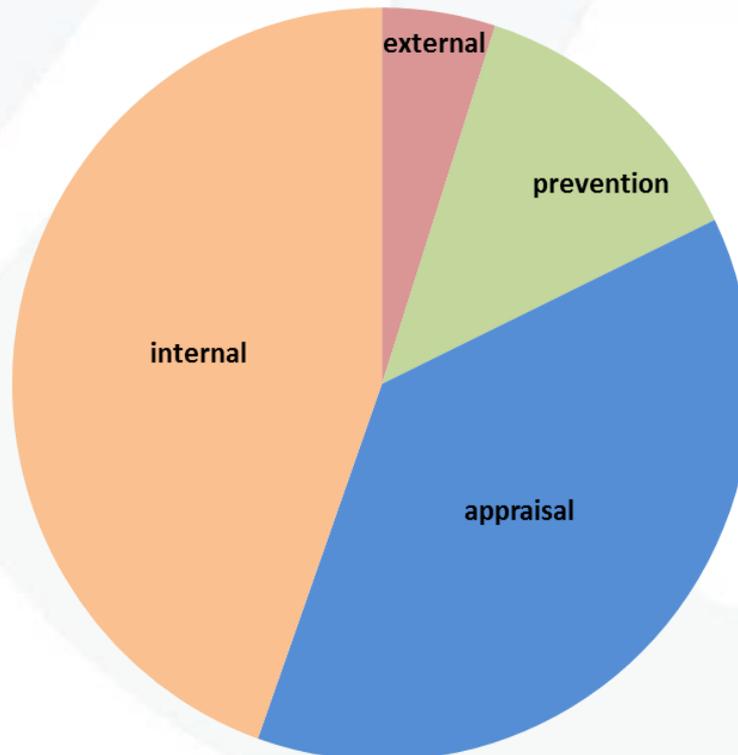
- **Guidance for Industry: Quality Systems Approach to Pharmaceutical cGMP Regulations, September 2006**
  - ... CAPA is a well-known cGMP regulatory concept that focuses on investigating, understanding, and correcting discrepancies while attempting to prevent their recurrence. Quality system models discuss CAPA as three separate concepts, all of which are used in this guidance.
    - Remedial corrections of an identified problem
    - Root cause analysis with corrective action to help understand the cause of the deviation and potentially prevent recurrence of a similar problem
    - Preventive action to avert recurrence of a similar potential problem

# CAPA SYSTEM

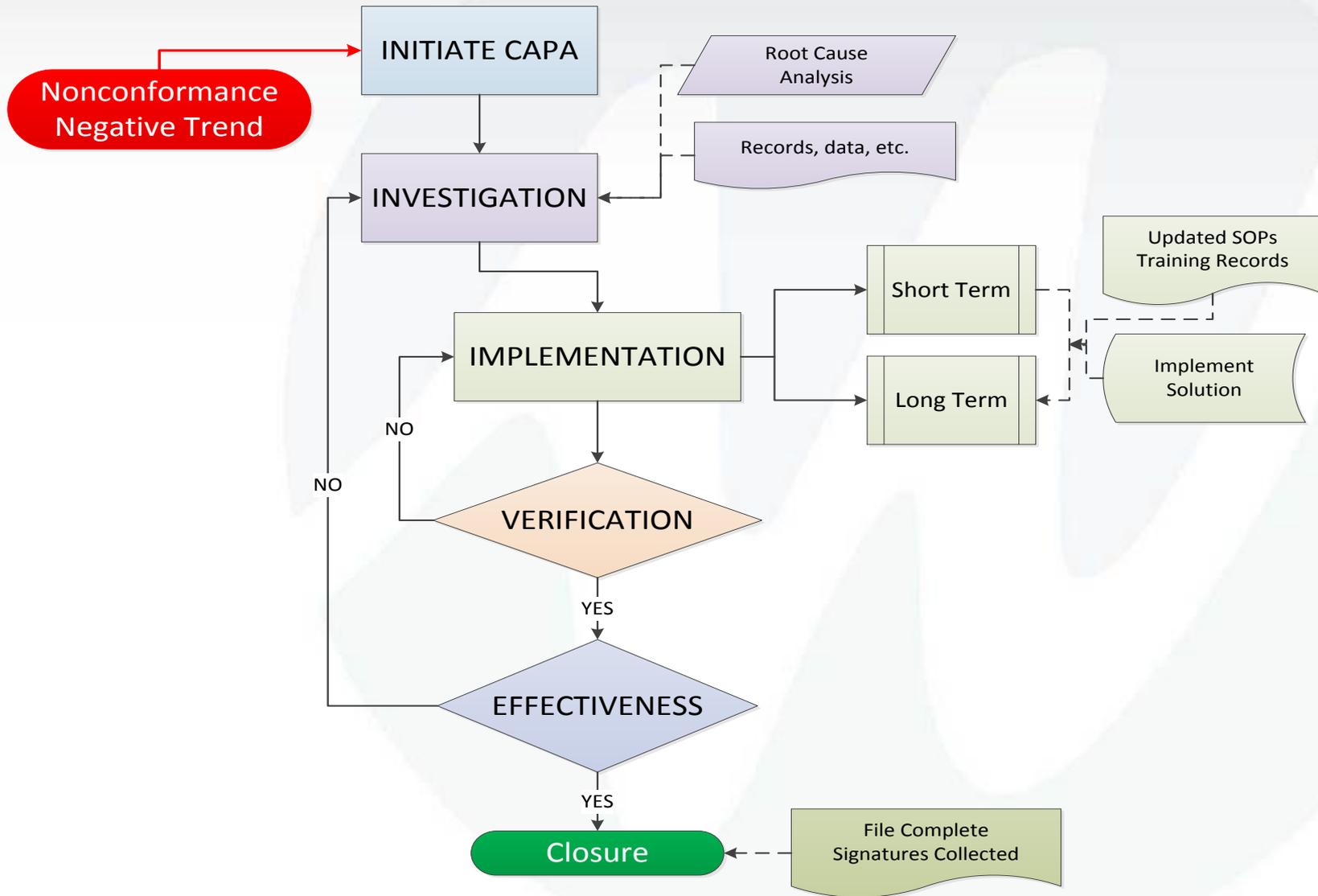
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- **21CFR 820.100 Corrective and preventive action.**
  - (a) Each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for:
    - ...(2) Investigating the cause of nonconformities relating to product, processes, and the quality system;
    - (3) Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;
    - (4) Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device...

# CAPA

- CAPA = Corrective Action(s) and Preventive Action(s)
  - Corrective Action (CA) fixes the immediate issue
  - Preventive (PA) finds ways to fix weaknesses that have not yet caused a problem



# CAPA SYSTEM



# CAPA SYSTEM

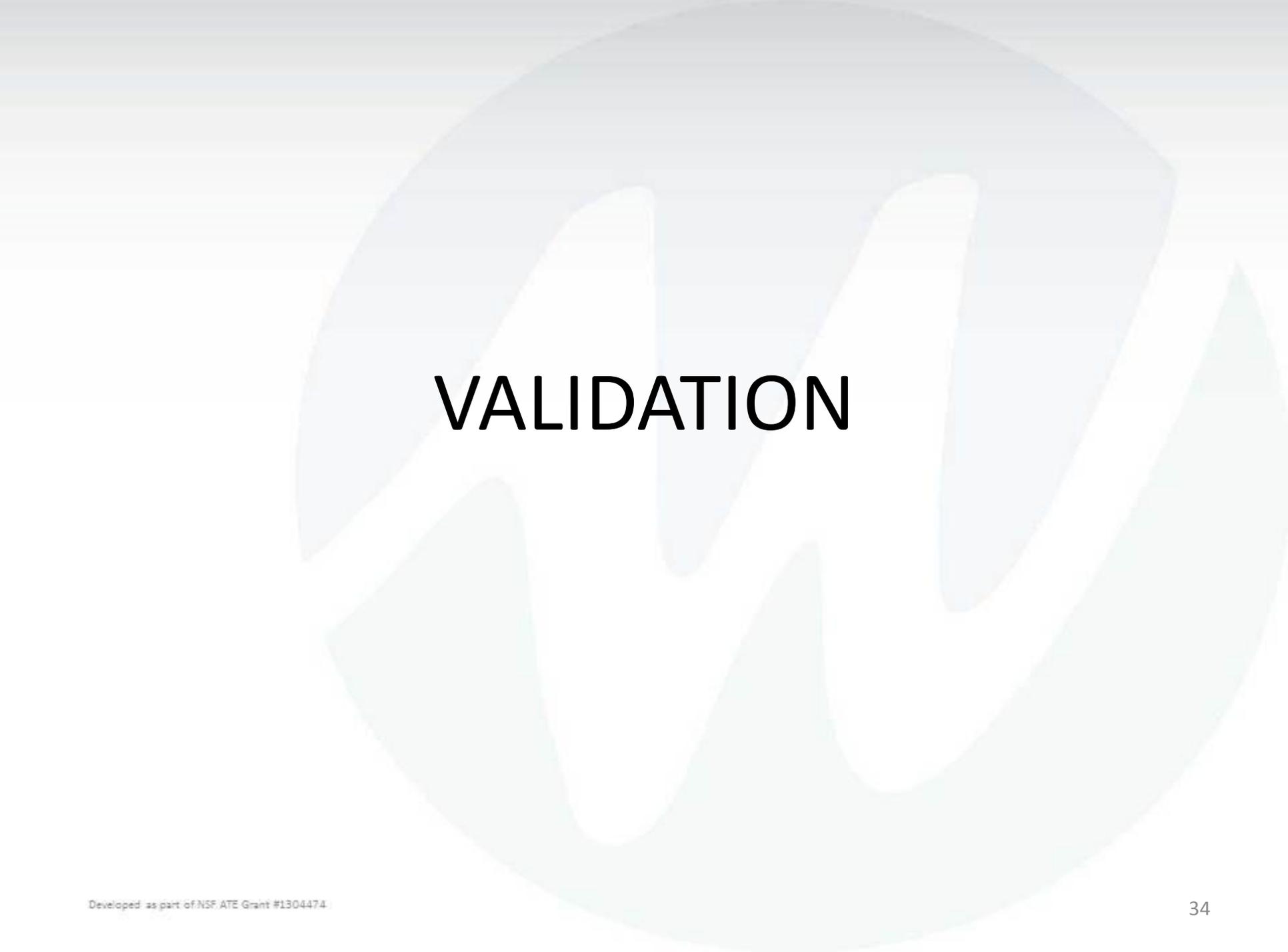
- Documentation – Phases
  - Initiation
  - Investigation
  - Implementation
  - Verification
  - Effectiveness
- *Response time can be critical*
  - *Product Manufacture*
  - *Audit Findings*
  - *Management Review Trends*
  - *Customer Complaints*
    - *Adverse Events*

# CAPA SYSTEM

- **Initiation**
  - Source
    - Customer Complaint (Adverse Event)
    - Audit Findings
    - Management Review Adverse Trend(s)
  - Team assigned based on complexity and urgency
    - Initiator
    - Investigator(s)
- **Investigation**
  - Root cause analysis
- **Implementation**
  - Immediate correction
  - Short Term
  - Long Term

# CAPA SYSTEM

- **Verification**
  - Review implementation
    - Documentation, training
    - Validation, change control
- **Effectiveness**
  - Management Review
  - Recurrence
    - 30days, 60days, 90days, etc.
    - Trend(s)
- **Closure**
  - File complete (documentation)
  - Signatures

A large, light blue, stylized letter 'W' is centered in the background of the slide. The 'W' is composed of several rounded, overlapping shapes that create a sense of depth and movement. The word 'VALIDATION' is superimposed over the center of the 'W' in a bold, black, sans-serif font.

# VALIDATION

# VALIDATION PROGRAM

- **Validation** – process of establishing documented objective evidence to demonstrating procedure, process or activity carried out in validated production environment, operated with trained personnel provides expected predictable results while maintaining desired level of compliance at all stages

# VALIDATION

## 21CFR Part 820 Definitions

- Validation: confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled  
***Are you building the right thing? Meeting User needs.***
- Verification: confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.
  - *documented evidence confirming that the device can be manufactured and processes can be repeated.****Did you build it right? Meeting User specifications.***

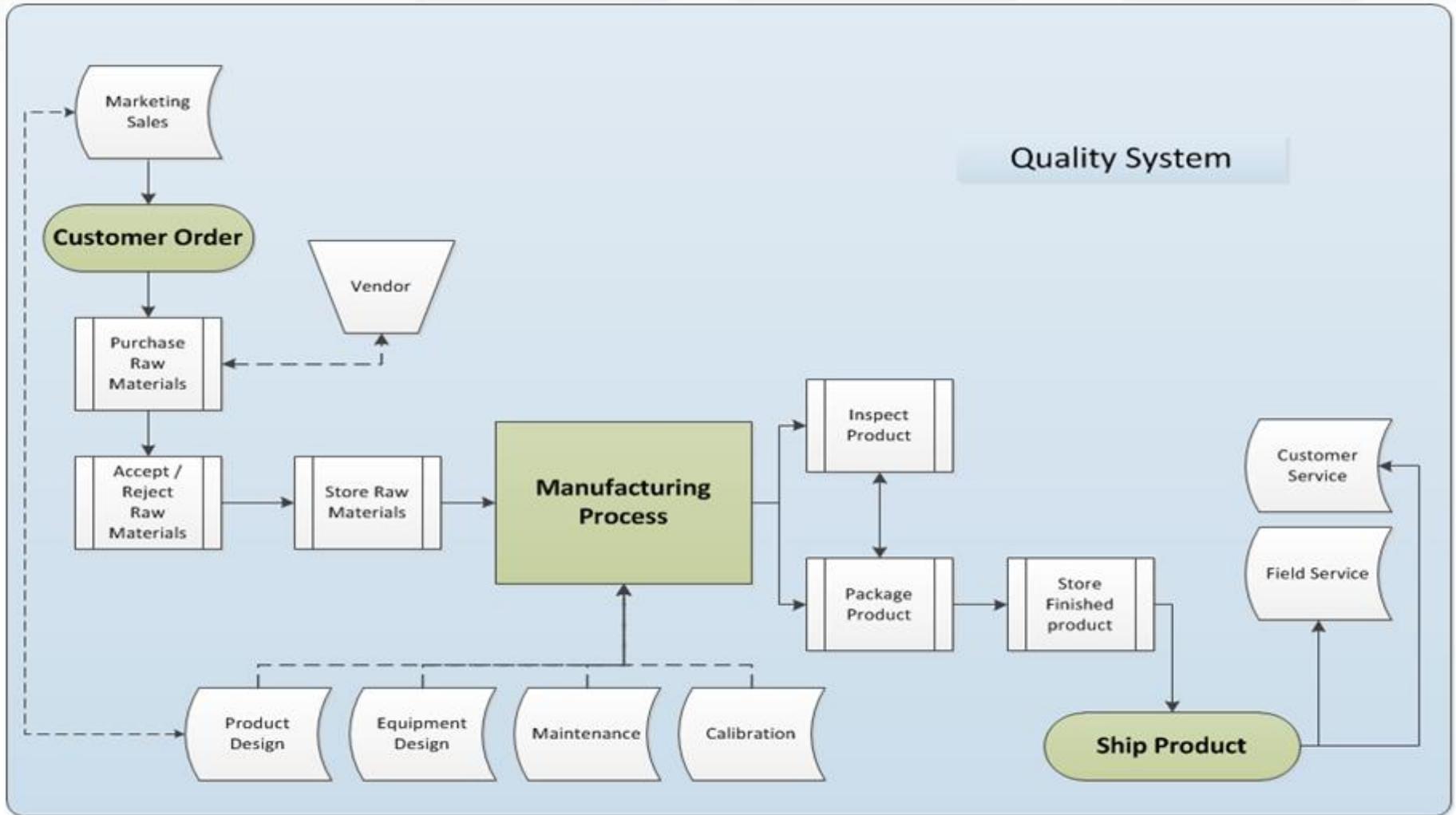
# VALIDATION TYPES

- Facilities
- HVAC systems
- Cleaning
- Manufacturing Process
- Analytical Method
- Packaging
- Equipment
- Computer System
- Plus many others...

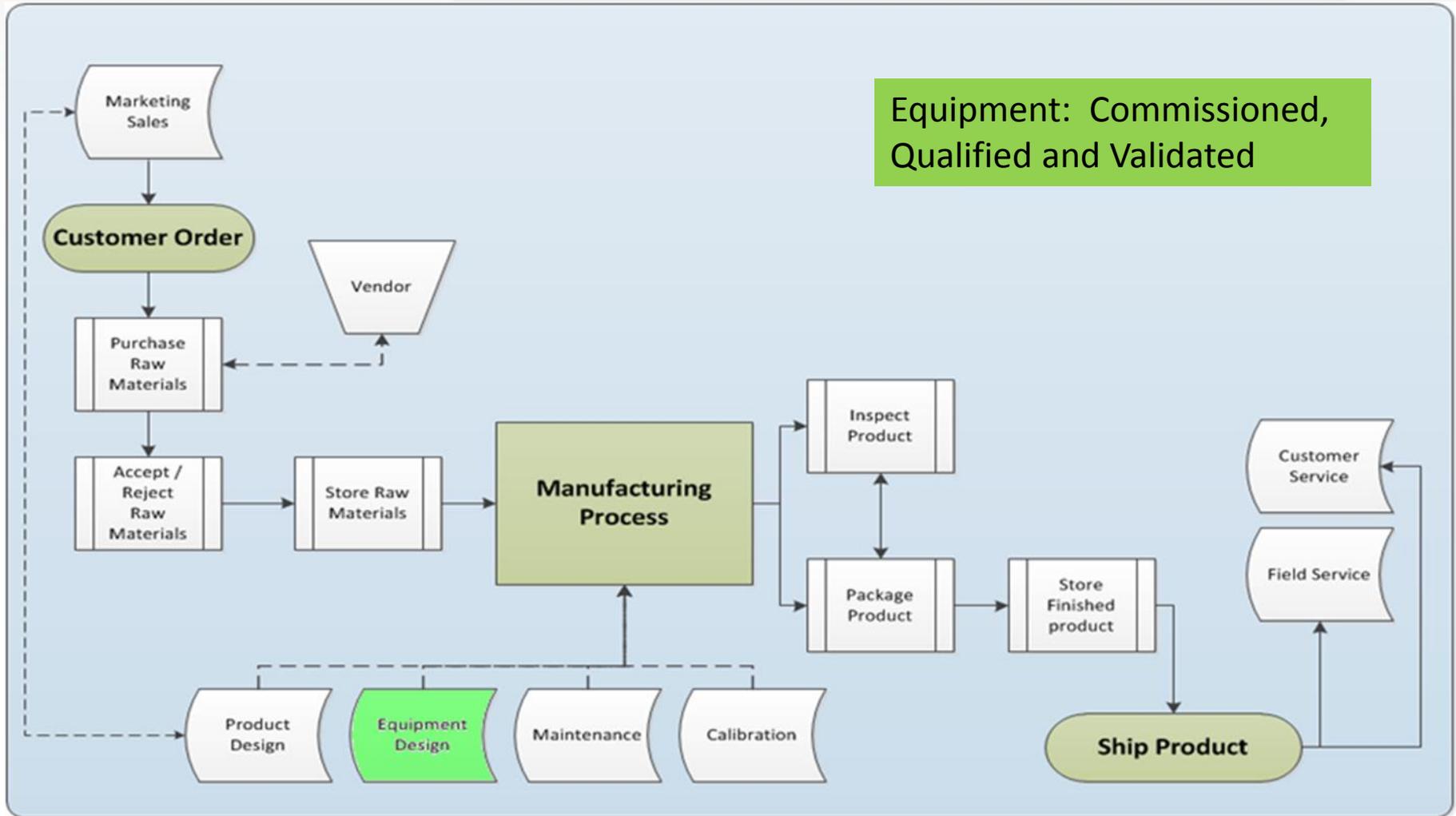
# VALIDATION PROGRAM - DOCUMENTATION

- Protocol
  - What you plan to do
  - How we'll know it worked
- Report
  - What happened
  - Did it work
- Deviation
  - What went wrong and how it was corrected

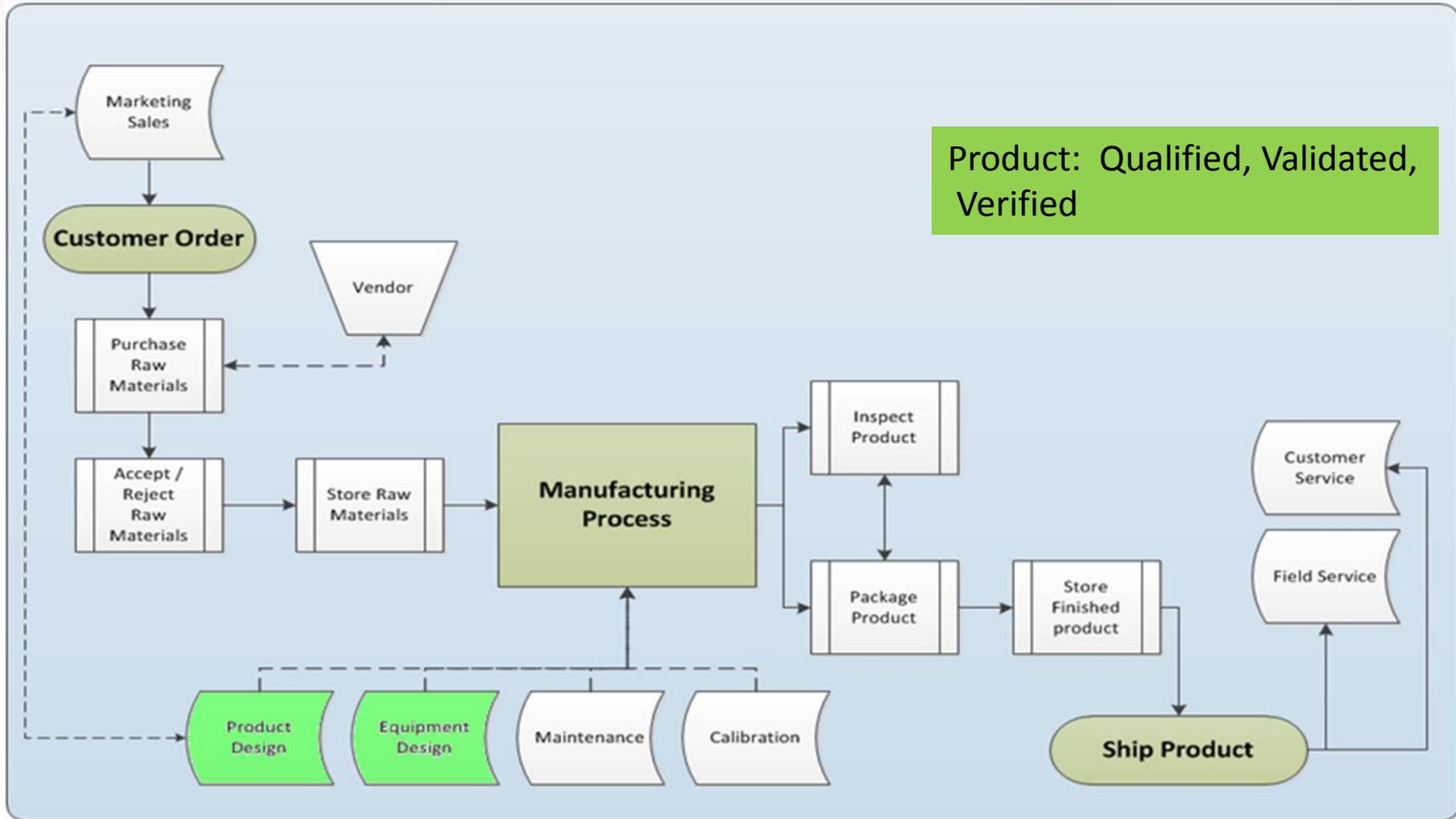
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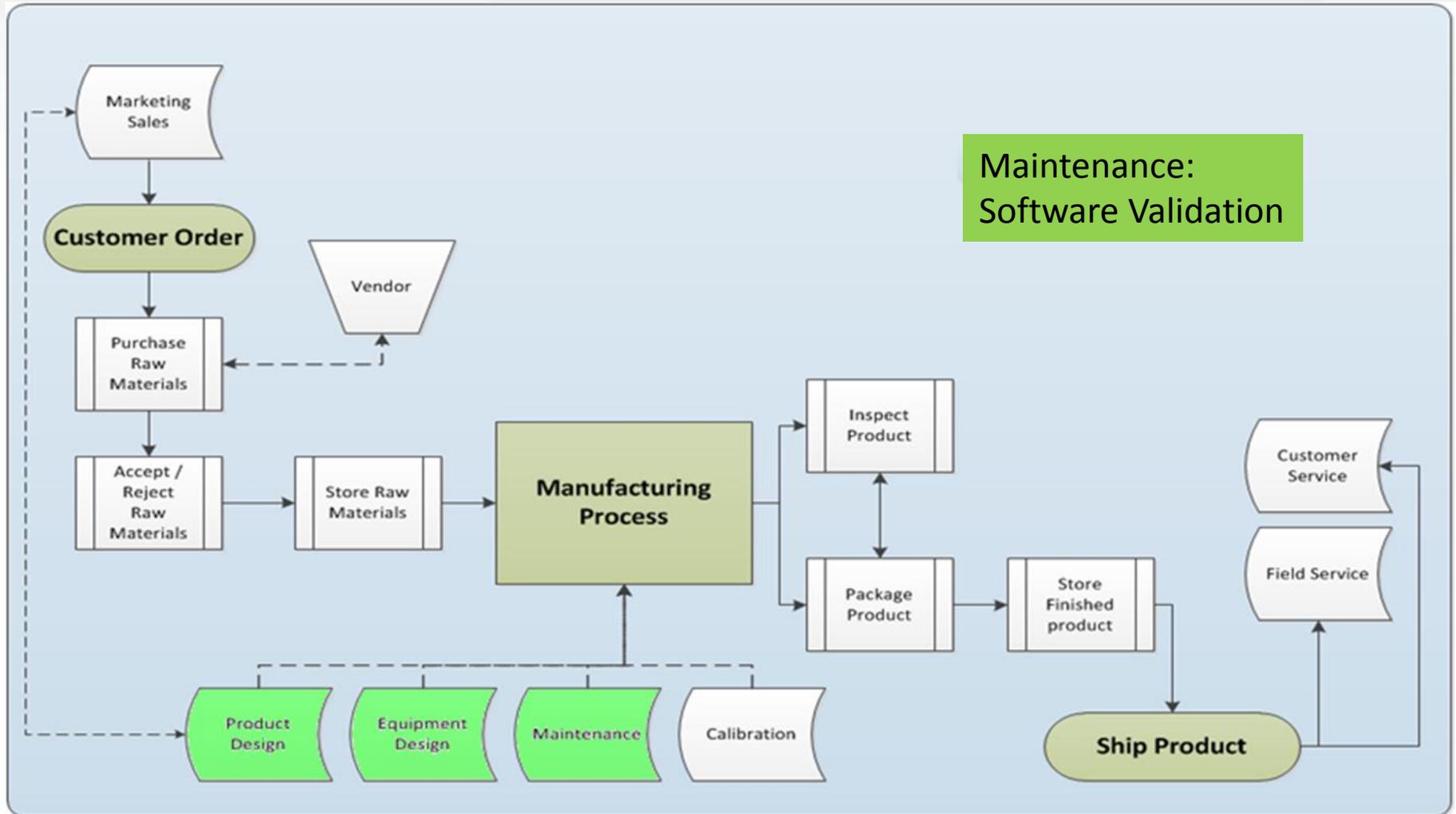
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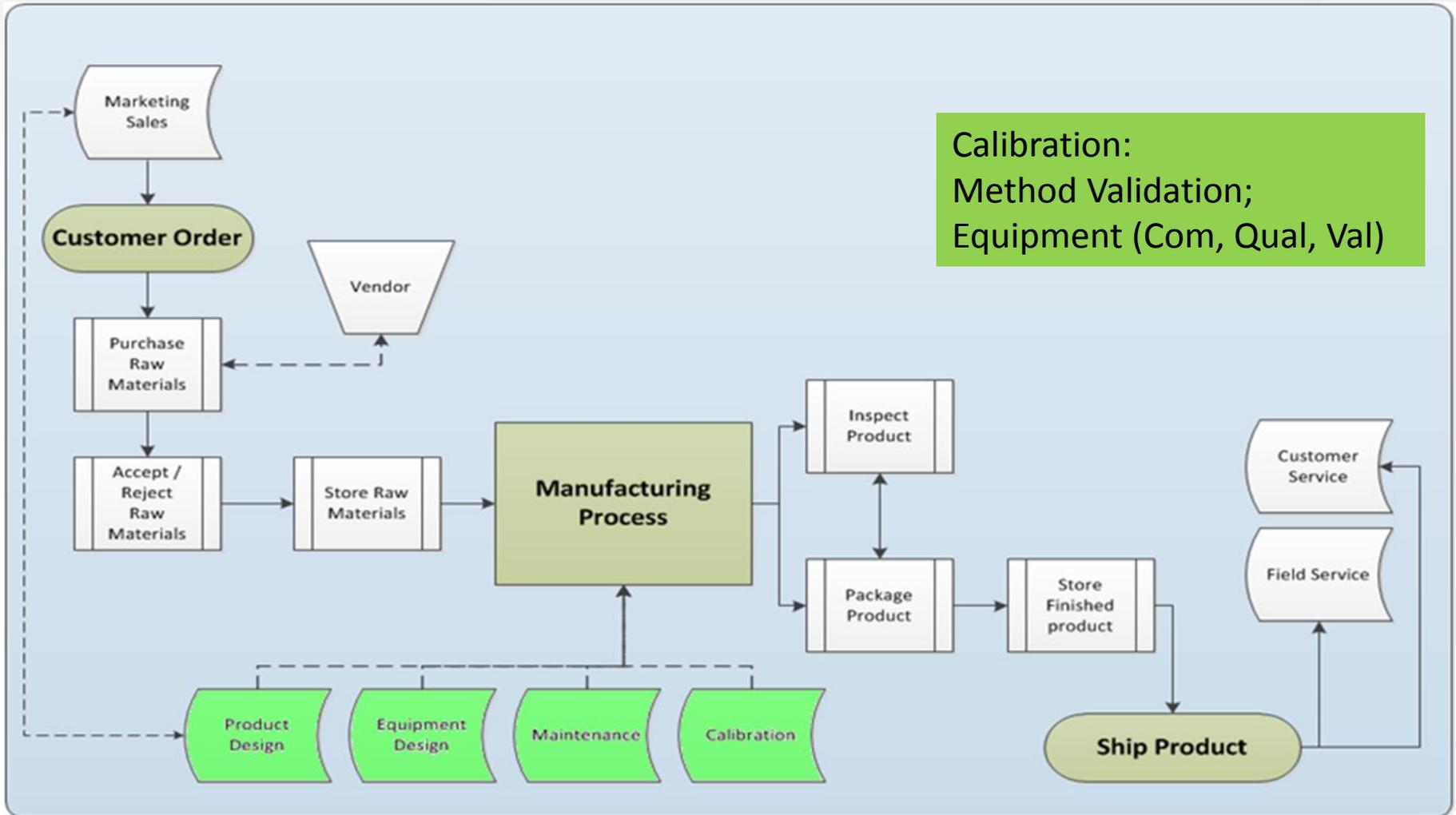
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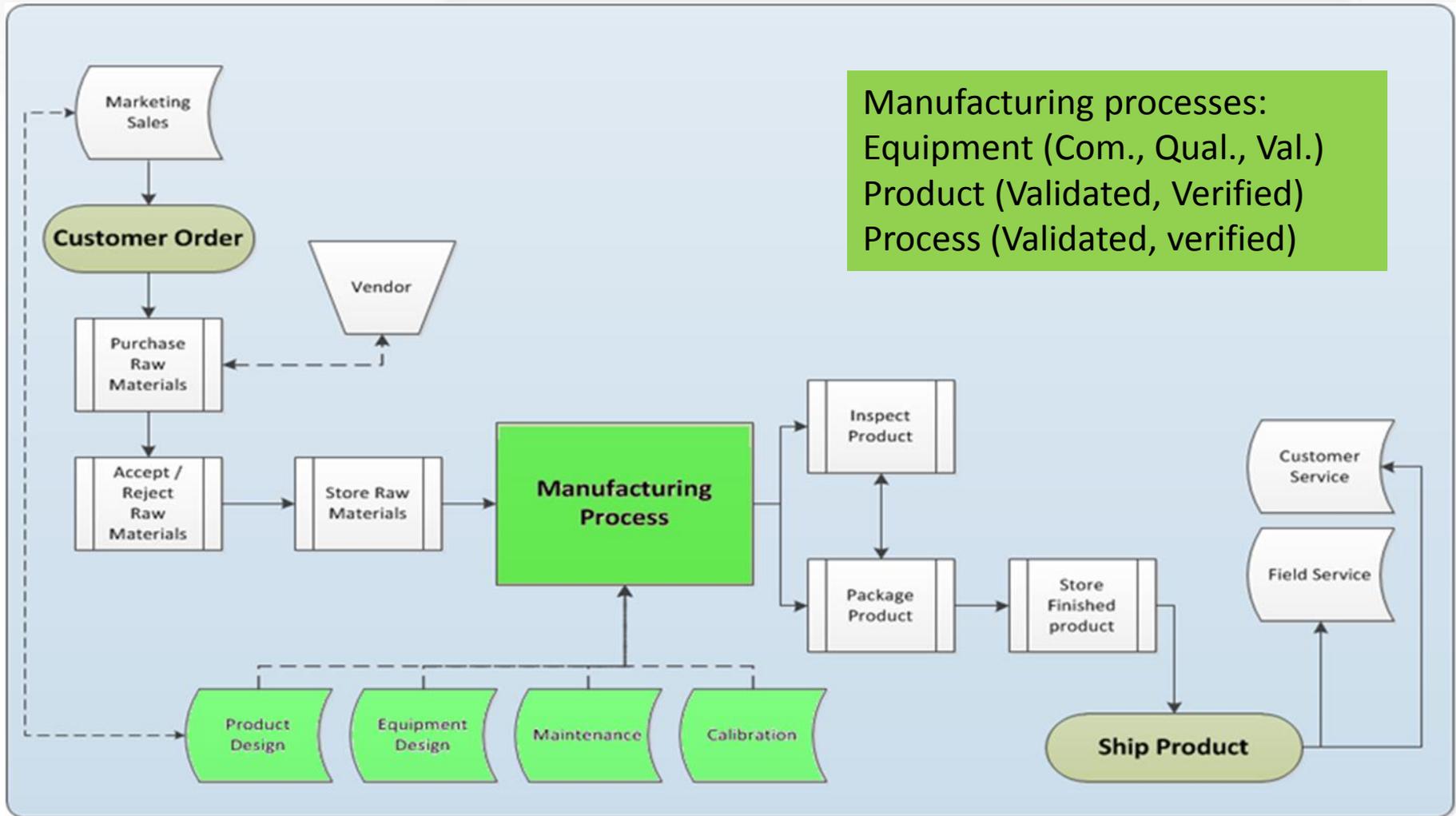
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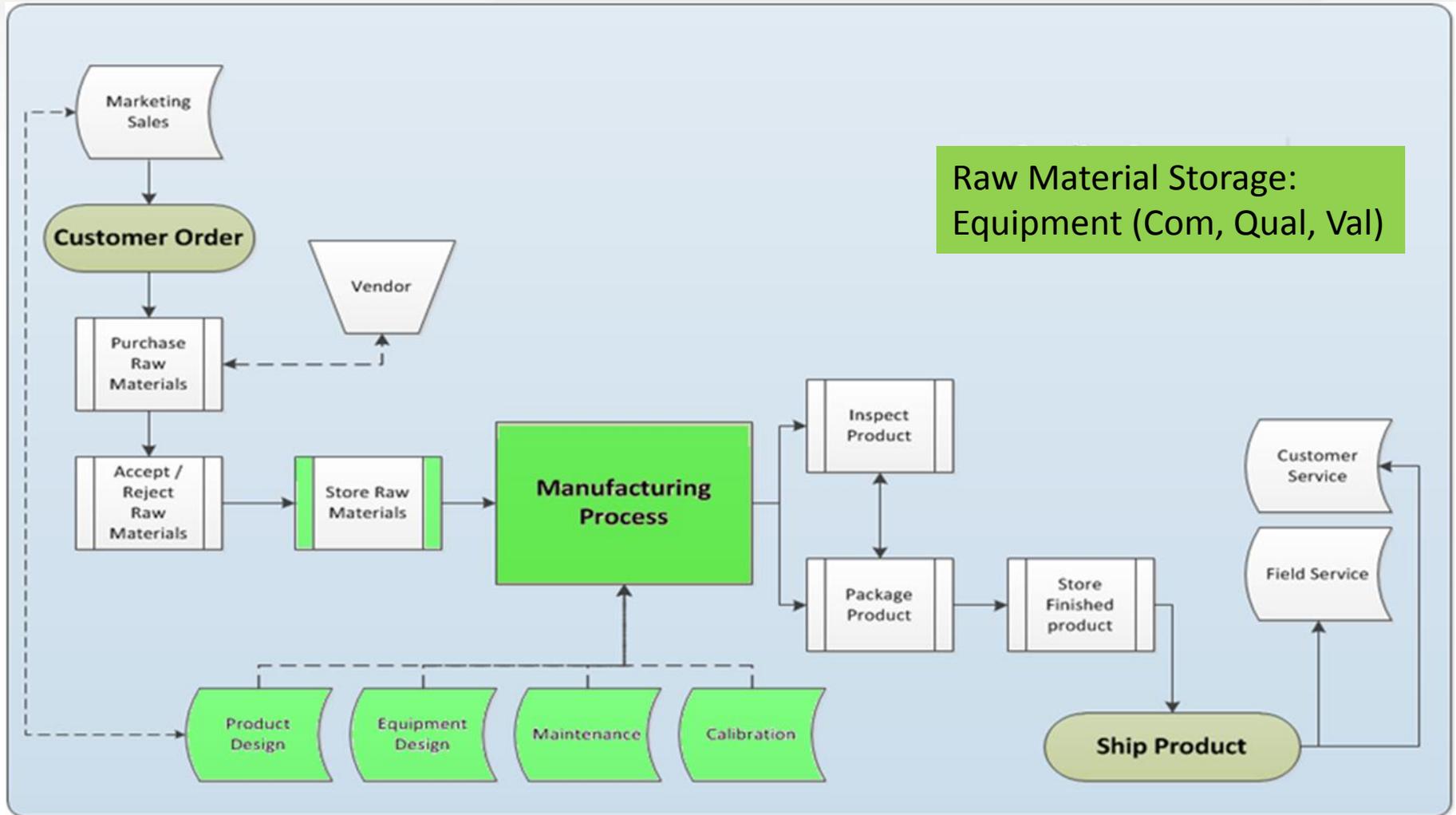
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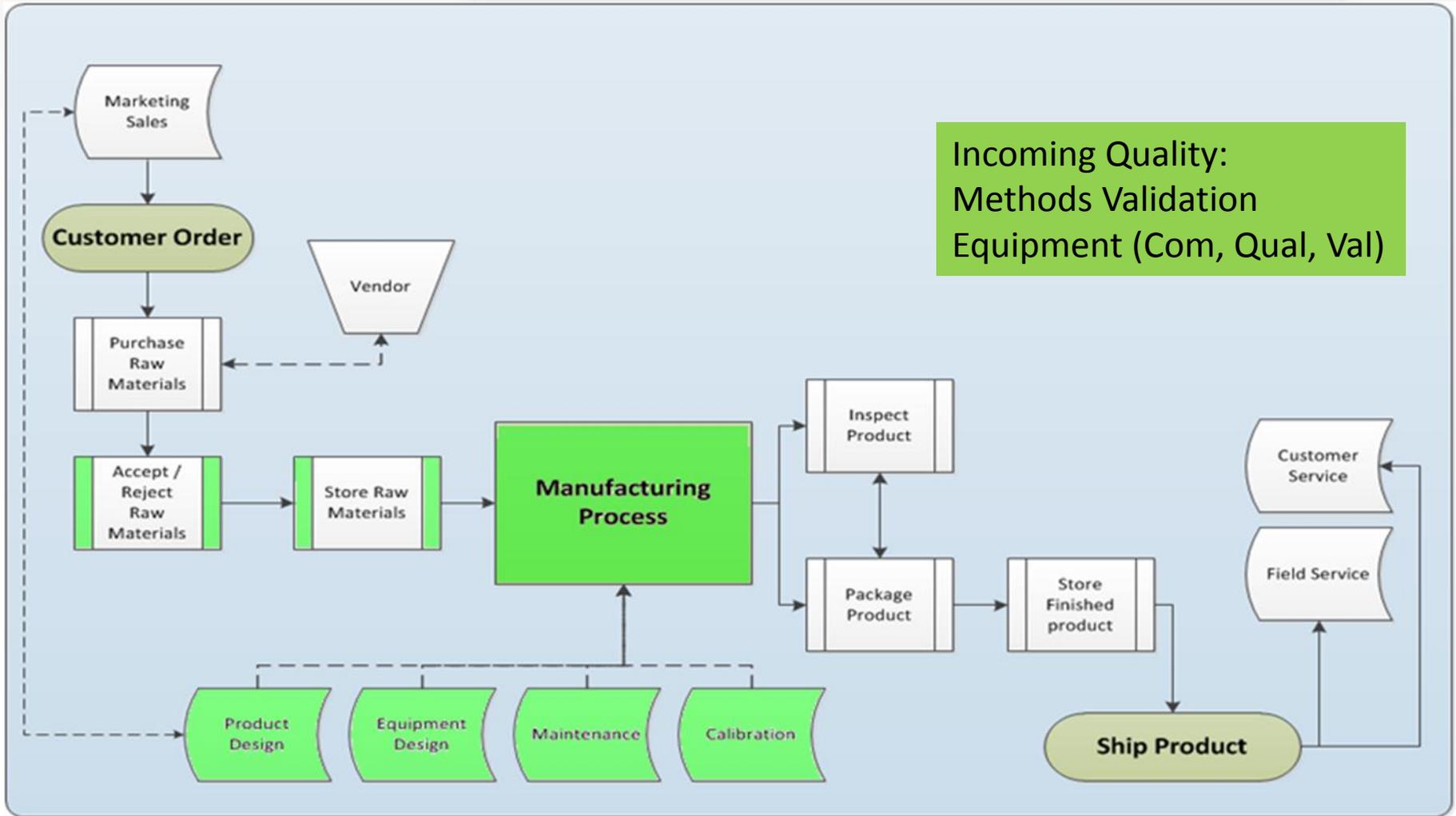
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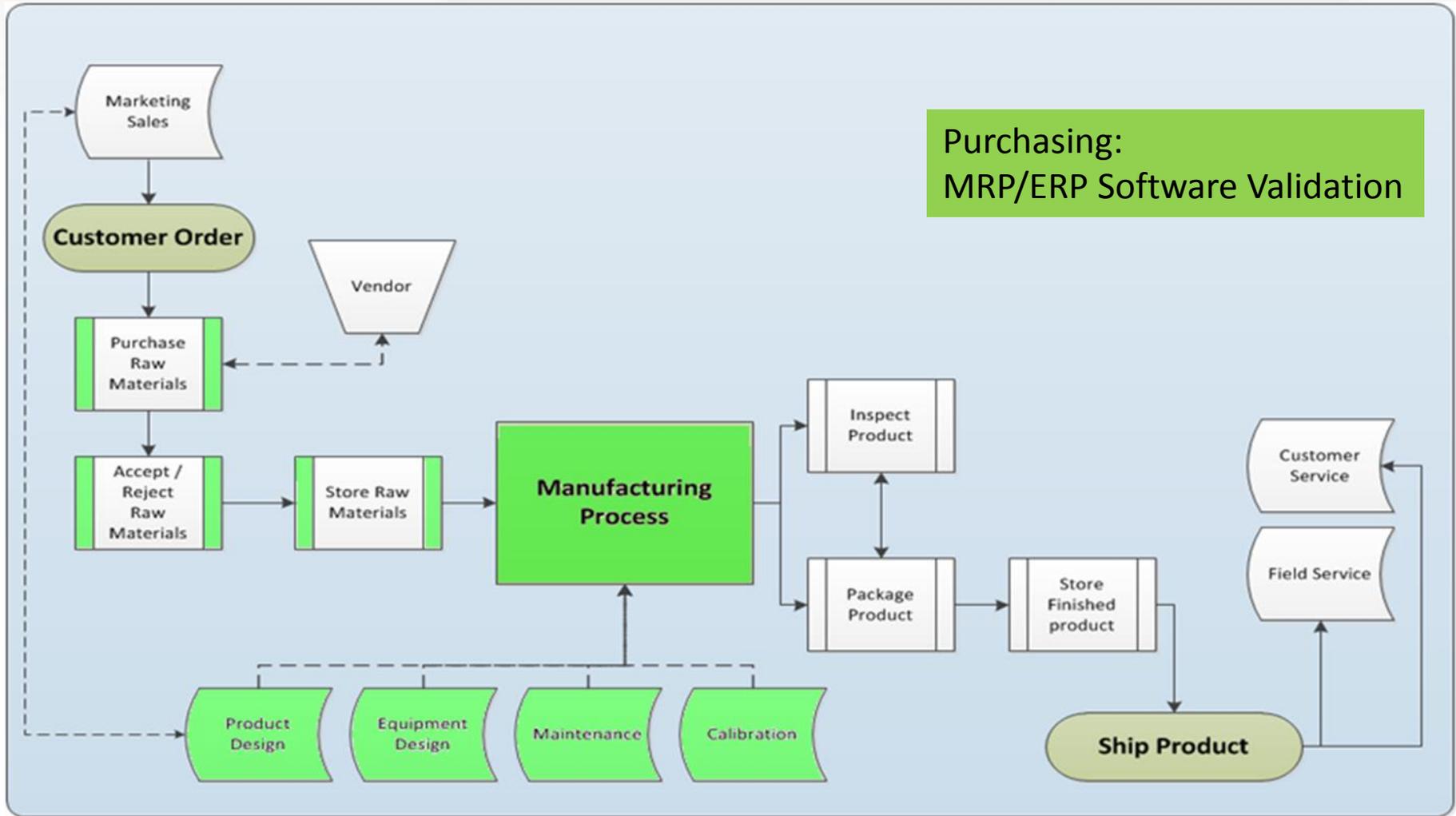
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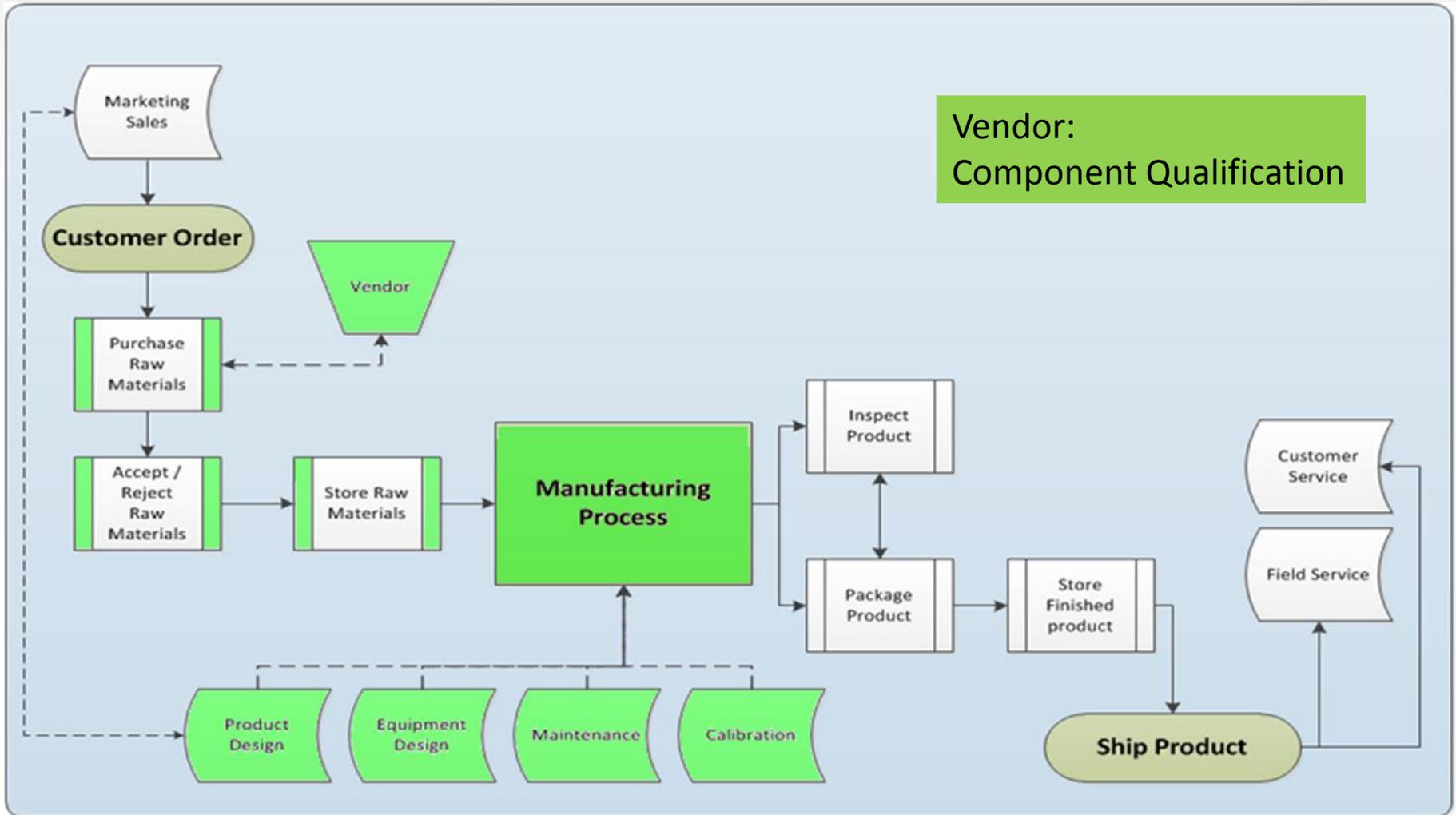
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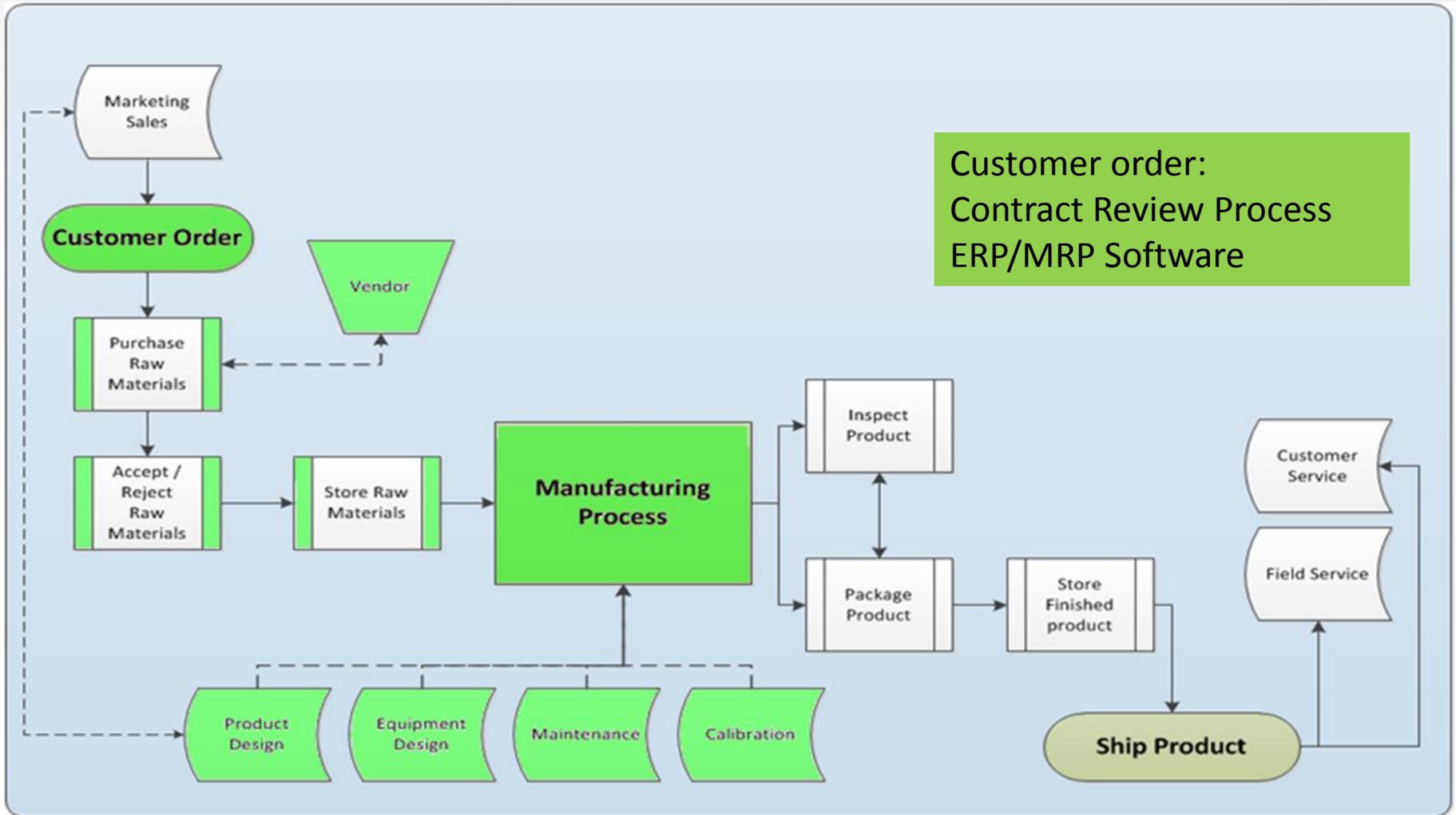
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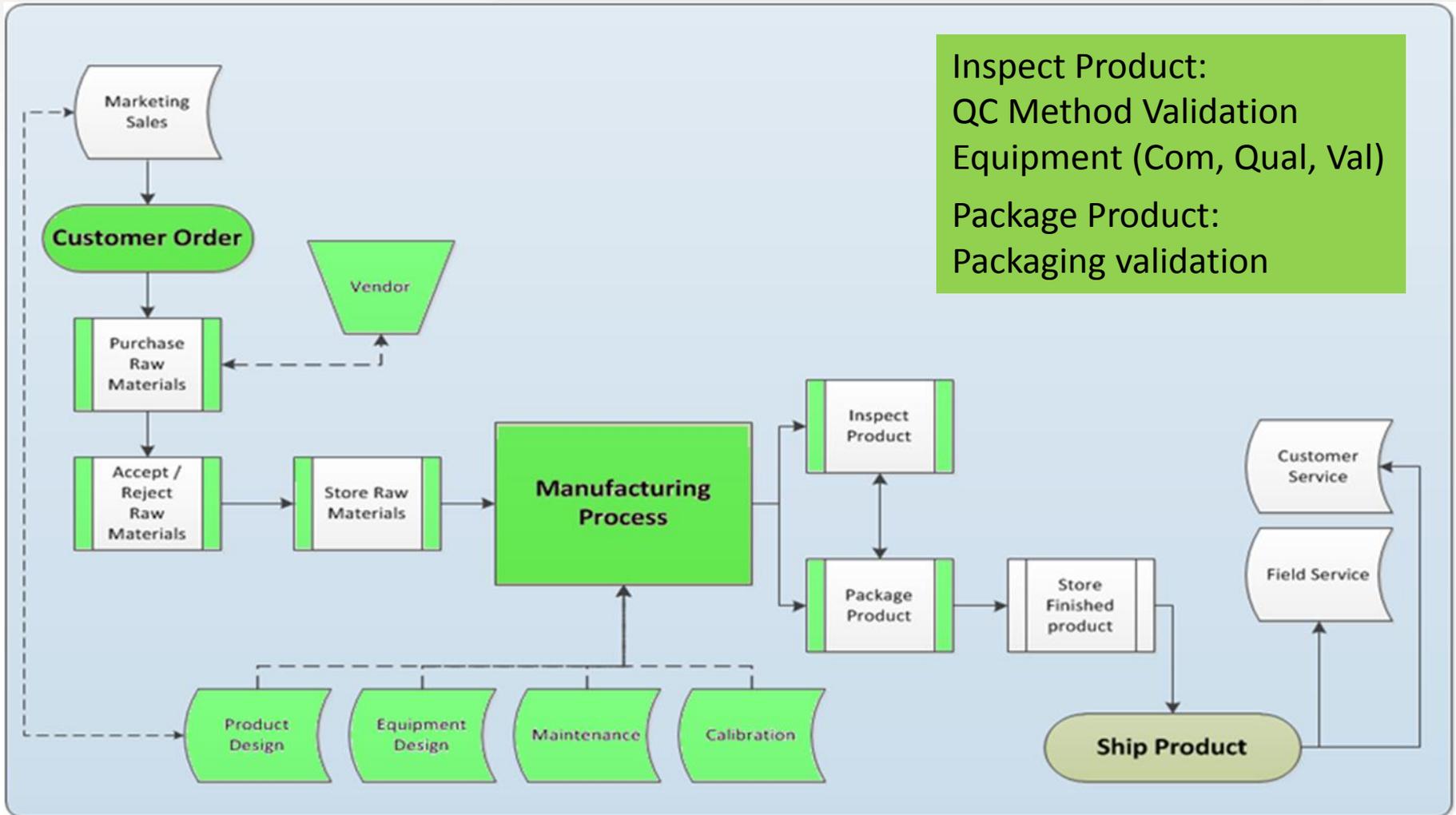
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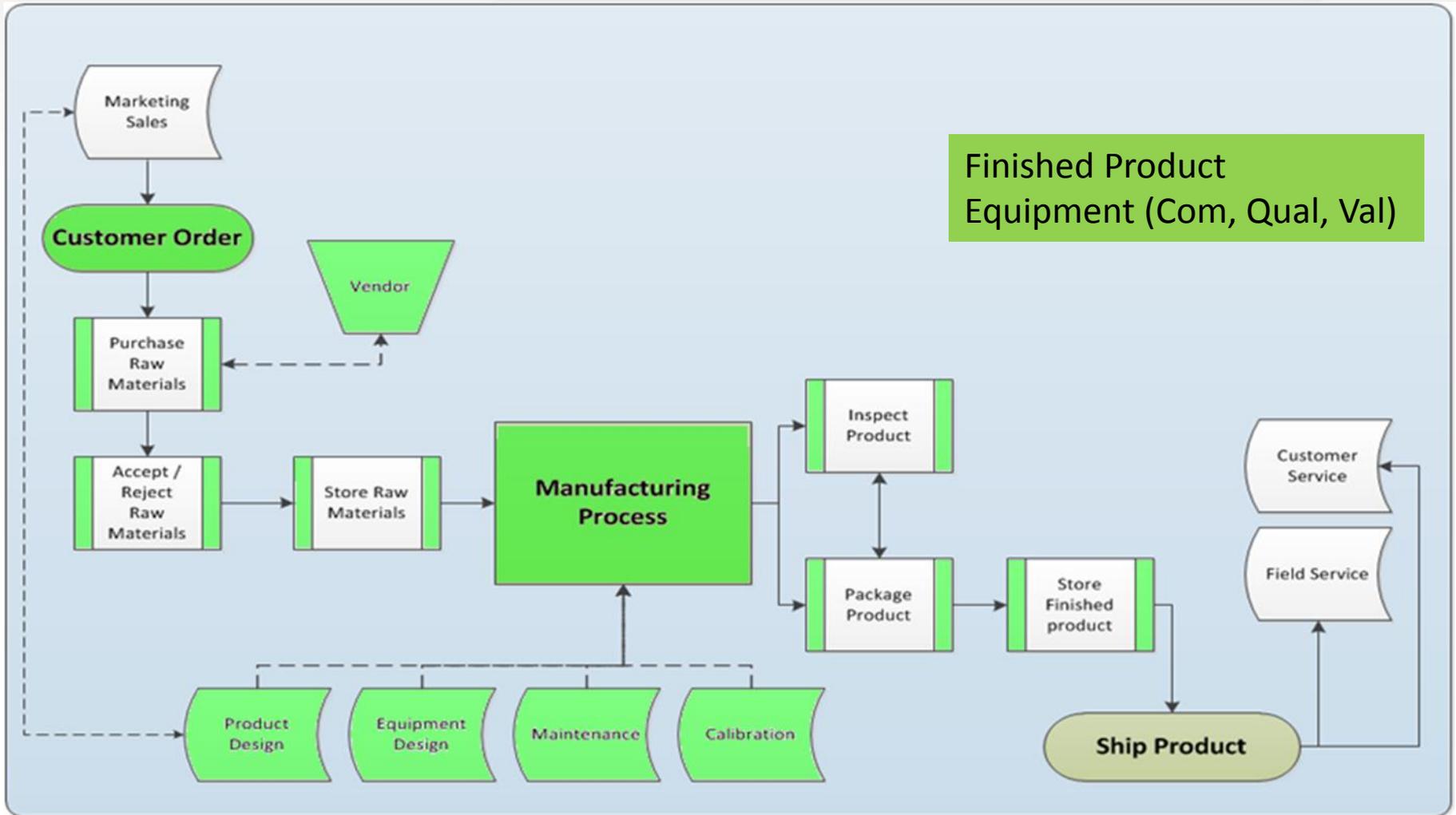
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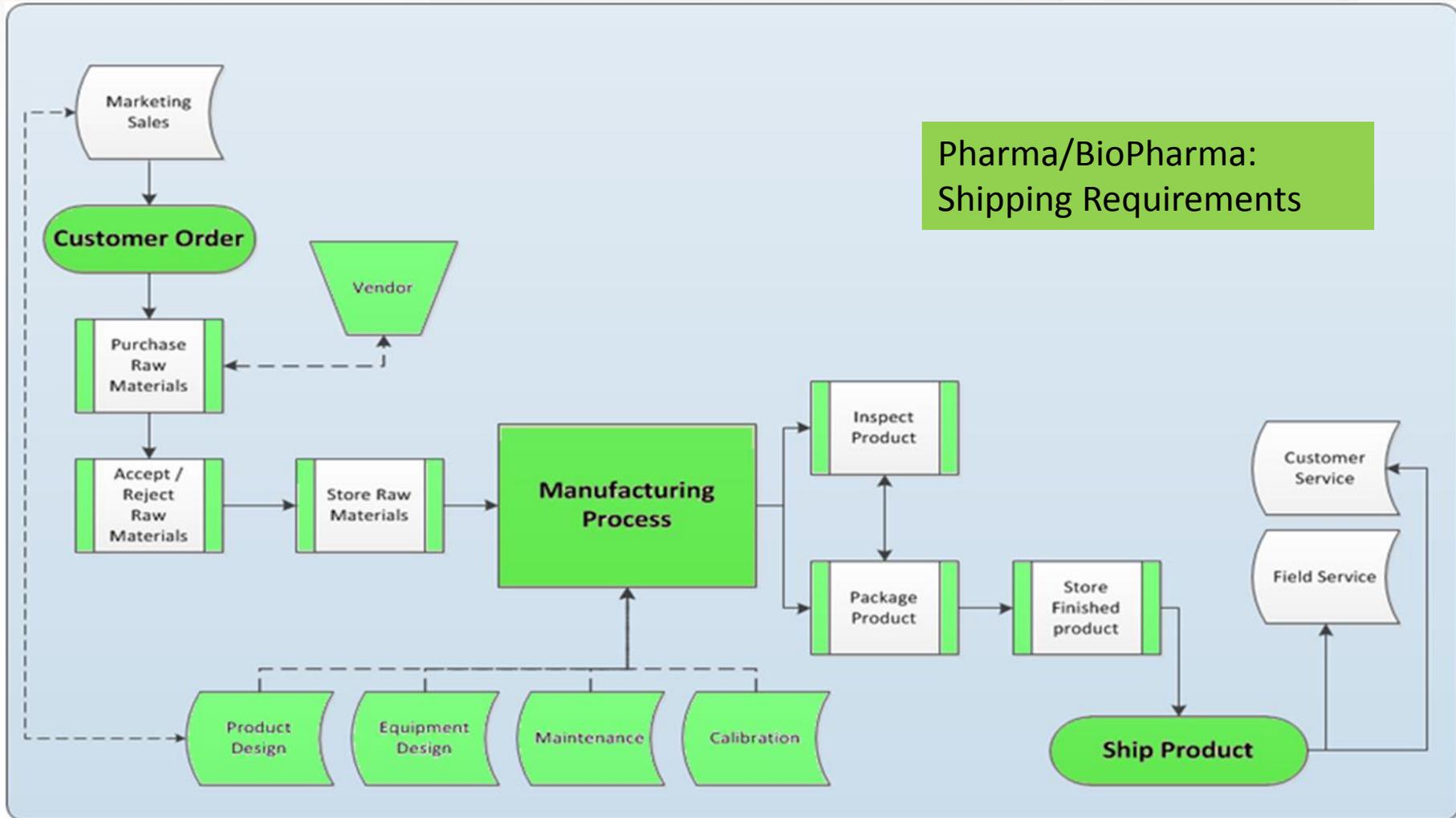
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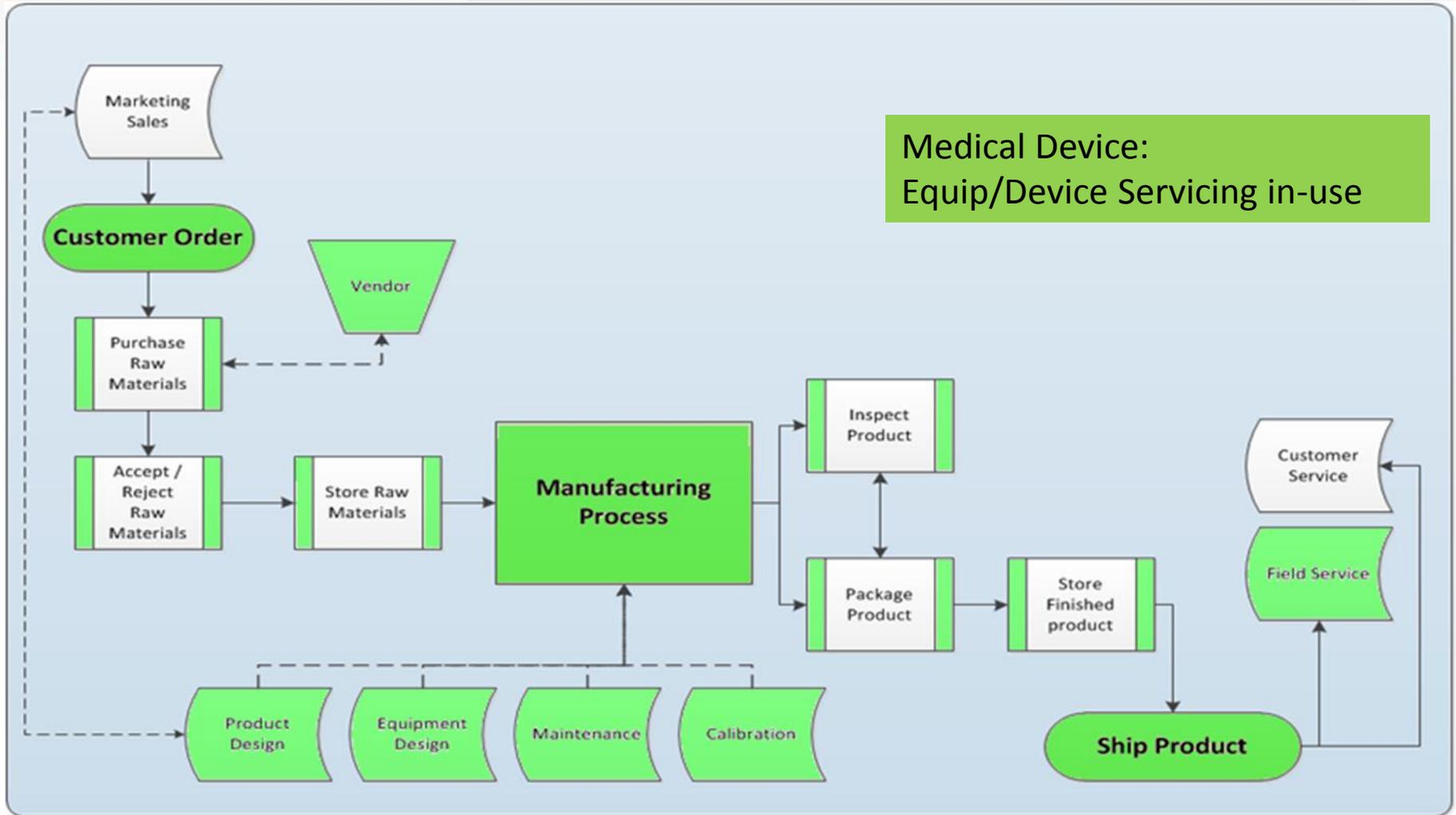
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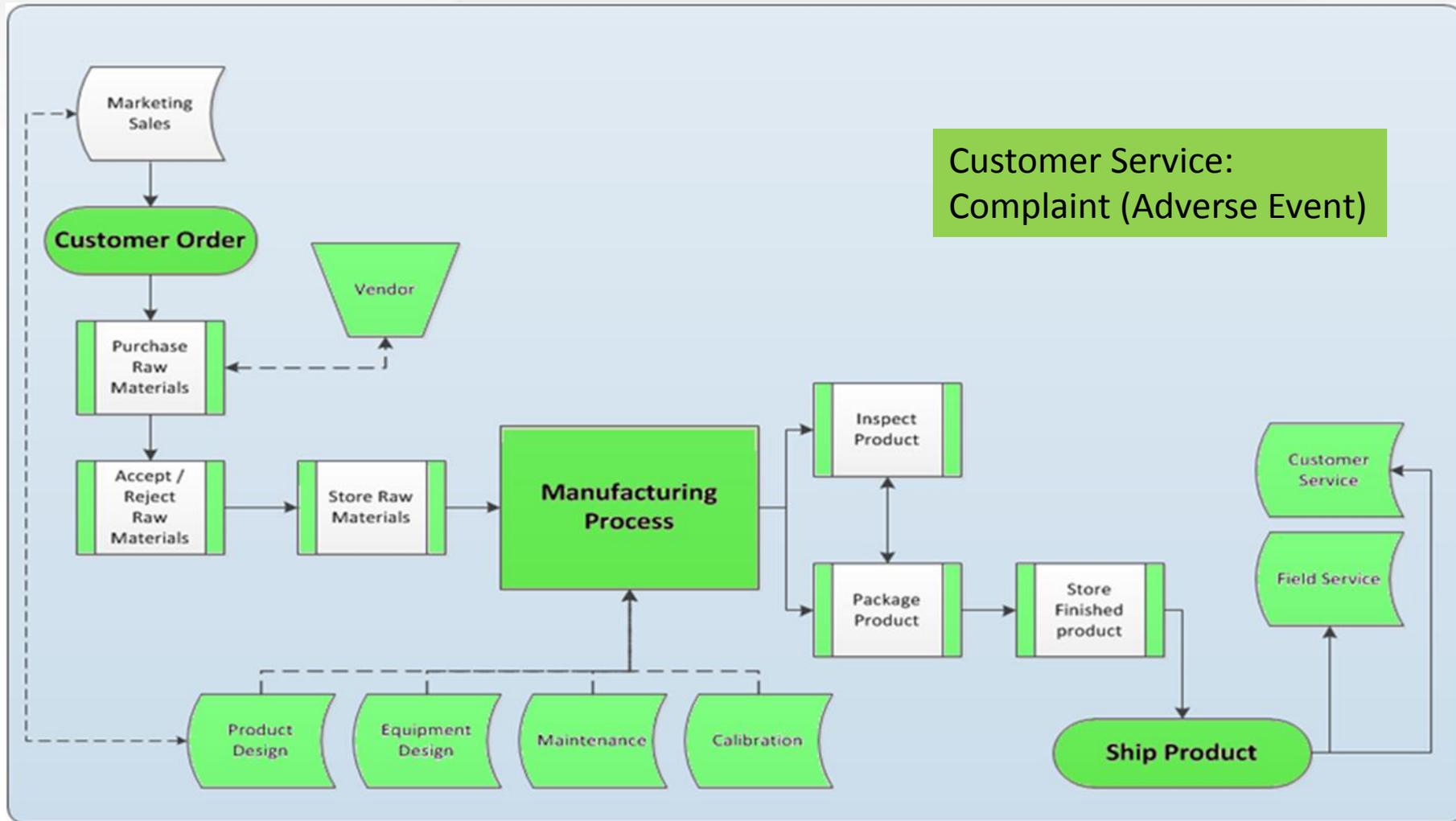
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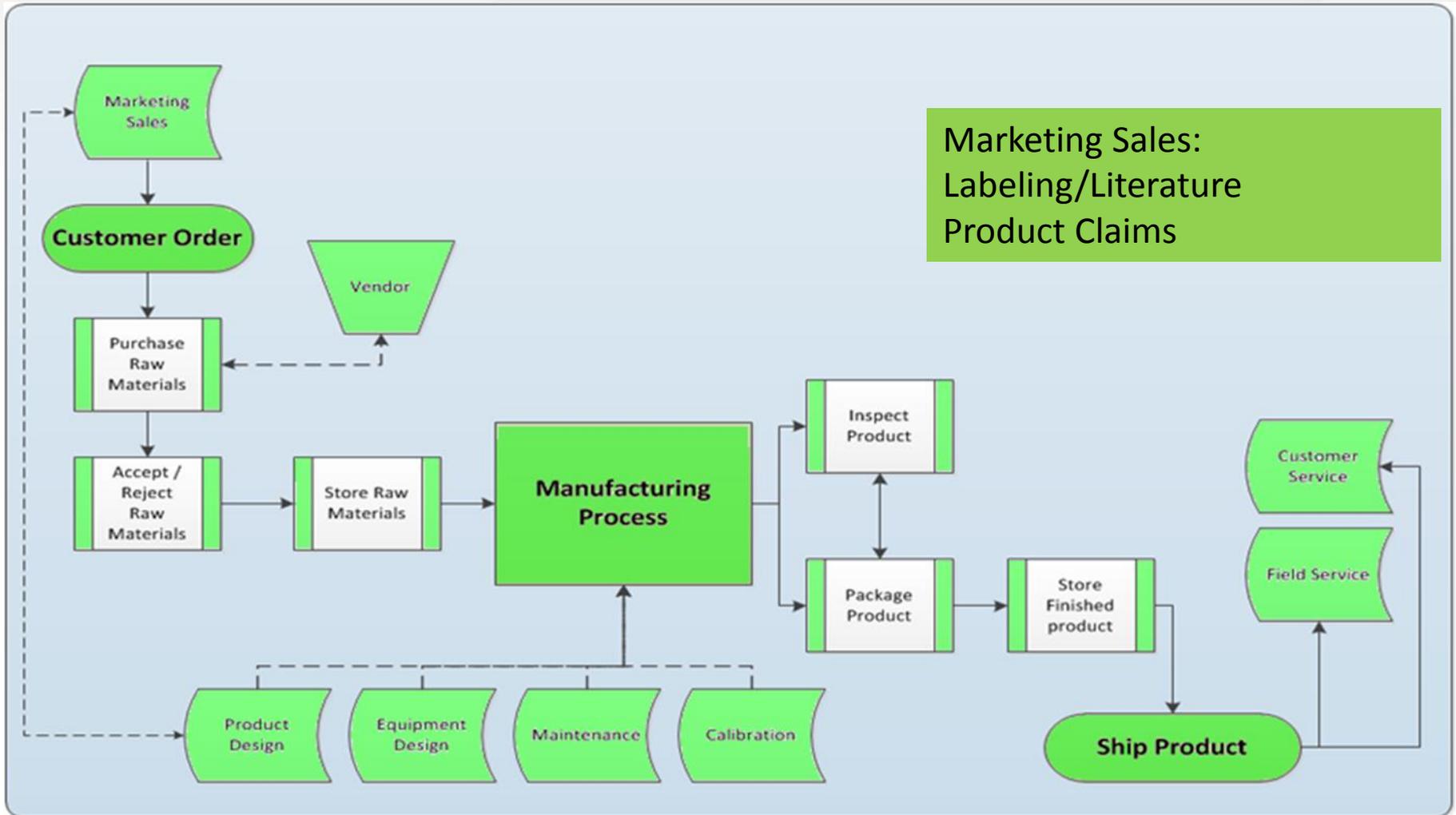


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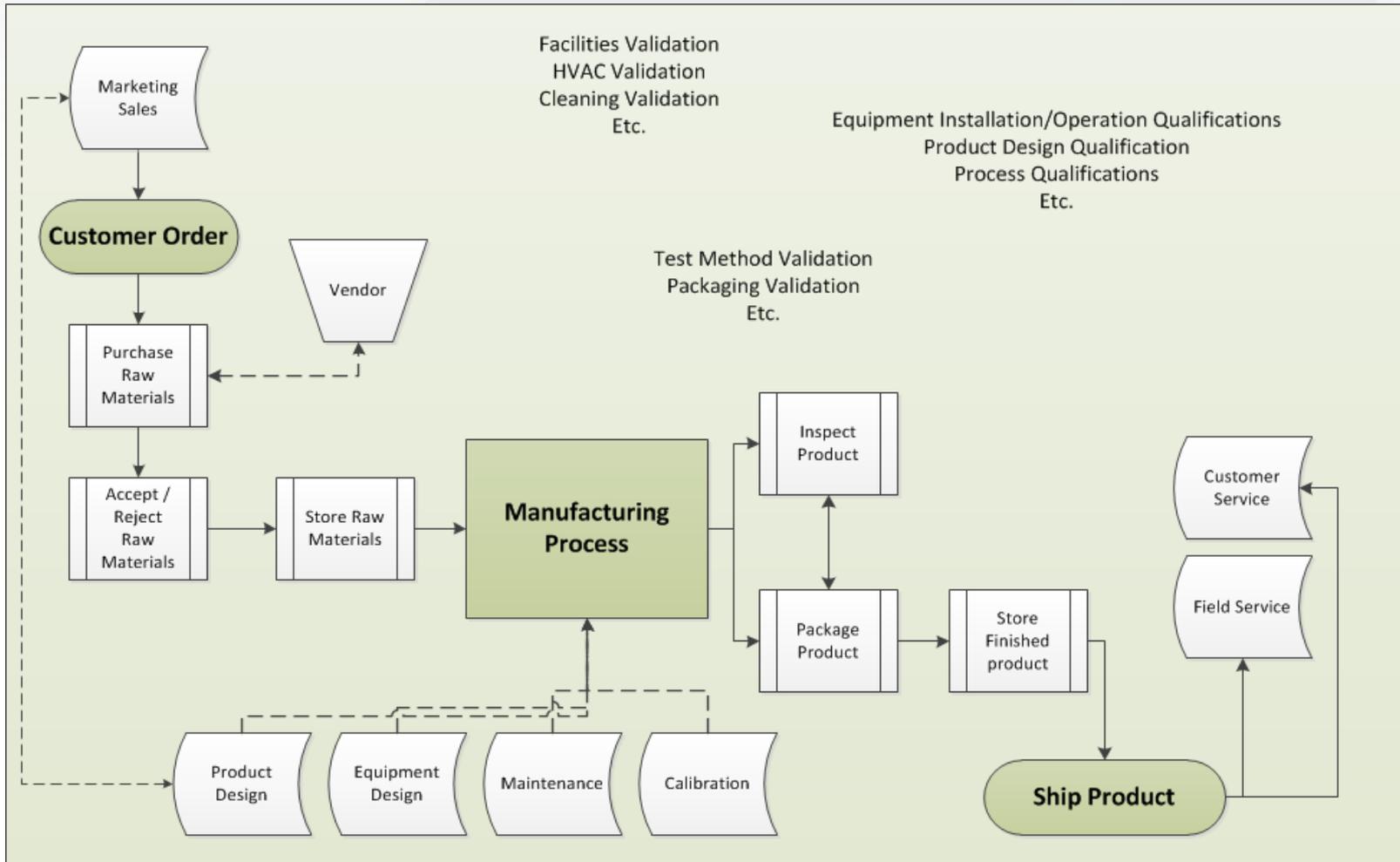


Customer Service:  
Complaint (Adverse Event)

# VALIDATION PROGRAM



# VALIDATED STATE



# Process - Summary

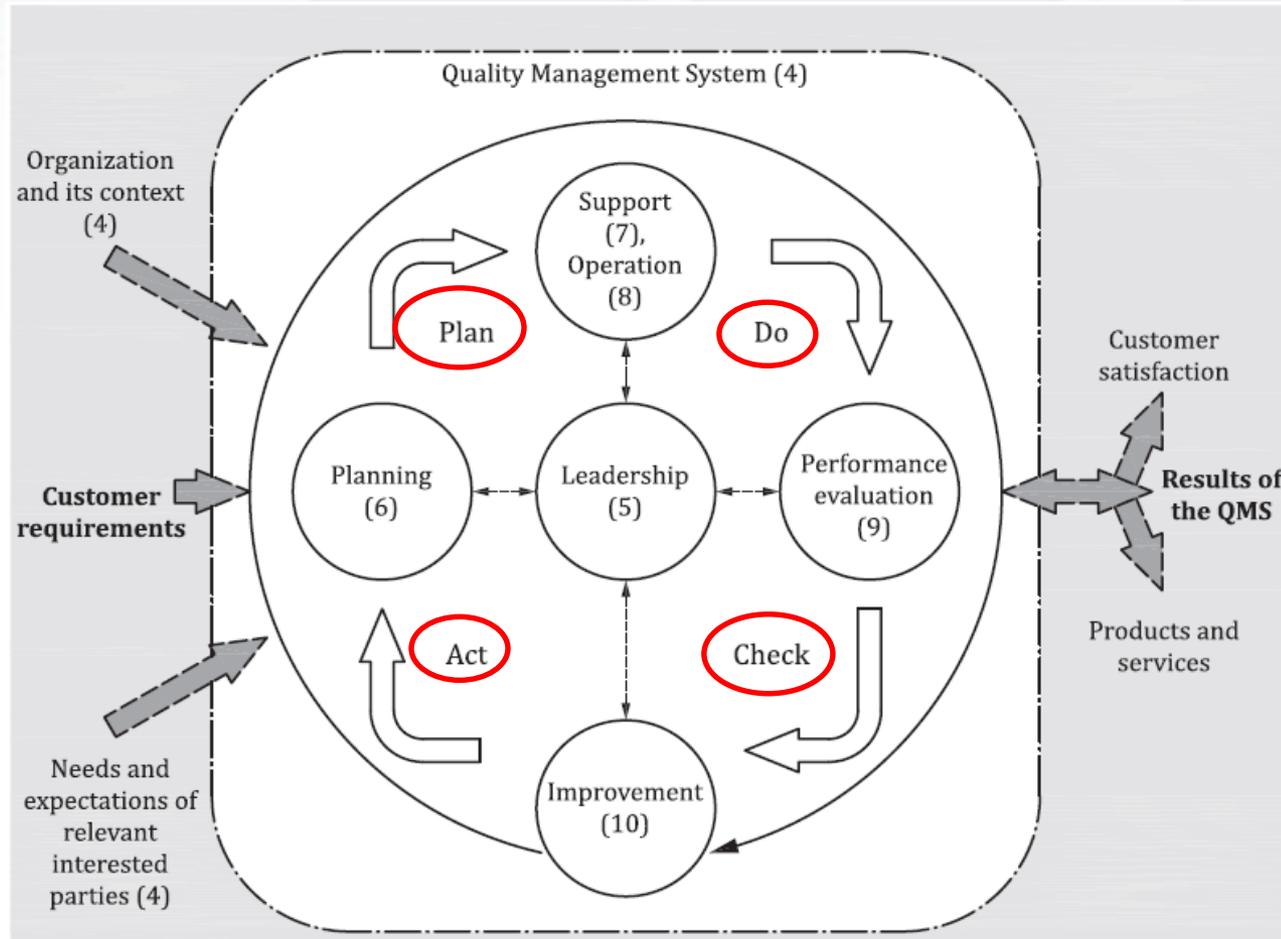
# Process Characteristics

- Is defined
- Is documented
- Established Relationships to other process
- Is monitored and measured
- Records are maintained
- Has an owner
  - Responsibility & authority
  - Defines expectations
  - Assures competent personnel

\* The Memory Jogger™ 9001:2008

# Quality System Process Overview

ISO 9001:2015



# Plan–Do–Check–Act

- **Plan:** Recognize an opportunity and plan a change.
- **Do:** Test the change. Carry out a small-scale study.
- **Check:** Review the test, analyze the results and identify what you've learned.
- **Act:** Take action based on what you learned in the study step: If the change did not work, go through the cycle again with a different plan. If you were successful, incorporate what you learned from the test into wider changes. Use what you learned to plan new improvements, beginning the cycle again.

