

AQS 110

Introduction to Metrology

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• **MODULE 4**

Validation & Lean Six Sigma



INTRODUCTION TO METROLOGY



VALIDATION

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Design/Installation/Operation/Performance

Product Claims

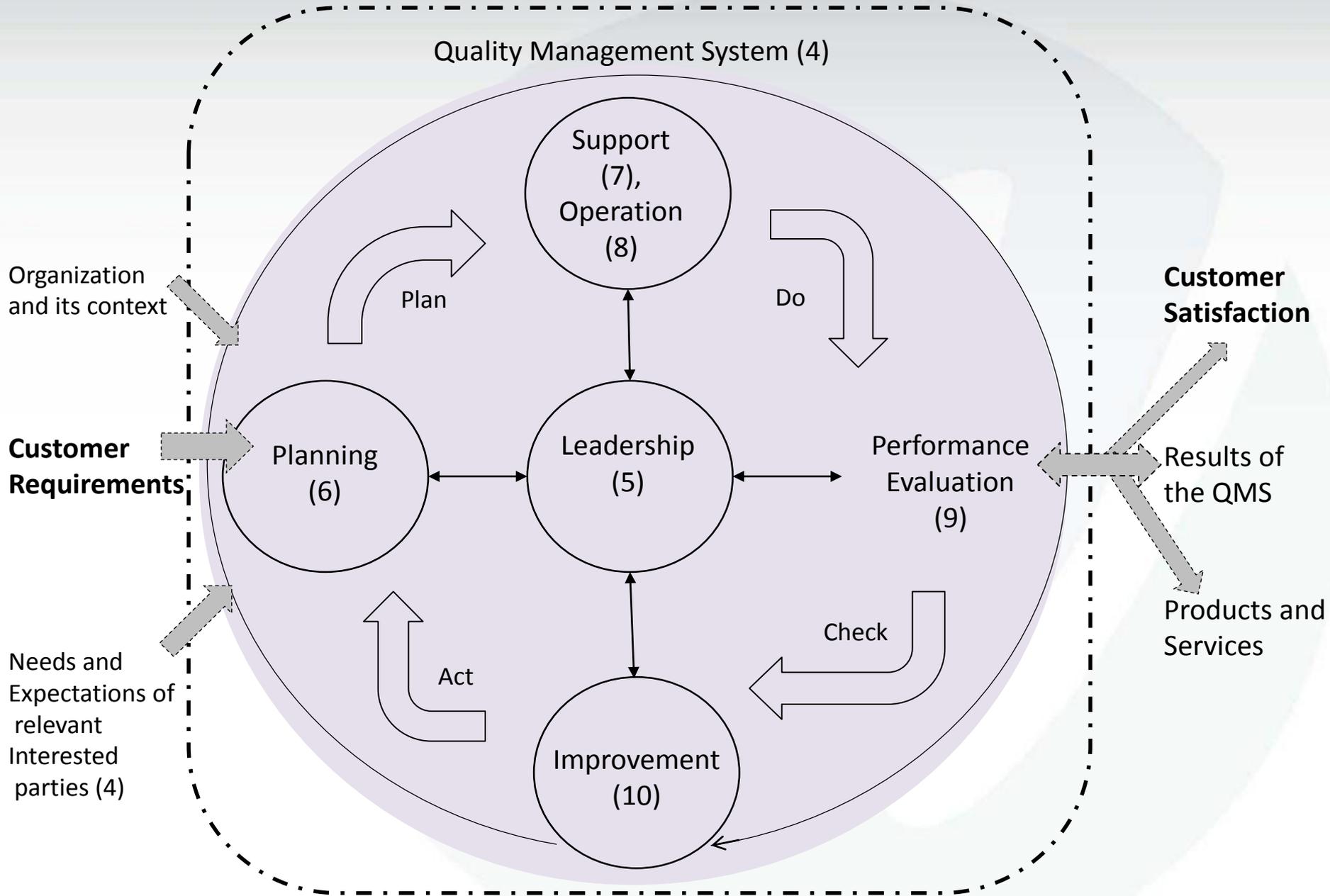
Process Stability

VALIDATION

- Integral part of overall quality system
 - ISO 9001:2015E
 - Section 8.3.4 c & d
 - ISO 13485:2016
 - Section 7.5.6
 - FDA GMPs for pharmaceutical and medical devices
 - 2011 General Guidance for Process Validation
 - 21CFR Part 211.42, 211.63, 211.68, 211.100, 211.110, 211.180
 - 21CFR Part 820.30(f)(g), 820.75

VALIDATION

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 - ISO 9001:2015E
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 - ISO 13485:2016
 - Section 7.5.6
 - FDA GMPs for pharmaceutical and medical devices
 - 2011 General Guidance for Process Validation
 - 21CFR Part 211.42, 211.63, 211.68, 211.100, 211.110, 211.180
 - 21CFR Part 820.30(f)(g), 820.75
- Terminology
 - Commissioning; Qualification; Validation; Verification**
 - Terms used interchangeably, but technical differences



VALIDATION - Terminology

- **Commissioning:** process to evaluate equipment to make sure it was properly designed and built
 - Testing inclusive of factory and site acceptance testing
 - Testing not a complete validation
- Verifies environment surrounding equipment will support proper functioning of equipment
- Similar to validation/qualification multiple types of activities (i.e. HVAC, assembly machines, etc.)
 - Industry, site (facility) and equipment type dependent

VALIDATION - Terminology

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VALIDATION - Terminology

- Qualification is a predefined scripted set of tests with expected results
 - Developed based on available documentation
 - May evaluate only the functionality that will be used

QUALIFICATION TYPES

- Design (DQ)
 - User Requirement Specification (URS)
- Installation (IQ)
 - Factory Acceptance Testing (FAT)
- Operational (OQ)
 - Range Testing
- Performance or Process (PQ)
 - Stability & Repeatability
- Component (CQ)
 - Supplier Responsibility
- Re-qualification (RQ)
- Plus many others...

VALIDATION - Terminology

- 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 - Terminology

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 – COMPONENTS

- Site Validation Master Plan
 - Covers entire facility location and/or company
- Validation Standard Operating Procedures
 - Standardized approach to executing activities
- Validation Plan
 - Initiates and documents the project planned approach
- Re-Validation
 - Periodic review of validated system(s)

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

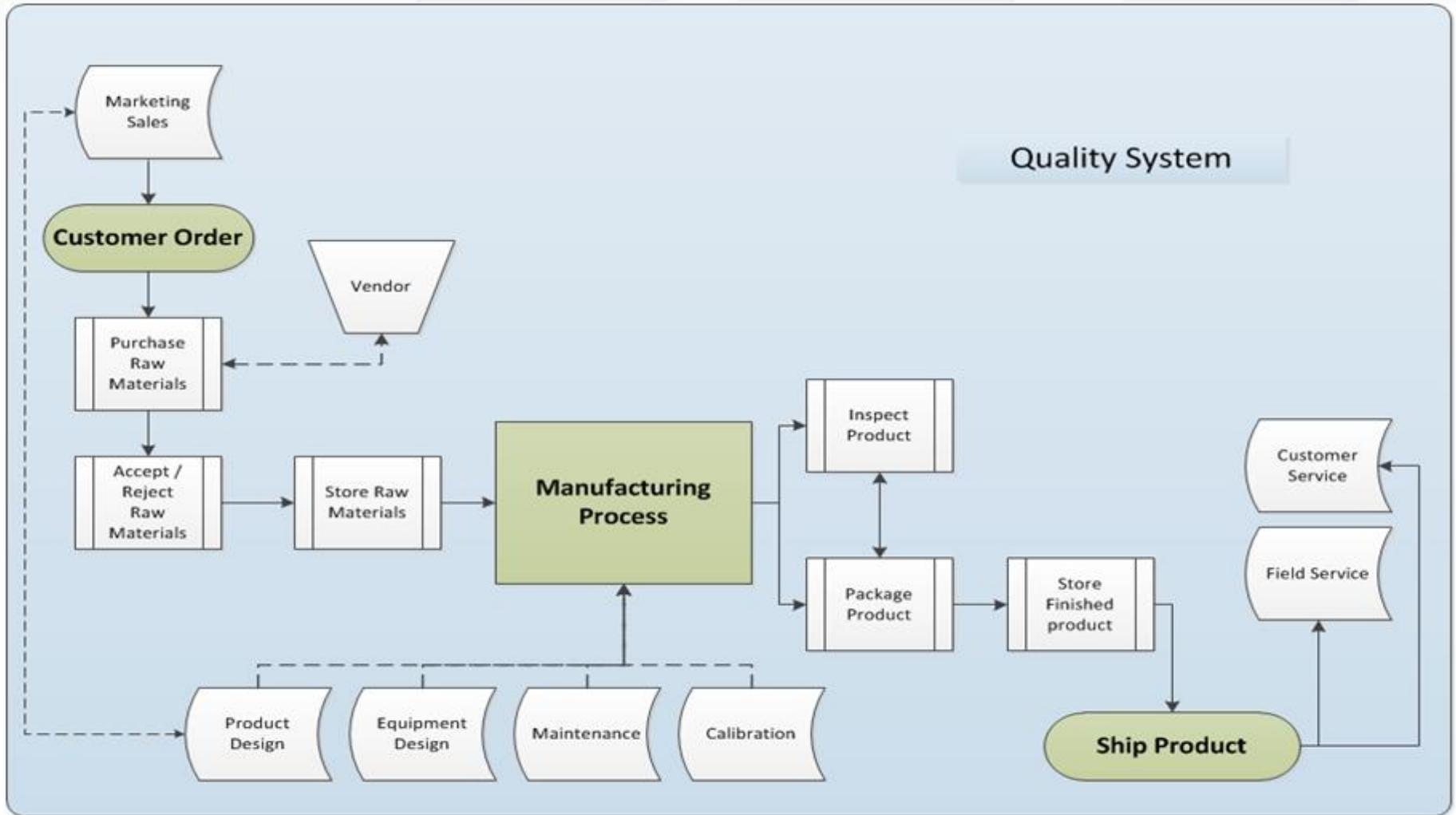
VALIDATION PROGRAM - DOCUMENTATION

- Protocol - Describes the **PLAN** for demonstrating/evaluating the process
 - Purpose, Scope, Background
 - References, Definitions
 - Validation Plan
 - Acceptance Criteria (Specifications)
 - Responsibilities and Resources
 - Materials, Equipment / Tooling
 - Manufacturing Conditions (Procedures)
 - Test Methods, Sampling Requirements
 - Data Evaluation (statistical requirements)
 - Approvals

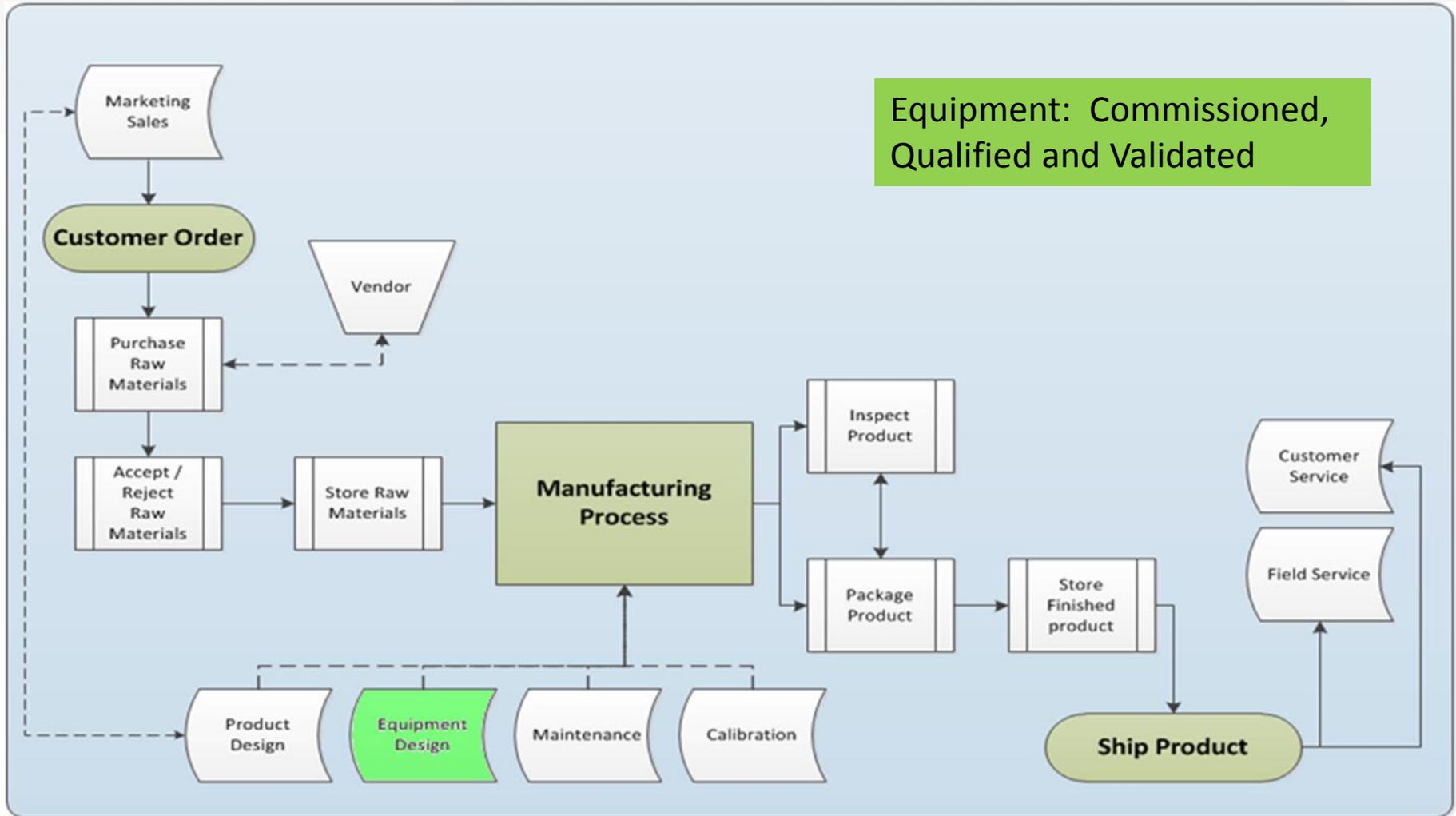
VALIDATION PROGRAM - DOCUMENTATION

- Report describes **what HAPPENED** during the validation
(the good, the bad, the ugly)
 - Results – Data Evaluation / Analysis
 - Discussion
 - Summary
 - Conclusion
 - Approvals

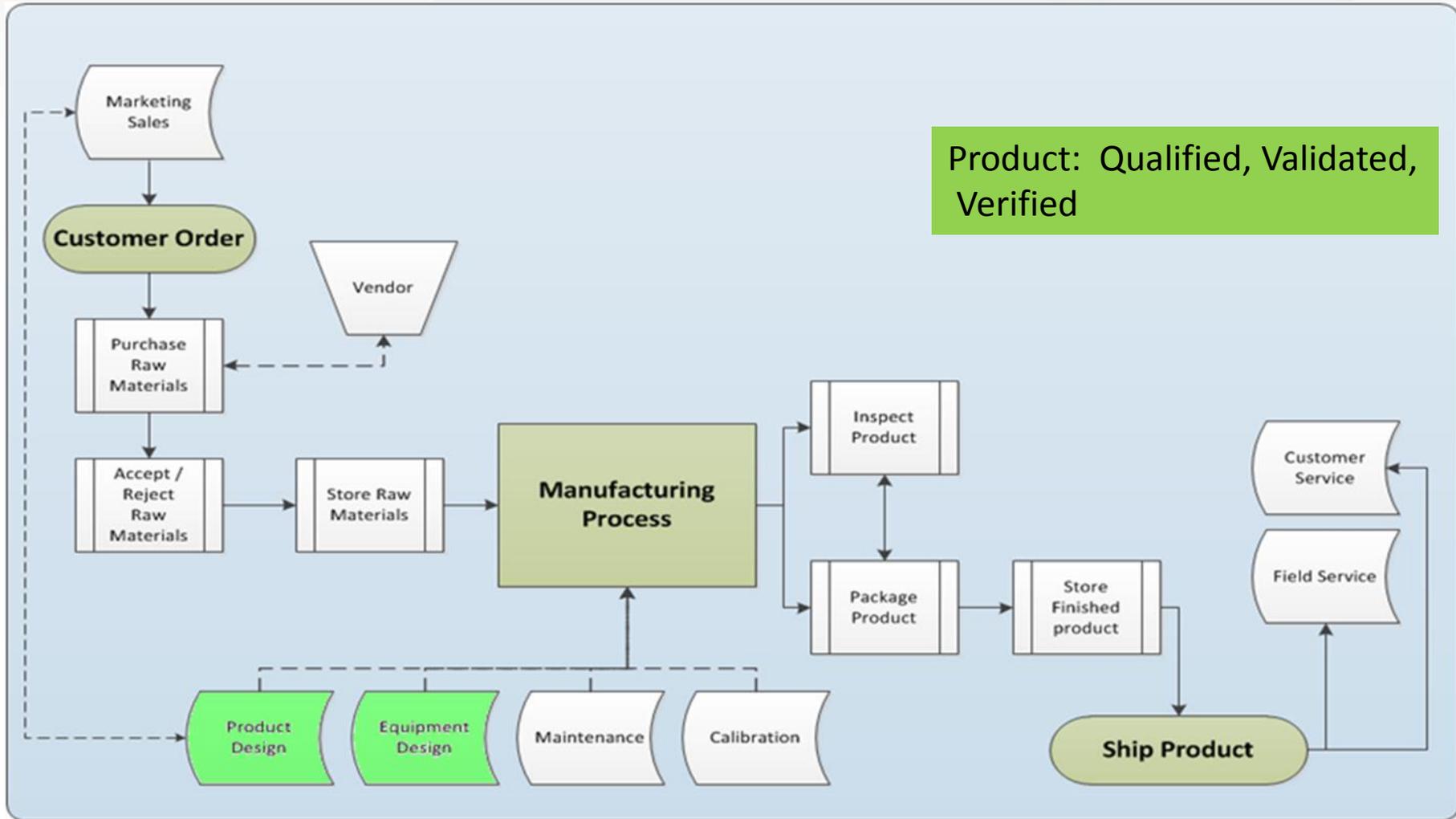
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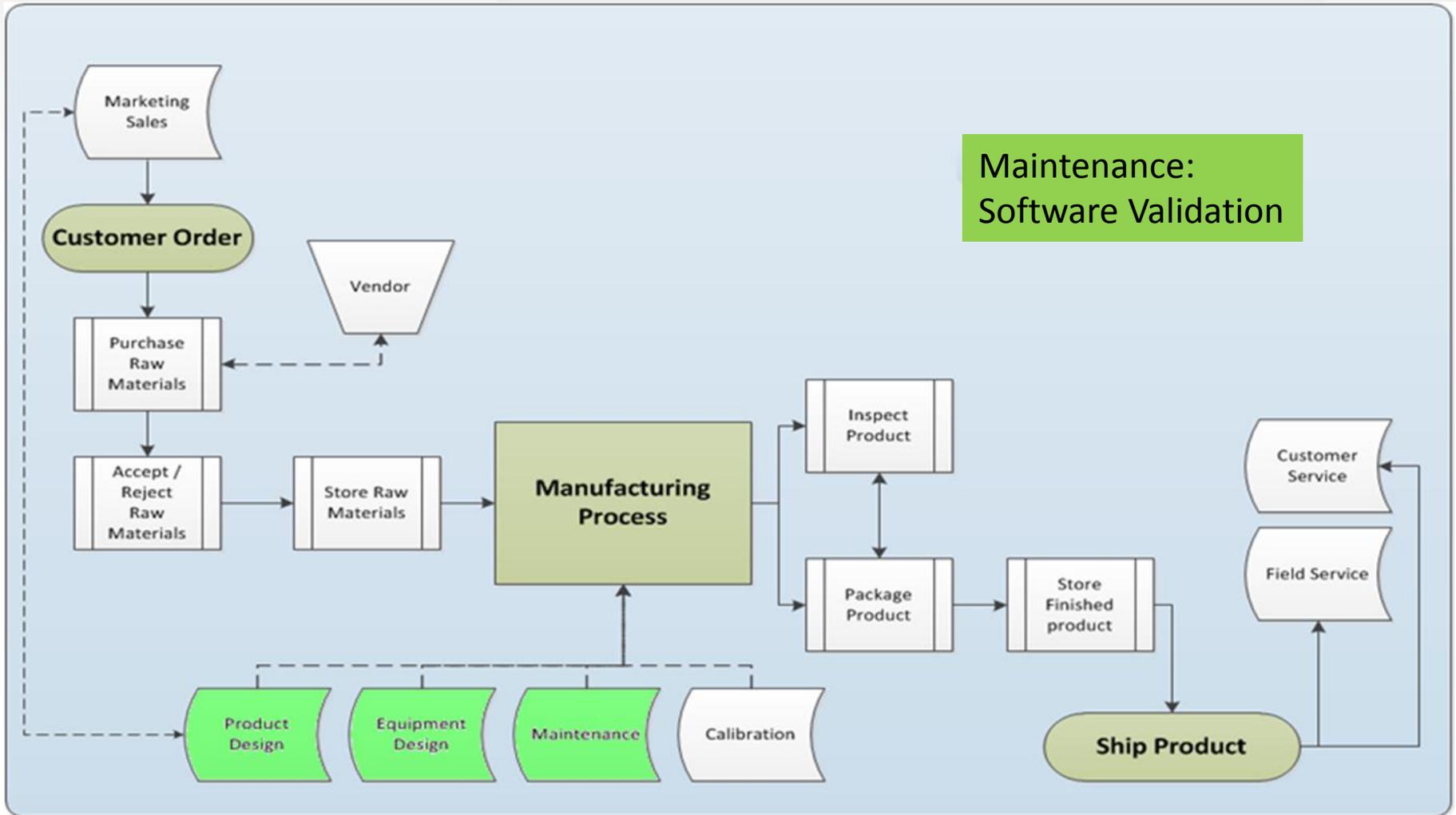
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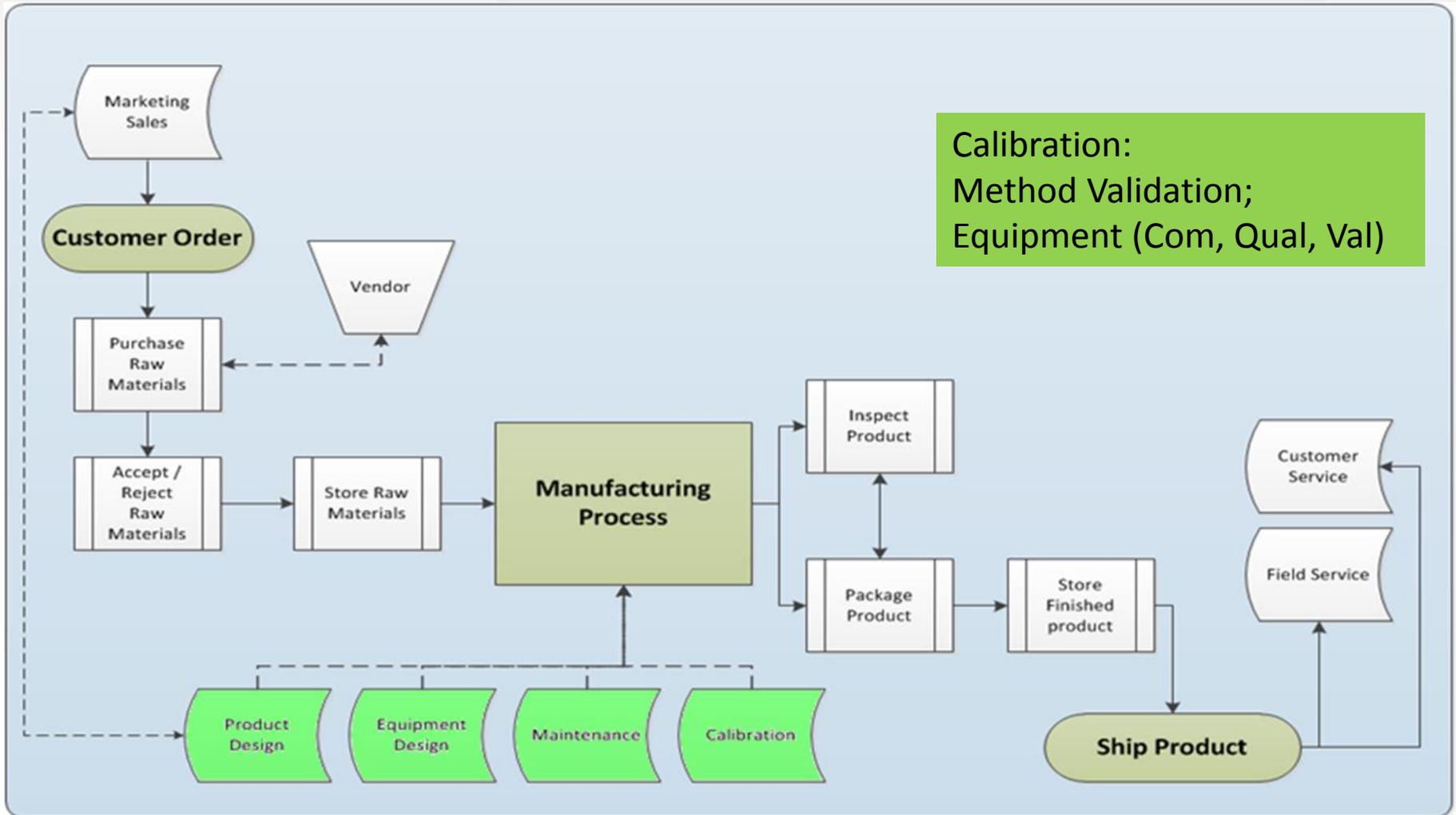
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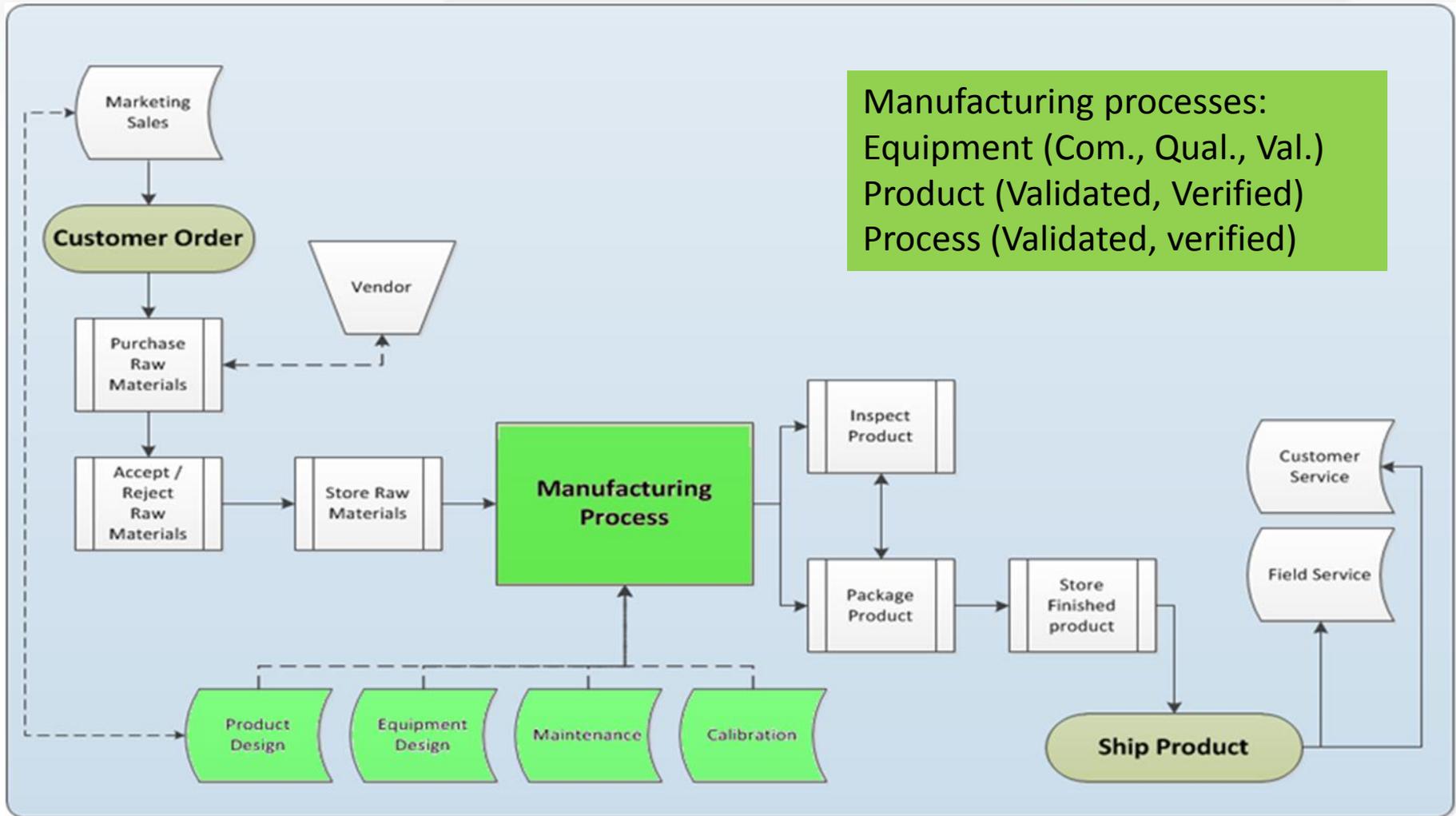
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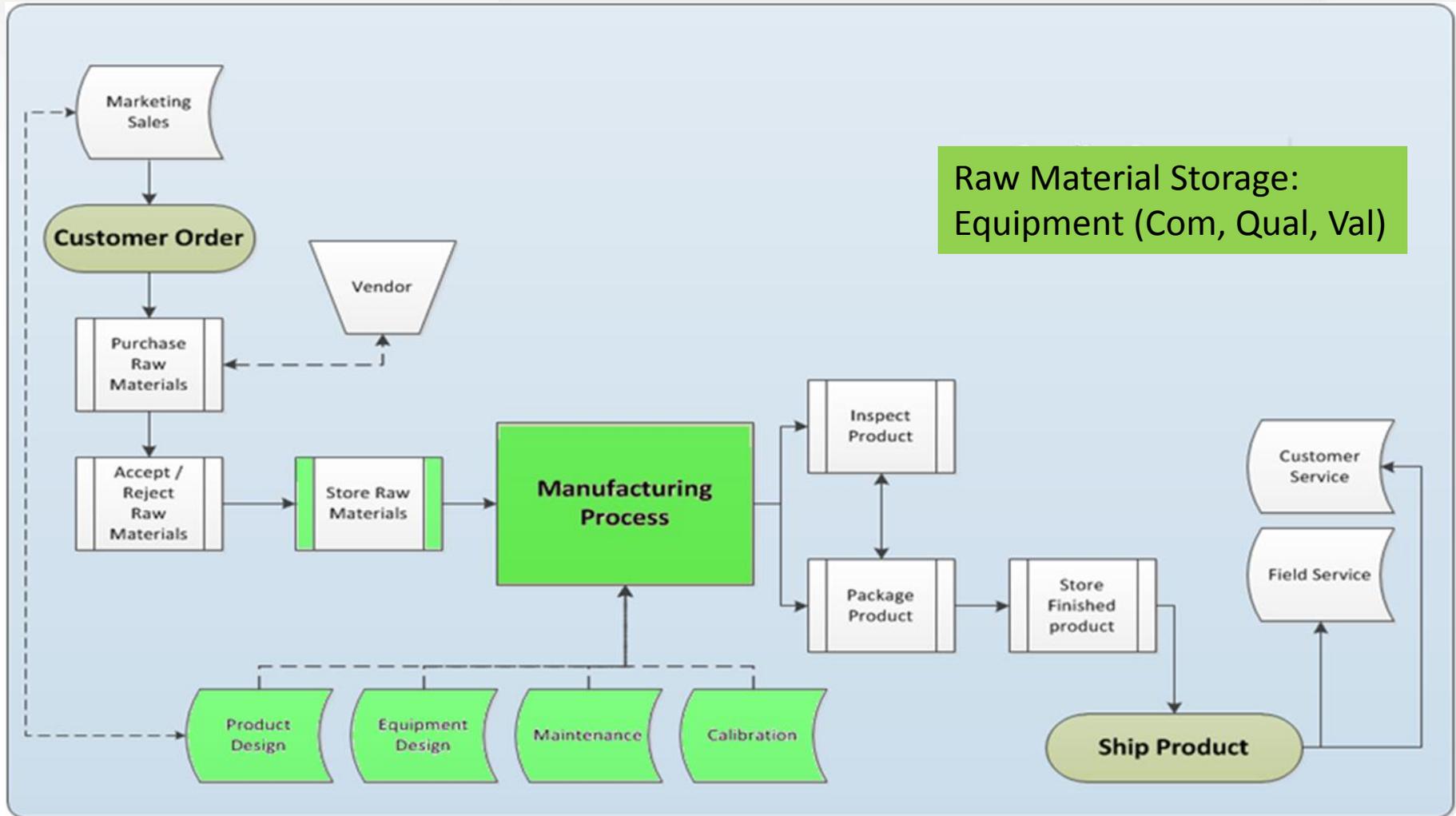
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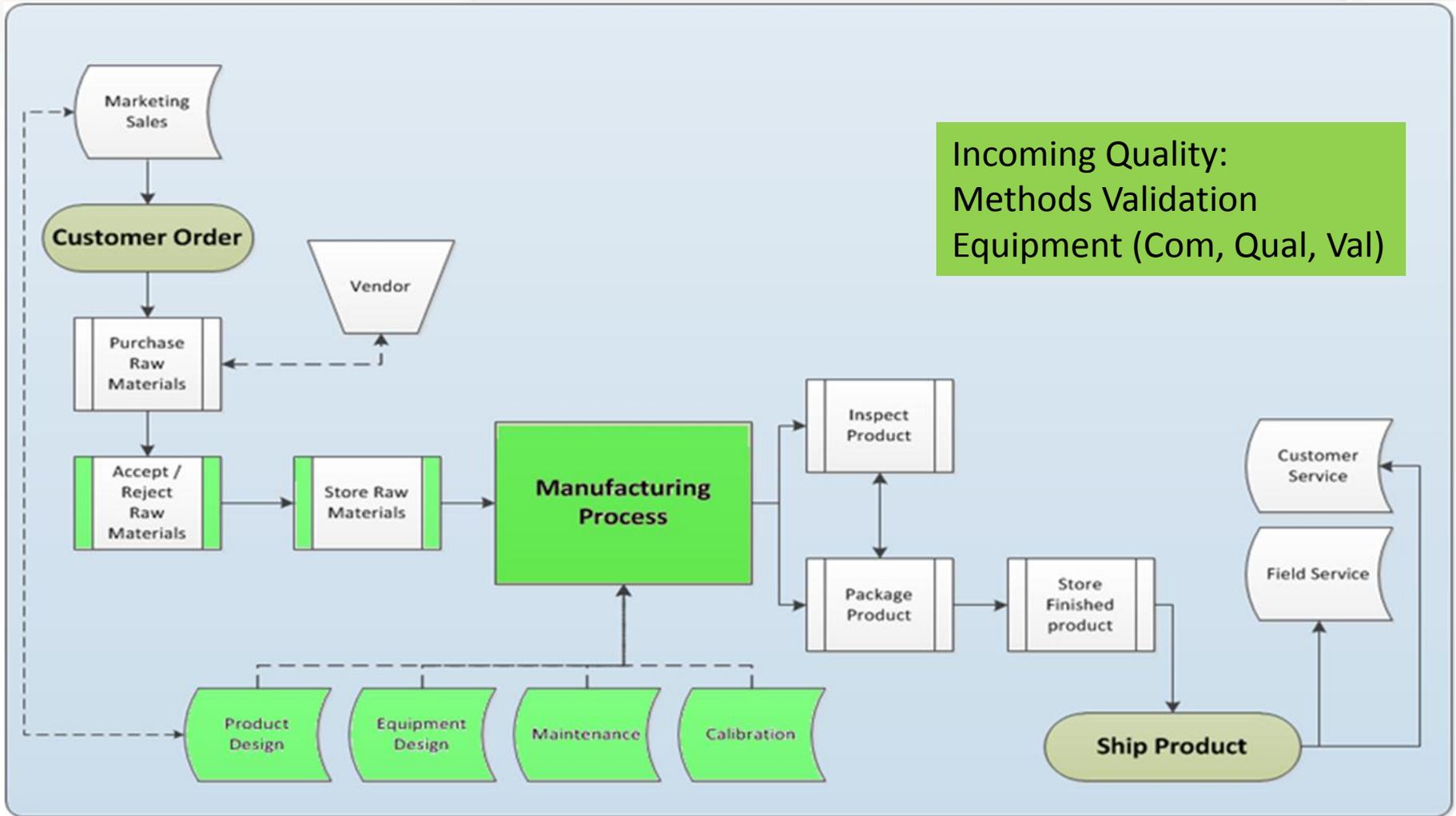
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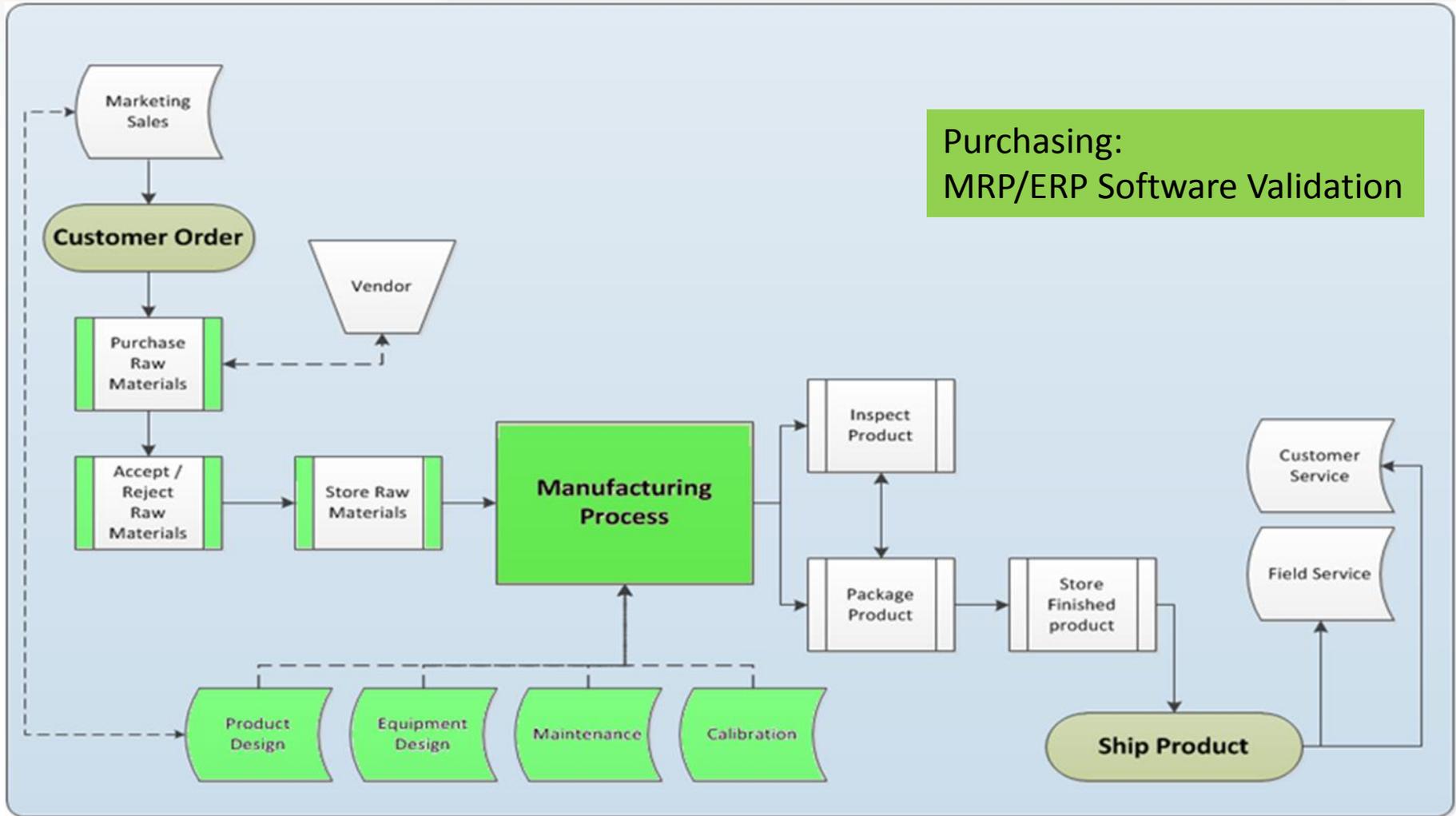
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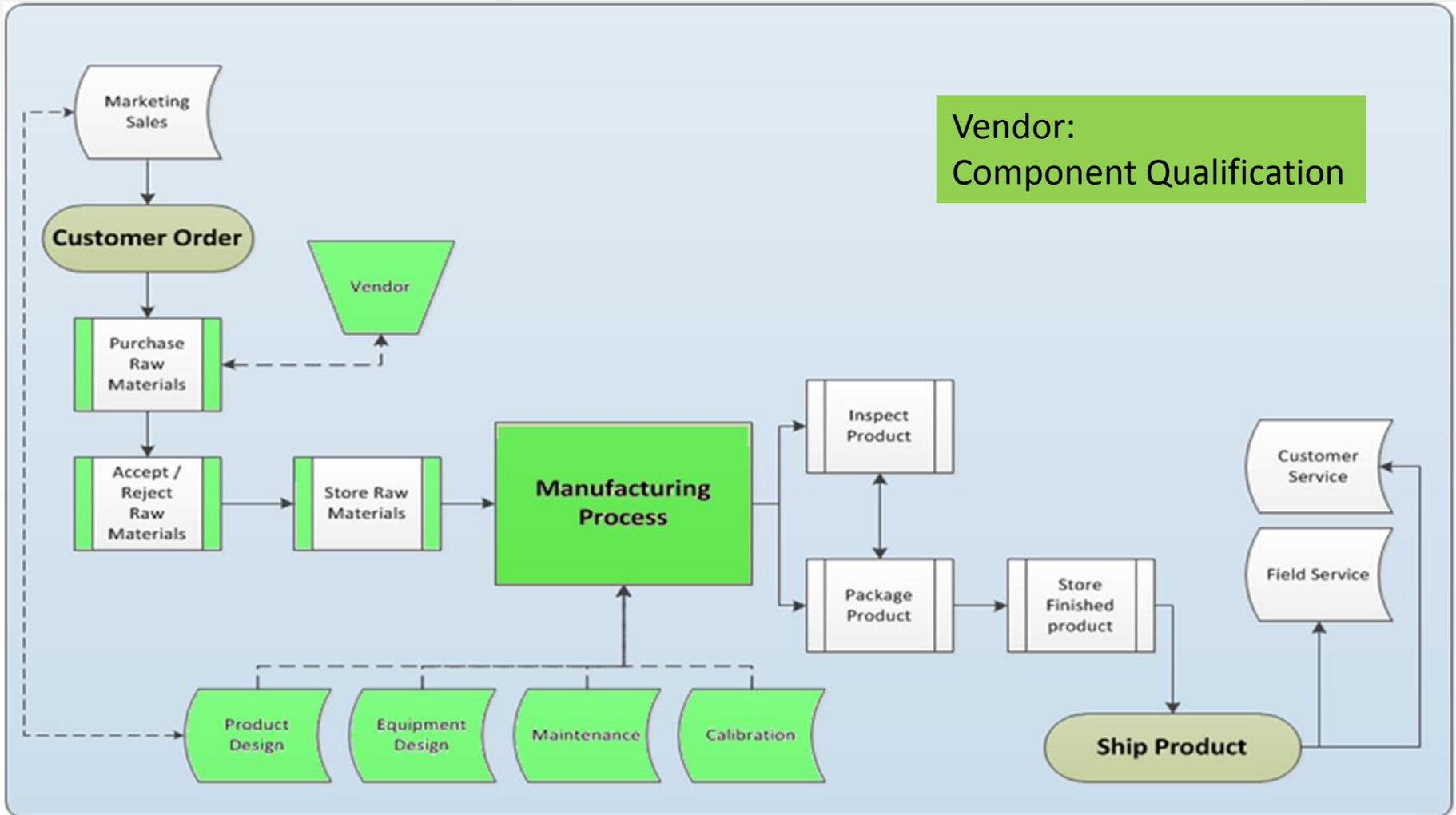
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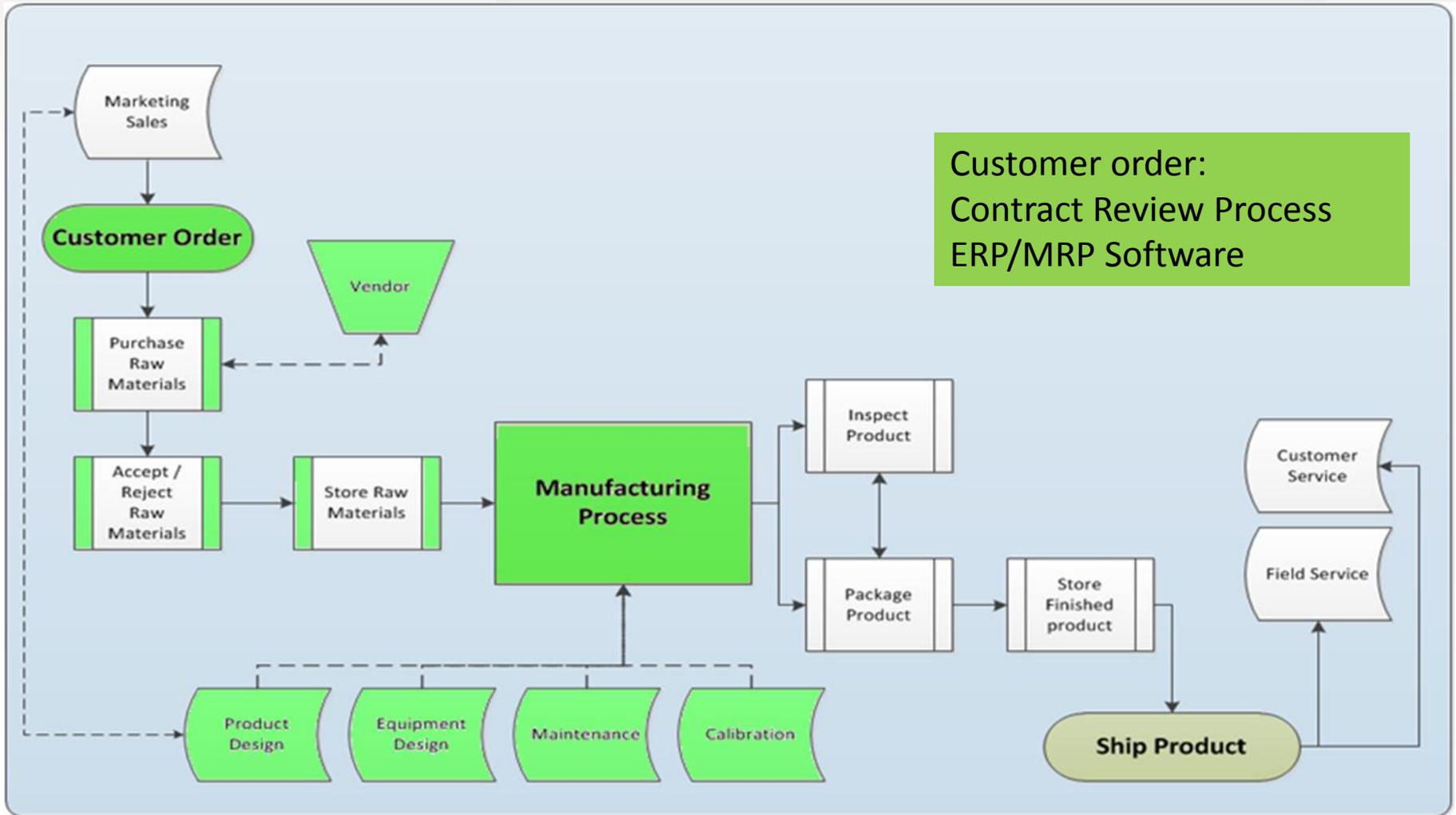
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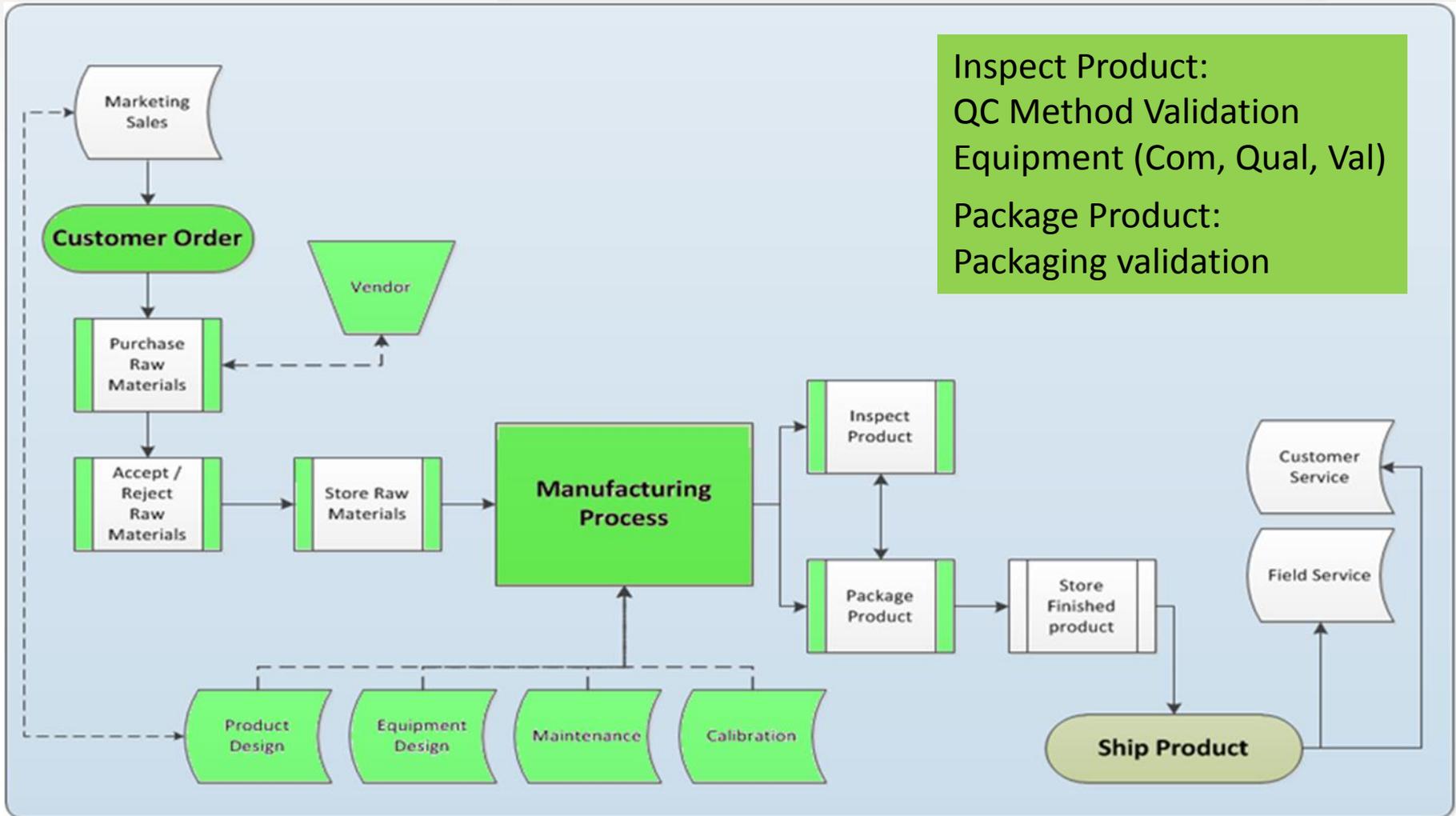
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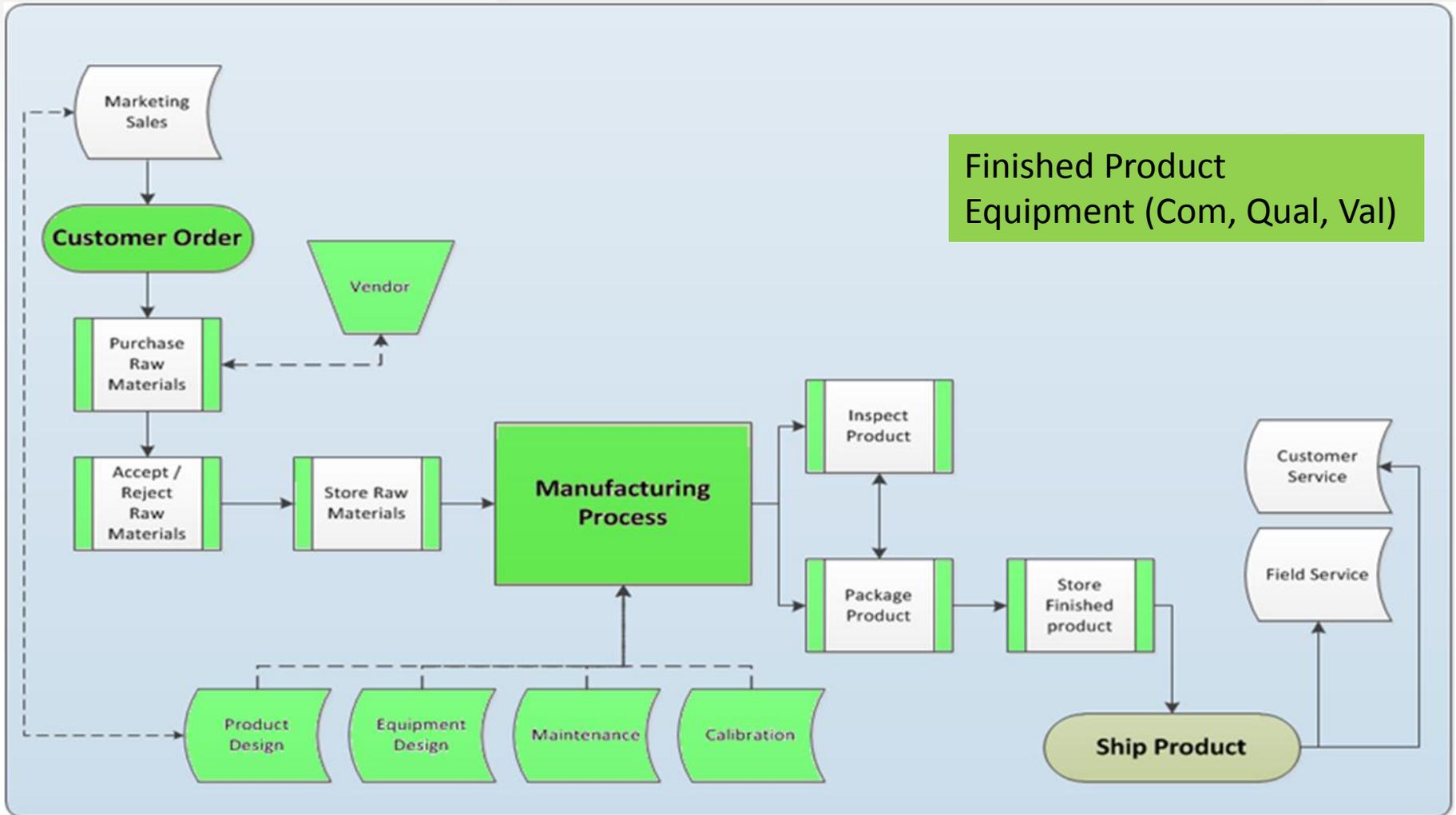
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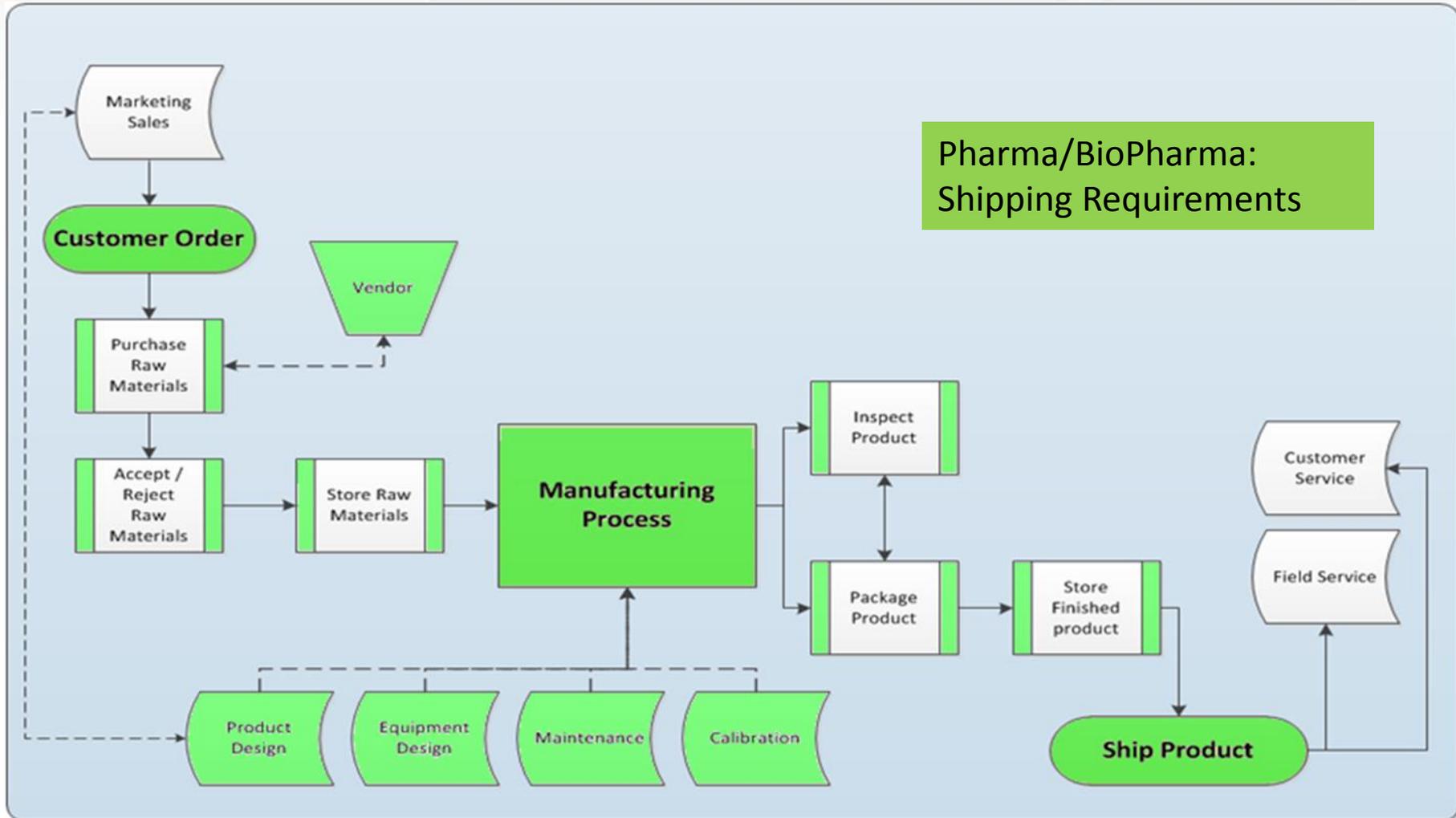
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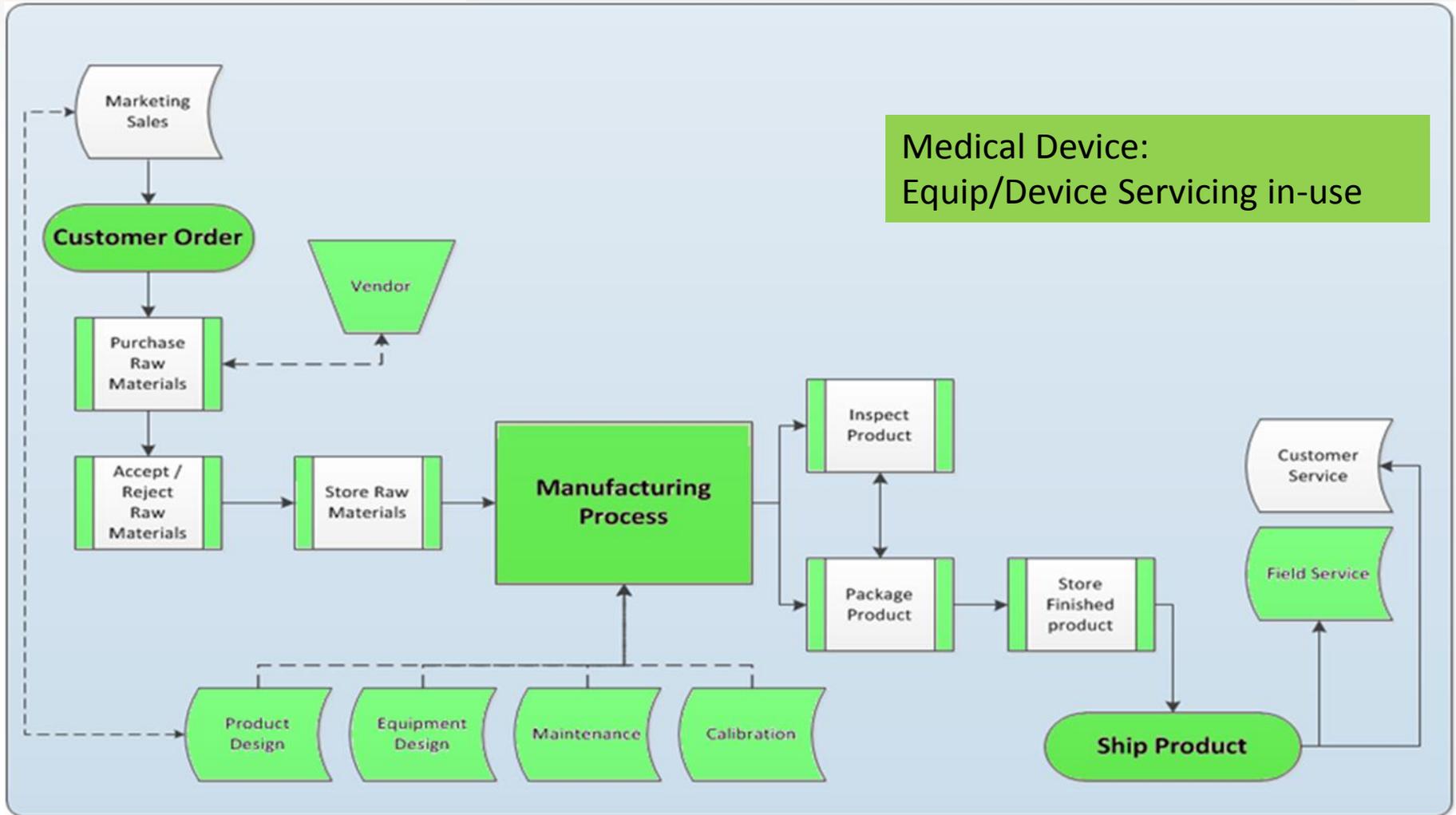
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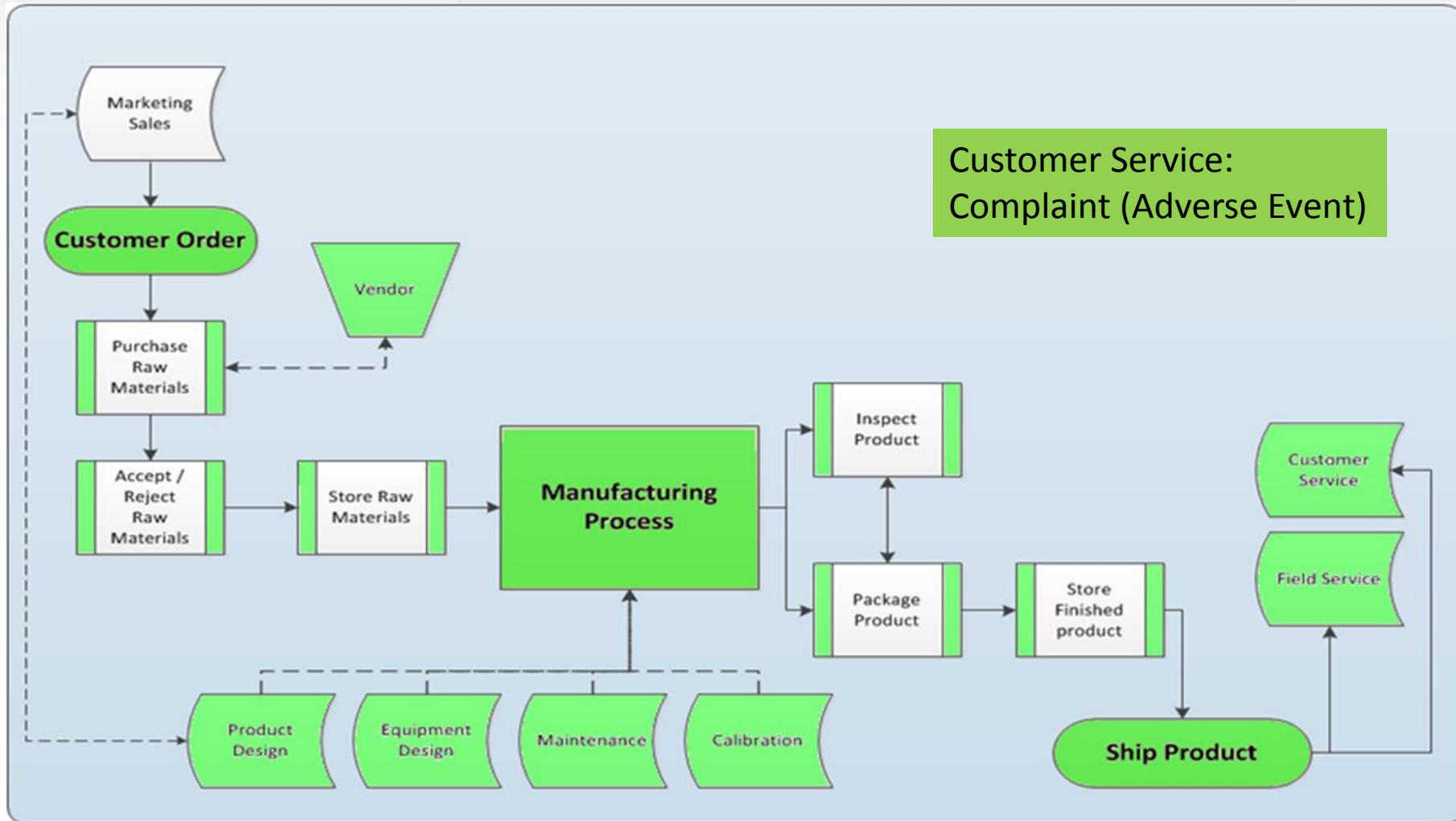
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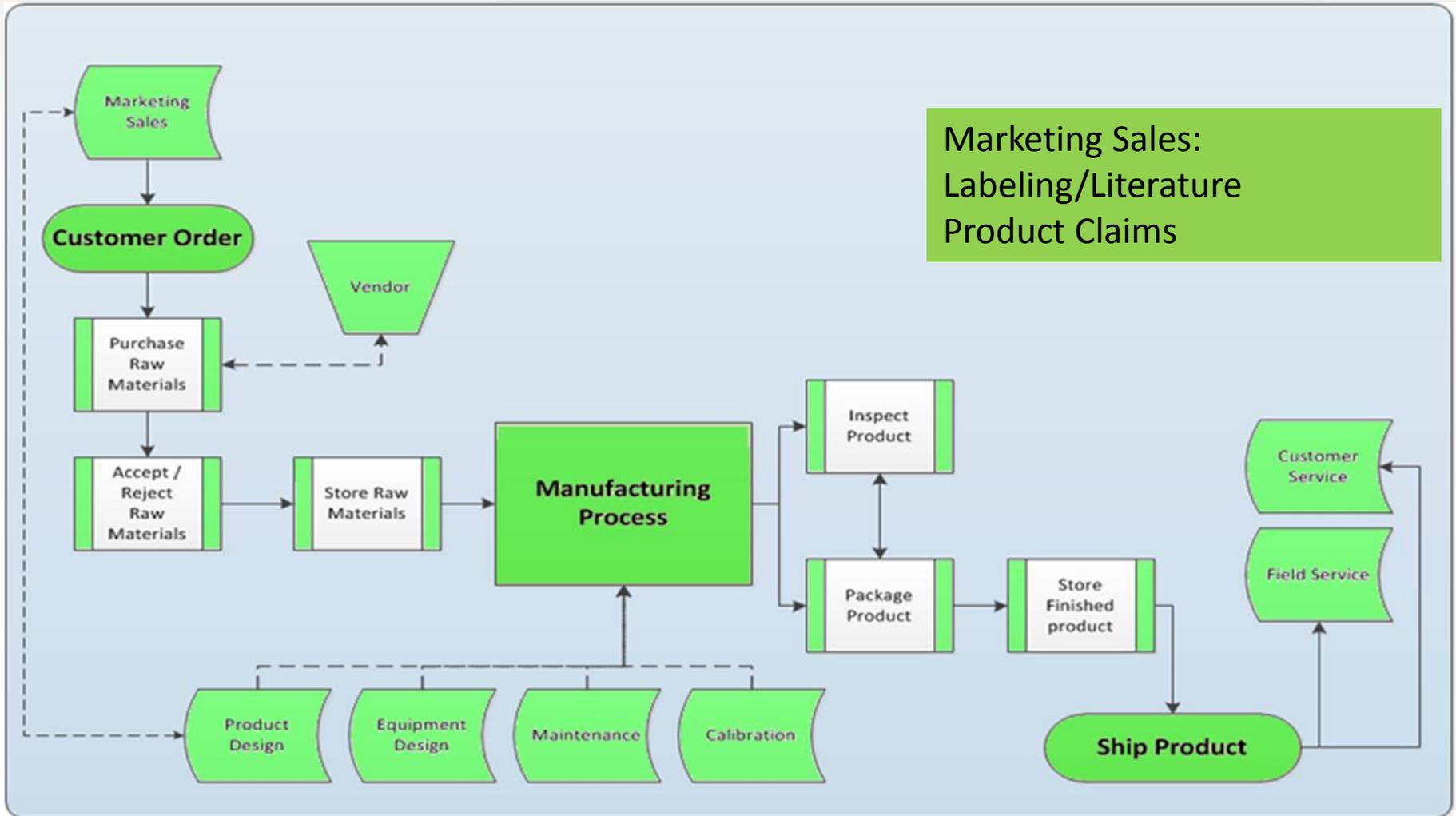
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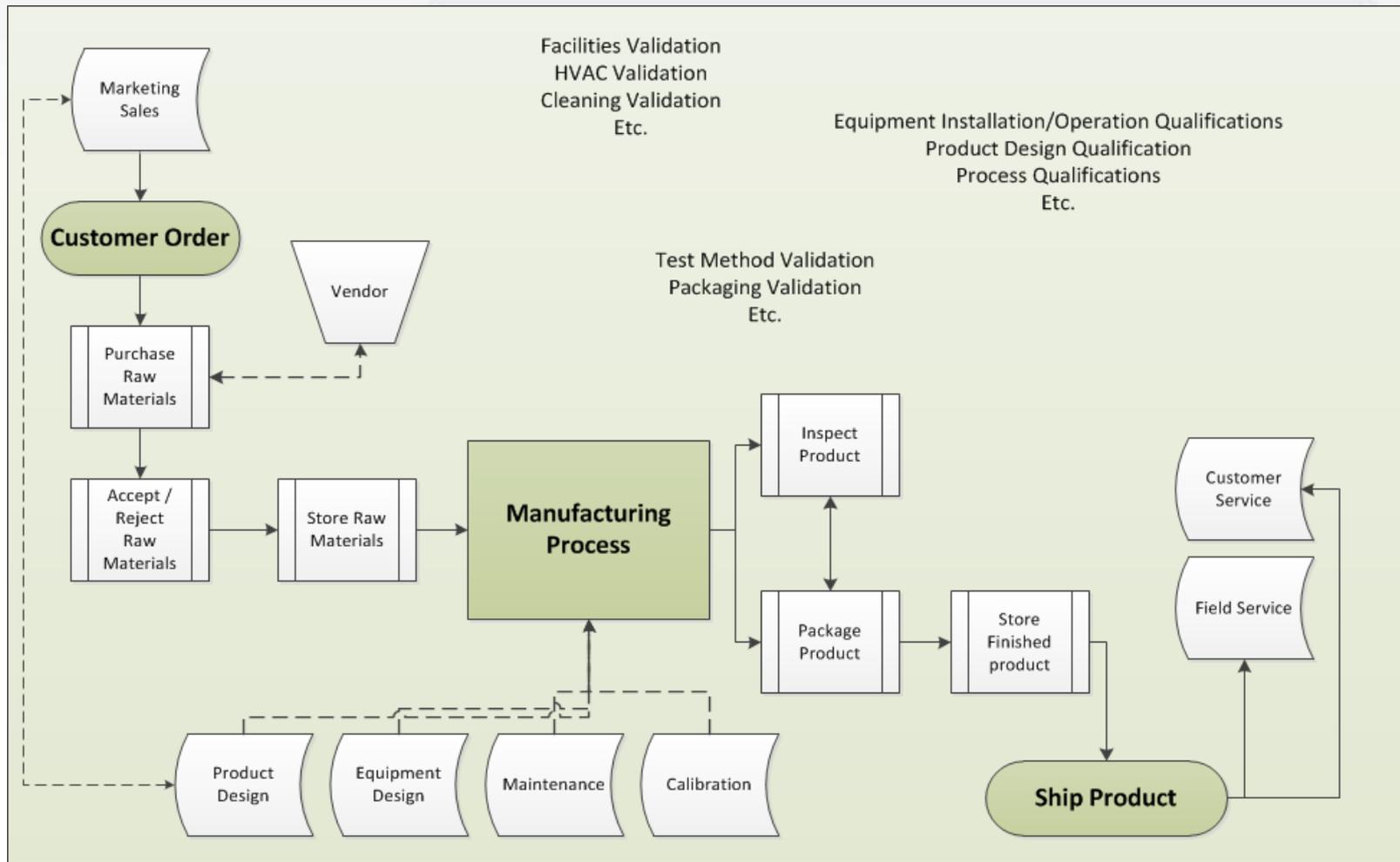
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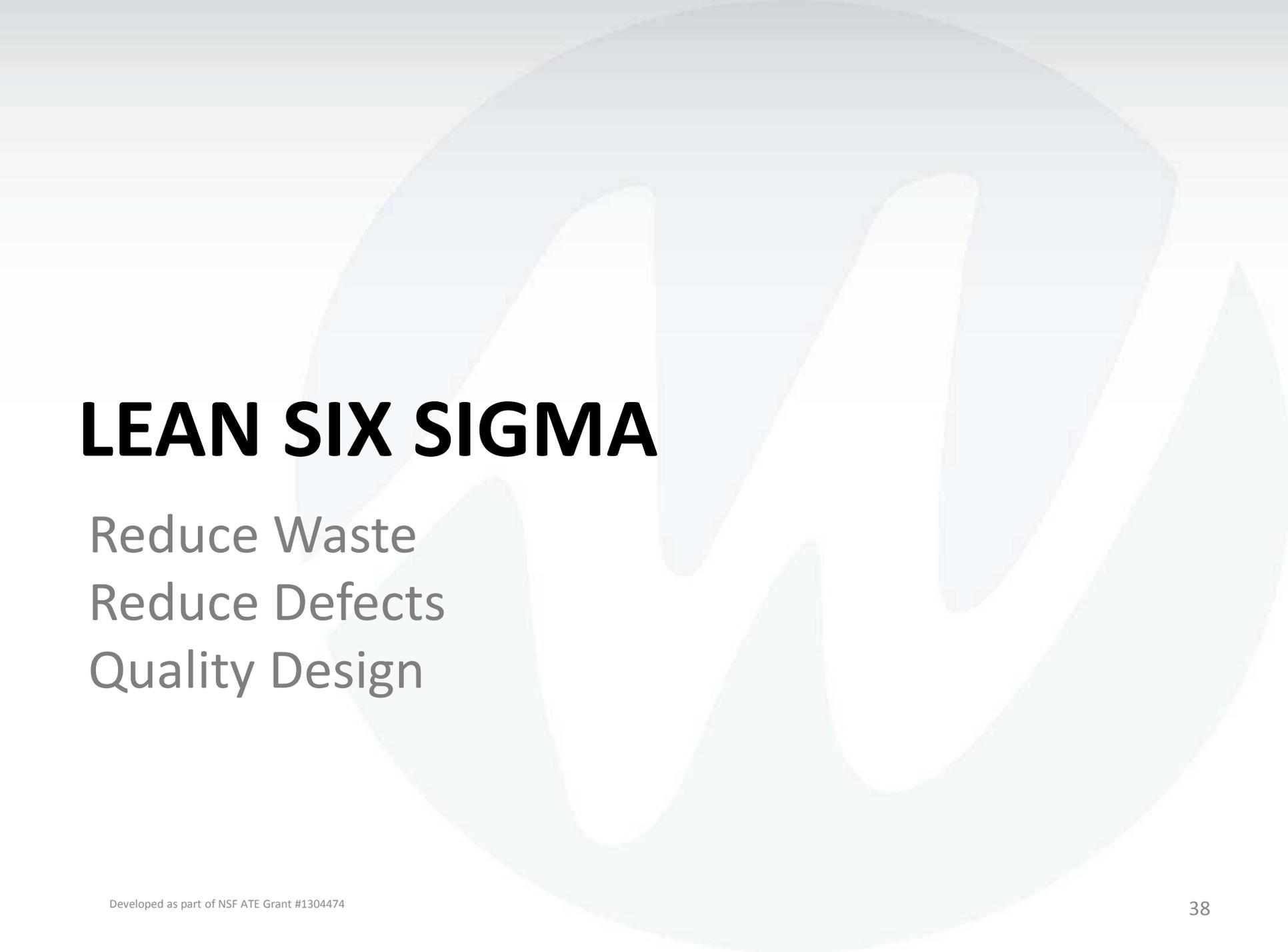
VALIDATION PROGRAM



VALIDATED STATE





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LEAN SIX SIGMA

Reduce Waste
Reduce Defects
Quality Design

LEAN SIX SIGMA

- Two separate business tools
 - Beyond the Quality Management System
 - Support QMS

LEAN SIX SIGMA

- Lean Manufacturing
 - Production Management Strategy
 - Reduces (eliminates) waste
 - Focused on creating the most value with the least amount of work
- Six Sigma
 - Business Management Strategy
 - Process Improvements
 - Define, Measure, Analyze, Improve, Control

LEAN MANUFACTURING

*Production Management Strategy; Reduces (eliminates) waste
Focused on creating the most value with the least amount of work*

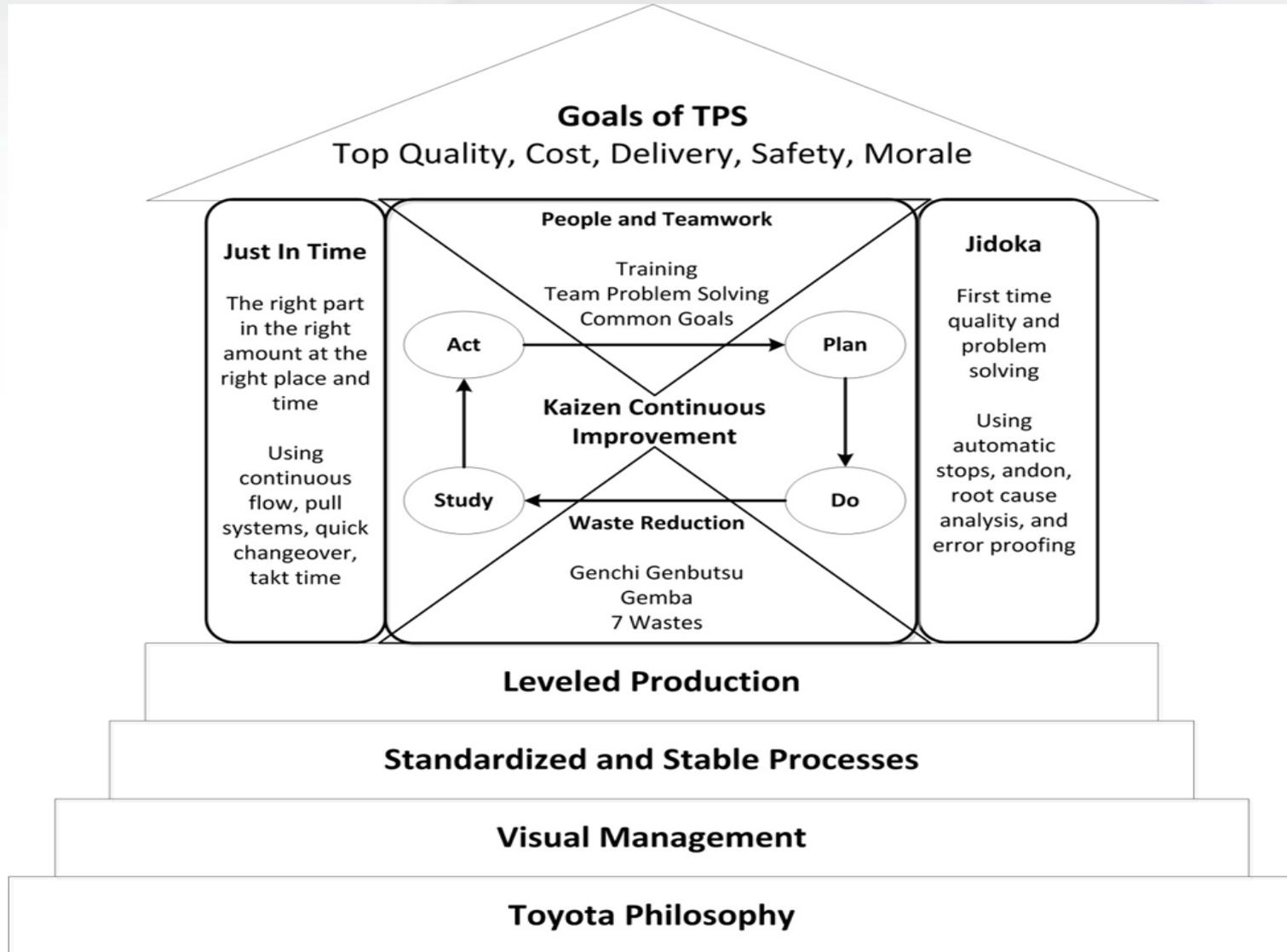
- Lean process improvement
 - Culture of ideas
 - Tools and processes
 - Improve flow
 - Reduce waste

“The Machine That Changed the World”

Daniel Jones, Daniel Roos, and James Womack (1990, reprinted 2007)

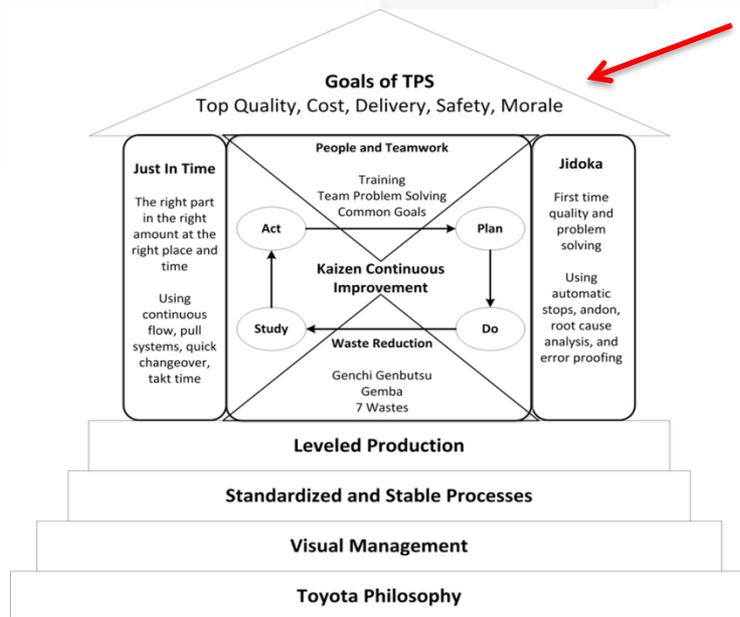
Introduced Toyota Production System (TPS)

Toyota Production System



LEAN MANUFACTURING

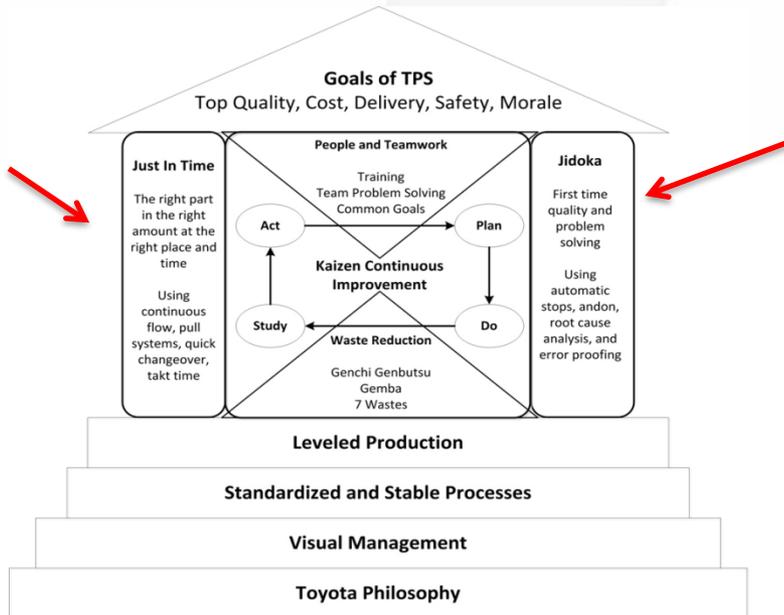
- Toyota Production System



Roof = Goals and Objectives
top quality
minimal cost
proper delivery time
good safety & morale

LEAN MANUFACTURING

- Toyota Production System



Roof = Goals and Objectives

Pillars = materials availability
error free production

Just-in-time

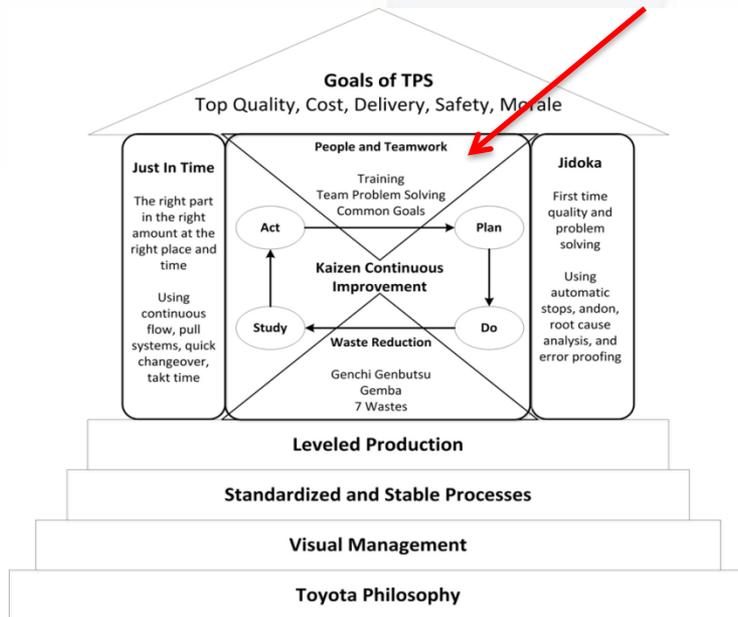
what needed, when needed
no shortages, waste, bottlenecks, or waiting
continuous flow, pull, quick changeover, takt

Jidoka

getting right first time, every time
stop if defect found, RCA, error proofing
assigning appropriate work (machine/person)
visual signals (andon)

LEAN MANUFACTURING

- Toyota Production System



Roof = Goals and Objectives

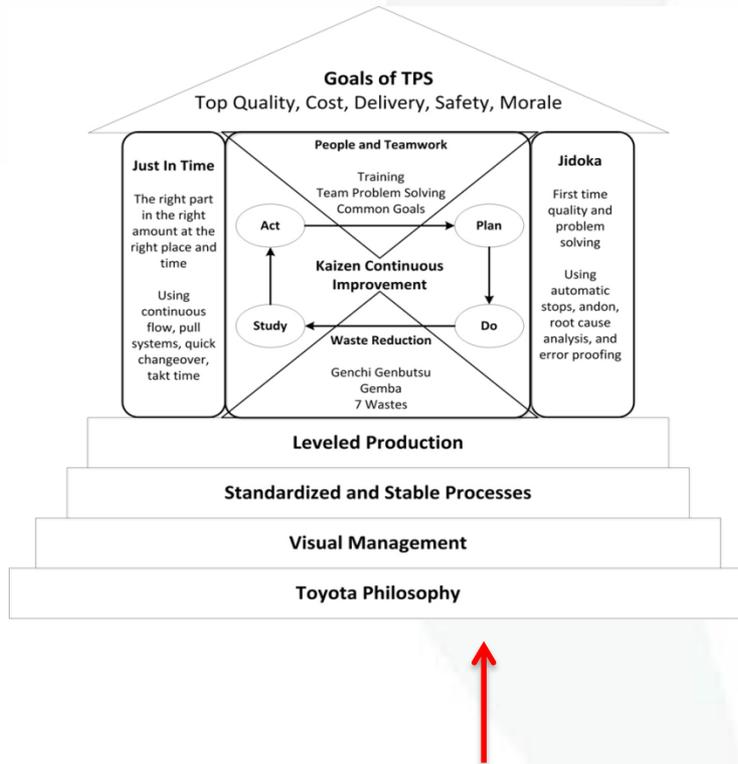
Pillars = materials availability
error free production

Core = culture, principles

people, problem solving, waste reduction

LEAN MANUFACTURING

- Toyota Production System



Roof = Goals and Objectives

Pillars = materials availability
error free production

Core = culture, principles

Foundation = level, standardized, visual & committed

Heijunka – leveled production

Standardized/stable processes

Visual Management (signs, lights, etc)

Commitment to philosophy

(long term learning, problem solving, involvement)

LEAN MANUFACTURING

- Toyota Production System – Liker Pyramid
“The Toyota Way” Jeffery Liker (2003)

Philosophy
(long term thinking, lean as culture)

Principle 1 – base management decision
on long term philosophy

LEAN MANUFACTURING

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Process
(Eliminate Waste, Improve Flow)

Philosophy
(long term thinking, lean as culture)

- Principle 2 – create continuous flow
- Principle 3 – Use pull production system
- Principle 4 – Level out the workload
- Principle 5 – Build culture of stopping to fix the program and get it right the first time
- Principle 6 – Work should be standardized and documented
- Principle 7 – Use visual control tools
- Principle 8 – use reliable proven technology that serves people and processes

LEAN MANUFACTURING

- Toyota Production System – Liker Pyramid
“The Toyota Way” Jeffery Liker (2003)

People and Partners
(Respect, Grow and Challenge)

Process
(Eliminate Waste, Improve Flow)

Philosophy
(long term thinking, lean as culture)

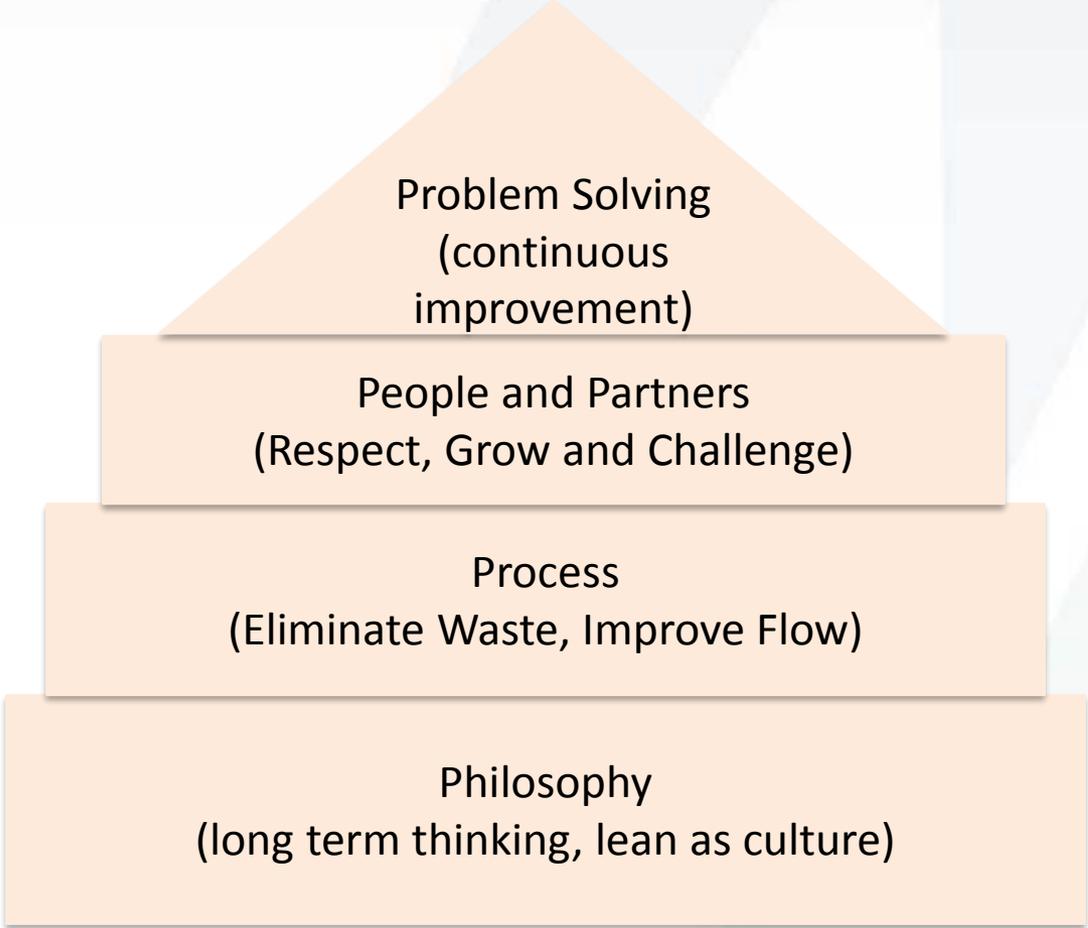
Principle 9: Grow leaders

Principle 10: Develop exceptional people and teams

Principle 11: Respect your extended network of partners and suppliers by challenging them and helping them improve

LEAN MANUFACTURING

- Toyota Production System – Liker Pyramid
“The Toyota Way” Jeffery Liker (2003)



Problem Solving
(continuous
improvement)

People and Partners
(Respect, Grow and Challenge)

Process
(Eliminate Waste, Improve Flow)

Philosophy
(long term thinking, lean as culture)

Principle 12: go and see

Principle 13: make decisions slowly,
but implement decisions quickly

Principle 14: become a learning
organization

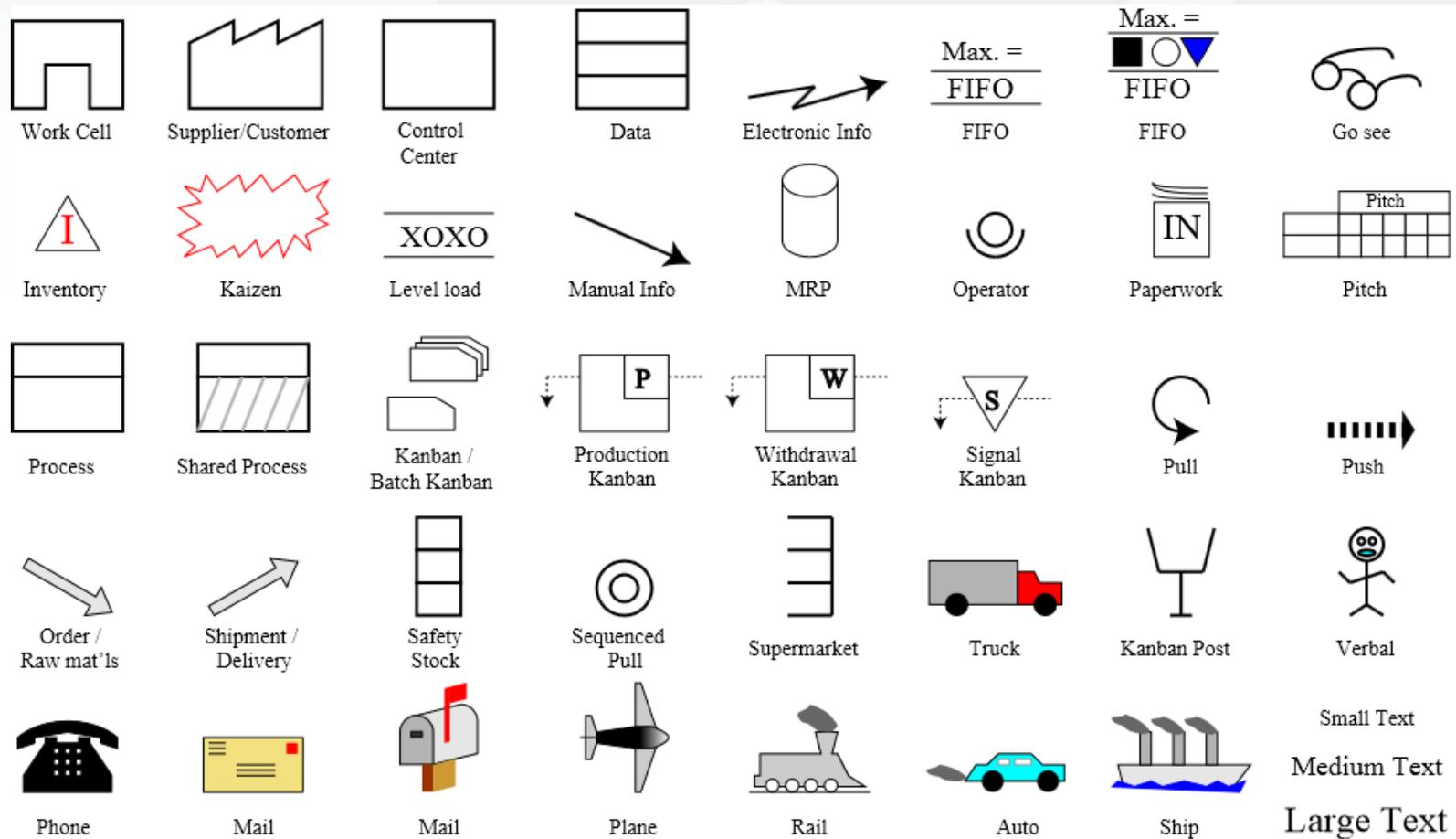
LEAN MANUFACTURING

- Vocabulary
 - Value: desired characteristics provided to the customer at the right time, place and cost
 - Value Stream: process of designing, producing and delivering a product
 - Value Stream Map: Analyze current state and determine future state (material and information flow)

VALUE STREAM MAPPING

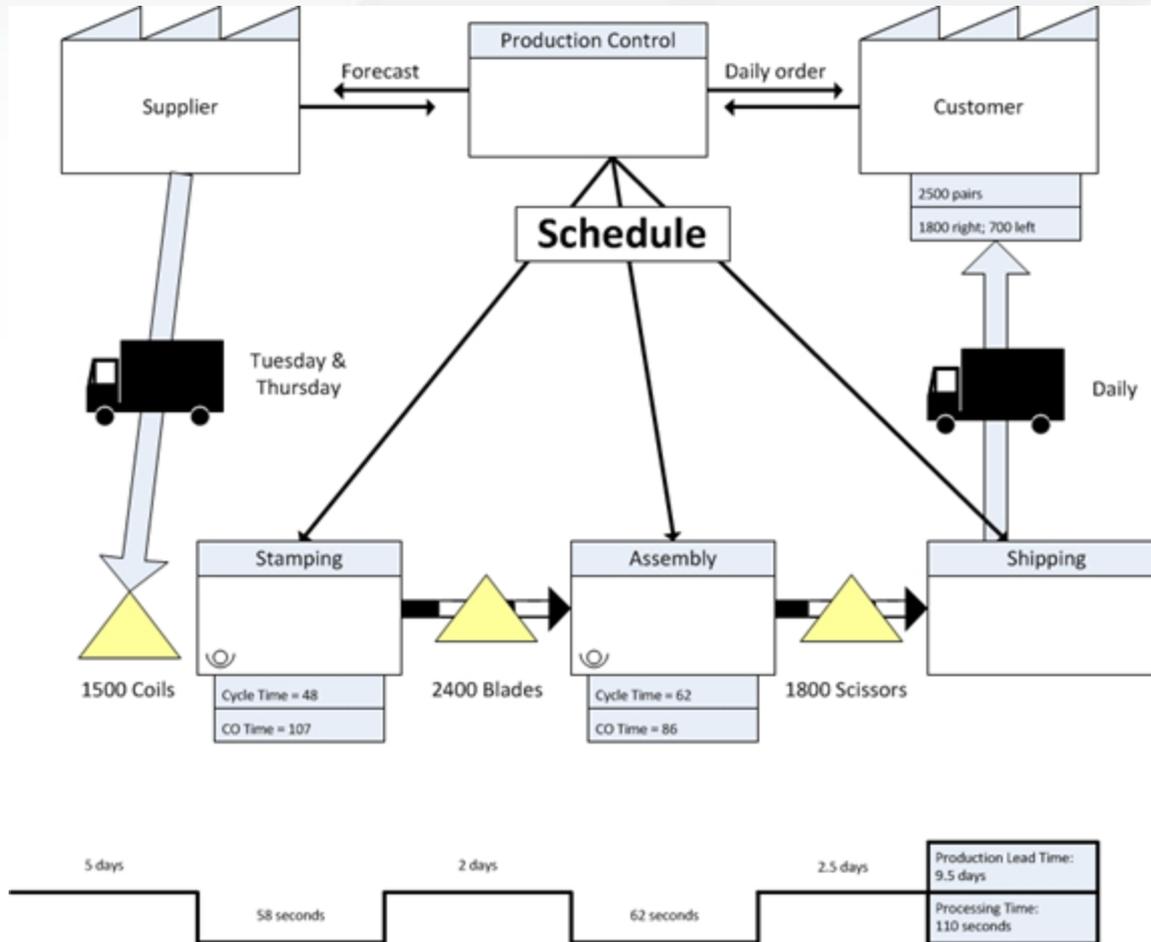
- Determine which process to map
- Create “how are things now”
- Create “how do we want things to be”
- Create workplan

VALUE STREAM MAPPING



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VALUE STREAM MAPING



LEAN MANUFACTURING

- Vocabulary
 - Just-in-Time (JIT): each item required is produced and available precisely when needed, in the exact amount
 - Pull: only what is ordered by customer is produced
 - Push: products created regardless of demand
 - Cycle time: time required to complete one cycle of a particular operation
 - Takt time: rate at which customers demanding product
 - Kanban: scheduling system (not inventory control)
 - uses the rate of demand to control the rate of production, passing demand from the end customer up through the supply chain
 - Muda (waste): activity that creates no value but consumes resources

MUDA (Waste)

D defects

O overproduction

W waiting

N non-utilized/under utilized talent

T transportation

I inventory

M motion

E excess processing

LEAN MANUFACTURING

- Vocabulary (cont.)
 - Pokayoke: mistake proofing device (i.e. checklist, fixtures, testing, etc.)
 - Kaizen: constant gradual improvement to reduce waste and increase value
 - Blitz: fast, structured, focused process for improving specifics
 - Five S (5S) principles for achieving & maintaining effective workplace
 - Sort , Set, Sweep/Shine, Standardize, Sustain *(Safety, Security)*

LEAN MANUFACTURING

- Key Elements (“The Lean Toolbox, John Bicheno”)
 1. Customer is the starting and ending point
 2. Simplicity
 3. Reduce or remove waste
 4. Process oriented
 5. Increase visibility / transparency
 6. Encourage standardization
 7. Make flow constant and smooth
 8. Pull at customer rate rather than pushing product
 9. Get the timing right (DOWNTIME)
 10. Proactive and preventive rather than reactive

LEAN MANUFACTURING

- Key Elements (cont.)
 11. Keep timelines short (production/process)
 12. Continuous improvement is a priority for all
 13. Encourage partnership rather than competitors (internal and external)
 14. Supply chain that creates value
 15. Gemba walks
 16. Reduce variation
 17. Encourage participation/accountability from all
 18. Start with smallest component and build up
 19. Build trust by sharing information and acting like partner (internal/external)
 20. Build / distribute knowledge throughout organization

SIX SIGMA

- Business Management Strategy
- Process Improvements

SIX SIGMA

Business Management Strategy; Process Improvements

- Works with lean – source of improvement project
- Developed by Motorola 1986
 - 1995 Jack Welch made business strategy at General Electric
- Utilizes quality tools and statistical methods
- 6-sigma process is 99.99966%
 - 3.4 defect parts/million manufactured
 - DPMO defects per million opportunities

SIX SIGMA

- Continued effort to achieve stable and predictable process results are vital to business
- Manufacturing (and business) process have characteristics that can be measured, analyzed, controlled, improved
- Achieving sustained quality improvement requires total organization commitment , particularly top management.

SIX SIGMA

- Continued effort to achieve stable and predictable process results are vital to business
- Manufacturing (and business) process have characteristics that can be measured, analyzed, controlled, improved
- Achieving sustained quality improvement requires total organization commitment , particularly top management.
- **Why successful**
 - Clear focus on financial returns
 - Increased emphasis on top-level support
 - Clear commitment making decisions based on verifiable data and statistical methods

SIX SIGMA PROGRAMS

- Structured investigation process
 - Improve quality by identifying (removing) defects and minimizing process variability.
 - Utilizes quality management and statistical method
 - Practitioners – with expertise in methods
 - Champions –organizational integration; identify projects
 - Master Black Belt – 100% on projects, guide black and green belts; ensure consistent application across various functions/departments
 - Black Belt: apply methodology to specific projects; focus on project execution
 - Green Belt: work on projects along with other job duties
 - Yellow Belt: basic training and participate in projects

SIX SIGMA PROGRAMS

- Structured investigation process
 - Improve quality by identifying (removing) defects and minimizing process variability.
 - Utilizes quality management and statistical method
 - Practitioners – with expertise in methods
 - Champions, MBB, BB, GB, YB
 - Project oriented
 - Define
 - Measure
 - Analyze
 - Improve
 - Control
- } “DMAIC”

SIX SIGMA - DMAIC

- **Define**
 - clearly articulate the business problem, goal, potential resources, project scope and high-level project timeline.
 - Project Charter
 - Documents reason for project
 - Objectives and constraints
 - Identify main stakeholders
 - Identify overall goals and performance expectations

SIX SIGMA - DMAIC

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SMART Goal

Specific **M**easurable **A**ttainable **R**elevant **T**ime bound

SMART Goals Guide	
Specific	<ul style="list-style-type: none"> » What exactly needs to be accomplished? » Who else will be involved? » Where will this take place? » Why do I want to accomplish the goal?
Measurable	<ul style="list-style-type: none"> » How will I know I've succeeded? » How much change needs to occur? » How many accomplishments or actions will it take?
Attainable	<ul style="list-style-type: none"> » Do I have, or can I get, the resources needed to achieve the goal? » Is the goal a reasonable stretch for me? (neither out of reach nor too easy) » Are the actions I plan to take likely to bring success?
Relevant	<ul style="list-style-type: none"> » Is this a worthwhile goal for me right now? » Is it meaningful to me—or just something others think I should do? » Would it delay or prevent me from achieving a more important goal? » Am I willing to commit to achieving this goal?
Time-bound	<ul style="list-style-type: none"> » What is the deadline for reaching the goal? » When do I need to take action? » What can I do today?

SIX SIGMA- DMAIC

- Define

SMART Goal

Specific Measurable Attainable Relevant Time bound

Example:

improve customer service by 50%

???

SIX SIGMA- DMAIC

- Define

Example:

~~improve customer service by 5%~~

The dropped call rate in Customer Service shall be reduced from the 10% level recorded in fiscal year 2014 to 5% for fiscal year 2015, by increasing efficiency.

SIX SIGMA- DMAIC

- Define

Example:

~~improve customer service by 5%~~

The **dropped call rate** in **Customer Service** shall be reduced from the 10% level recorded in fiscal year 2014 to **5%** for **fiscal year 2015**, by **increasing efficiency**.

Specific - reduce dropped calls

Measurable - 5% rate

Attainable - improved efficiency

Relevant – Customer Service

Time Bound – 2015 FY

SIX SIGMA- DMAIC

- **Define**

- clearly articulate the business problem, goal, potential resources, project scope and high-level project timeline.
- **Project Charter**
 - Documents reason for project
 - Objectives and constraints (beware scope creep)
 - Identify main stakeholders
 - Identify overall goals (SMART) and performance expectations
- **Team formation**
 - Black Belt as leader, green belt for support
 - Subject Matter Experts (i.e. purchasing, production, etc.)

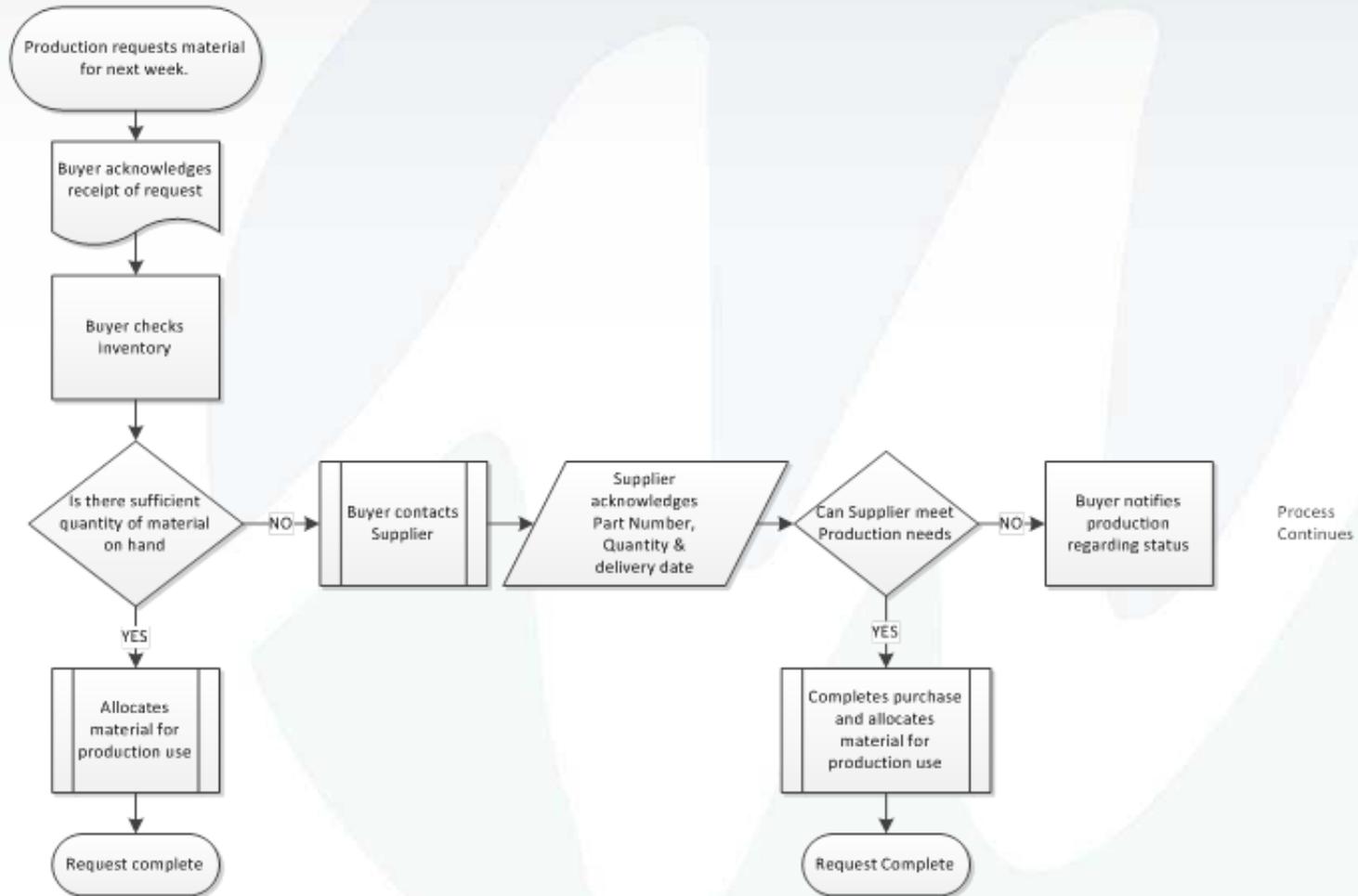
SIX SIGMA - DEFINE TOOLS

- Flowcharts are useful for mapping a process to:
 - Illustrate where problems can occur
 - Provide detailed understanding of the process looking for what can influence the problem

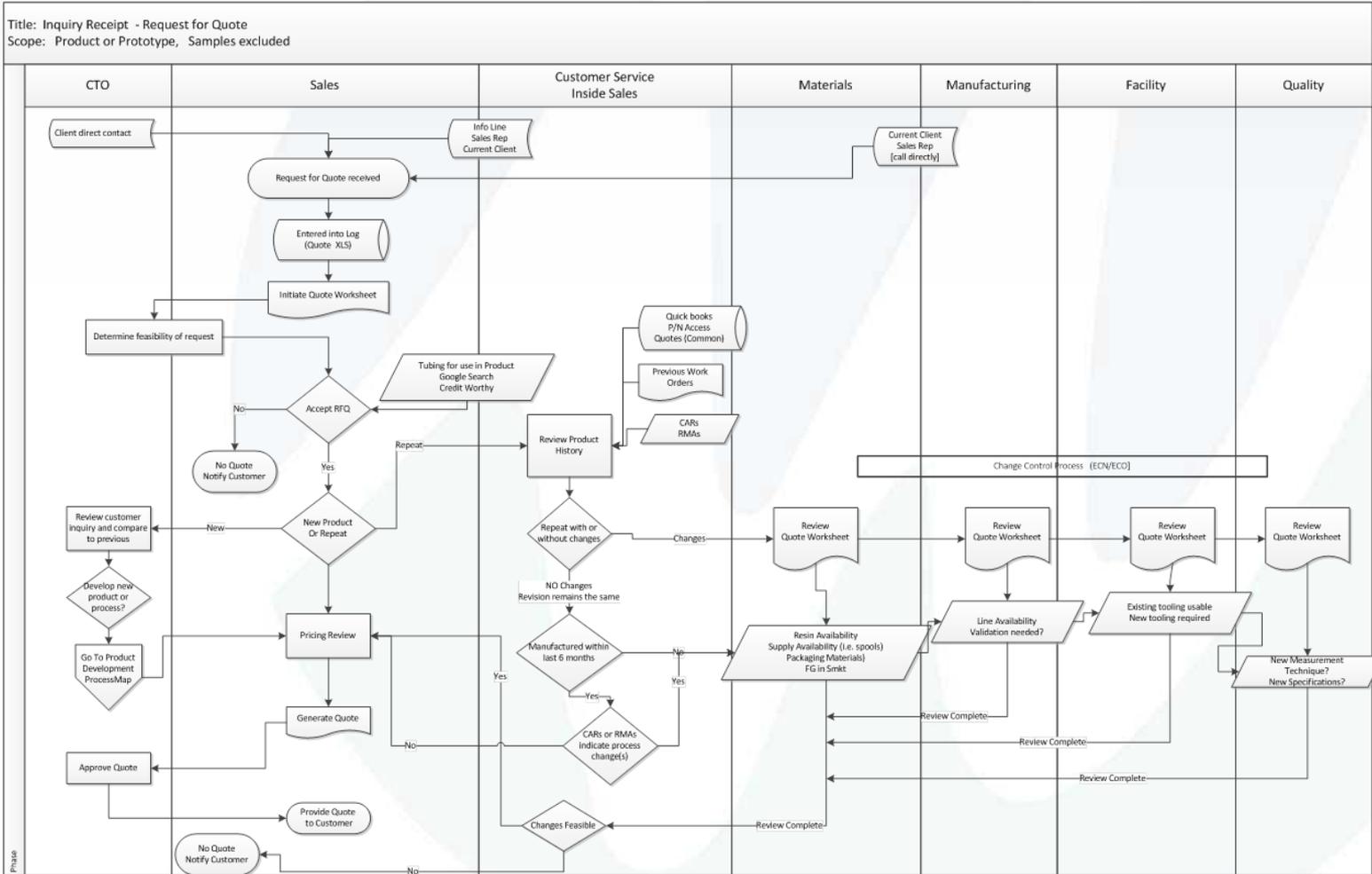
SIX SIGMA - DEFINE TOOLS

- Flowcharts are useful for mapping a process to:
 - Illustrate where problems can occur
 - Provide detailed understanding of the process looking for what can influence the problem
- Different types of flow charts
 - Regular – depicts activities/tasks
 - Cross-Functional – adds person/department that is responsible for activity
 - Multi-Level – Starts at beginning with high level activities, individual tasks are then outlined on a lower level (separate page).

STANDARD FLOW CHART

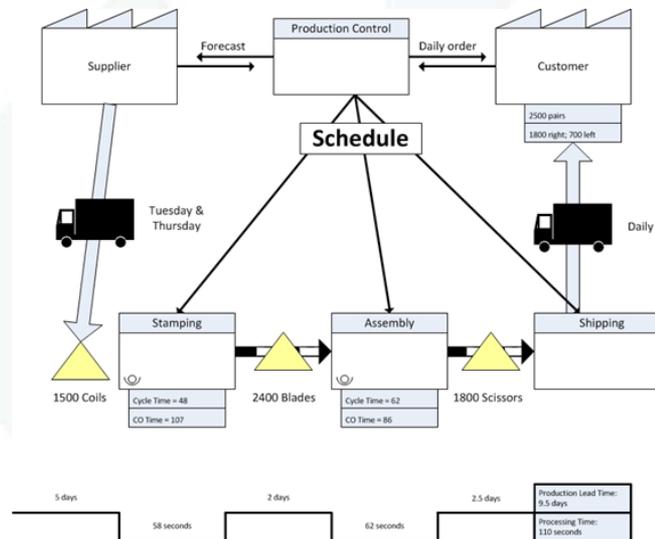


CROSS FUNCTIONAL FLOW CHART



SIX SIGMA - DEFINE TOOLS

- Flowcharts are useful for mapping a process to:
 - Illustrate where problems can occur
 - Provide detailed understanding of the process looking for what can influence the problem
- Value-Stream map can be source or projects and provide detail for defining issues



SIX SIGMA - DEFINE TOOLS

- Flowcharts are useful for mapping a process to:
 - Illustrate where problems can occur
 - Provide detailed understanding of the process looking for what can influence the problem
- Value-Stream map can be source or projects and provide detail for defining issues
- **SIPOC Diagram**
 - Supplier
 - Input
 - Process
 - Output
 - Customer

SIPOC

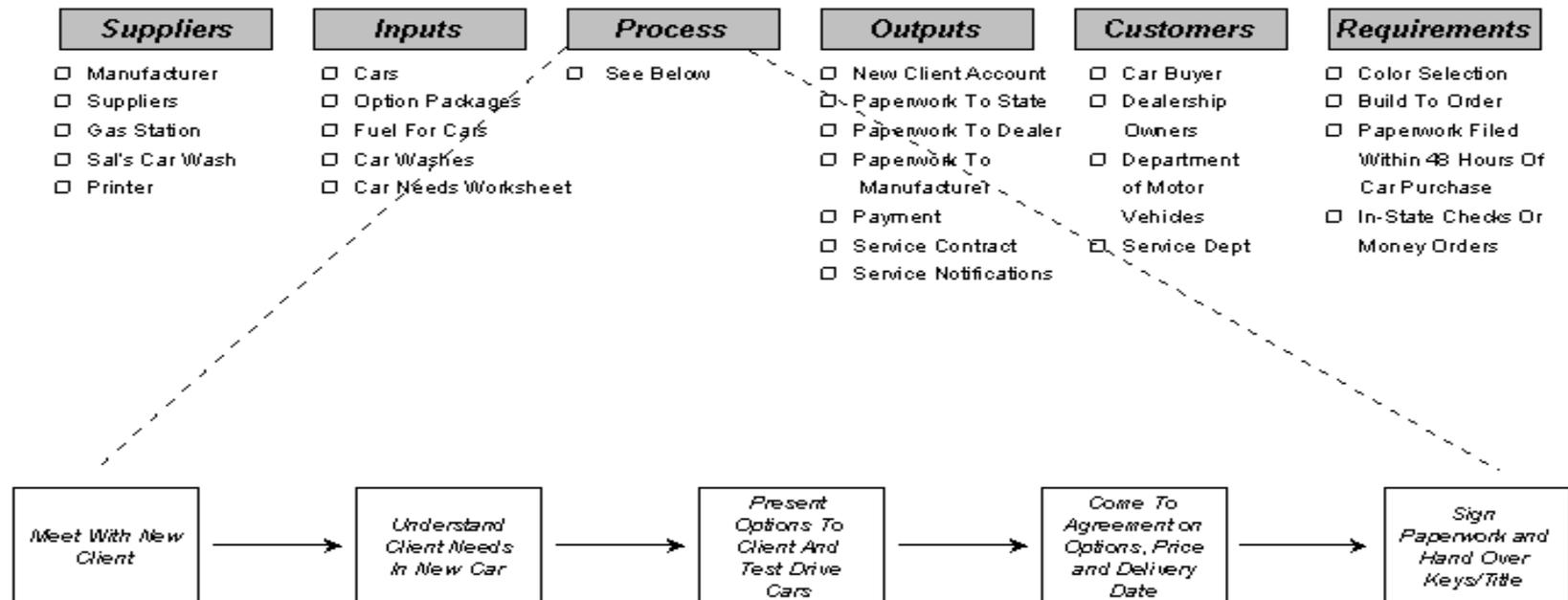
Supplier	Input	Process	Output	Customer
Person or Organization	Information, materials or service provided	Set of action steps to transform input into output	Final product or service resulting from process	Person, process organization that receives the output
Providing resources to process of concern		Adding customer value		

Additional columns for controls/requirements or general comments are sometimes also added

SIPOC

SIPOC Diagram

Fictitious Car Dealer Example



SIX SIGMA- DMAIC

- Define: clearly articulate the business problem, goal, potential resources, project scope and high-level project timeline.
- **Measure**
 - objectively establish current baselines as the basis for improvement.
 - data collection step to establish process performance baselines

Measurement Fundamentals

Inspection / Sampling

Data Collection

SIX SIGMA- DMAIC

- Define clearly articulate the business problem, goal, potential resources, project scope and high-level project timeline.
- Measure objectively establish current baselines as the basis for improvement. (data collection)
- **Analyze**
 - identify, validate and select root cause for elimination

Statistical Analysis (comparisons)

Histograms, Scatter charts

Root Cause Analysis (Fishbone, 5W'sH)

SIX SIGMA- DMAIC

- Define: clearly articulate the business problem, goal, potential resources, project scope and high-level project timeline.
- Measure: objectively establish current baselines as the basis for improvement (data collection).
- Analyze: identify, validate and select root cause for elimination.
- **Improve**
 - identify, test and implement a solution to the problem
 - in part or in whole

Revalidate

Change control

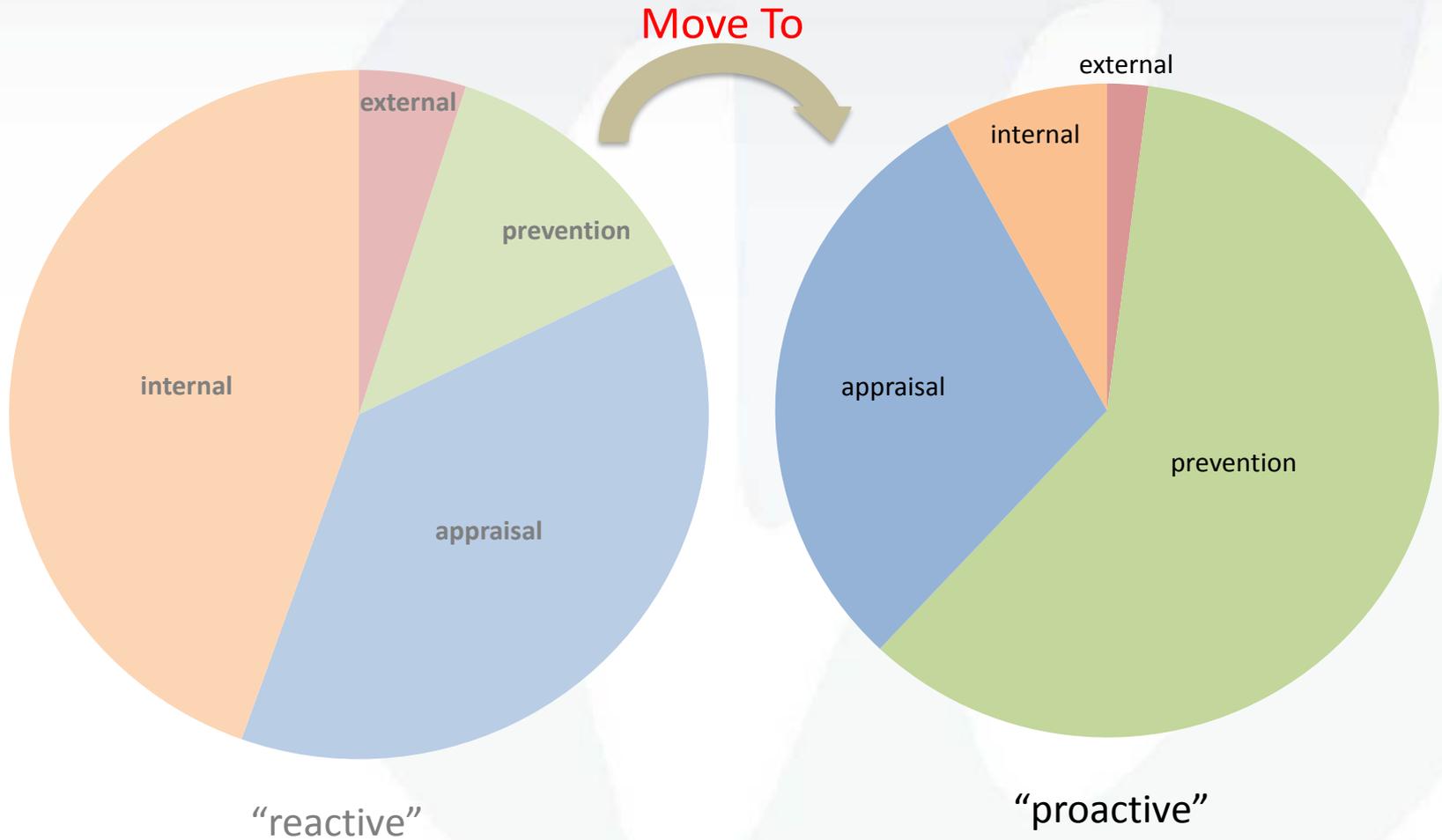
SIX SIGMA- DMAIC

- Define: clearly articulate the business problem, goal, potential resources, project scope and high-level project timeline.
- Measure: objectively establish current baselines as the basis for improvement (data collection).
- Analyze: identify, validate and select root cause for elimination.
- Improve: identify, test and implement a solution to the problem.
- **Control**
 - monitor the improvements to ensure continued and sustainable success

Evaluate effectiveness

Update procedures / training

SIX SIGMA PROCESS





MODULE 4 VALIDATION & LEAN SIX SIGMA