Mount Wachusett Community College

QUALITY SYSTEMS INTENSIVE WORKSHOP

40 hour (2 week, 5hr/day, 4-day)

Prepared by Gretchen Ingvason as part of NSF ATE Grant #1304474 - (National Science Foundation Advanced Technical Education)

QUALITY SYSTEMS INTENSIVE WORKSHOP

This material is based upon work supported by the National Science Foundation under Grant No. 1304474

MODULE 4
BUSINESS PROCESSES

Developed as part of NSF ATE Grant #1304474

ROOT CAUSE INVESTIGATION

7-Step Process

5W's1H, Whys

Tools (pareto, cause/effect, etc.)

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ACT ON THE DIFFERENCE

21CFR 211.22 Responsibilities of quality control unit.

(a)There shall be a quality control unit that shall have the responsibility and authority to approve or reject … and the authority to review production records to assure that no errors have occurred or, **if errors have occurred, that they have been fully investigated.** …

Guidance for Industry, Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients

B. Reprocessing (14.2)

..reprocessing by repeating a crystallization step or other appropriate chemical or physical manipulation steps …is generally considered acceptable… should be **preceded by careful evaluation** to ensure that the quality … is not adversely affected due to the potential formation of by-products and over-reacted materials.

C. Reworking (14.3)

Before a decision is taken to rework batches … **an investigation into the reason for nonconformance** should be performed… documentation to show that the reworked product is of equivalent quality to that produced by the original process. Concurrent validation …….

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ACT ON THE DIFFERENCE

21CFR 820.90 Nonconforming product.

(a) *Control of nonconforming product.* … The procedures shall address the identification, documentation, evaluation, segregation, and disposition of nonconforming product. The evaluation of nonconformance shall include a determination of the need for an investigation and notification of the persons or organizations responsible for the nonconformance. The **evaluation and any investigation shall be documented**.

ISO9001:2008 (E) 8.5.2 Corrective Action
ISO 13485:2003

"… define requirements for

a) reviewing nonconformities (including complaints)
b) determining causes of nonconformities
c) evaluate need for action…do not recur
d) determining and implementing action needed
e) recording results of any investigation and action taken…"

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ACT ON THE DIFFERENCE

- Root Cause
  - The fundamental (true) reason a product or process nonconformance occurred.
- Root Cause Analysis (RCA)
  - Structured investigation (review) aiming to identify (determine) the true cause of a product or process nonconformance (problem) AND the actions necessary to eliminate it.
    - This extends beyond solving the symptoms of a problem, instead drilling down to discover its most fundamental cause.

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INDUSTRY TERMS (PROGRAMS)

- Plan – Do – Study – Act (PDSA)
  a.k.a. Plan – Do – Check – Act (PDCA)
- Six Sigma DMAIC
  define, measure, analyze, improve, control
- Lean 7-Step process R-DMAIC-S
  recognize, define, measure, analyze, improve, control, sustain
- Automotive 8-Disciplines (8D)
  plan, use a team, define, interim containment/actions, root cause/escape points, permanent corrections, validate CA, preventive measures, congratulate team

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ROOT CAUSE ANALYSIS

- Tools used for root cause are applicable to issues both large and small
  - Thought process
- Not all issues may require a formal RCA investigation and team
  - Severity & Occurrence of the issue
  - Complexity of the product / process / service
- RCA is a method for finding permanent solutions
  - Corrective: after problem has occurred
    (i.e. customer complaint, scrap lot, etc.)
  - Preventive: understanding for specific product/process can be translated to others, thereby preventing future recurrences
    (i.e. cleaning process on large die applied to all dies)

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ROOT CAUSE ANALYSIS

- Used following occurrence of a product , process or service nonconformance
  - Production /Service Issues
    - Product release delays due to scrap lots
    - Repeat production due to returns
    - Equipment usage
  - Process break-downs
    - Contract review
    - Raw material supply
    - Machine Shop (multiple priorities)
    - Customer Service (dropped calls)
  - Audit Findings
  - Customer Complaints

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ROOT CAUSE ANALYSIS

- Used following occurrence of a product , process or service nonconformance
  - Production /Service Issues
  - Process break-downs
  - Audit Findings
  - Customer Complaints
    - Adverse Event reporting for pharmaceuticals & medical device

REPORTER	WHAT TO REPORT	REPORT FORM #	TO WHOM	WHEN
Manufacturers	30 day reports of deaths, serious injuries and malfunctions	Form FDA 3500A *	FDA	Within 30 calendar days of becoming aware of an event
	5-day reports for an event designated by FDA or an event that requires remedial action to prevent an unreasonable risk of substantial harm to the public health	Form FDA 3500A *	FDA	Within 5 work days of becoming aware of an event
Importers	Reports of deaths and serious injuries	Form FDA 3500A *	FDA and the manufacturer	Within 30 calendar days of becoming aware of an event
	Reports of malfunctions	Form FDA 3500A *	Manufacturer	Within 30 calendar days of becoming aware of an event

From FDA.gov for medical devices

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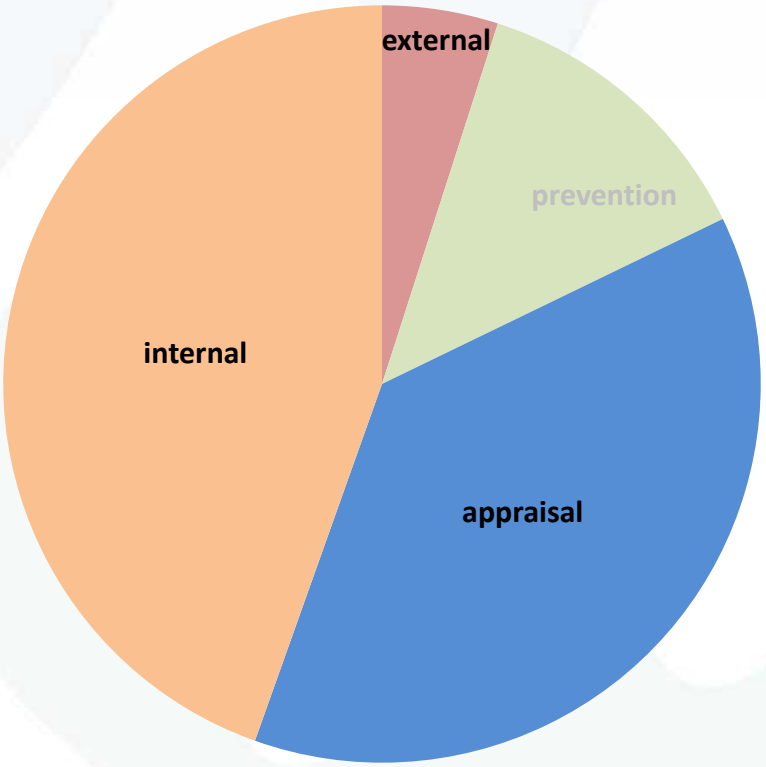
ROOT CAUSE ANALYSIS

- Why bother?
- Nonconformance's are costly in time, money and perceptions.



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ROOT CAUSE ANALYSIS

- Nonconformance's are costly in time, money and perceptions.
  - Customer Complaints
    - Costly to investigate
    - Customer confidence
  - Audit Findings
    - Practices mirror procedures (and vice versa)
    - FDA or ISO compliance
    - Customer expectations
  - Production Issues
    - Material costs
    - Production delays (time is money)
    - Capacity for new business
  - Personnel (Manpower)
    - FRUSTRATION !

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ROOT CAUSE ANALYSIS

- Nonconformance's are costly in time, money and perceptions.
  - Customer Complaints (costly, customer confidence)
  - Audit Findings (compliance, customer expectations)
  - Production Issues (costs, delays, capacity)
  - Personnel (Frustration!)

- Decisions based on **data** rather than guesswork

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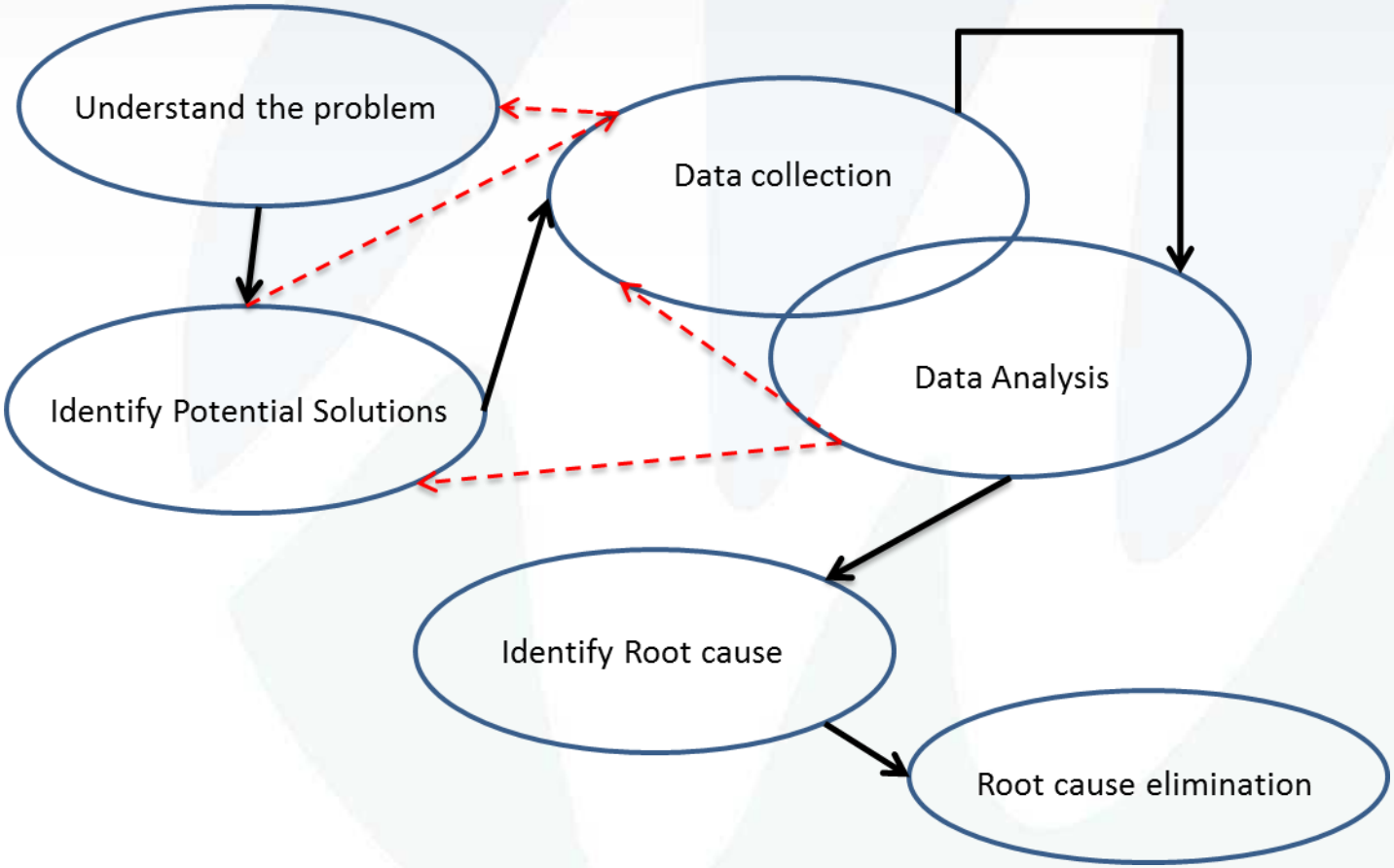
ROOT CAUSE ANALYSIS

As described in
Root Cause Analysis, 2nd Edition
Andersen & Fagerhaug



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METHOD COMPARISON

Andersen & Fagerhaug	PDSA	Six Sigma	7-Step	8-Disciplines (8D)
			Recognize	
Understand the Problem	Plan	Define	Define	Plan
				Select Team
Identify Potential Solutions				Define
				Interim Containment & Actions
Data Collection	Do	Measure	Measure	Determine/ ID / Verify Root Cause & Escape Points
Data Analysis	Study	Analyze	Analyze	
Identify Root Cause		Improve	Improve	Choose / Verify Permanent Corrections
Root Cause Elimination	Act	Control	Control	Validate Corrective Actions
			Sustain	Preventive Actions
Acknowledge Success				Congratulate Team

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SEVEN QUALITY TOOLS

1. Flow Chart / Run Chart
2. Check Sheet
3. Control Charts
4. Cause and Effect Diagram (a.k.a. Ishikawa or Fishbone)
5. Histogram
6. **Pareto Chart**
7. Scatter Plot (Diagram)

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PARETO CHART

- Pareto Principle
  - Most effects (80%) are the result of the small number of causes (20%)
  - Evaluate the vital few
- Pareto Chart
  - Similar to histogram, but typically categories rather than dimensions
    - NCR findings
    - Customer Complaints
    - Audit findings (i.e. process, documents, training, etc)
  - Provides visual regarding rank of the problems or causes

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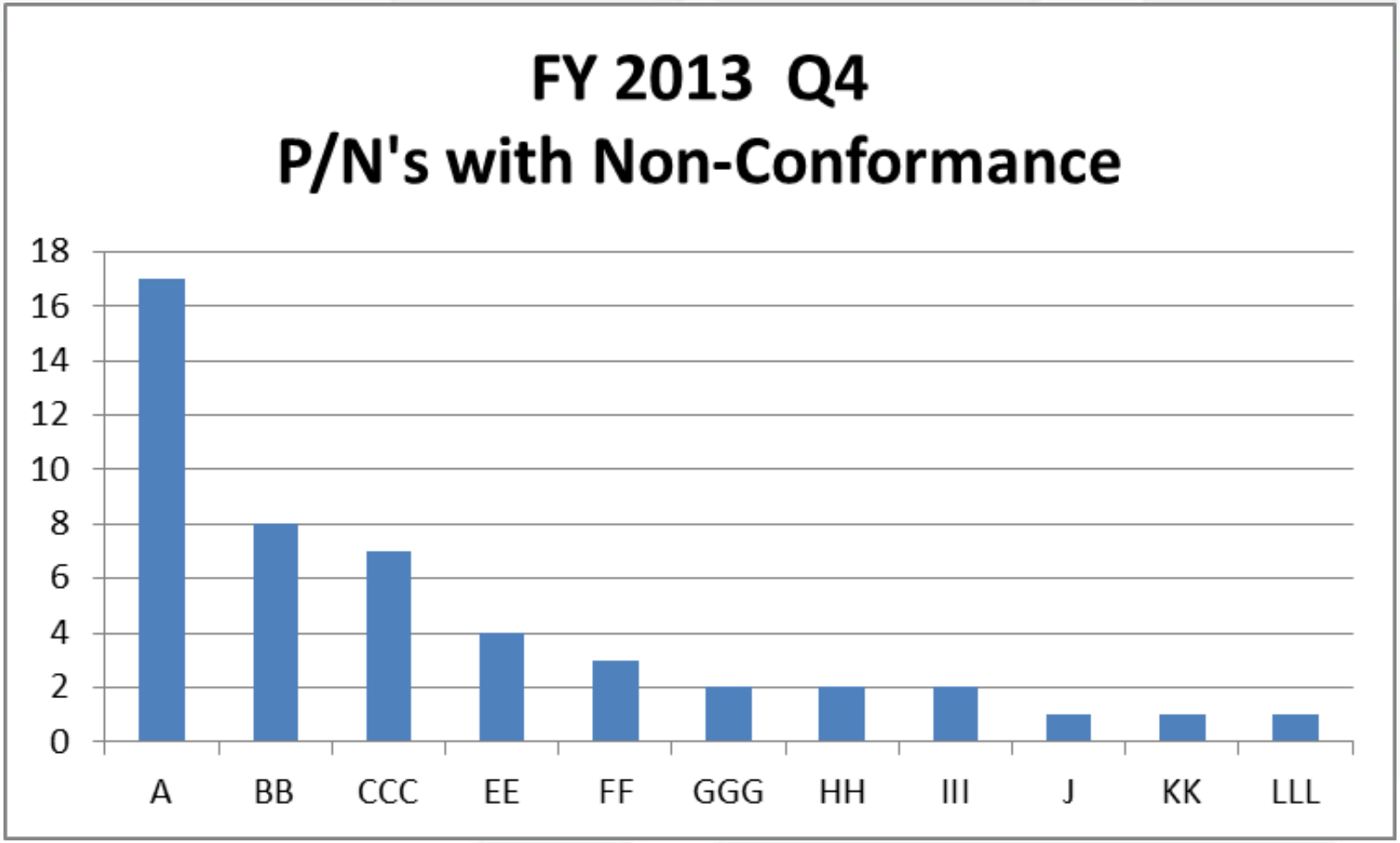
PARETO CHART - EXAMPLE



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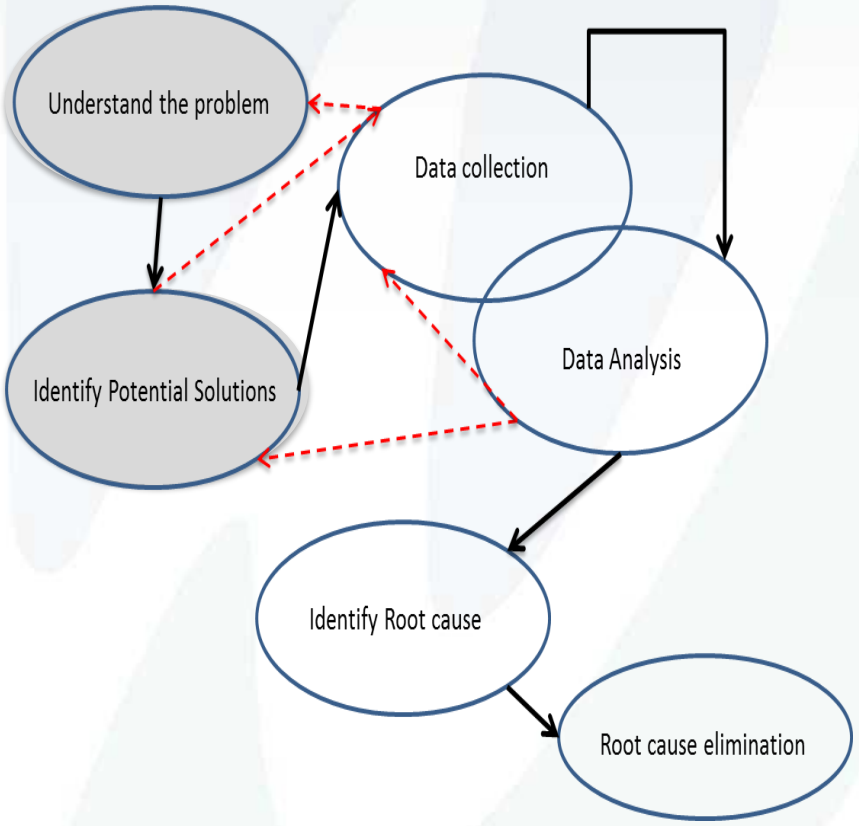
INVESTIGATIVE PROCESS - TOOLS

- Pareto Chart
- 5W's and 1H
  - Who, what, where, when, why and how



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5 W'S AND 1 H

- Example: Color Defects
  - What (which product, which material)
  - When (lot, only one?, day (end of quarter, start of year, before/after shut-down))
  - Where (plant?, line?, process step?)
  - Who (manufacturing, QC; new, apprentice, experienced?)
  - How *(..is it possible?, ….can it happen? etc.)*
  - Why
    - Did controls work? Inspection results?
    - This lot only, others?

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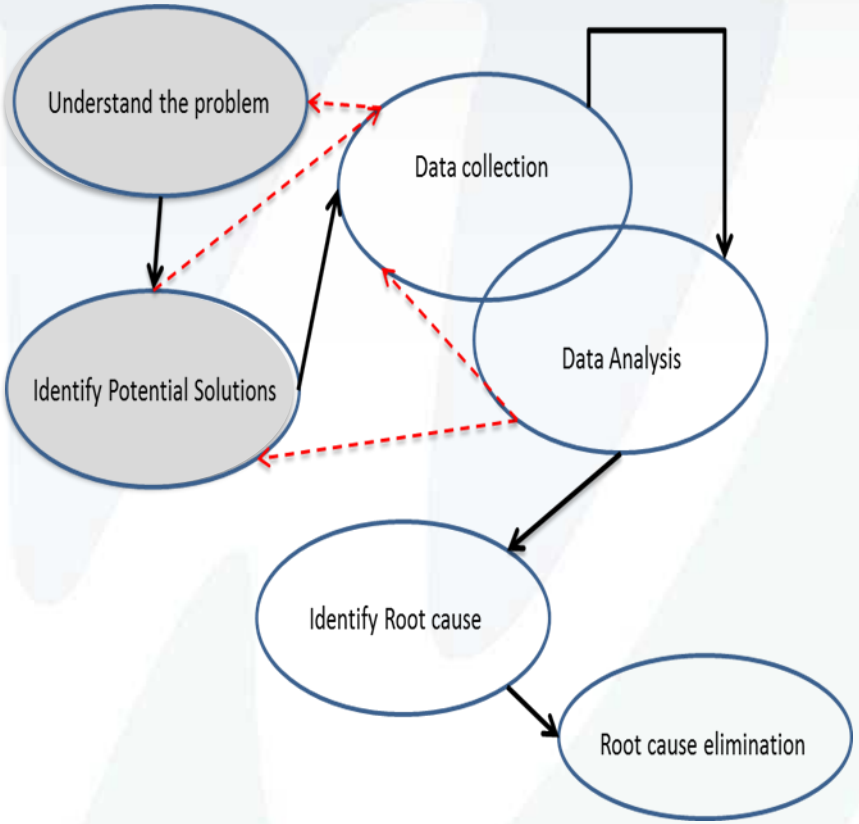
INVESTIGATIVE PROCESS - TOOLS

- Pareto Chart
- 5W's and 1H
  - Who, what, where, when, why and how
- 5 Whys
  - Ask why 5 times
  - Progress from symptom to lower level cause to root cause



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5 WHY's

- Ask Why five times
- Progress from symptom to lower level cause to root cause
- Example
  - Dissatisfied Web Site Customers
    - Why dissatisfied – lacking functionality
    - Why lacking – poor customer communication
    - Why poor communication – too much time pressure
    - Why time pressure – too many projects
    - Why too many – report to multiple bosses

Root cause: Department goals not aligned.

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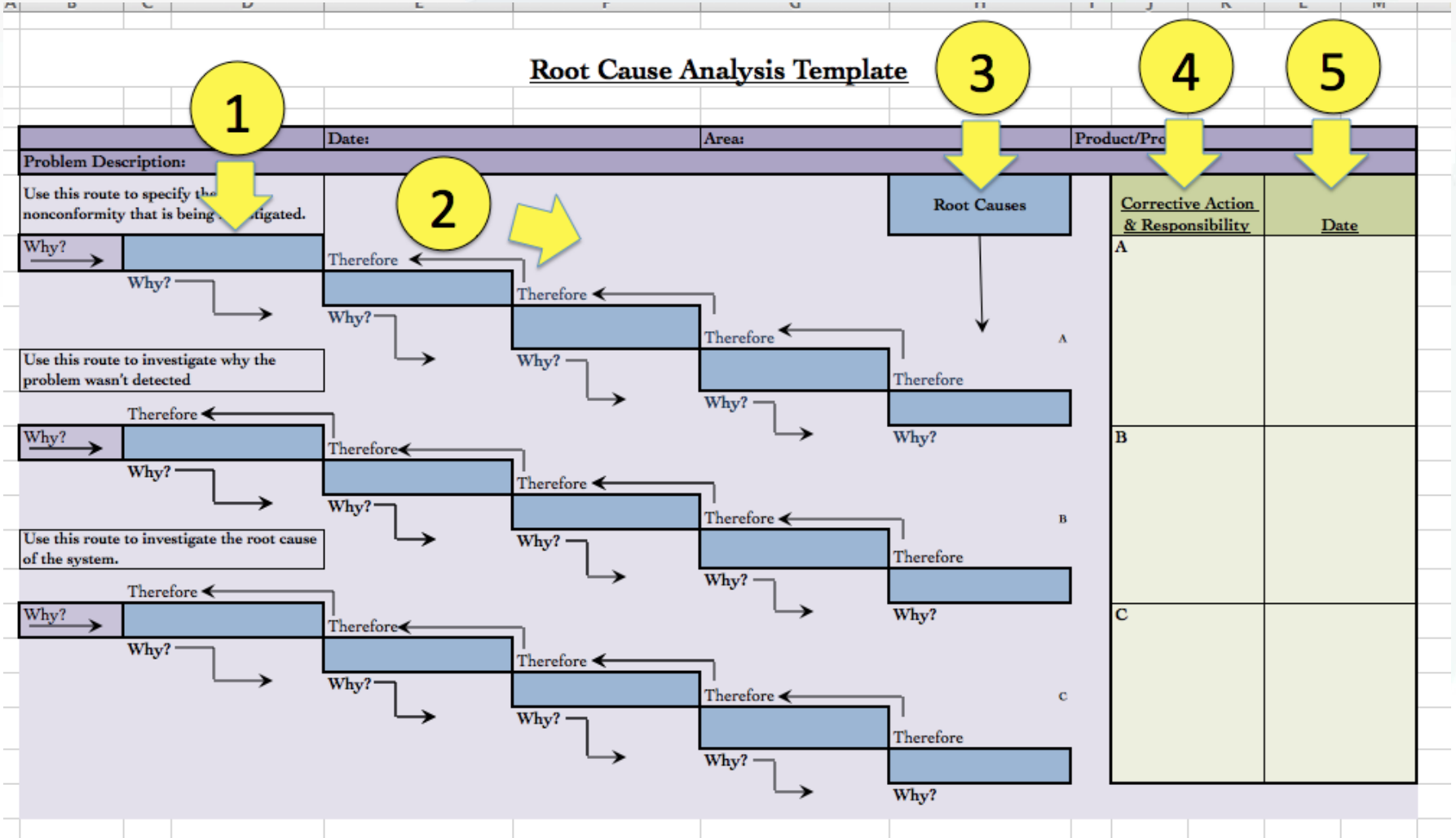
5 WHY's



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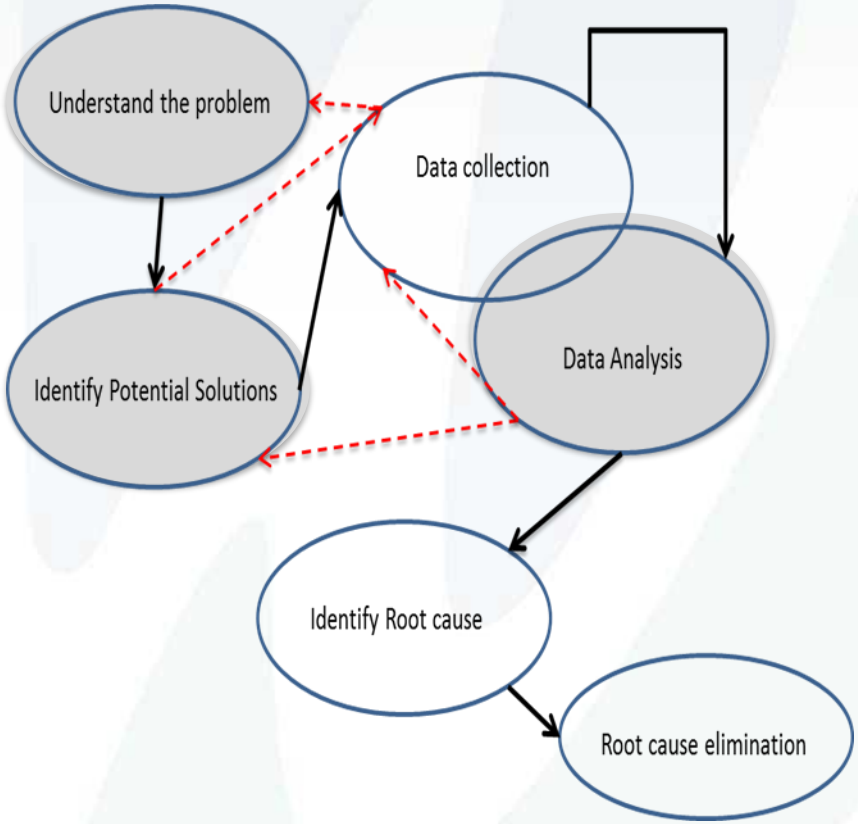
INVESTIGATIVE PROCESS - TOOLS

- Pareto Chart
- 5W's and 1H
  - Who, what, where, when, why and how
- 5 Whys
  - Ask why 5 times
- Ishikawa diagram (Fishbone)
  - Material, method, machine, measurement, environment, personnel



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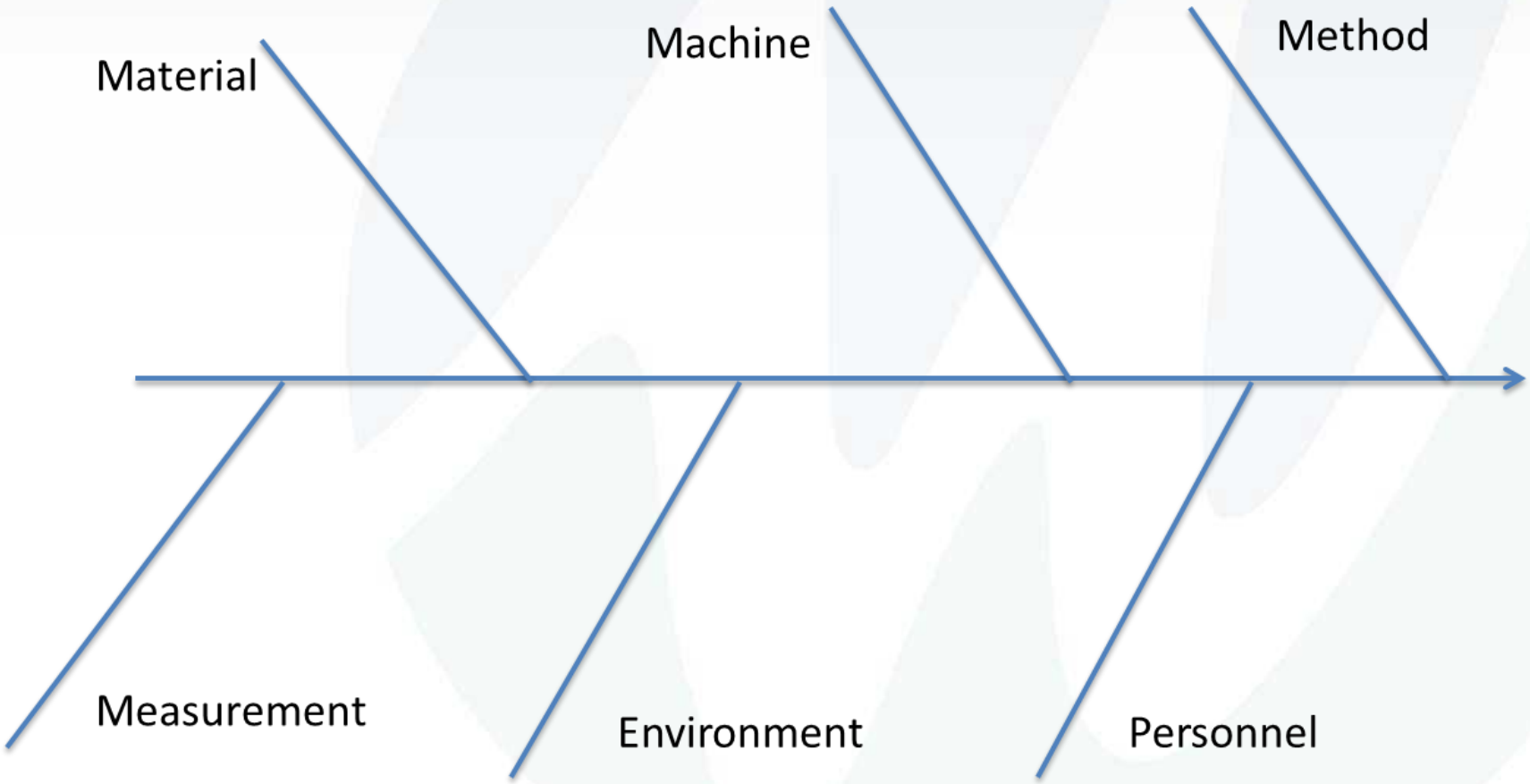
Ishikawa Diagram
(Cause & Effect) (Fishbone)



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ISHIKAWA DIAGRAM

- Similar to 5W's and H, but specific to process
  - Machine
  - Materials
  - Method
  - Measurement
  - Personnel
  - Environment
- Look at inputs that could affect output

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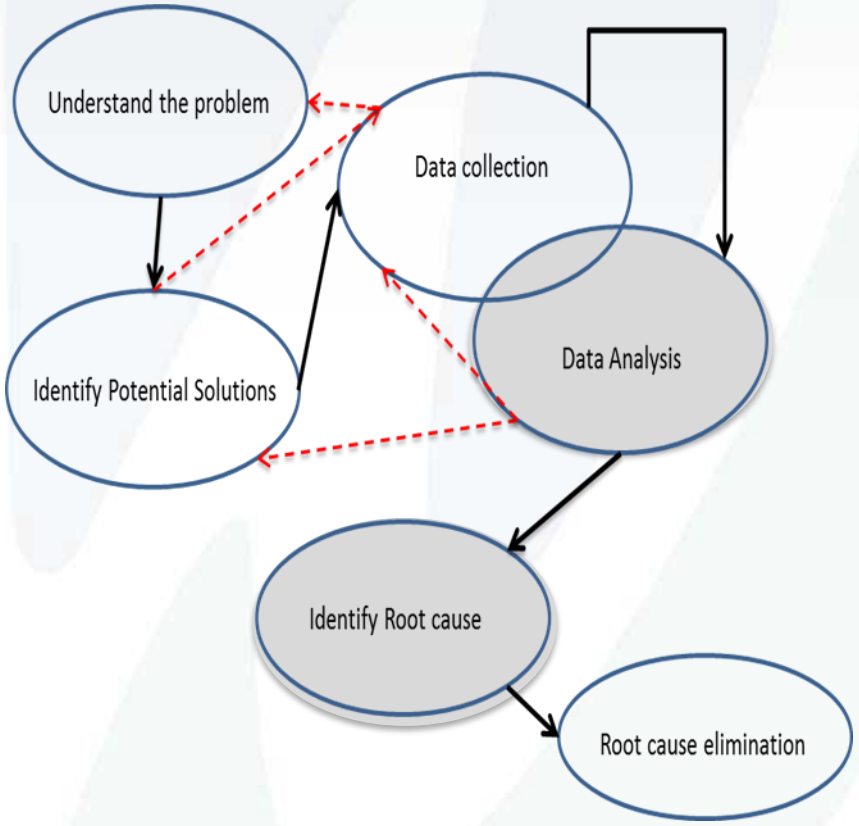
INVESTIGATIVE PROCESS - TOOLS

- Pareto Chart
- 5W's and 1H
  - Who, what, where, when, why and how
- 5 Whys
  - Ask why 5 times
- Ishikawa diagram (Fishbone)
  - Material, method, machine, measurement, environment, personnel
- Is / Is-Not Matrix



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IS – IS NOT MATRIX

- Tool to clarify problem definition and sort through brainstorming ideas
  - What the problem is or is not
  - Understand plausible problem causes
  - ID issues definitely not related

Problem (state issue here)	IS	Is Not	Distinctions
What occurred What objects affected	*What is..*	*What is not..*	*Is there a pattern, describe*
Where occurred			
When it occurred			
Extent of Problem(s)			
Who was involved			

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IS – IS NOT MATRIX

Problem Taper length incorrect	IS	IS NOT	Distinction
What happened	*Reported as short*	*Found in retains*	*OOS at customer*
Where it happened	*Reported by customer*	*final inspection data for product lot*	*OOS at customer*
When it happened	*Most recent product lot*	*10 lots shipped in past 8 months*	*No pattern in complaints*
Extent (frequency)	*Reported as every piece inspected*	*No NCRs reported last 16 months First complaint in 24 months*	*No internal pattern*
Who did the inspections	*Unknown inspector*	*multiple inspectors over 16 months*	*New inspector at Customer?*

This was determined to be an inspection issue at the Customer.

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SIX SIGMA PROGRAMS

- Business Management Strategy
- Process Improvements
- Developed by Motorola 1986
  - 1995 Jack Welch made business strategy at General Electric

- Structured investigation process
  - Improve quality by identifying (removing) defects and minimizing process variability.
  - Utilizes quality management and statistical methods

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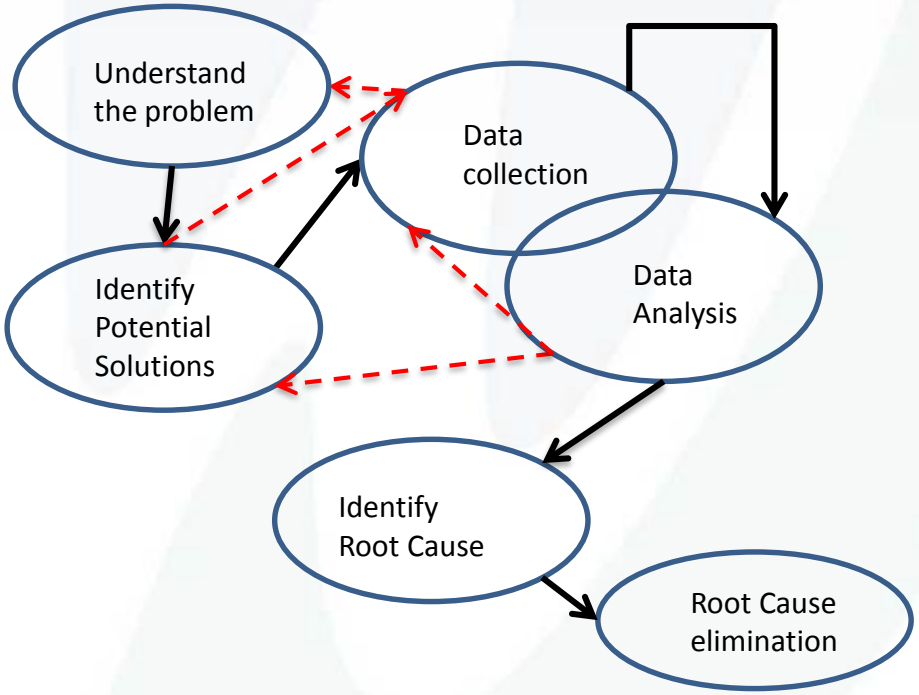
- Six Sigma
  - Project oriented
    - Define
    - Measure
    - Analyze
    - Improve
    - Control

- Root Cause Analysis
  - Investigation process



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LEAN SIX SIGMA

- Six Sigma
  - Define
  - Measure
  - Analyze
  - Improve
  - Control
- Lean Improvement
  - Recognize
    - Identify areas and keep an inventory
  - Define
  - Measure
  - Analyze
  - Improve
  - Control
  - Sustain
    - Share learning throughout the organization

http://en.wikipedia.org/wiki/DMAIC

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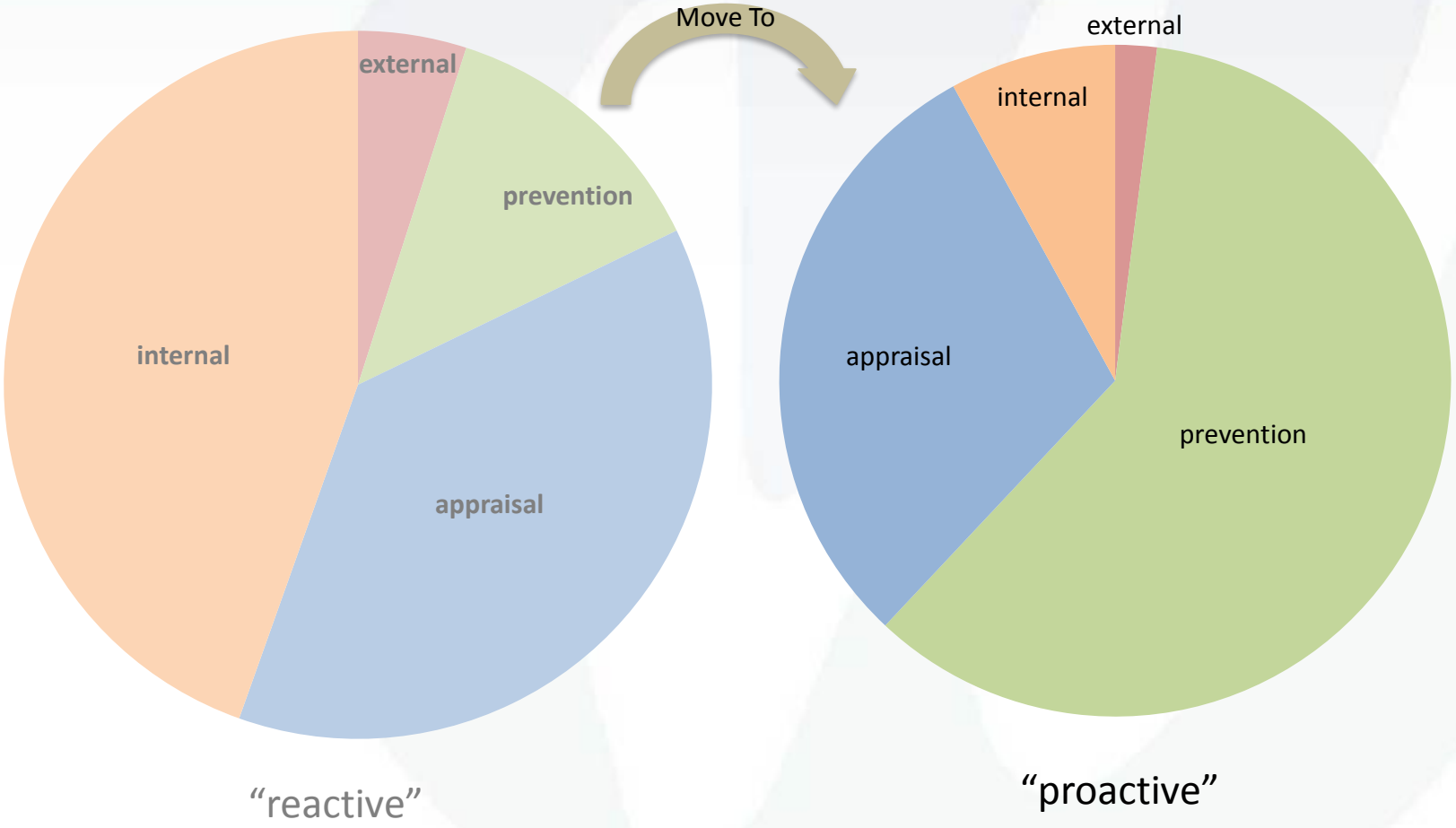
Six Sigma projects



"reactive"

"proactive"

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CAPA

Corrective Action
Preventive Action

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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

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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

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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…

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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

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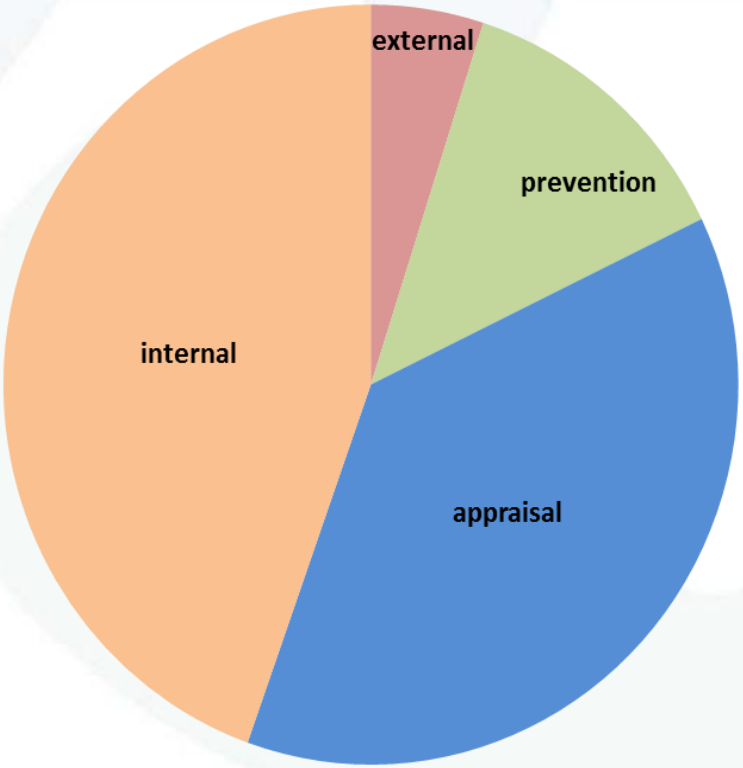

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CAPA SYSTEM

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

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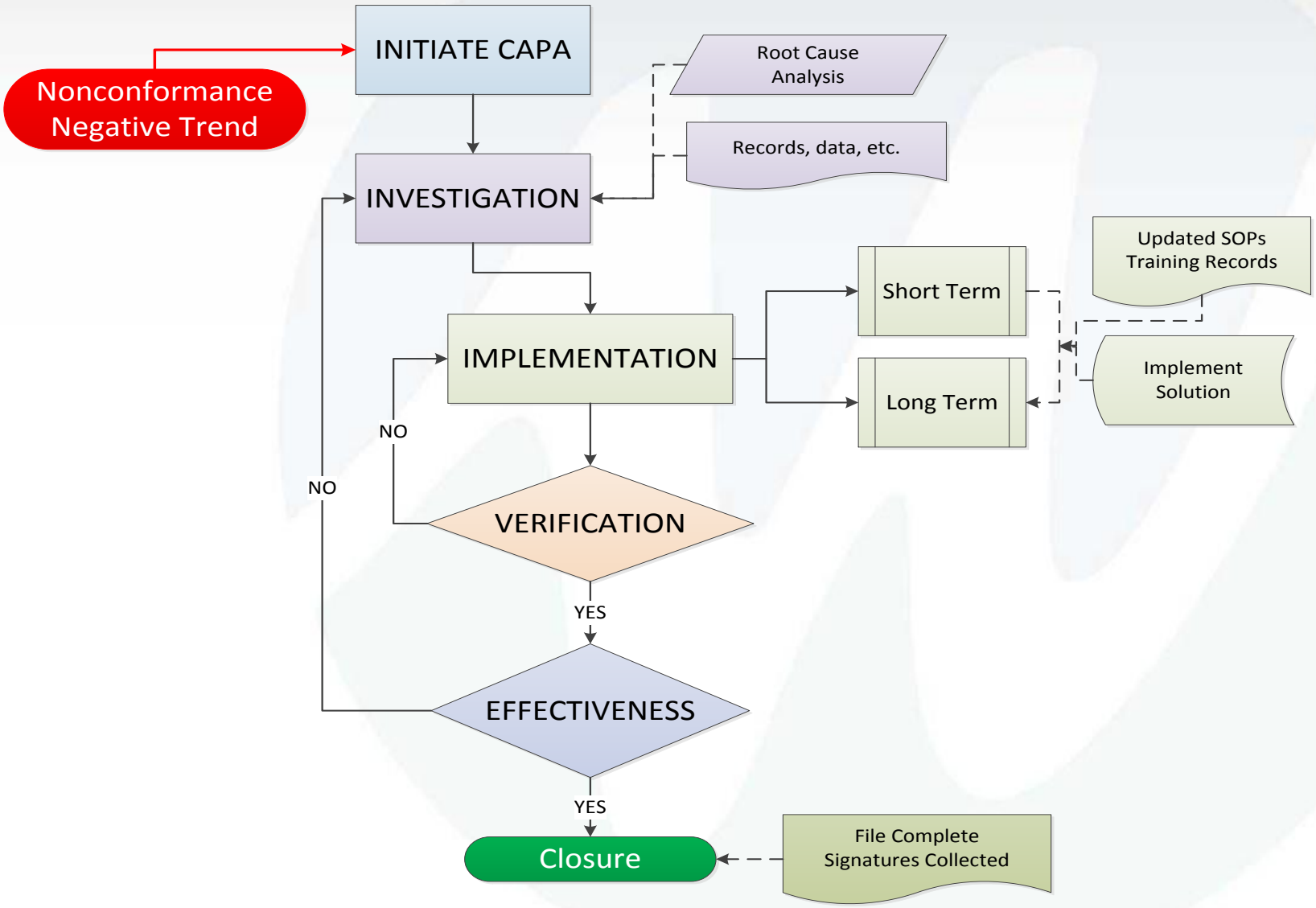
CAPA SYSTEM



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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

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CAPA SYSTEM

- Implementation
  - Immediate correction
  - Short Term
  - Long Term
- Verification
  - Review implementation
    - Documentation, training
    - Validation, change control
- Effectiveness
  - Management Review
  - Recurrence
    - 30days, 60days, 90days, etc.
    - Trend(s)

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CAPA SYSTEM

- Initiation
- Investigation
- Implementation
  - Immediate, short term, long term
- Verification
  - Review implementation; Recurrence (?)
- Effectiveness
  - Management Review; Recurrence; Trend(s)
- Closure
  - File complete (documentation)
  - Signatures

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PREVENTIVE ACTION

- Using knowledge from Corrective Action to prevent occurrence elsewhere in the facility, process, etc.
- Risk assessment during design phase
  - Failure Mode Error Analysis
- Control Plans
  - Start-up, in-process, final testing
  - Equipment monitoring (SPC)
  - Process Alarms
  - Etc.

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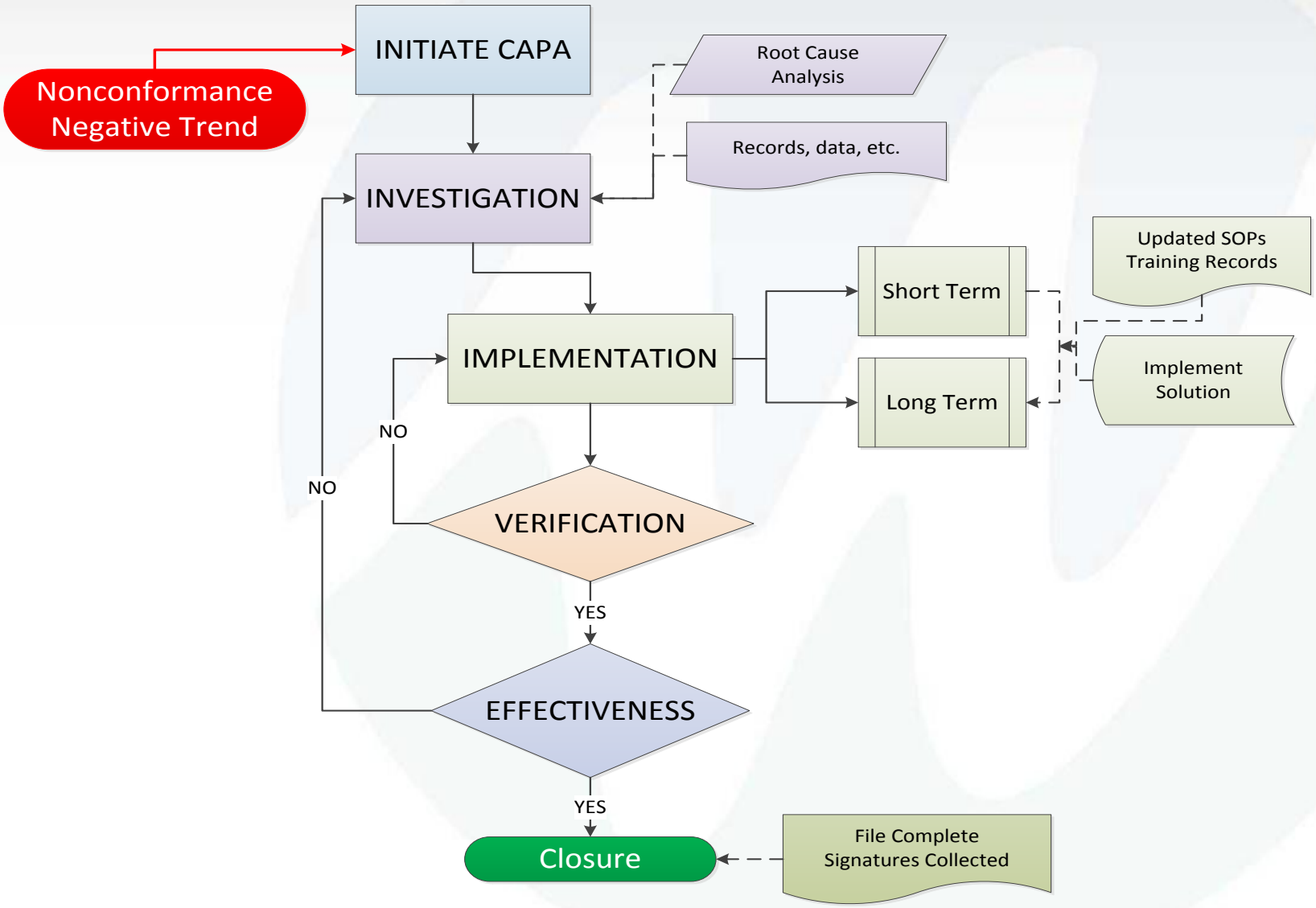
PREVENTIVE ACTION

- Control plan example

CAPA SYSTEM



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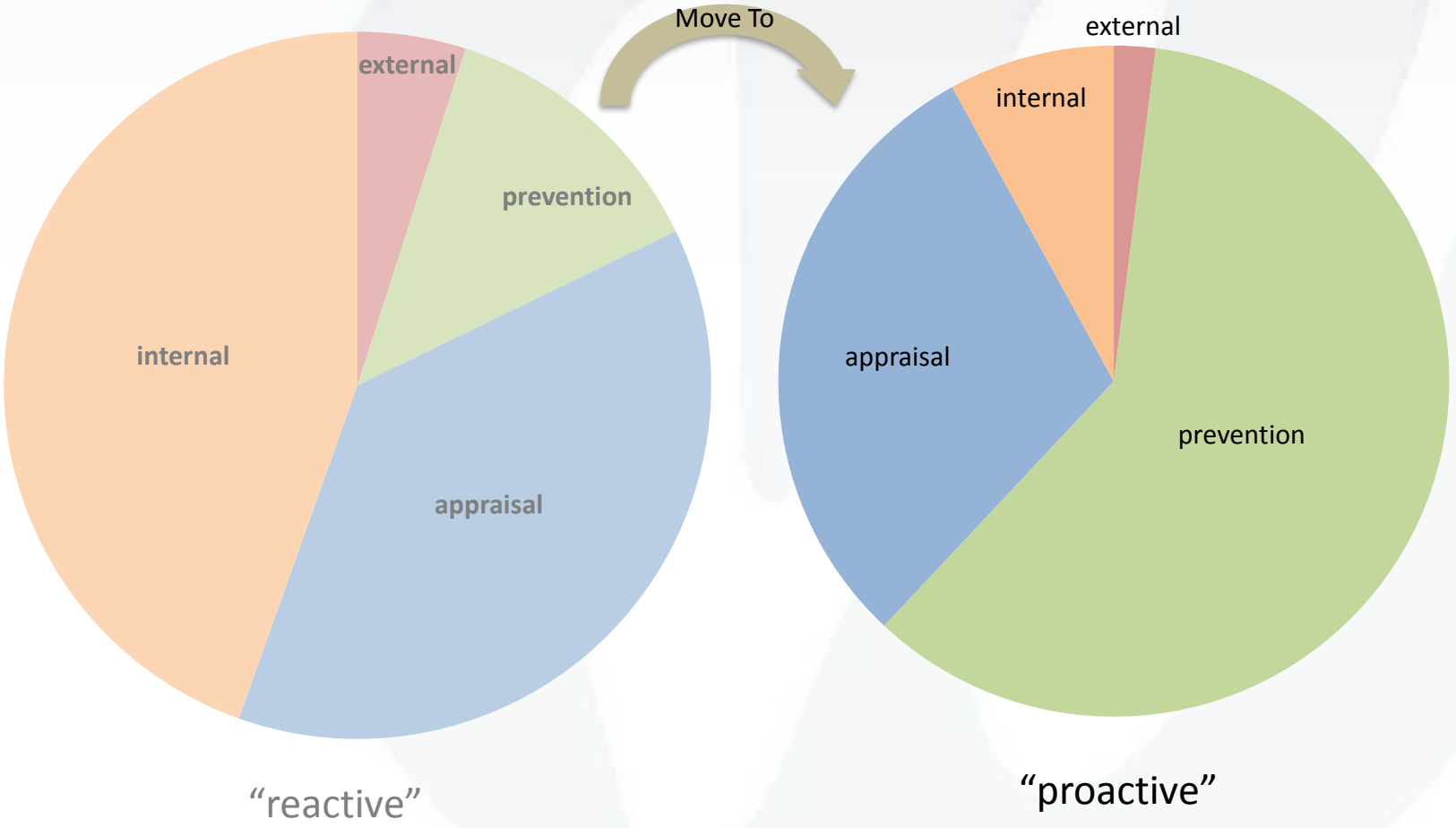

"reactive"

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VALIDATION

PROVIDED BY VALIDATION SUPPORT.COM

Design/Installation/Operation/Performance
Product Claims
Process Stability

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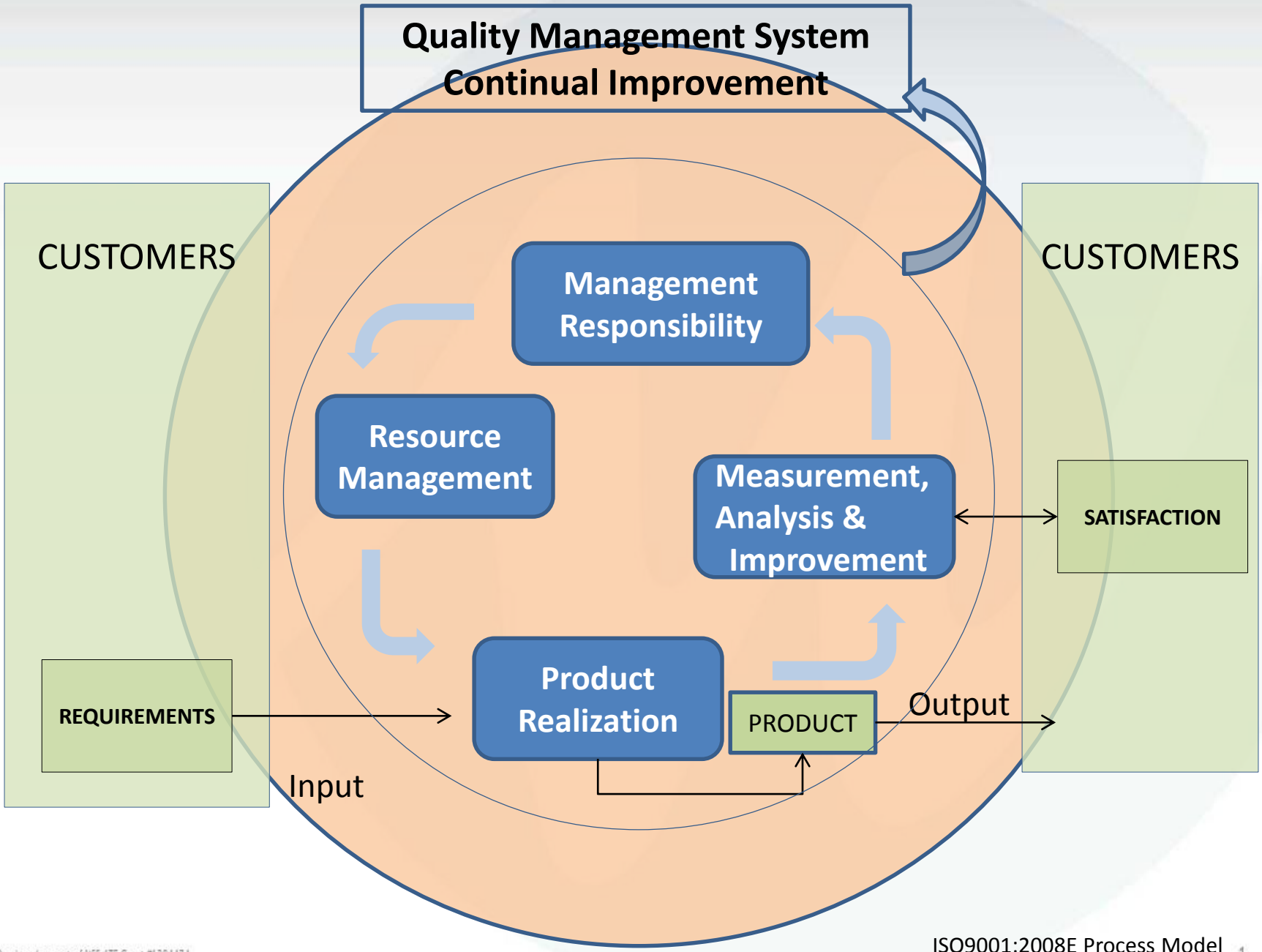
VALIDATION

- Integral part of overall quality system
  - ISO 9001:2008E
    - [listed in?]
  - 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



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VALIDATION PROGRAM

- Integral part of overall quality system
  - ISO 9001:2008E
  - FDA GMPs for pharmaceutical and medical devices
- Terminology

  Commissioning; Qualification; Validation; Verification

  Terms used interchangeably, but technical differences

COMMISSIONING

- A well planned, documented, and managed engineering approach to the start-up and turnover of facilities, systems, and equipment to the end-user, that results in a safe and functional environment that meets established design requirements and stakeholder expectations.
  Publication Source: ISPE Baseline® Guide, Vol. 1: Active Pharmaceutical Ingredients, Second Edition
  Publication Date: 2007
- Planned and documented series of inspections, adjustments, and tests carried out systematically to set the installation into correct technical operation as specified.
  Publication Source: ISO/TC209 Working Groups at 2001-03-31 – Committee Draft ISO/CD 14644-6 "Cleanrooms and associated controlled environments" – Part 6: Terms and Definitions
- The documented process of verifying that equipment and systems are installed according to specifications, placing the equipment and systems into active service, and verifying their proper operation.
  Publication Source: ISPE Baseline® Guide, Vol. 2: Oral Solid Dosage Forms (First Edition) Publication Date: 1998
- A prescribed number of activities designed to take equipment and systems from static, substantially complete state to an operable state.
  Publication Source: ISPE Baseline® Guide, Vol. 4: Water and Steam Systems (Second Edition) Publication Date: 2011
- Commissioning is a quality oriented process for verifying and documenting that the performance of facilities, systems and assemblies meets defined objectives and criteria.
  Publication Source: ISPE Good Practice Guide: Heating, Ventilation, and Air Conditioning (HVAC) Publication Date: 2009
- (IEEE) The process of providing to the appropriate components, the information necessary for the designed communication between components.
  Publication Source: GAMP® Good Practice Guide: A Risk-Based Approach to Testing of GxP Systems (Second Edition) Publication Date: 2012

COMMISSIONING

- 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

QUALIFICATION

- The process of demonstrating whether an entity is capable of fulfilling specified requirements.
  Publication Source: GAMP® Good Practice Guide: A Risk-Based Approach to Calibration Management (Second Edition) Publication Date: 2010
- (ISO) The process to demonstrate the ability to fulfill specified requirements.
  Publication Source: GAMP® 4: Good Automated Manufacturing Practice Guide for Validation of Automated Systems
- (MHRA) Action of proving that any instrument or equipment works correctly and actually leads to the expected results. The word "validation" is sometimes widened to incorporate the concept of qualification.
  Publication Source: GAMP® Good Practice Guide: A Risk-Based Approach to Calibration Management (Second Edition) Publication Date: 2010
- (ICH Q7) Action of proving and documenting that equipment or ancillary systems are properly installed, work correctly, and actually lead to the expected results. Qualification is part of validation, but the individual qualification steps alone do not constitute process validation.
  Publication Source: ISPE Baseline® Guide, Vol. 6: Biopharmaceutical Manufacturing Facilities Publication Date: 2004
- Process of demonstrating whether an entity – activity or process, product, organization, or any combination thereof – is capable of fulfilling specified requirements.
  Publication Source: ISO/TC209 Working Groups at 2001-03-31 – Committee Draft ISO/CD 14644-6 "Cleanrooms and associated controlled environments" – Part 6: Terms and Definitions

QUALIFICATION

- 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
- Design (DQ)
  - User Requirement Specification (URS)
- Installation (IQ)
  - Factory Acceptance Testing (FAT)
- Operational (OQ)
  - Range Testing
- Performance or Process (PQ)
  - Stability & Repeatability

QUALIFICATION TYPES

- Design (DQ)
- Installation (IQ)
- Operational (OQ)
- Performance or Process (PQ)
- Component (CQ)
  - Supplier Responsibility
- Re-qualification (RQ)
- Plus many others

VALIDATION

- Establishing documented evidence that the system does what it purports to do.

  Publication Source: American Society of Mechanical Engineers (ASME), Bioprocessing Equipment (BPE) - 2009
- The action of proving, in accordance with the principles of GxP, that any procedure, process, equipment material, activity or system actually leads to the expected results.

  Publication Source: GAMP® Good Practice Guide: A Risk-Based Approach to Calibration Management (Second Edition) Publication Date: 2010
- Establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes. FDA Guidelines on General Principles of Process Validation, May 1987.

  Publication Source: ISPE Baseline® Guide, Vol. 1: Active Pharmaceutical Ingredients, Second Edition (2007)
- (ICH Q7) A documented program that provides a high degree of assurance that a specific process, method, or system will consistently produce a result meeting pre-determined acceptance criteria.

  Publication Source: ISPE Baseline® Guide, Vol. 6: Biopharmaceutical Manufacturing Facilities (2004)
- Confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled.

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- Defined generically, a process to determine that a system or process is fit for the intended use. In ASTM 2500-07 and GAMP 5, verification in concert with design review activities fulfill this objective.

  Publication Source: GAMP® Good Practice Guide: Manufacturing Execution Systems - A Strategic and Program Management Approach (2010)
- For the purposes of this Guide (ISPE GPG Assessing the Particulate Containment Performance of Pharmaceutical Equipment) the term "validation" is used only in relation to quantitative, analytical methods and is not meant to denote a cGMP-related context

  Publication Source: ISPE Good Practice Guide: Assessing the Particulate Containment Performance of Pharmaceutical Equipment

VALIDATION PROGRAM

- Terminology
  - Commissioning – process through which equipment is tested in order to make sure that the equipment was properly designed and built
  - Qualification – predefined scripted set of tests with expected results
  - 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: *confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled; documented evidence the product functions as expected (meets expectations) and processes are ready for release*

    [21CFR Part 820 Definitions]

    Are you building the right thing? Meeting User needs.

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…

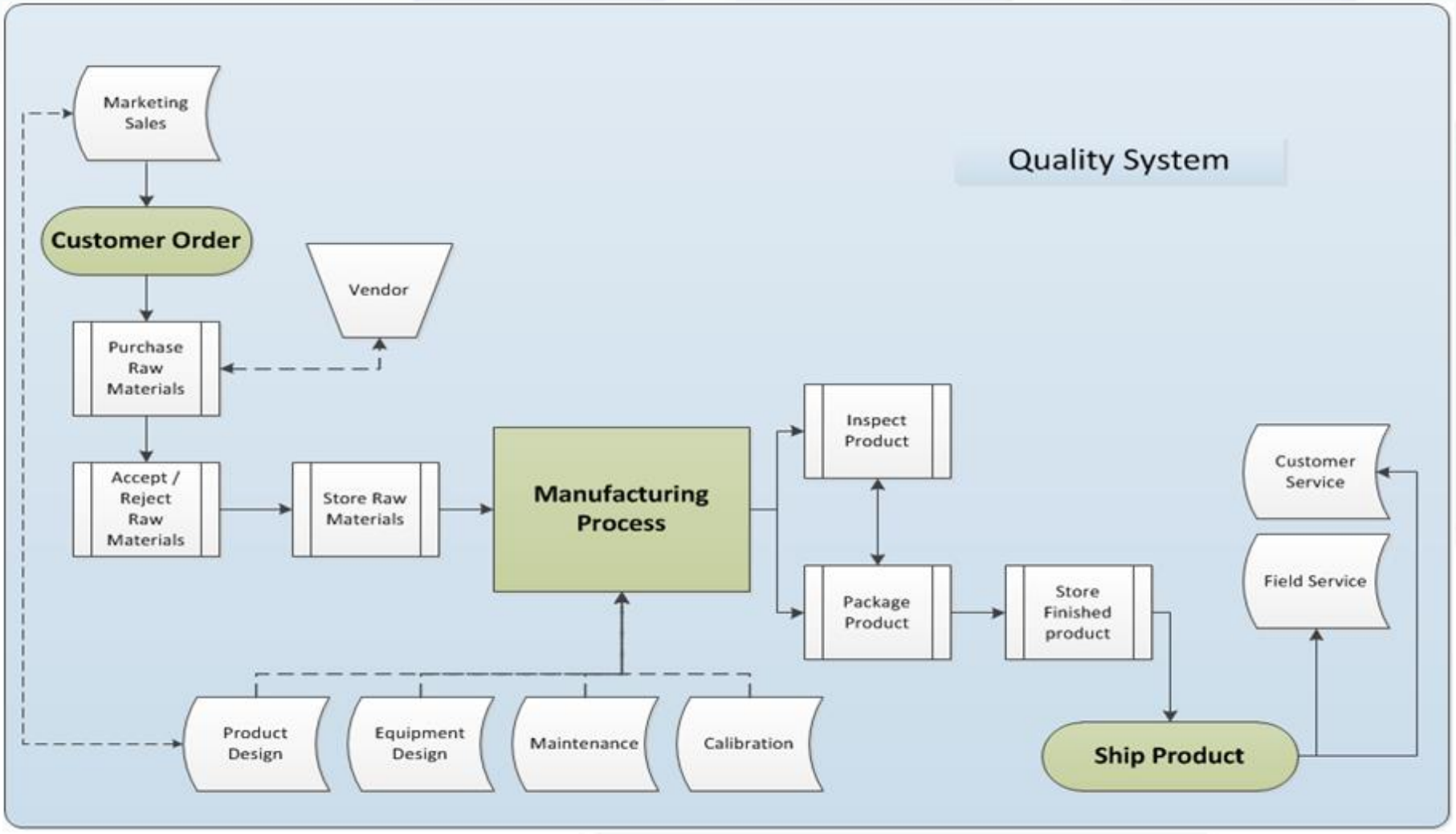
VALIDATION PROGRAM – COMPONENTS

- 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



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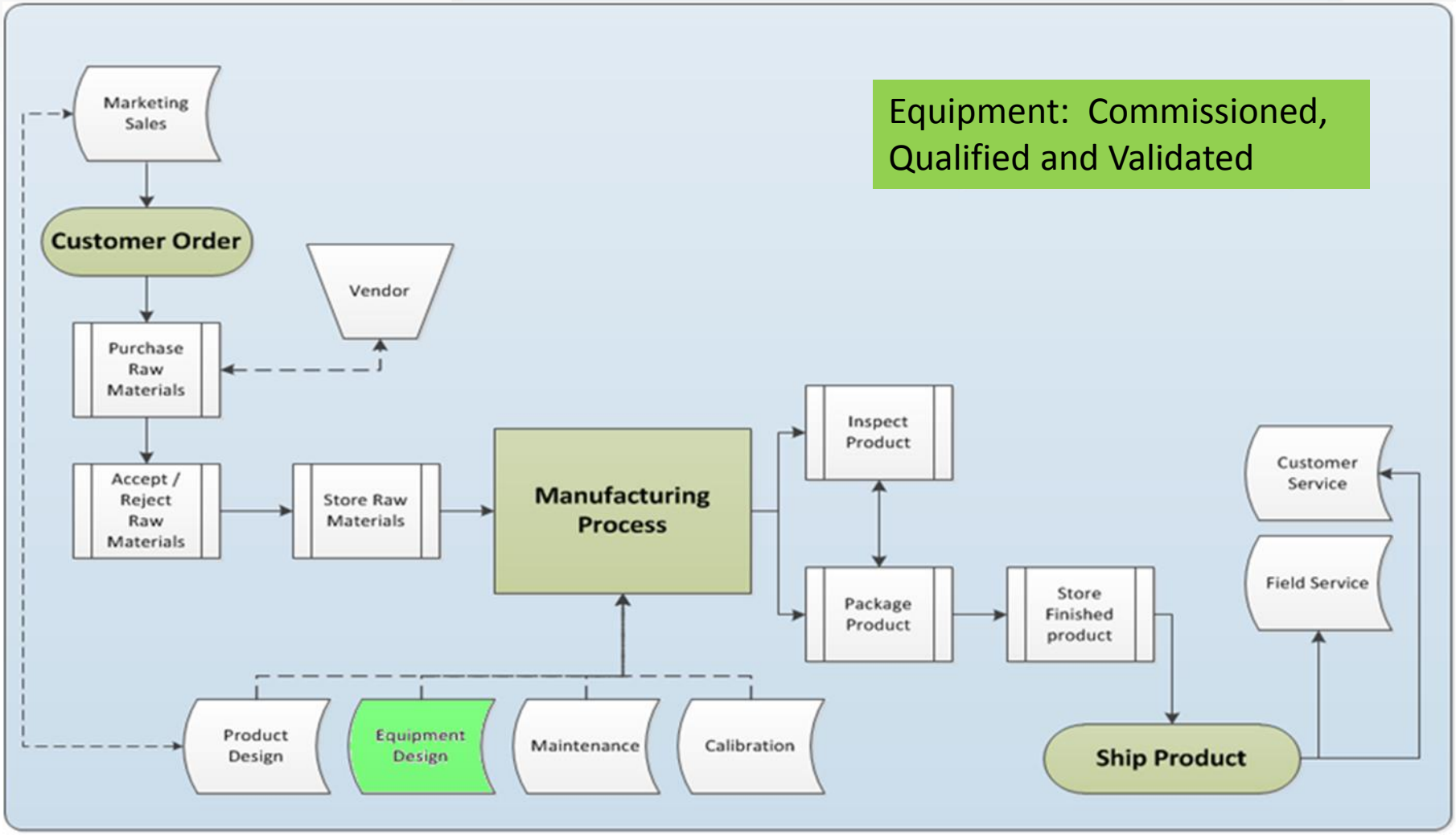

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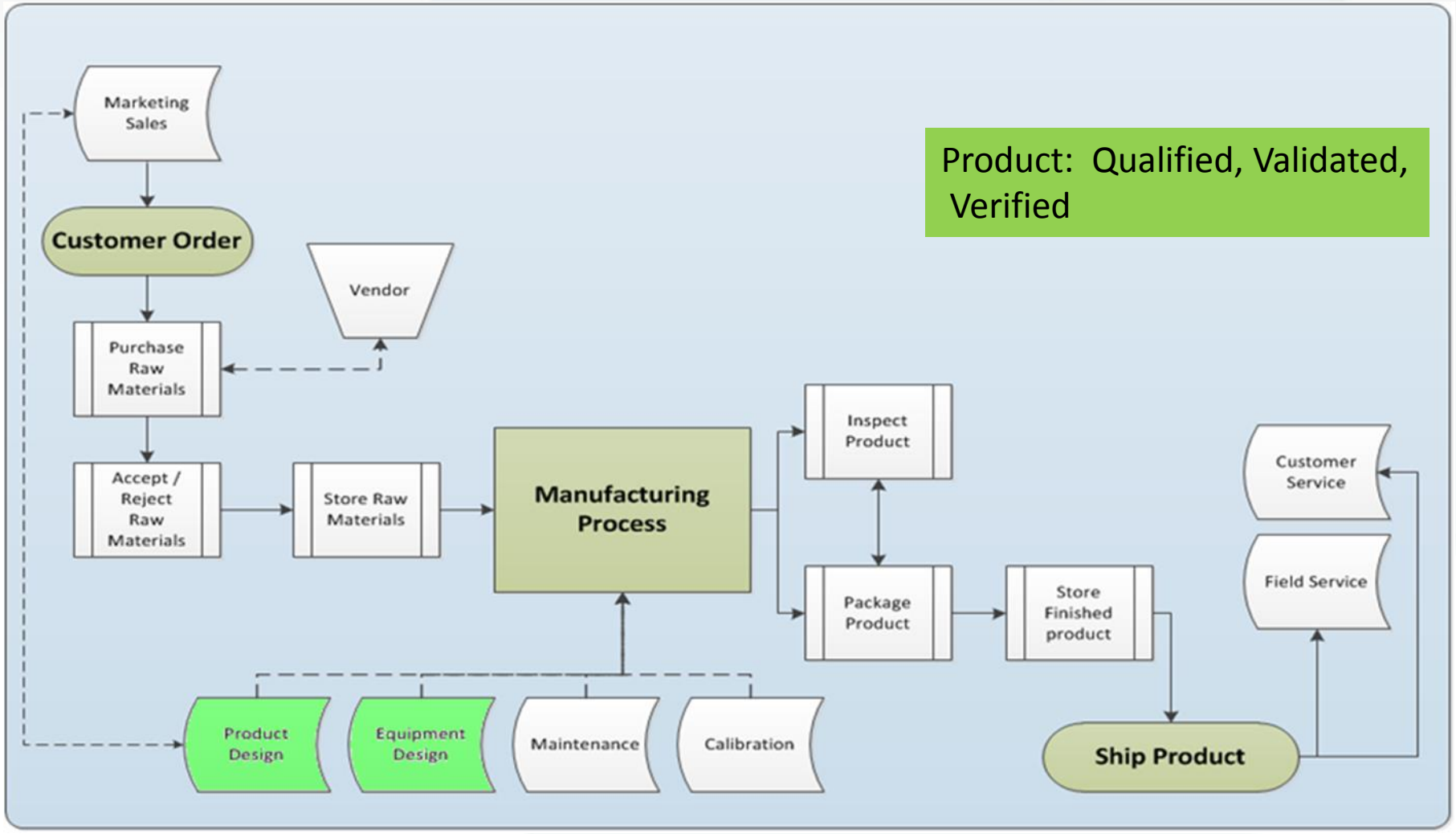

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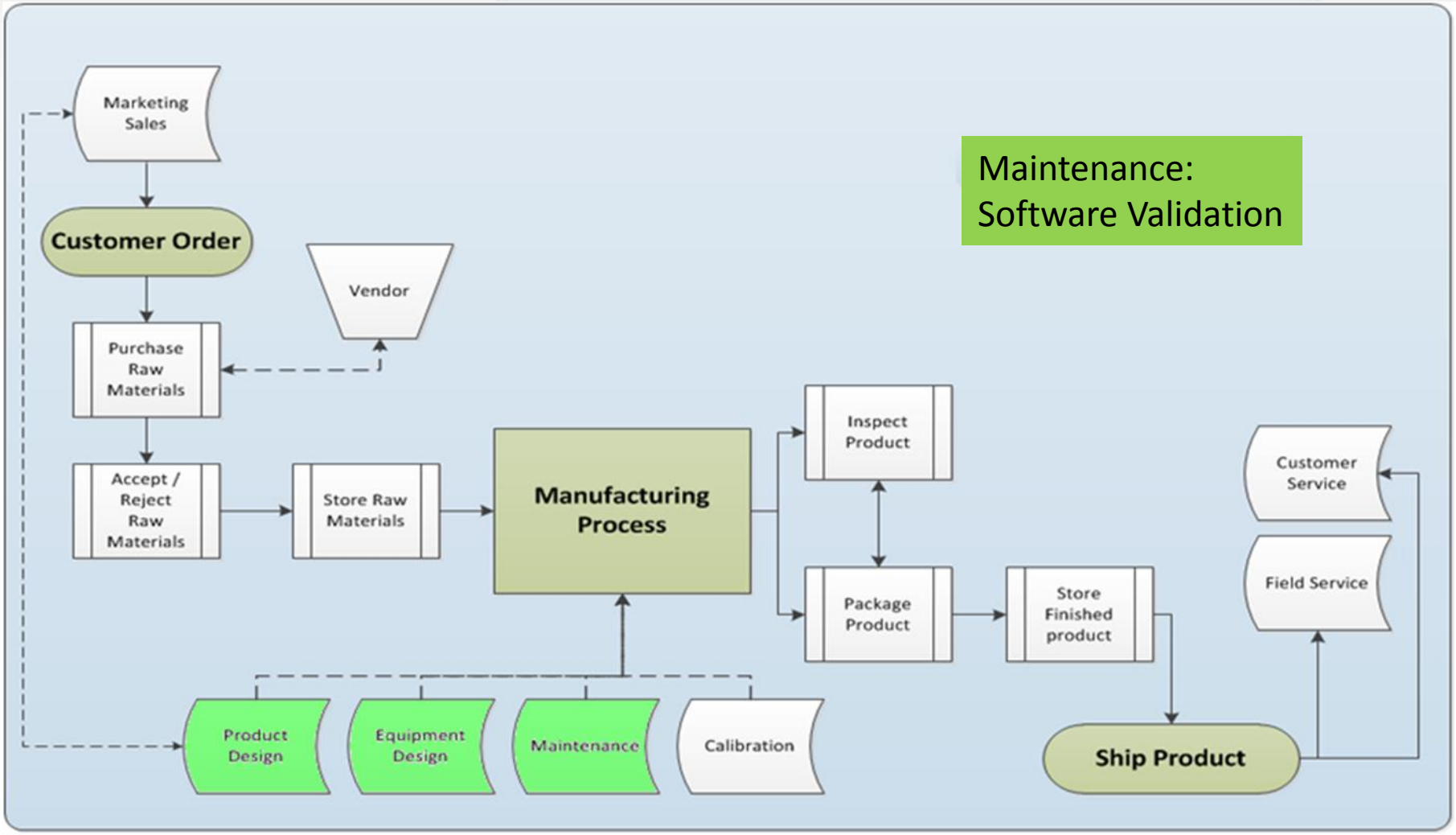

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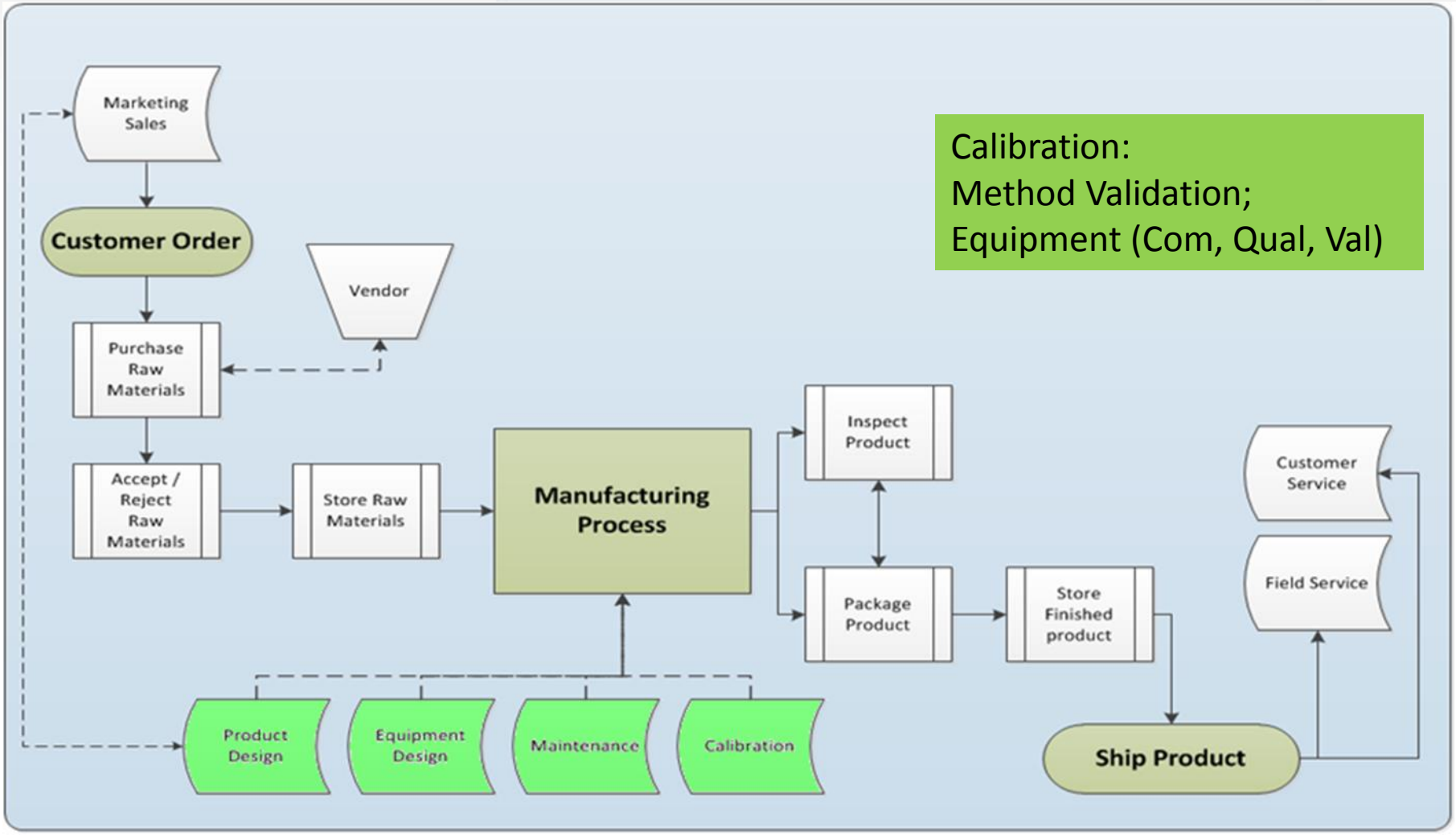

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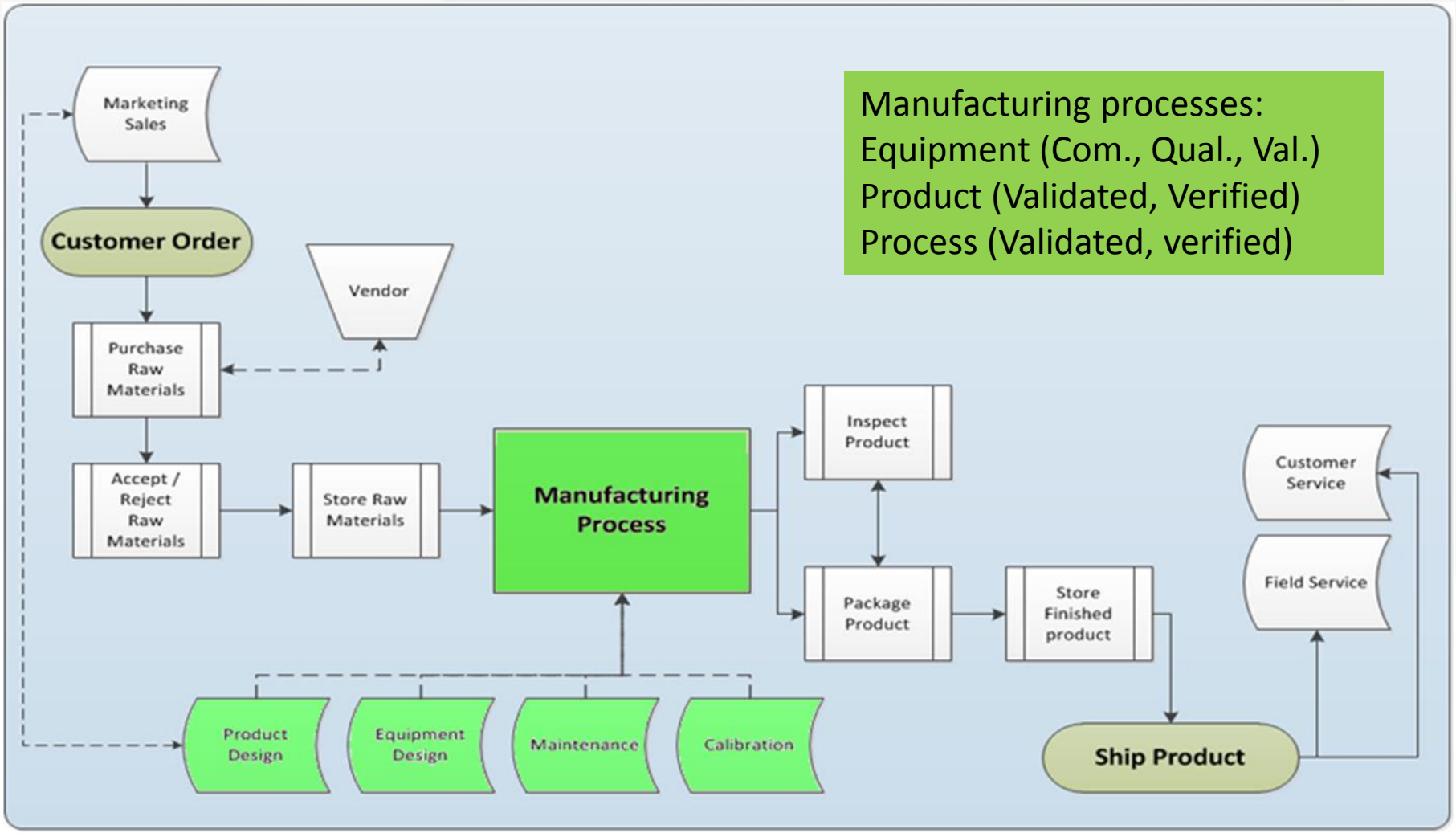

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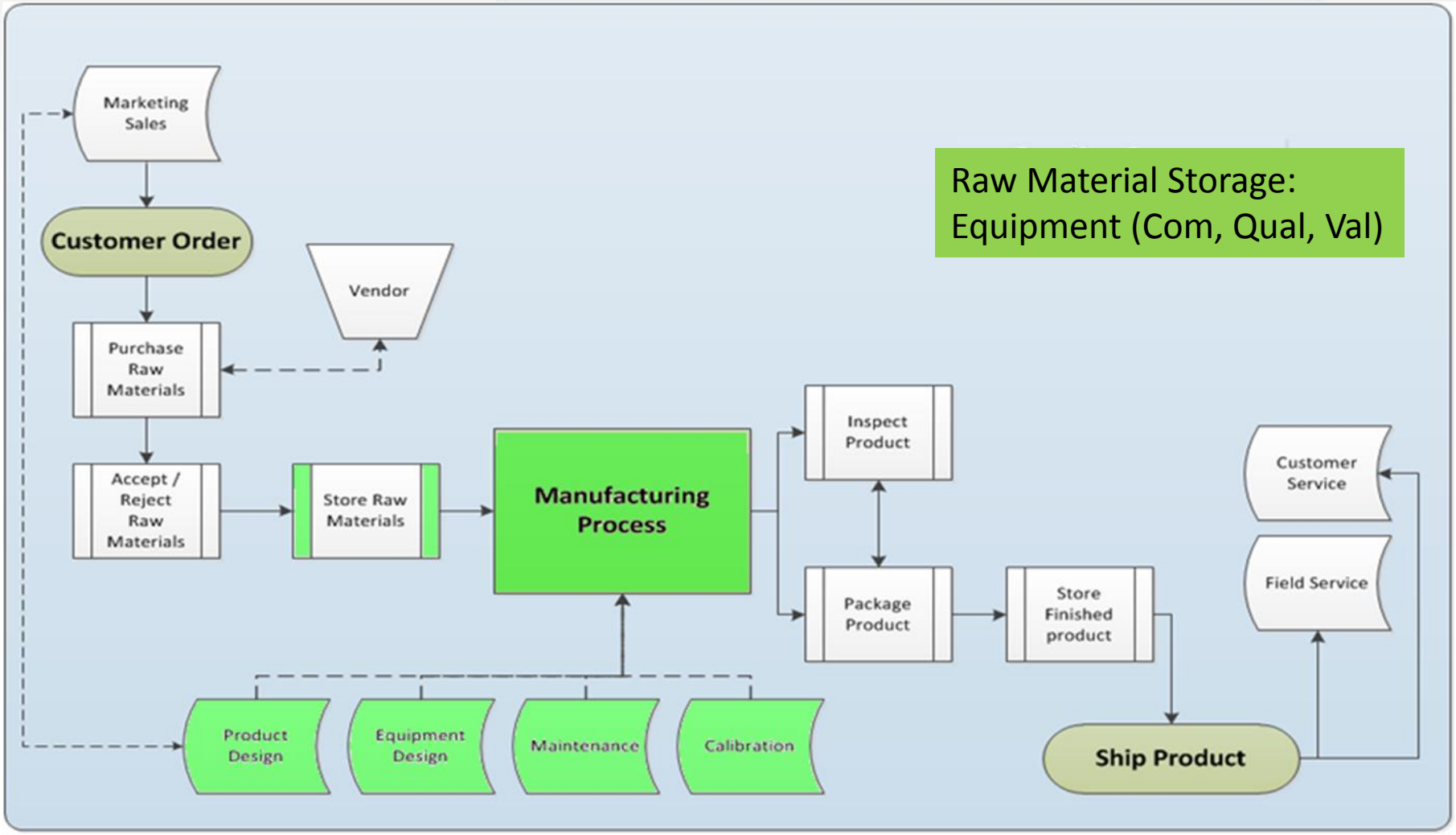

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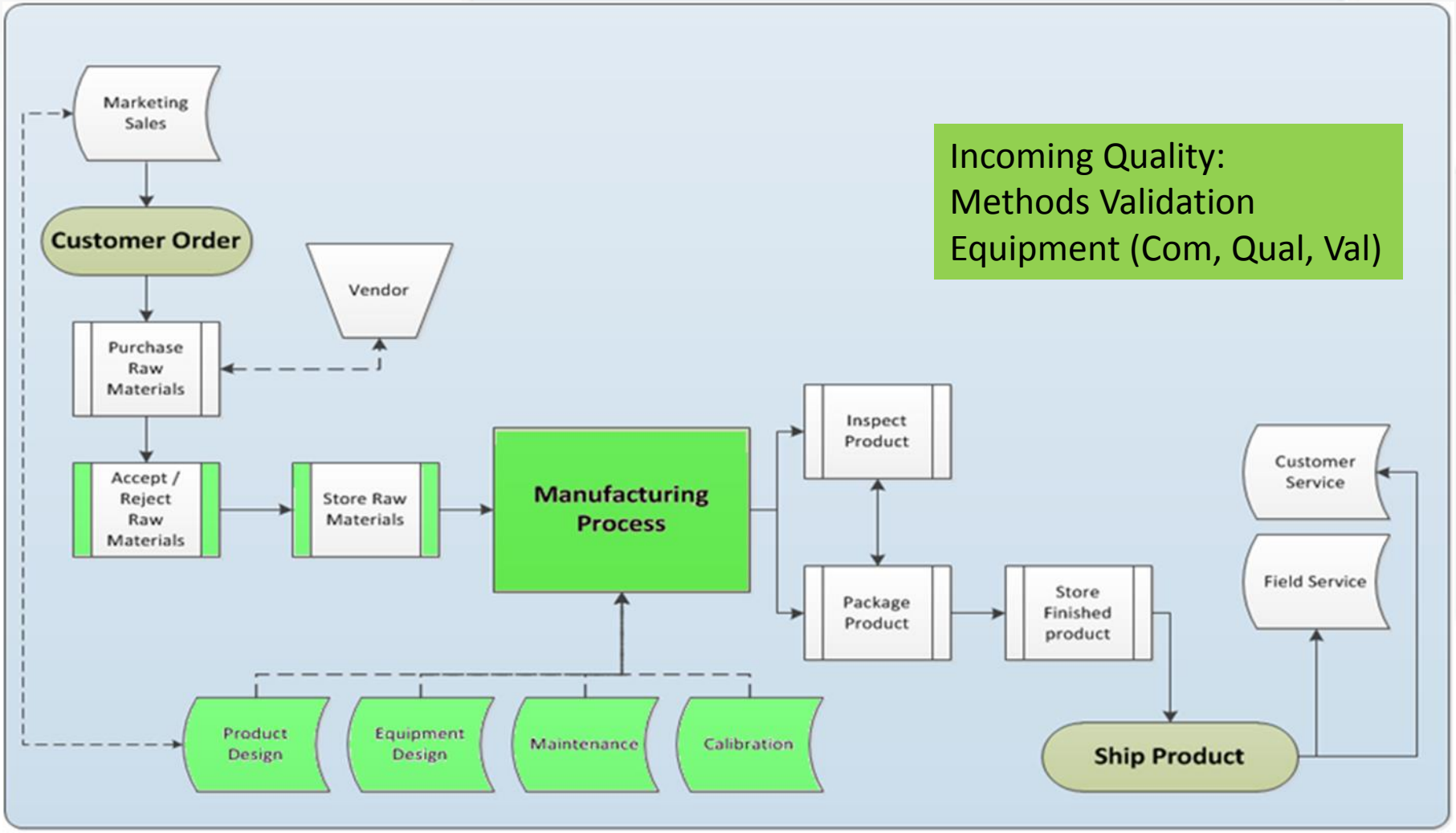

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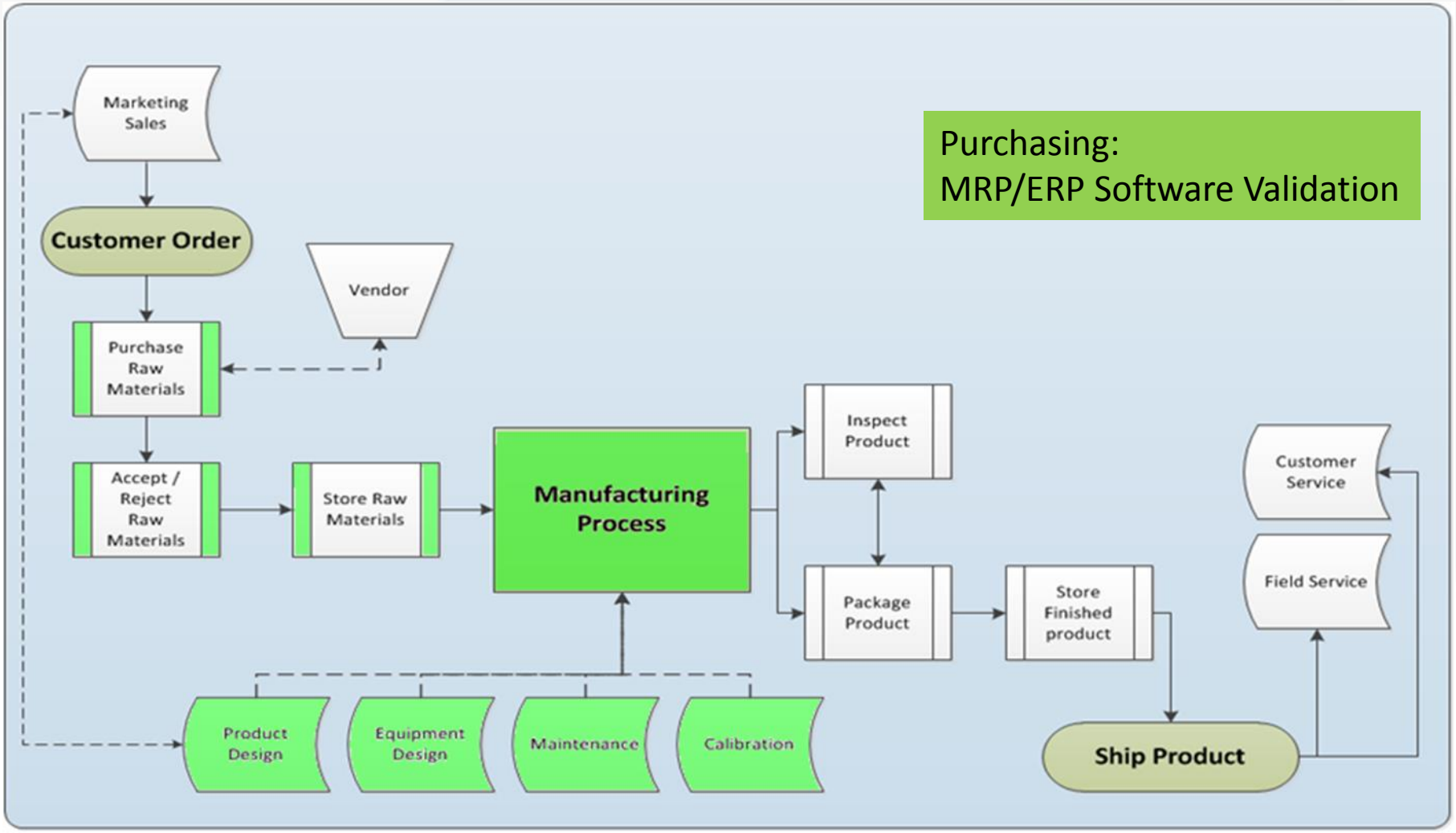

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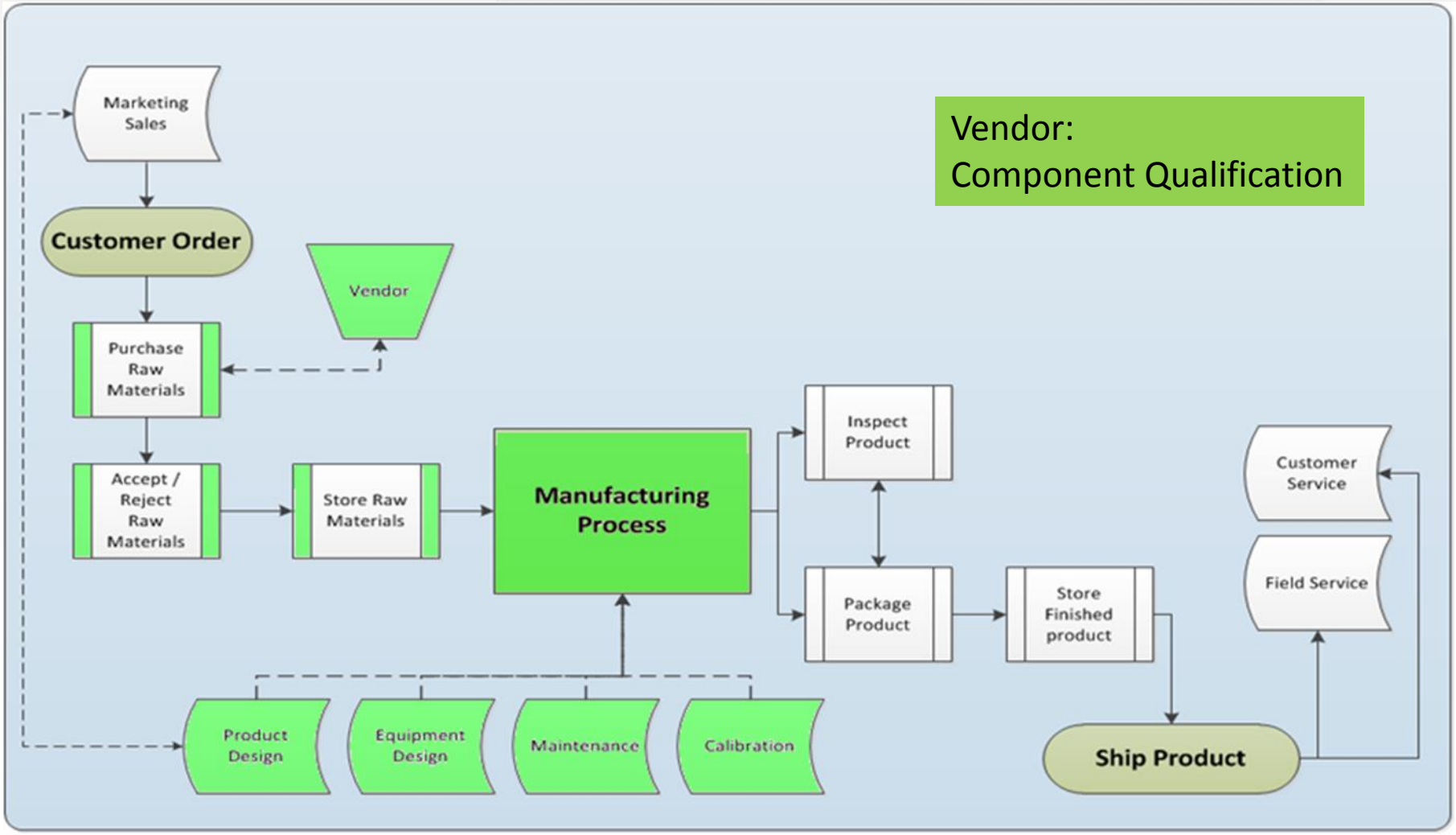

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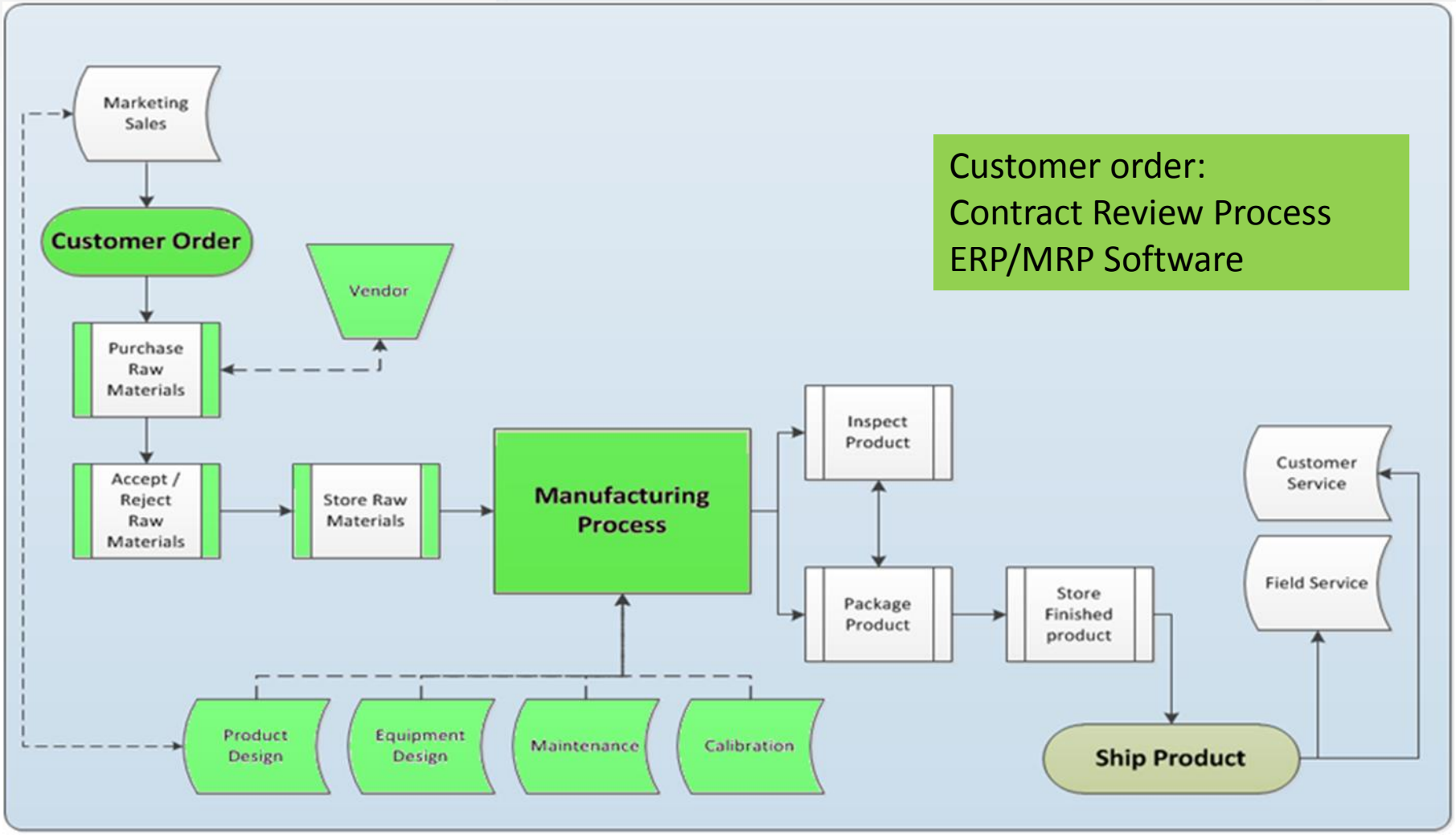

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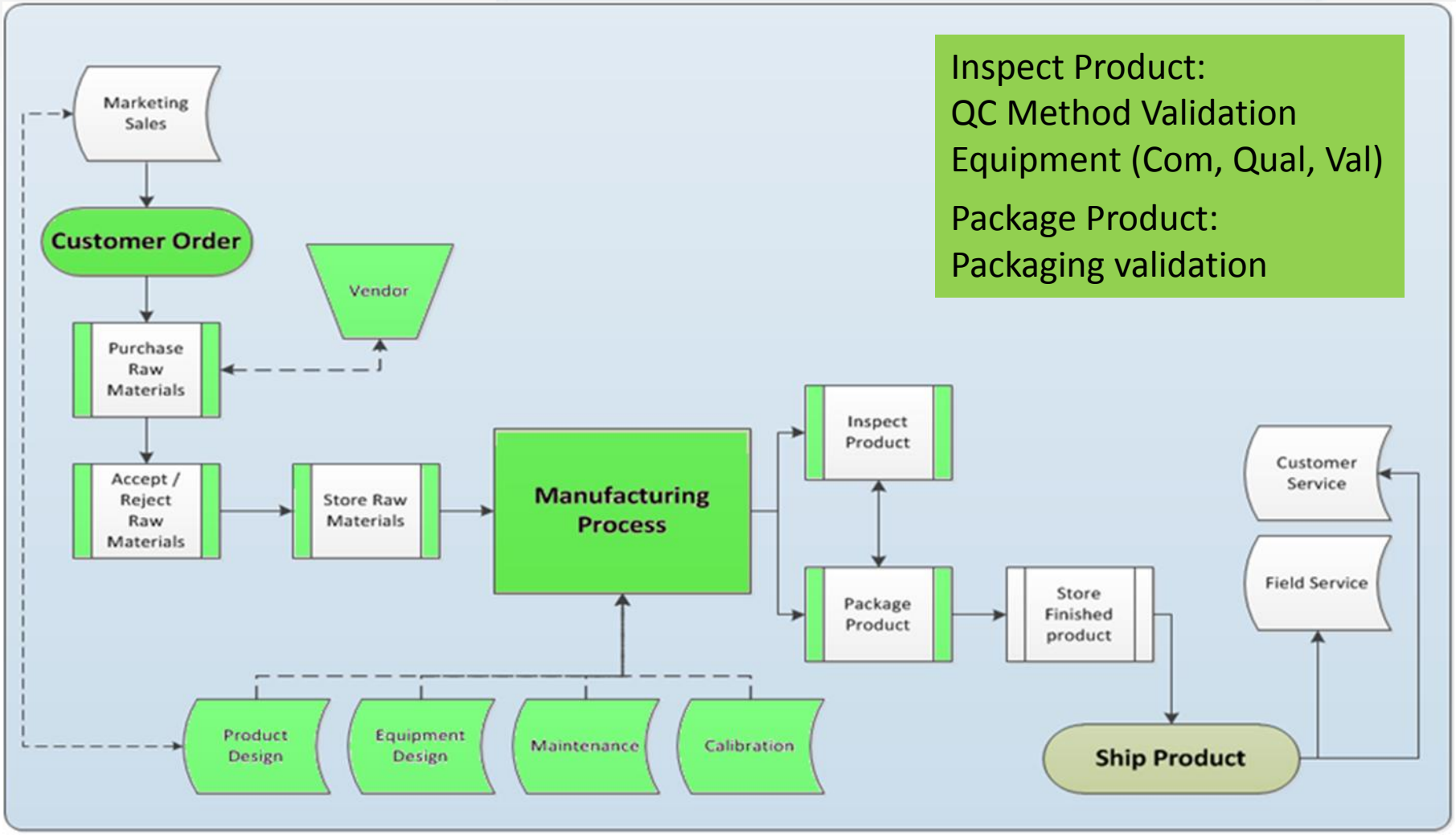

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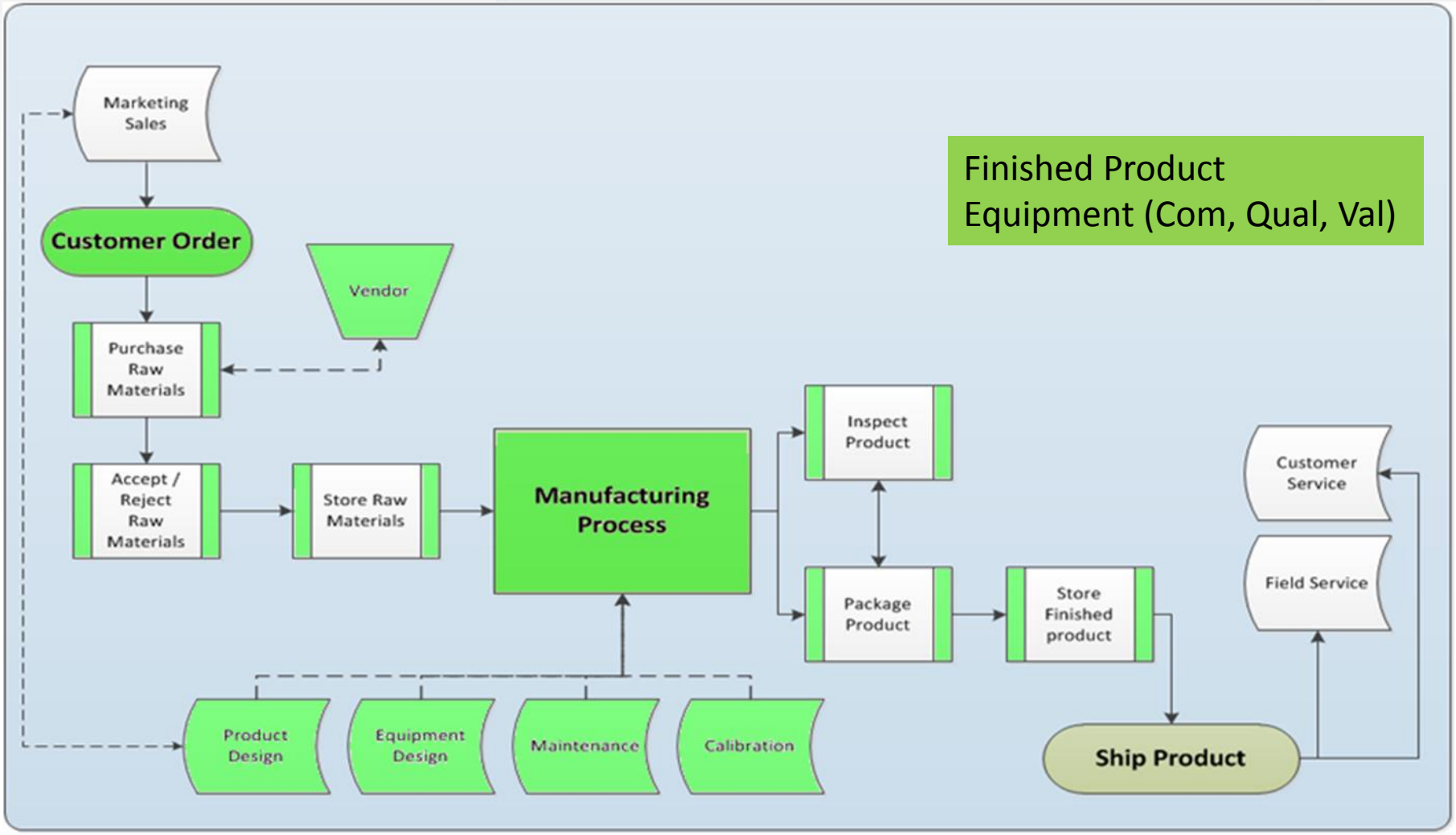

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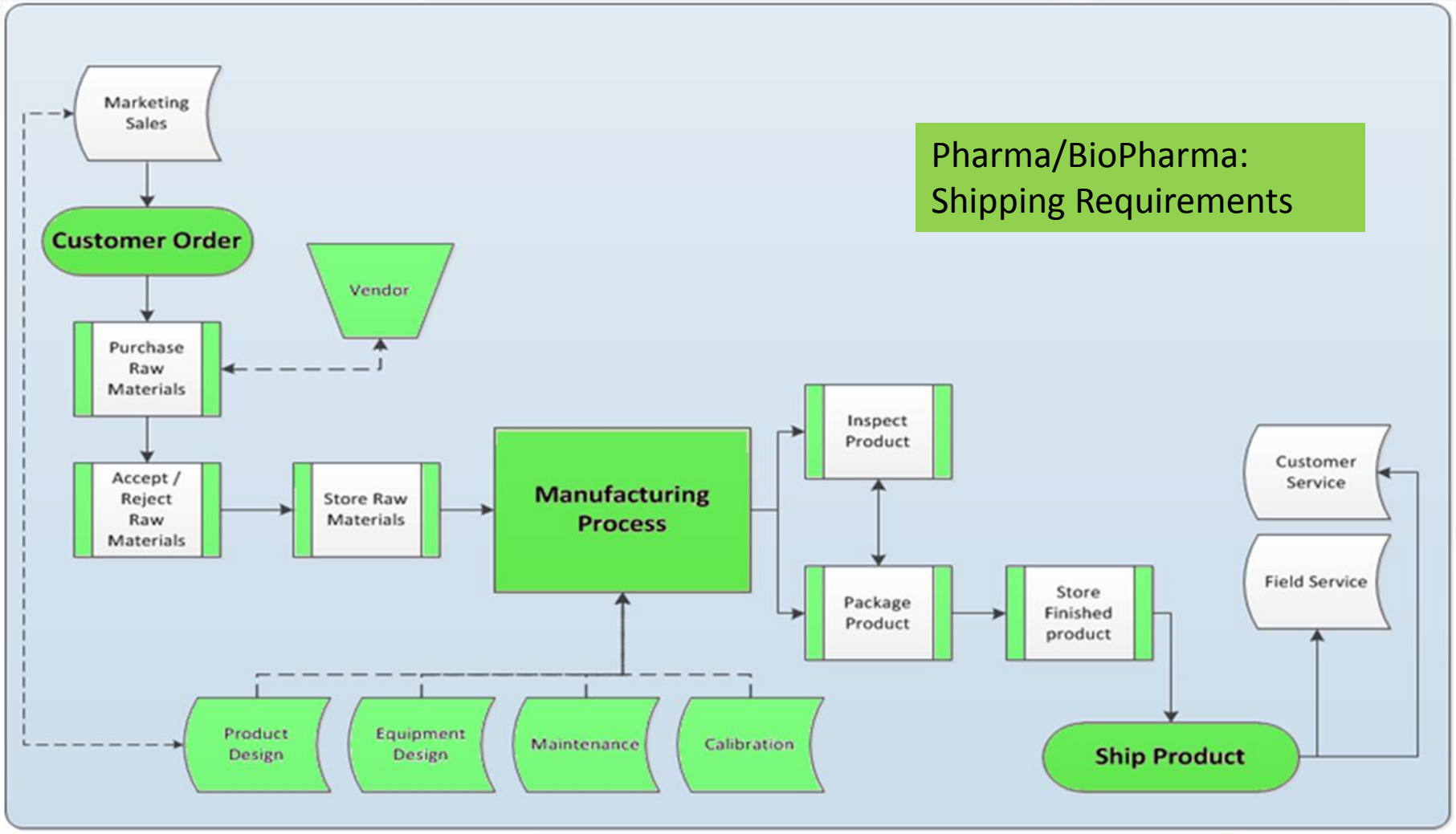

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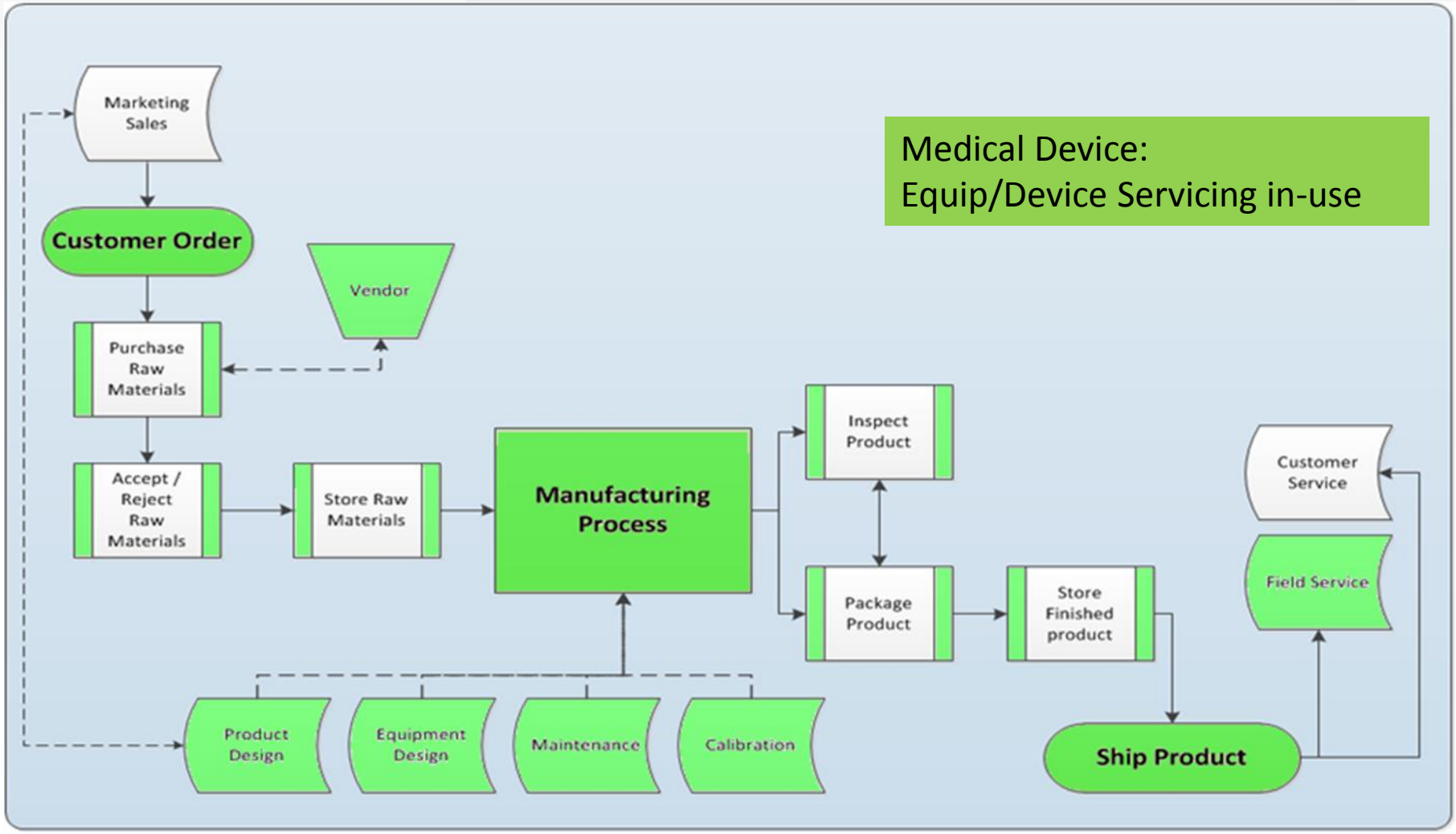

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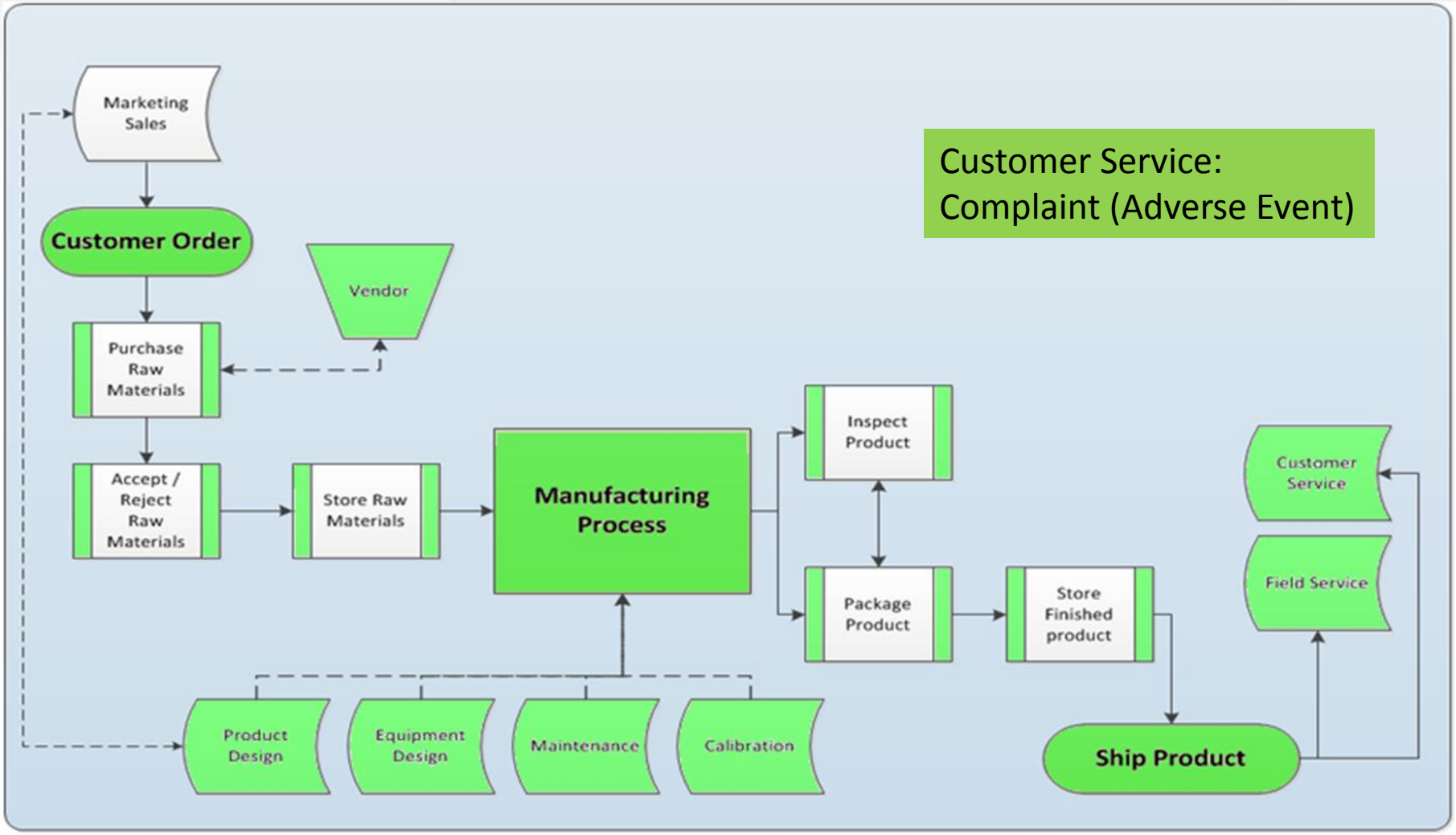

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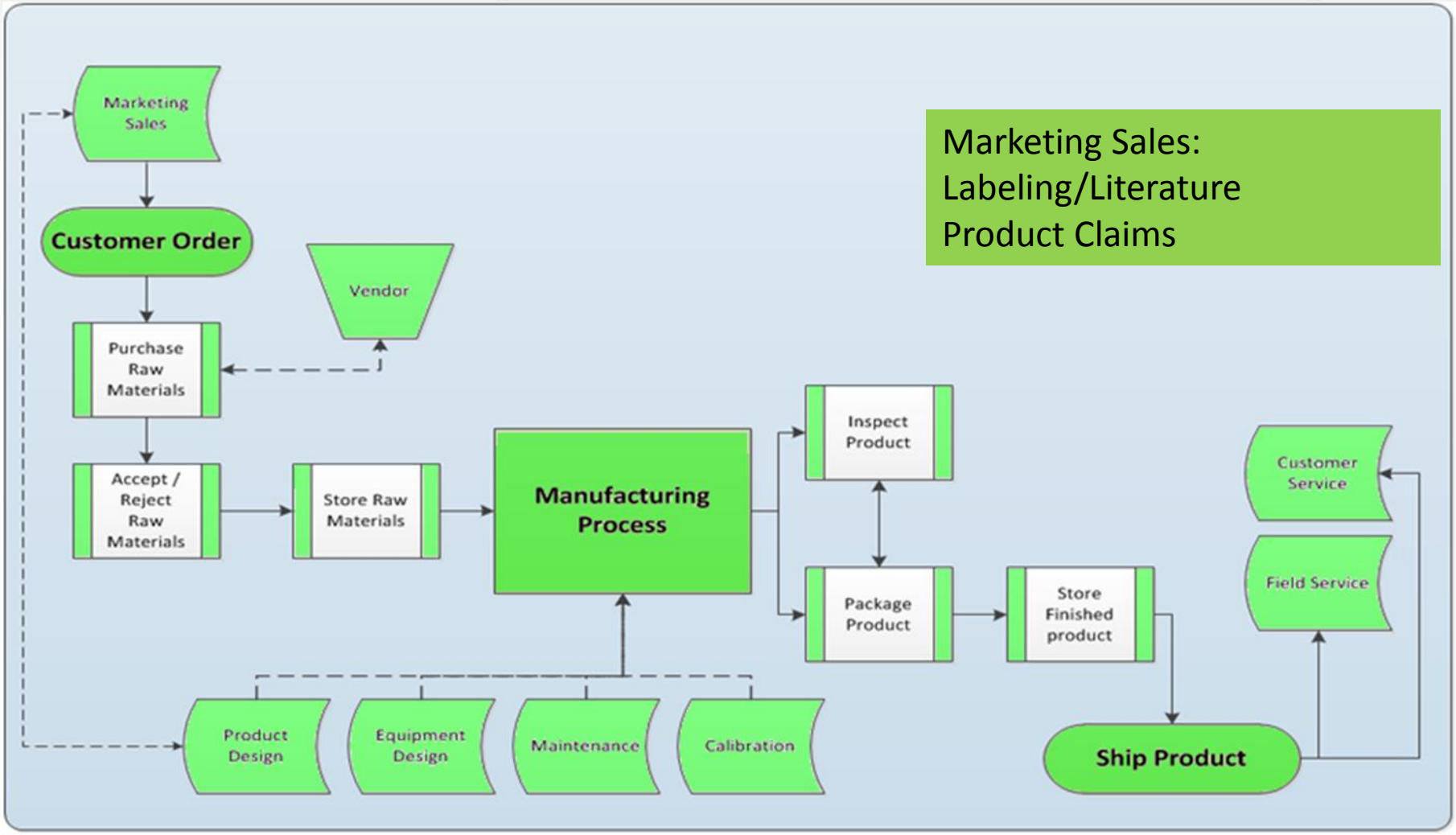
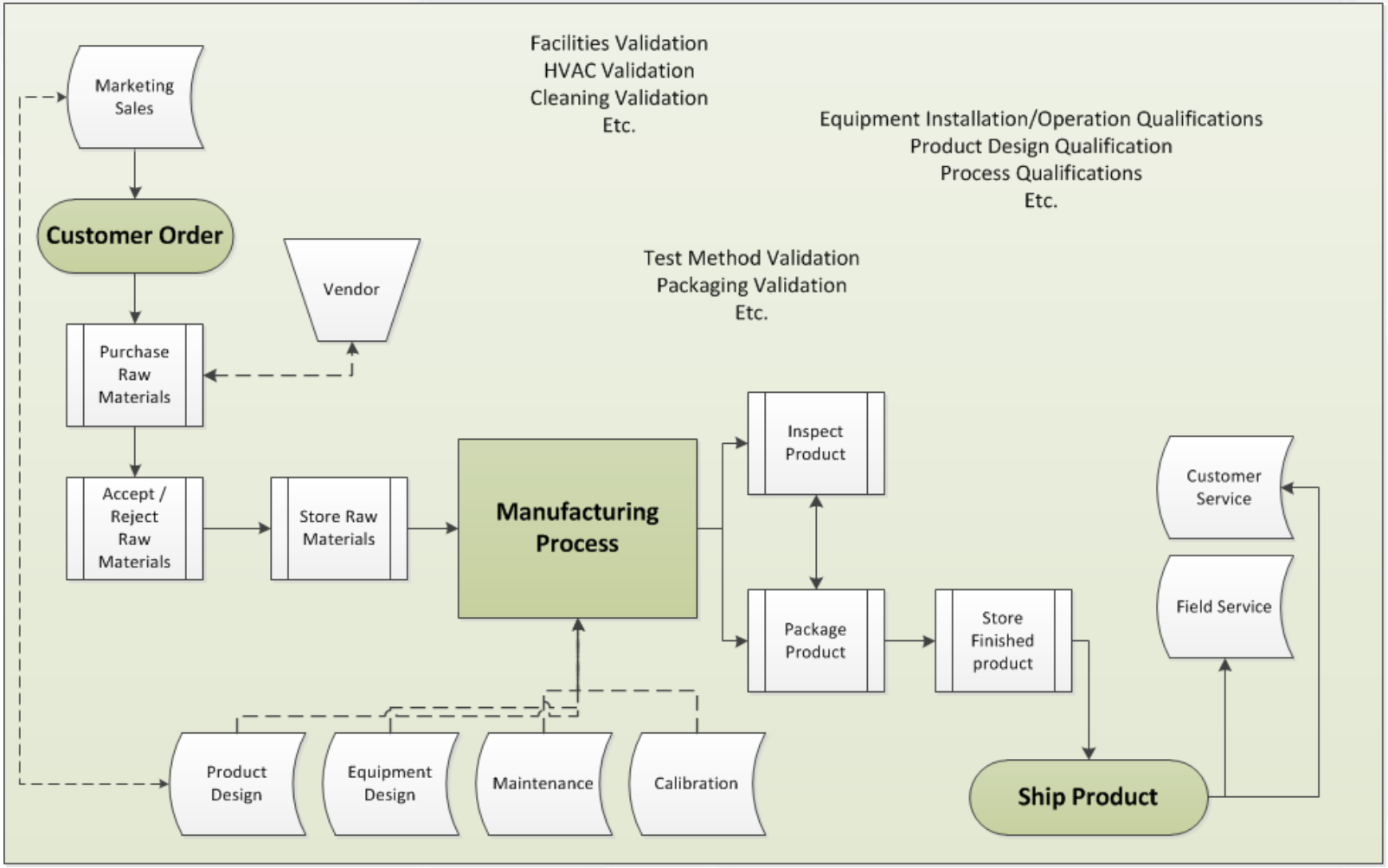


Marketing Sales:
Labeling/Literature
Product Claims

VALIDATED STATE



LEAN SIX SIGMA

Reduce Waste
Reduce Defects
Quality Design

Developed as part of NSF ATE Grant #1304474

LEAN SIX SIGMA

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

Developed as part of NSF ATE Grant #1304474

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

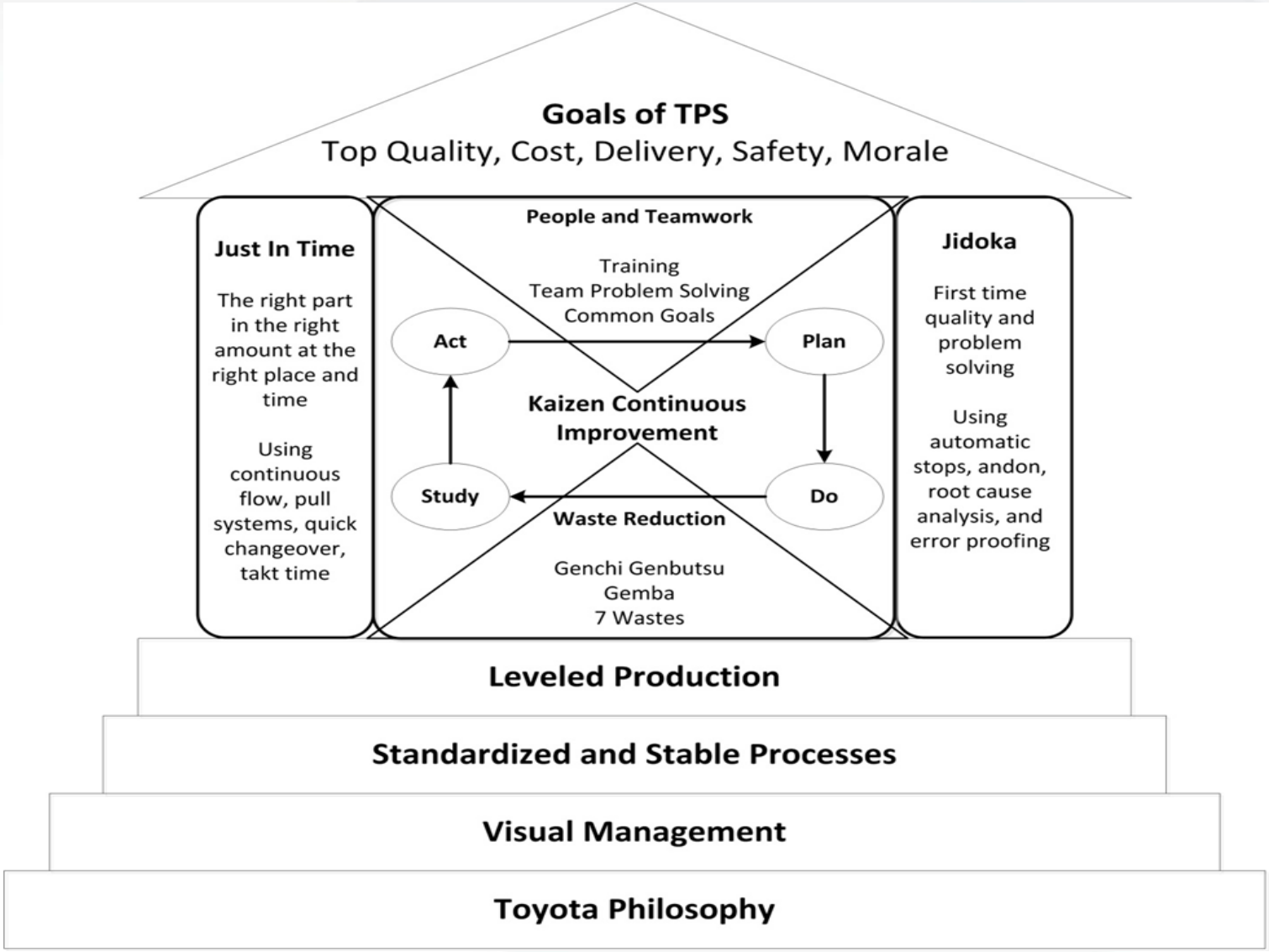
"The Machine That Changed the World"

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

Introduced Toyota Production System (TPS)

Developed as part of NSF ATE Grant #1304474

Toyota Production System



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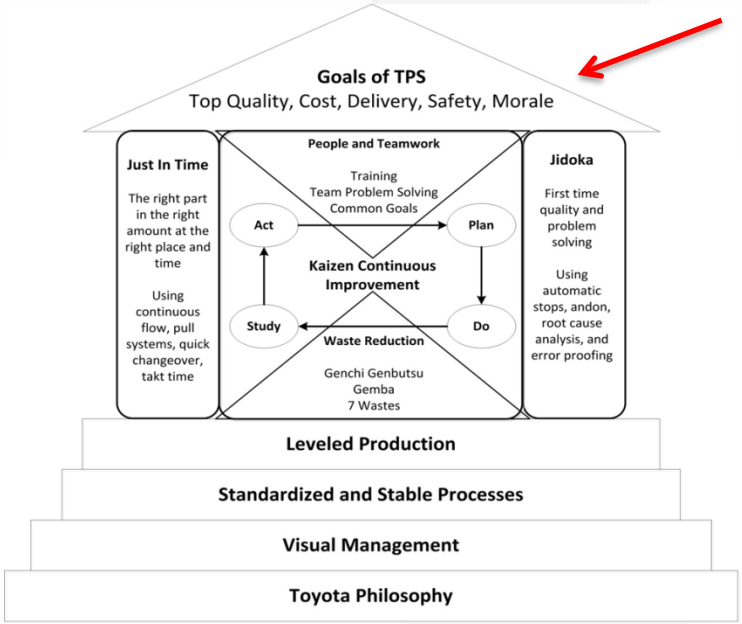
LEAN MANUFACTURING

- Toyota Production System



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

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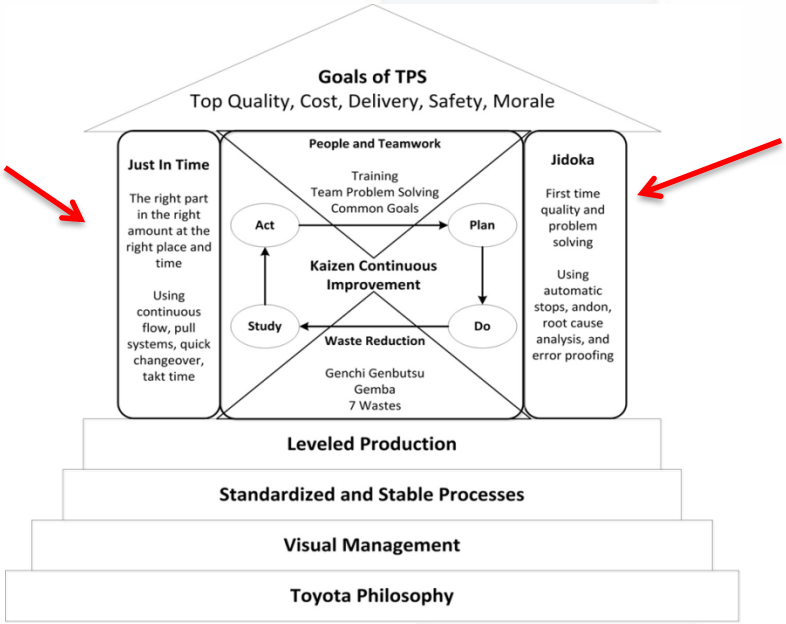
LEAN MANUFACTURING

- 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)

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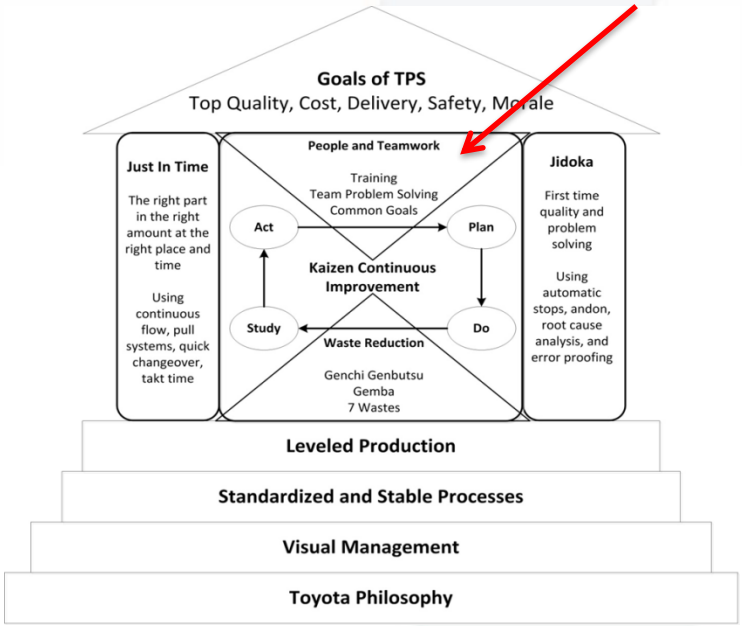
LEAN MANUFACTURING

- Toyota Production System



Roof = Goals and Objectives

Pillars = materials availability
error free production

Core = culture, principles

people, problem solving, waste reduction

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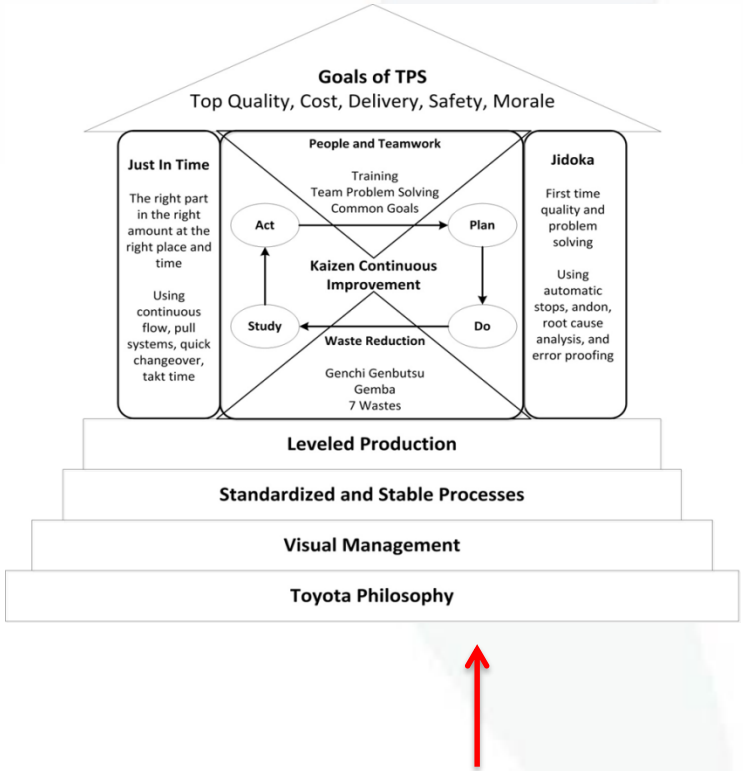
LEAN MANUFACTURING

- 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)

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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

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LEAN MANUFACTURING

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

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

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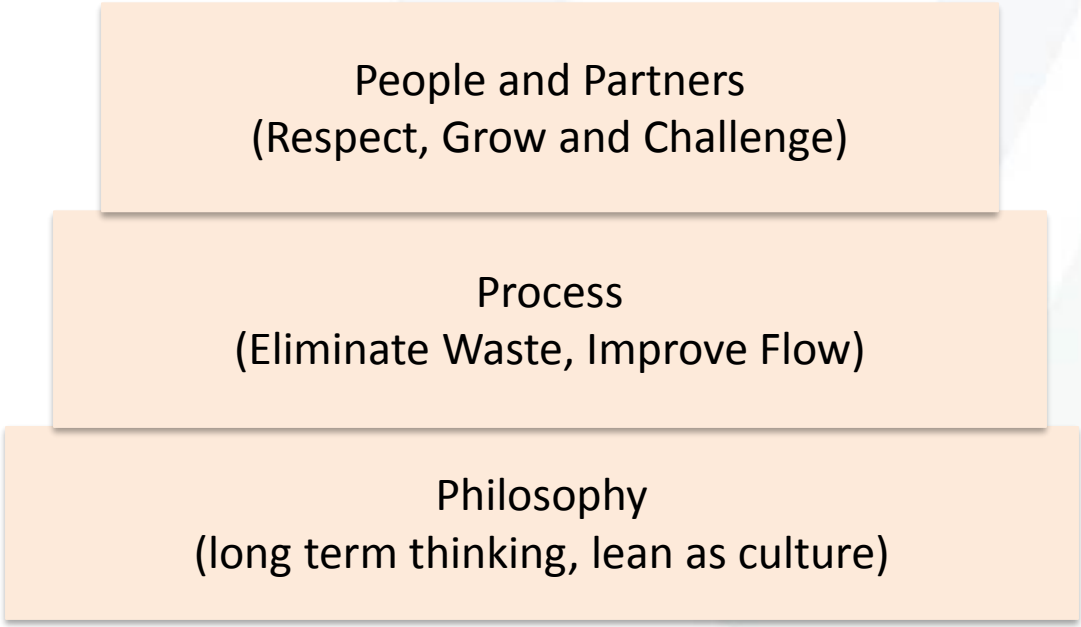

Principle 9: Grow leaders
Principle 10: Develop exception people and teams
Principle 11: Respect your extended network of partners and suppliers by challenging them and helping them improve

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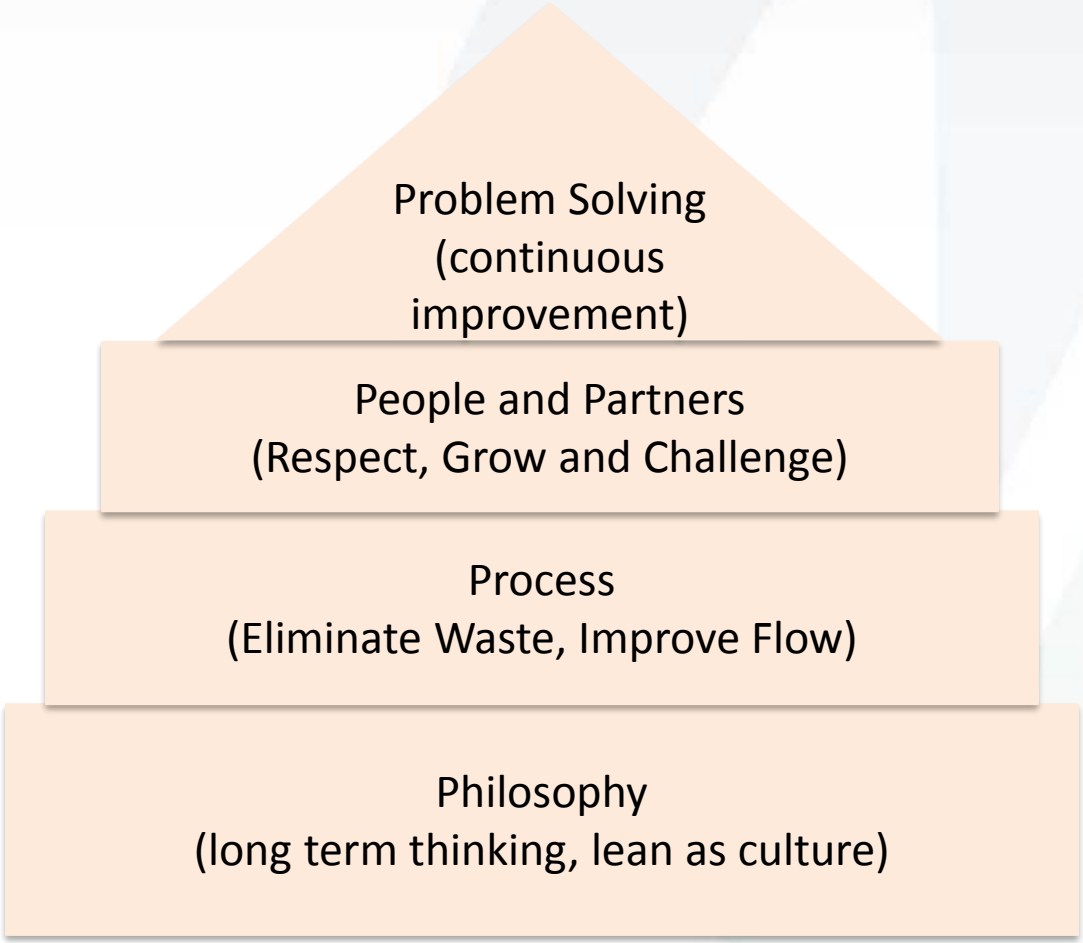

Principle 12: go and see
Principle 13: make decisions slowly, but implement decisions quickly
Principle 14: become a learning organization

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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)

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VALUE STREAM MAPPING

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

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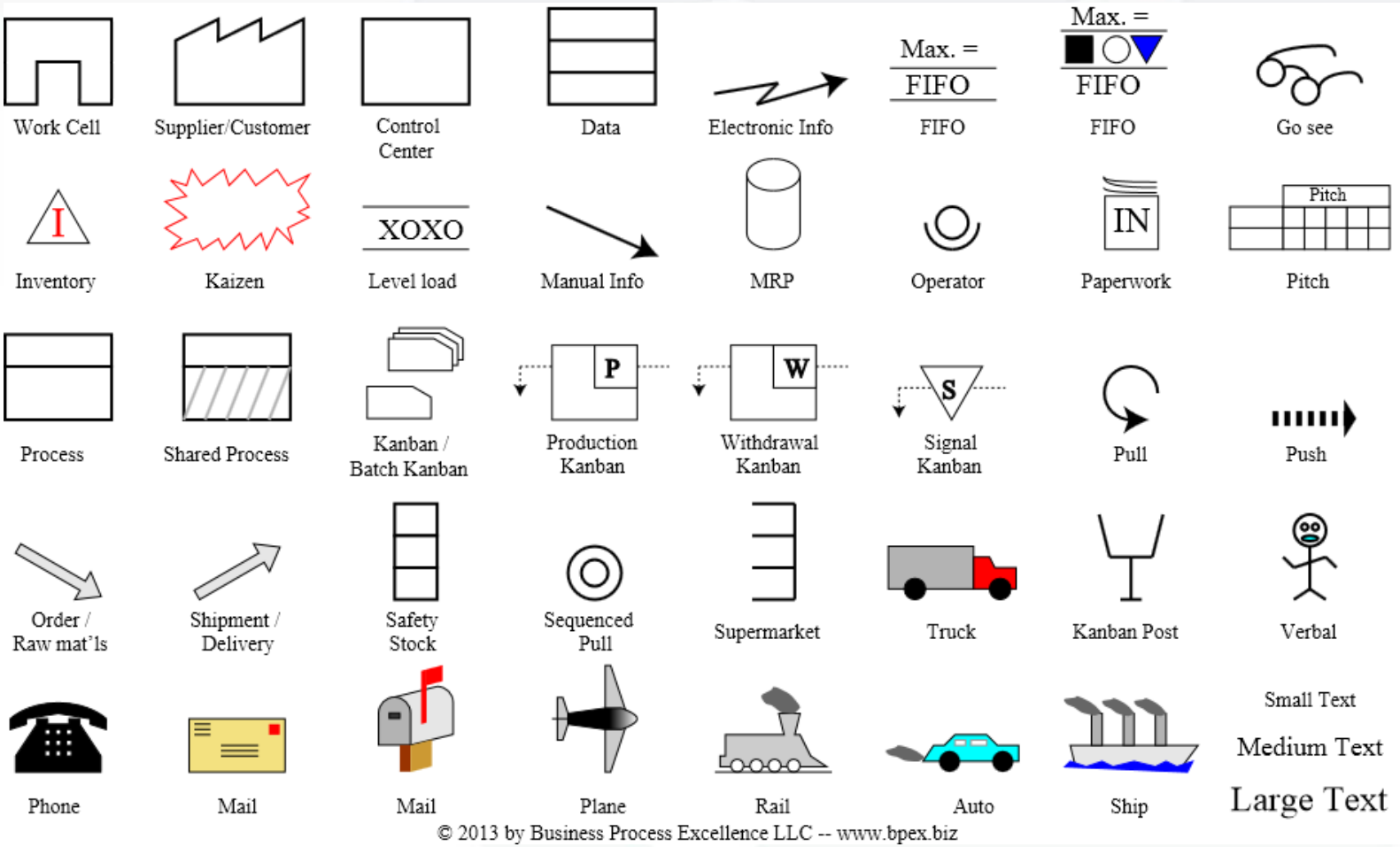
VALUE STREAM MAPPING



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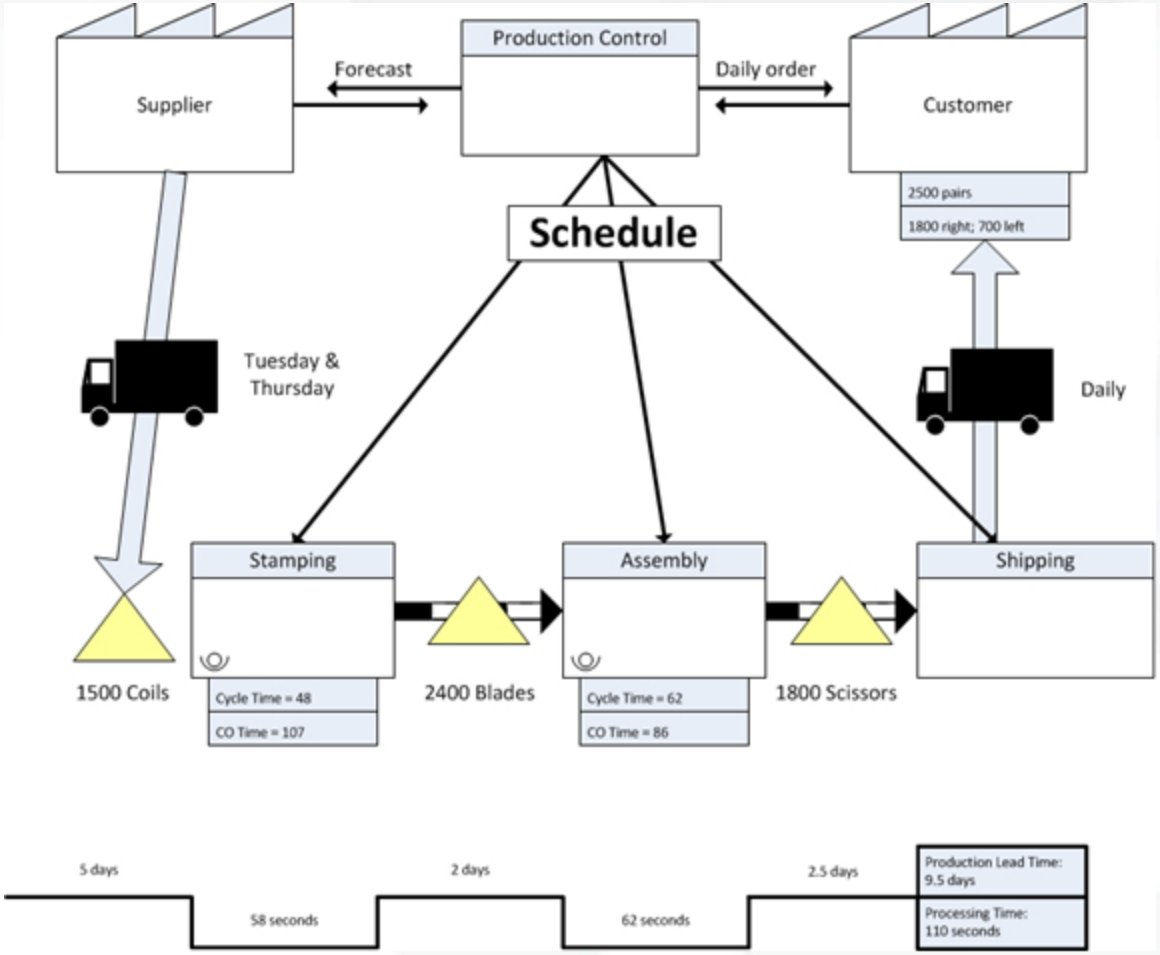

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  - Push: products created regardless of demand

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  - Takt time: rate at which customers demanding product *(heartbeat of lean enterprise)*

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LEAN MANUFACTURING

- Vocabulary (cont.)
  - Takt time: rate at which customers demanding product *(heartbeat of lean enterprise)*
  - Cycle time: time required to complete one cycle of a particular operation
  - 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

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MUDA (Waste)

D defects

O overproduction

W waiting

N non-utilized/under utilized talent

T transportation

I inventory

M motion

E excess processing

Developed as part of NSF ATE Grant #1304474

LEAN MANUFACTURING

- Vocabulary
  - Muda (waste): activity that creates no value but consumes resources
  - Pokayoke: mistake proofing device (i.e. checklist, fixtures, testing, etc.)

Developed as part of NSF ATE Grant #1304474

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  - Kaizen: constant gradual improvement to reduce waste and increase value

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    - 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

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LEAN MANUFACTURING

- Vocabulary (cont.)
  - Genchi Genbutsu: go and see
  - Gemba: where the action is

    "Gemba Walk"

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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

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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

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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

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SIX SIGMA

- Continues effort to achieve stable and predictable process results are vital to business
- Manufacturing (& business) process have characteristics that can be
  - Measured
  - Analyzed
  - Controlled
  - Improved

- Achieving sustained quality improvement requires total organization commitment , particularly top management.

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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

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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

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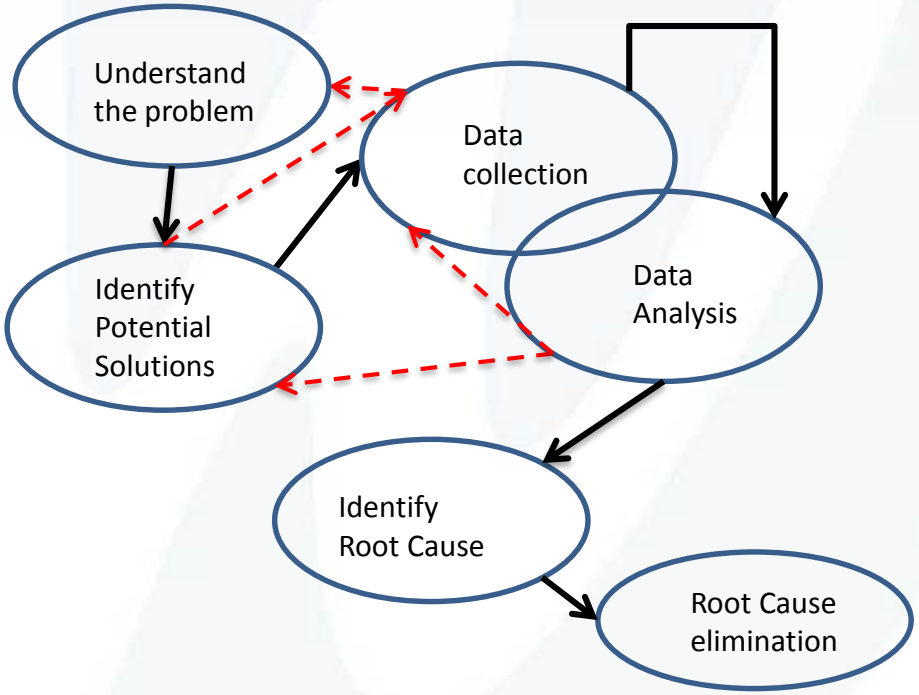
- Six Sigma
  - Project oriented
    - Define
    - Measure
    - Analyze
    - Improve
    - Control

"DMAIC"

- Root Cause Analysis
  - Investigation process



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Six Sigma

- 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

    SMART Goal

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

http://en.wikipedia.org/wiki/DMAIC

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SMART Goals Guide	
Specific	» 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	» How will I know I've succeeded? » How much change needs to occur? » How many accomplishments or actions will it take?
Attainable	» 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	» 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	» What is the deadline for reaching the goal? » When do I need to take action? » What can I do today?

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Six Sigma

- Define

  SMART Goal

  ***S**pecific **M**easurable **A**ttainable **R**elevant **T**ime bound*

  Example:

  improve customer service by 50%

  ???

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Six Sigma

- Define

  SMART Goal

  ***S**pecific **M**easurable **A**ttainable **R**elevant **T**ime bound*

  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

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Six Sigma

- 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.)

http://en.wikipedia.org/wiki/DMAIC

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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).

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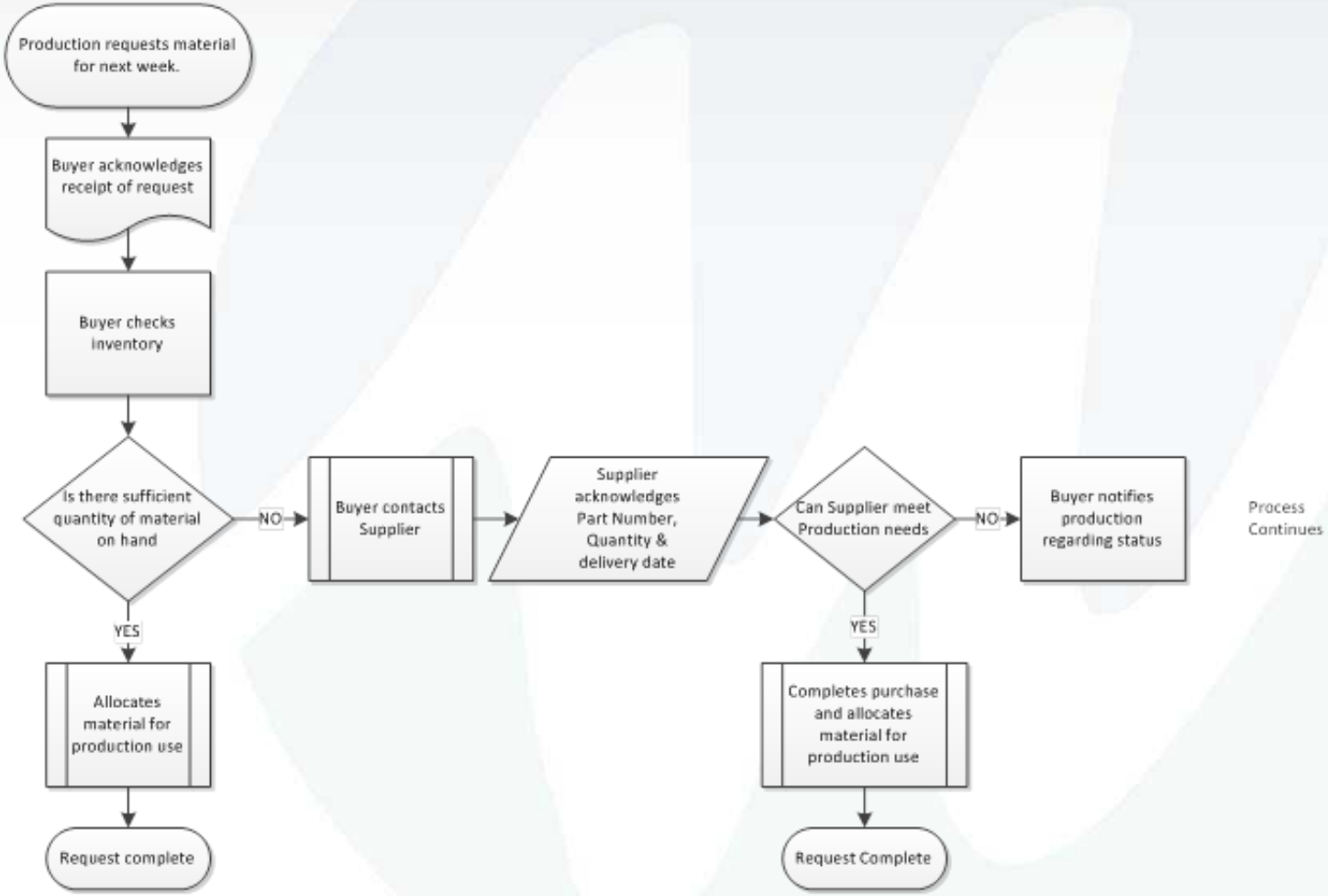
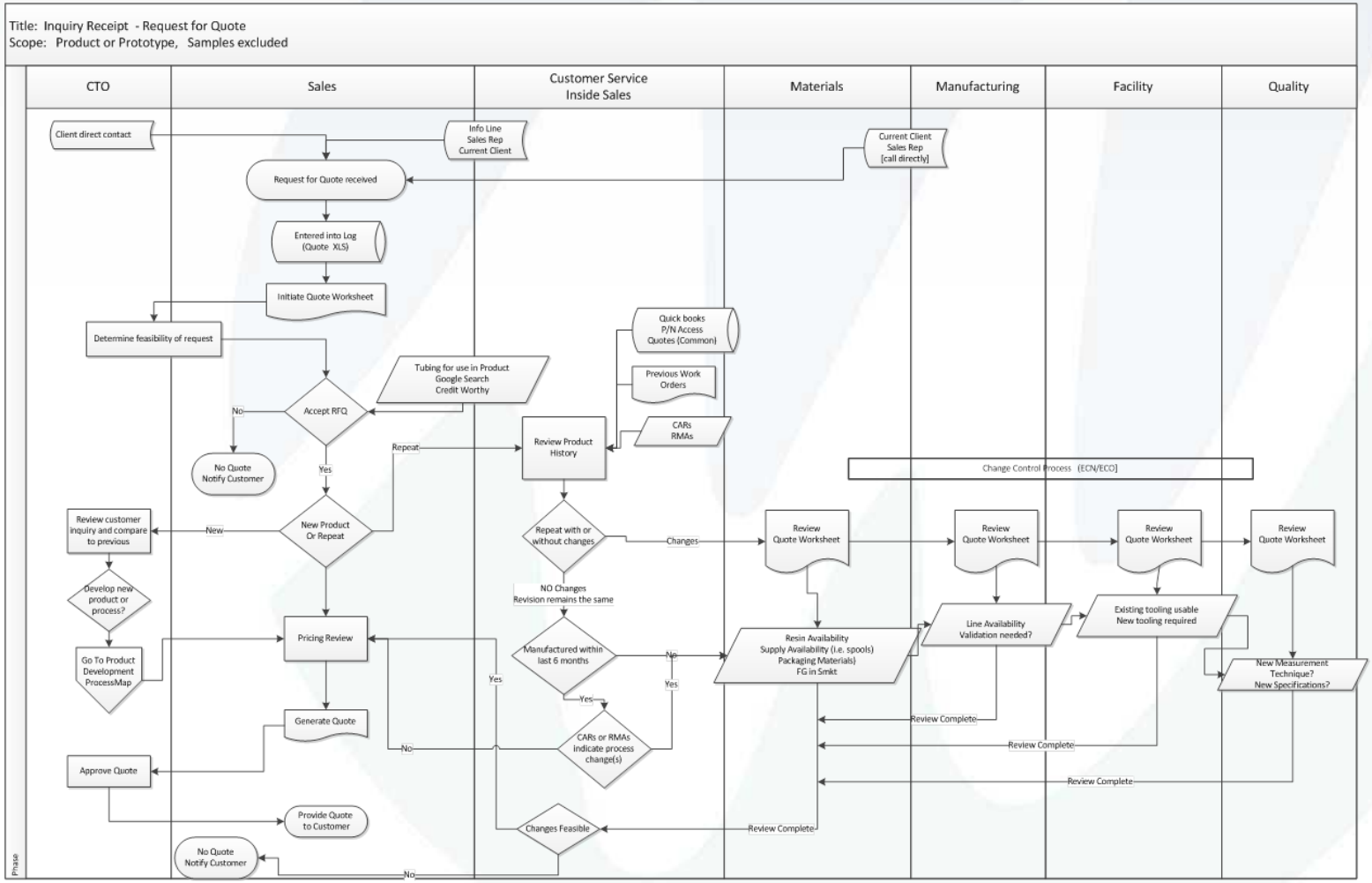
STANDARD FLOW CHART



CROSS FUNCTION 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
- SIPOC Diagram
  - Supplier
  - Input
  - Process
  - Output
  - Customer

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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

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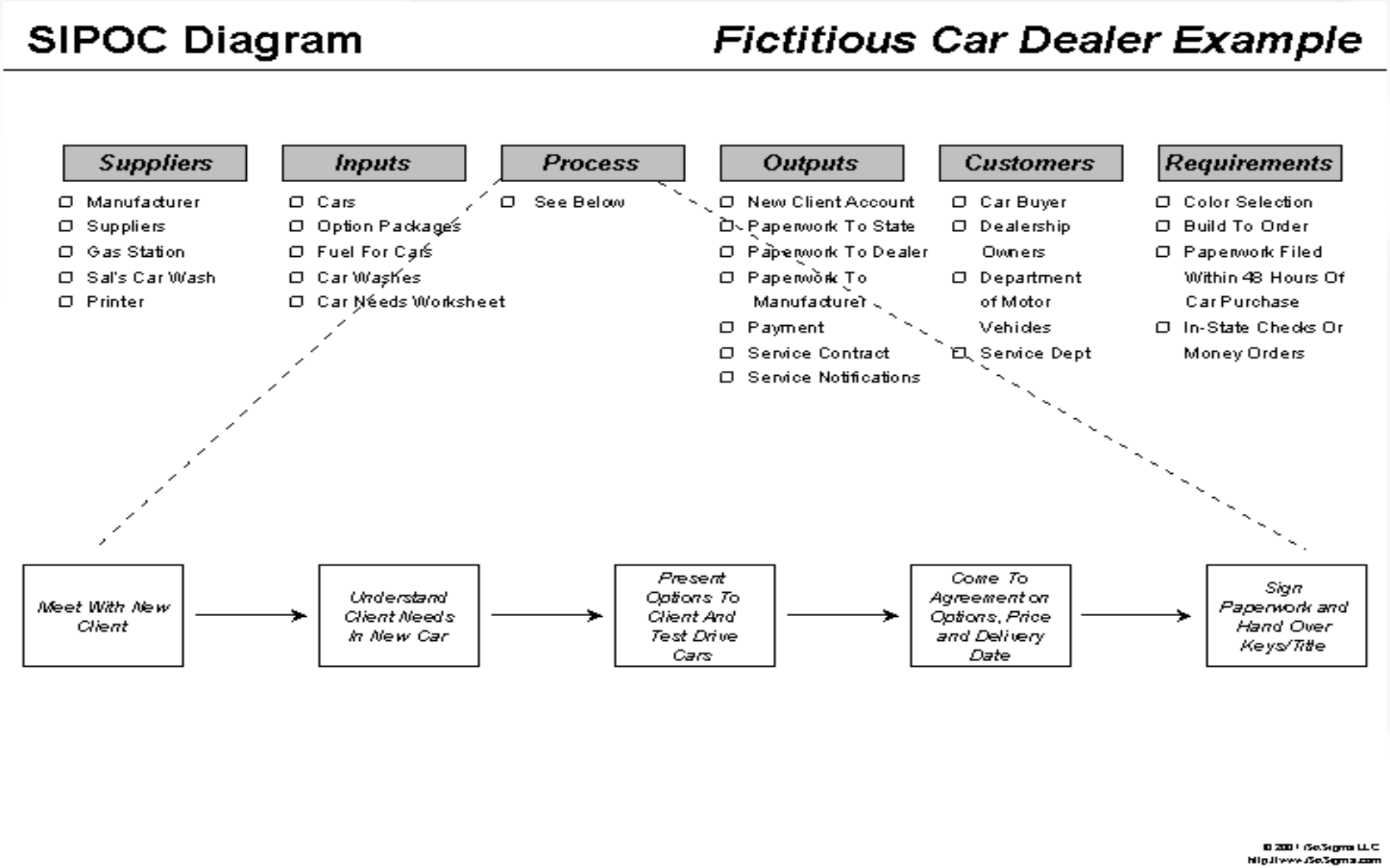
SIPOC



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Six Sigma

- 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

http://en.wikipedia.org/wiki/DMAIC

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Six Sigma

- 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)

http://en.wikipedia.org/wiki/DMAIC

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Six Sigma

- 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

http://en.wikipedia.org/wiki/DMAIC

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Six Sigma

- 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

http://en.wikipedia.org/wiki/DMAIC

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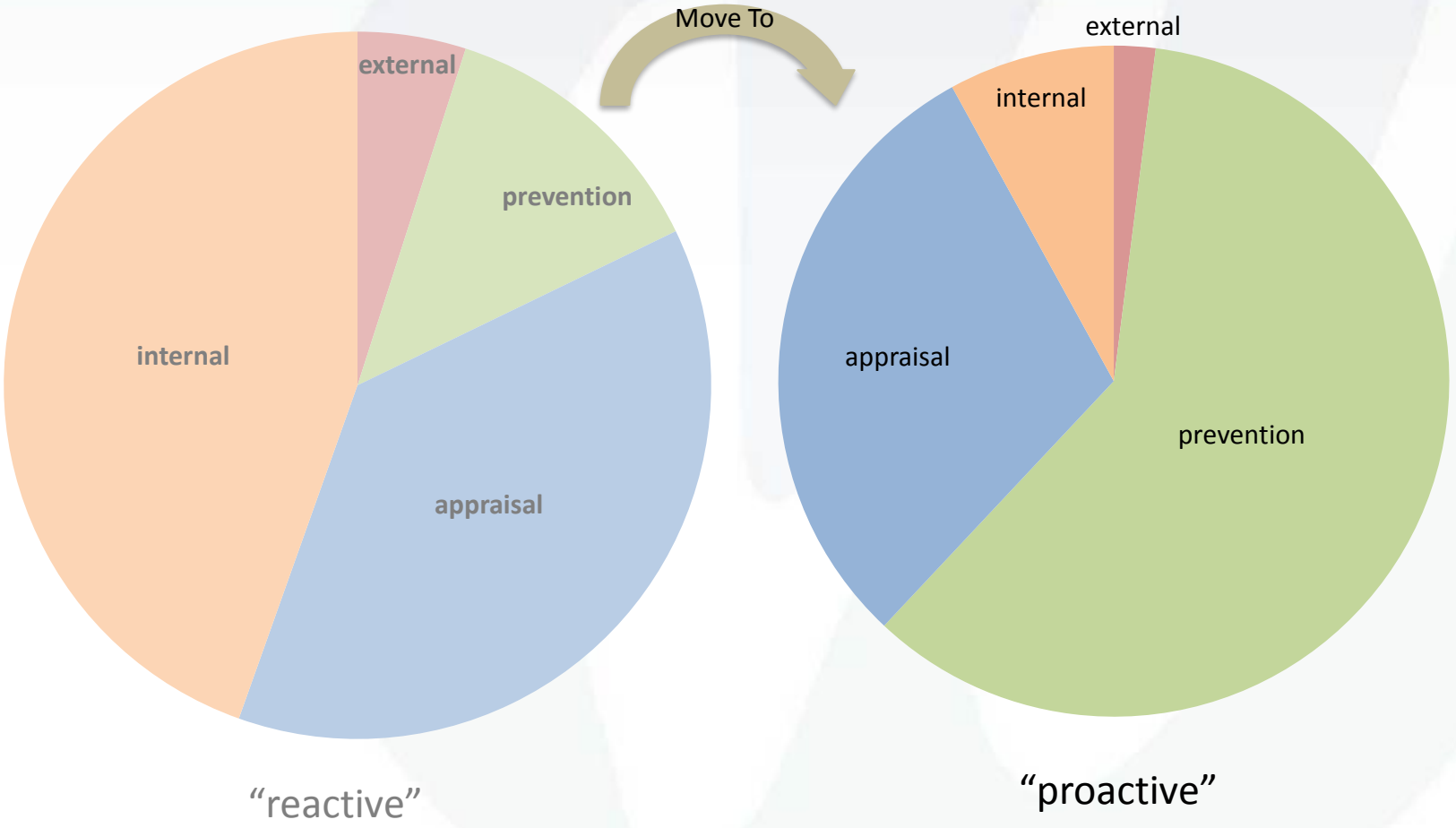
Six Sigma projects



"reactive"

"proactive"

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QUALITY DESIGN

Quality is a value that **must be built into** the product.
Quality **cannot be inspected into** the product

- Design for Six Sigma (DFSS)
  - Define
  - Measure
  - Analyze
  - Design
  - Verify

http://en.wikipedia.org/wiki/DMAIC

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DESIGN FOR SIX SIGMA - DMADV

- Design for Six Sigma (DFSS)
  - Define: Design goals consistent with customer demands
  - Measure: Identify CTQ, risk assessment, capabilities
  - Analyze: Develop and design alternatives
  - Design: improved alternative (per step above)
  - Verify

    the design - pilot runs, develop production process and

    transfer to owners

http://en.wikipedia.org/wiki/DMAIC

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REVIEW

Quality System Requirements Exam

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Purpose / Expectations

- Overview of Quality profession
- General tools and philosophies
- Regulations and Voluntary Standards
- Measurement Techniques
- General Business Practices
- Provide opportunity for credentials via ASQ

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WEEK	DAY	TOPIC	OBJECTIVE
1	1	Introduction to Quality & Quality Systems	Define Quality
		Industry Overview	Demonstrate diversity
		Quality Assurance and Quality Control	What's the difference
		Process Flow	Raw Materials to product shipped
		Standards and Regulations (ISO & FDA)	What's used and where
	2	ISO standards	Process Model – Voluntary Registration
		cGXP (GMP, GLP, GCP, GDP)	21CFR – FDA regulations
	3	Auditing	Principles (types, planning and conducting)
		Specifications and Print Reading	Drawings, Specifications, Introduction to GD&T
	4	Introduction To Metrology	Measurement Fundamentals, Calibration, etc.
		Inspection & Sampling	Methods, Plans, etc.
2	5	Data Analysis	Statistics, Shop Math, Excel® in Workplace
		Introduction to SPC	What is it?
	6	Quality Operations	Incoming Inspection, Product Release
		Root Cause Investigations/CAPA Systems	7-Step, Fishbone, etc.
	7	Validation	DQ/IQ/OQ/PQ
		Lean Six Sigma – Continuous Improvement	Provide terminology and general principles
	8	Review Discussion	
		Final Exam	

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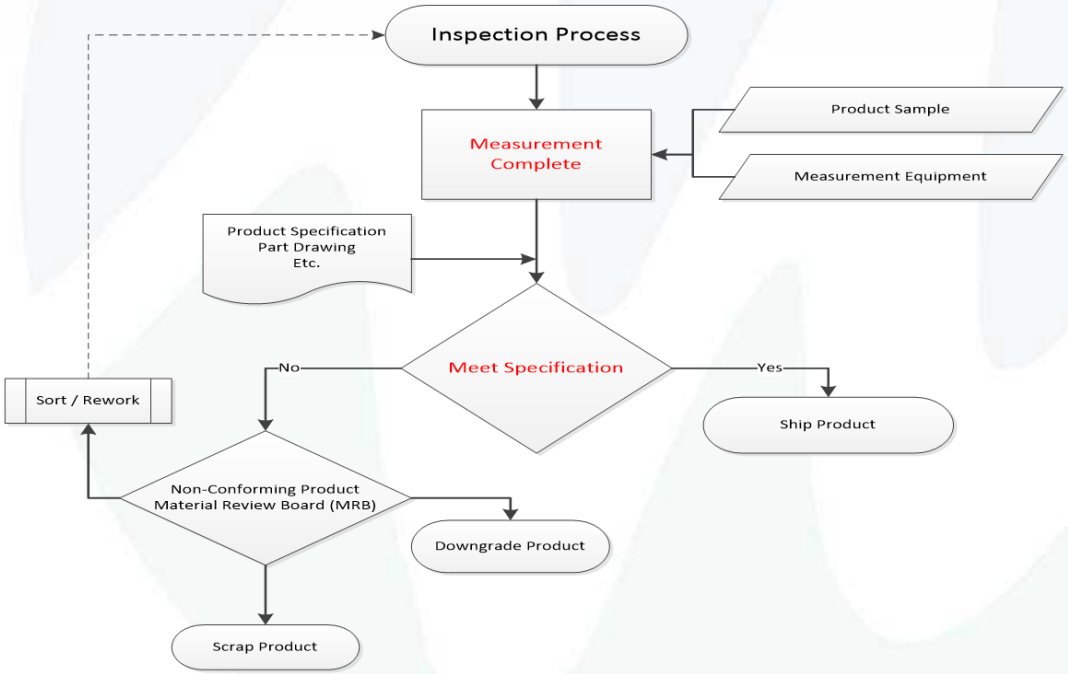
SEVEN QUALITY TOOLS

1. Flow Chart / Run Chart

- Documents process and associated steps
- Useful for delineating operational tasks



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SEVEN QUALITY TOOLS

1. Flow Chart / Run Chart
2. Check Sheet
   - Data collection
   - Operational or Audit Checklist

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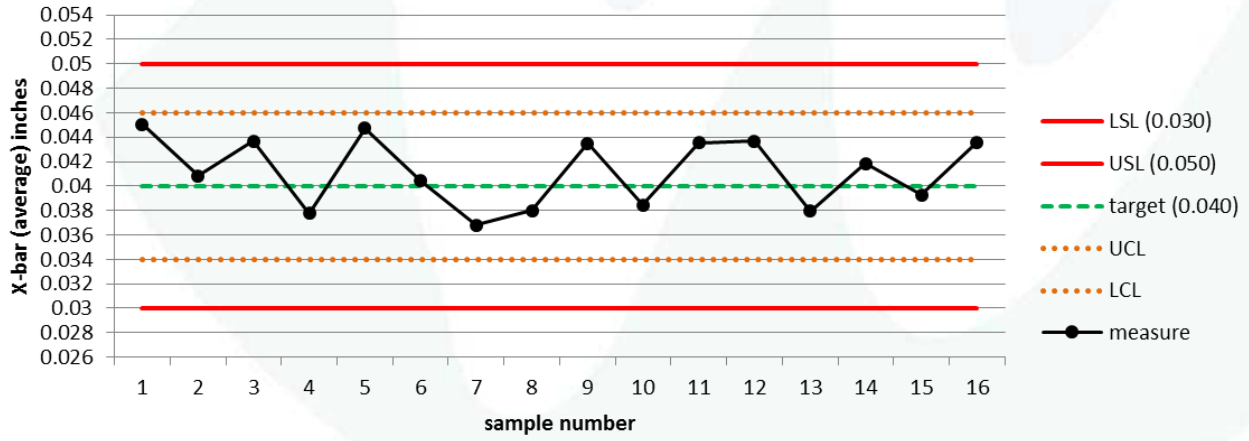
SEVEN QUALITY TOOLS

1. Flow Chart / Run Chart
   - Documents process and associated steps
   - Useful for delineating operational tasks
2. Check Sheet
   - Data collection
   - Operational or Audit Checklist
3. Control Chart
   - ➢ Visual used to monitor process stability / capability



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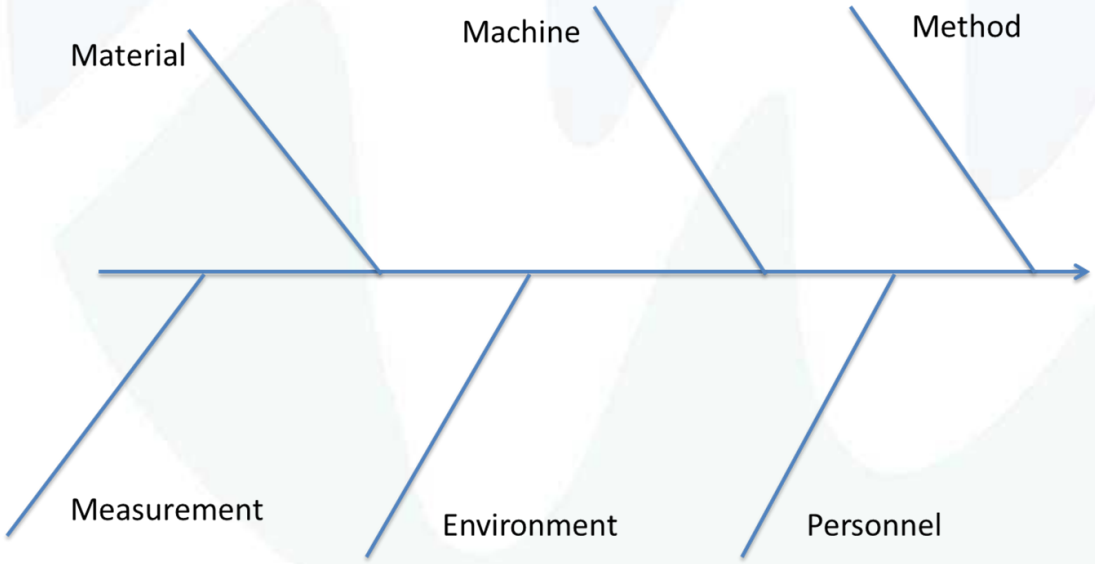
SEVEN QUALITY TOOLS

1. Flow Chart / Run Chart
2. Check Sheet
3. Control Chart
4. Cause and Effect Diagram
   - Used for root cause analysis
   - Evaluates Flow chart for root cause potential



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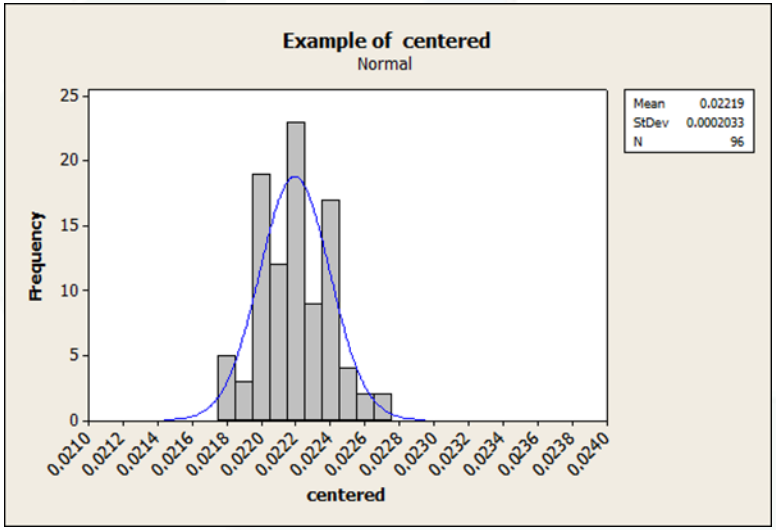
SEVEN QUALITY TOOLS

1. Flow Chart / Run Chart
2. Check Sheet
3. Control Chart
4. Cause and Effect Diagram
5. Histogram
   - ➢ Used for root cause analysis
   - ➢ Demonstrates distribution of data
   - ➢ Shape provides clues to stability/capability of process



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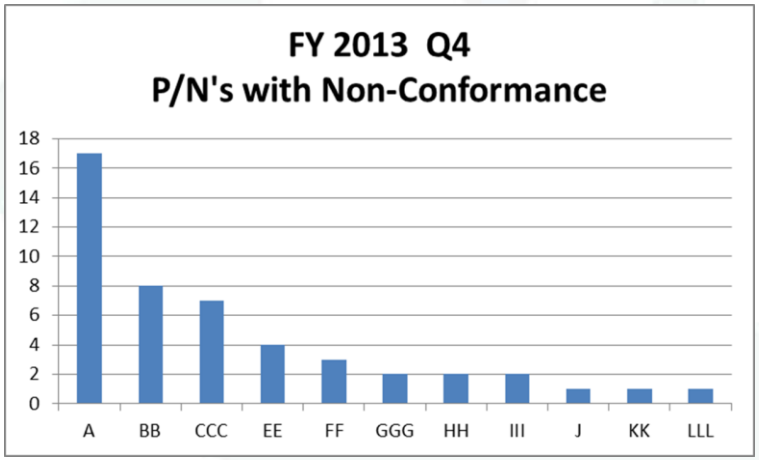
SEVEN QUALITY TOOLS

1. Flow Chart / Run Chart
2. Check Sheet
3. Control Chart
4. Cause and Effect Diagram
5. Histogram
6. Pareto Chart
   - Ranks data
   - Used in root cause analysis to prioritize / define investigation strategy



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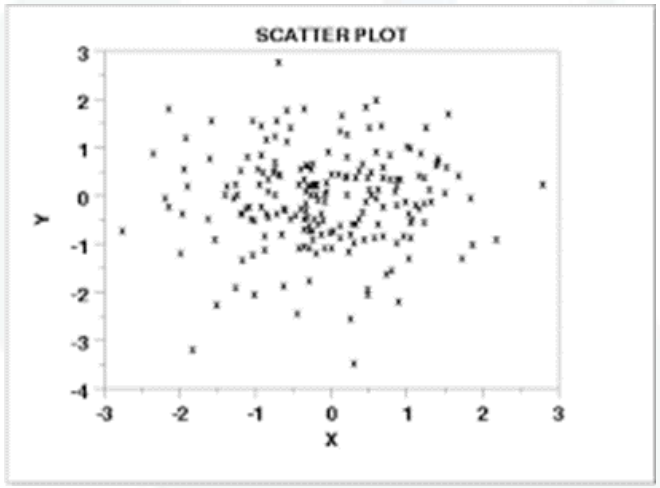
SEVEN QUALITY TOOLS

1. Flow Chart / Run Chart
2. Check Sheet
3. Control Chart
4. Cause and Effect Diagram
5. Histogram
6. Pareto Chart
7. Scatter Diagram
   - Demonstrates data relationships (i.e. linearity)
   - Used to analyze processes, investigation data, etc.



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PROFESSIONAL PRACTICES

- Honesty
- Integrity
- Transparency
- Accountability
- Confidentiality
- Objectivity
- Respectfulness
- Obedience to the Law

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PROFESSIONAL PRACTICES

- Honesty
- Integrity
- Transparency
- Accountability
- Confidentiality
- Objectivity
- Respectfulness
- Obedience to the Law

  - Teamwork
  - Conflict Management
  - Time Management
  - Communication

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REVIEW – Quality Concepts

- Quality is a product (or service) with the *features and characteristics* which determine *desirability* and can be *controlled* to *meet certain basic requirements*.
- Organizations
  - Regulatory: legal oversight of industry
  - Independent: provide external review of industry quality systems
  - Trade: provide support by representing common interests
- Manufacturing & Service Industries
- ISO Standards and FDA Regulations
- History of Quality (Taylor, Deming, Juran)

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REVIEW – Quality Concepts

- Quality System
  - Method of doing business
    - customer focused with everyone involved, process centered and continual improvement
  - Regulatory Requirements
  - Basic Premise
    - Say what you do (documents)
    - Do what you say (training)
    - Record what you did (write it down)
    - Check the results (analysis)
    - Act on the difference (improvement)
- Codes of Professional Practice
  - Integrity (ethics)

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REVIEW – Quality Management Systems

- ISO 9001:2008 General Quality System and ISO 13485:2003 Medical Devices
  - General Requirements
  - Management Responsibilities
  - Resource Management
  - Product Realization
  - Measurement, Analysis & Improvement
- cGXP -- Current Good (Manufacturing, Pharmaceutical, Laboratory & Clinical
  - 21CFR 820 (Medical Device cGMP)
  - 21CFR 210/211 (Pharmaceutical cGMP)
  - 21CFR 58 (Nonclinical Laboratory Studies cGLP)
  - ICH E6 (Clinical Studies cGCP)

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REVIEW – Auditing

- Quality Management Systems
  - ISO 9001:2008 and ISO 13485:2003
  - US FDA cGXP
- Auditing Principles
  - Types
  - Participants, Roles & Responsibilities
  - Activities (planning, conducting, reporting)
- Codes of Professional Practice
  - Confidentiality

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REVIEW – Metrology & Calibration

- Measurement Fundamentals & Calibration System
- Specifications are documents that contain requirements necessary for Customer to convey needs to Supplier
- GD&T per ASME Y14.5-2009 used for part/product drawings to communicate geometric controls via symbols
  - Fit/form/function
  - Relationship between specific part features

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REVIEW – Inspection & Sampling

- Inspection Types
  - Acceptance Sampling
- Sample Planning & Logistics
  - Traceability
  - When/where/who to sample
  - Collection methods
  - Quantity needed (Sample plans vs 100%)
- Inspection process:
  - Measurement of sample
  - Comparison against specification
  - Decision based on results
  - Corrective action, if necessary

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REVIEW - Analysis

- Shop Math
  - Fractions, Ratios
  - Decimals, Percentages
  - Equations
  - Conversions
- Statistics
  - Definition
  - Descriptive vs Inferential
  - Sample vs Population
  - Understanding the data
    - Quantitative vs Qualitative
    - Discrete vs Continuous
    - Measure of central tendency
    - Measure of dispersion
    - Measure of shape
    - Sample error
    - Central limit theorem
  - Hypothesis testing

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REVIEW - Analysis

- Histogram
- Scatter Plot (Diagram)
- Using Excel®

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REVIEW - Analysis

- Control chart types
  - Variable (e.g. X-bar/R, Run charts (individuals), X/MR (individual – moving range))
  - Attribute (e.g. p chart (% defective), c chart (# defects))
- X-Bar / R Charts
  - Construction
  - Trends
- Capability Studies
  - Process Performance and respective indices (Pp, Ppk)
    - Internal measure
  - Process Capability (Cp, Cpk)
    - Customer typically $\geq$ 1.33 (or $\geq$ 1.67 for CTQ)

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REVIEW – Quality Operations

- Raw Material / Product Acceptance
  - Inspection processes follow same pattern
  - Pass/Fail
- CoA vs CoC
  - CoA contains actual results
  - CoC states conformance
- Non-Conforming
  - Quarantine
  - Investigation
- Material Review Board
  - Determines disposition
- Professional Practices
  - Teamwork
  - Conflict Management
  - Communication / Listening

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REVIEW - Investigation

- Root Cause
  - The fundamental (true) reason a product or process nonconformance occurred.
- Root Cause Analysis (RCA)
  - Structured investigation (review) aiming to identify (determine) the true cause of a product or process nonconformance (problem) AND the actions necessary to eliminate it.
- Industry Methods
  - Plan-Do-Check-Act
  - Define-Measure-Analyze-Improve-Control (6 Sigma)
  - Recognize – DMAIC – Sustain (7-step process)
  - 8Disciplines (8D)
- Tools
  - Pareto Chart
  - Who, what, where, when, why and how
  - 5 Why's
  - Cause-Effect (Fishbone) diagram
  - Is / Is-Not matrix

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REVIEW

- CAPA System
  - Captures corrective actions
  - Measures/verifies effectiveness
  - Take credit for preventive action
- Documentation – Phases
  - Initiation
  - Investigation
  - Implementation
  - Verification
  - Effectiveness

REVIEW - Validation

- Terminology & Types
  - Commissioning – process through which equipment is tested in order to make sure that the equipment was properly designed and built
  - Qualification – predefined scripted set of tests with expected results
    - Design, Installation, Operation, Process, etc.
  - 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
    - Facilities, HVAC, Manufacturing Process, Software, etc.
- Validation Program Components
  - Site Validation Master plan
  - Validation SOPs
  - Validation Plan
  - Re-Validation

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REVIEW – Lean Six Sigma

- Two separate business tools
  - Beyond the Quality Management System
  - Support QMS
- Lean Manufacturing
  - Production Management Strategy
  - Reduces (eliminates) waste
  - Focused on creating the most value with the least amount of work
  - Value Stream Mapping, Muda (DOWNTIME),
  - Toyota Production System
- Six Sigma
  - Business Management Strategy
  - Process Improvements
  - Define, Measure, Analyze, Improve, Control (DMAIC)
- Quality Design
  - Design for Six Sigma (DFSS)
  - Define, Measure, Analyze, Design, Verify (DMADV)

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THANK YOU

QUESTIONS?

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