QUALITY SYSTEMS INTENSIVE WORKSHOP

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

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

Developed as part of NSF ATE Grant #1304474

Facts / Assumptions

- Compressed Content
- Prior work experience
- Completed Secondary Education
  - Associates, Bachelor's or Master's
- Transition to Manufacturing or Service Industry

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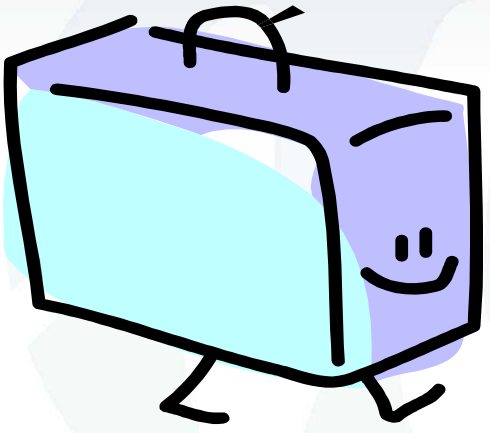
Overview

- My Background
- Topic Schedule
- Why - Quality
  - ASQ Certification
  - Career Pathway
  - Education Pathway
- 7 Quality Tools

MY BACKGROUND



HOW ABOUT YOU?

- Name
- Work history
- Hobbies
- Expectations for class

WEEK	DAY	TOPIC	OBJECTIVE
1	1	Introduction to Quality & Quality Systems	Define Quality
		Industry Overview	Demonstrate diversity
		Quality Assurance & Quality Control	What's the difference
		Process Flow	Raw Material 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)
		Print Reading	Drawings, Specifications, Introduction to GDT
	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 Investigation / 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	

Quality – Career Pathways

- Multitude of industries
  - Pharmaceutical, Biotechnology, Medical Device, Automotive, Aerospace, Plastics, Food and Beverage, etc.
- ASQ Certifications (www.asq.org)
  - Certified Quality Improvement Associate
  - Certified Process Analyst
  - Certified Quality Inspector
  - Certified Quality Technician
  - Certified Calibration Technician
- Career Path
  - Quality Engineering
  - Regulatory Specialist
  - Utilize (leverage) current experience
- Entry into Engineering Technology or 4-year degree

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)

MODULE 1
QUALITY SYSTEMS

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CONCEPTS IN QUALITY

What is Quality?
Industry Overview
History of Quality

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QUALITY IN MANUFACTURING

- Quality is an important component of cost of goods sold.
- Tracked through multiple measures.
- Lack of quality can lead to product and company failure.

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WHAT IS QUALITY

- Merriam-Webster dictionary

  qual·i·ty noun \ˈkwä-lə-tē\

  : how good or bad something is

  : a characteristic or feature that someone or something has

  : a high level of value or excellence

- Quality is a relative concept

  Quality is a product (or service) with the features and characteristics which determine desirability and can be controlled to meet certain basic requirements.

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WHAT IS QUALITY

Quality is a product (or service) with the *features and characteristics* which determine *desirability* and can be *controlled* to *meet certain basic requirements*.

- Who determines desirability of features and/or characteristics?
- Why are they desirable?
- What are the requirements that can be controlled?
- How is it known if the requirements are met?

Quality is determined by the Customer (end-user) based on their expectation and needs.

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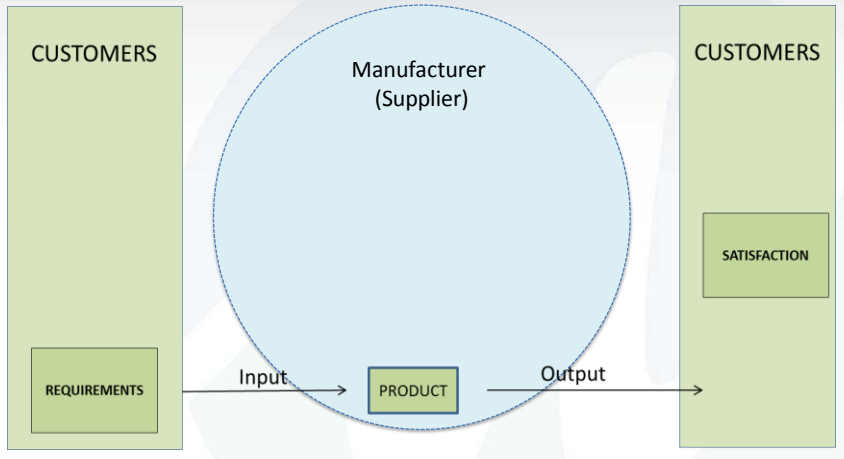

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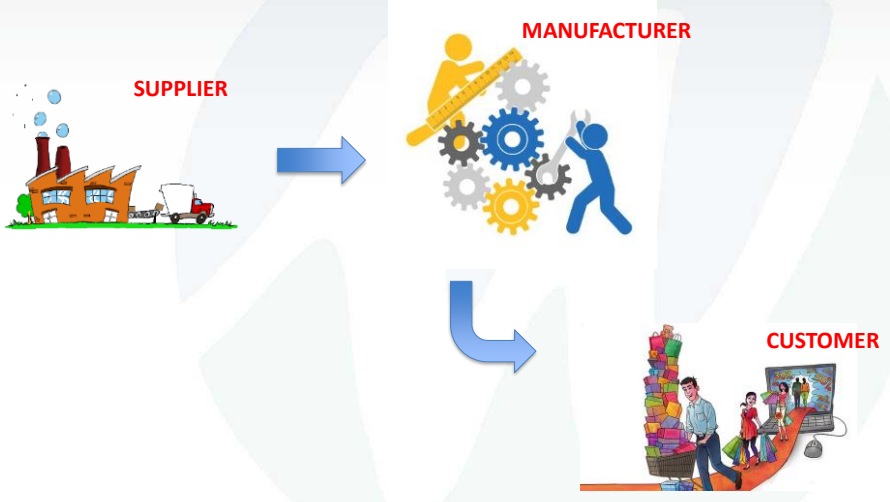
CUSTOMER vs. SUPPLIER

- Who is the Customer?
  - Internal versus External

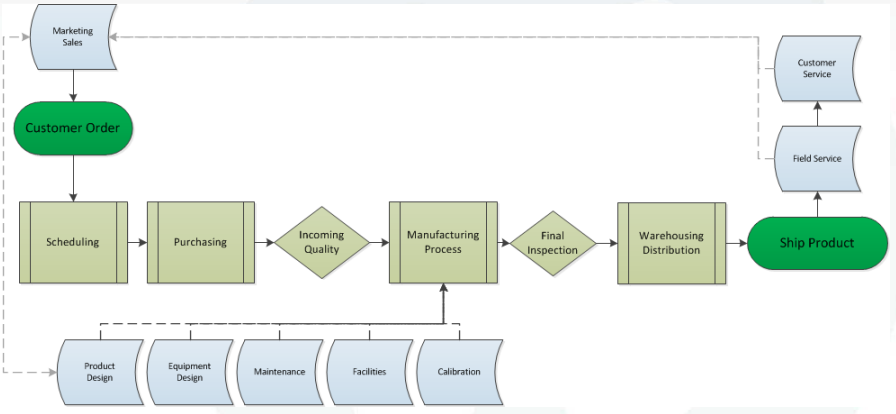
Customer vs. Supplier



Customer vs. Supplier

- Who is the Customer?
  - User of the material, product, service
  - Internal – within the company / department

PROCESS FLOW - MANUFACTURING



Customer vs. Supplier

- Who is the Customer?
  - User of the material, product, service
  - Internal – within the company / department
  - External – outside the company
    - Designer / Assembler
    - End-User

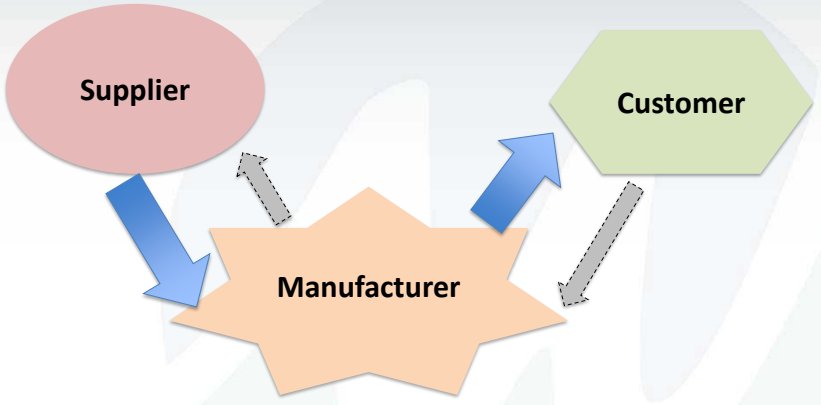
Customer vs. Supplier

- Who is the Customer?
  - User of the material, product, service
  - Internal – within the company / department
  - External – outside the company
- Who is the Supplier?
  - Provider of materials, products, services, etc.
  - Internal vs External

Customer vs. Supplier

- Who is the Customer? Who is the Supplier?
- Internal versus External

Example: manufacturing pen



Supplier is who provides material/service
Customer is user of material/service

Roles are interchangeable to communicate expectations (requirements)

QUALITY ORGANIZATIONS

- Regulatory
- Independent
- Trade

QUALITY ORGANIZATIONS

- ***Regulatory:*** Government organizations with legal oversight of industry
  - US FDA, European Union, etc.
- ***Independent:*** Organizations providing external review of industry processes
  - International Organization for Standardization (ISO)

    International standard-setting body composed of representatives from various national standards organizations; various standards (documents) along with technical reports, specifications and guides.

    Wikipedia.com

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  - International Organization for Standardization (ISO)
  - American National Standards Institute (ANSI)

    Oversees development of voluntary consensus standards for products, services, processes, systems and personnel in US; also coordinates US standards with international standards for worldwide American product use. (documents and physical standards)

    Wikipedia.com

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  - International Organization for Standardization (ISO)
  - American National Standards Institute (ANSI)
  - US Pharmacopeia Convention (USP)

    Establishes written (documentary) and physical standards (reference) for medicines, food ingredients and dietary supplements. Standards rea used by regulatory agencies and manufacturers to help ensure products are of appropriate identity, as well as strength, quality, purity and consistency

    Wikipedia.com

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- ***Independent:*** Organizations providing external review of industry processes
  - International Organization for Standardization (ISO)
  - ANSI (American National Standards Institute)
  - USP (US Pharmacopeia Convention)
- ***Trade:*** Organizations supported by industry representing common interests and processes
  - American Society for Quality (ASQ)
  - ASTM International (American Society for Testing & Materials)

VARIOUS INDUSTRIES & SECTORS

- Manufacturing
  - Corporate offices, Plants
  - Controlled Environments
- Service
  - Corporate Offices
  - Field work

MANUFACTURING

- Aerospace
  - Complete vehicles, components
- BioTechnology
- Chemicals
  - Adhesives, paint, pesticides, soaps
- Computer & Electronics
  - Audio/video, components, etc.
- Fabricated Metal Products
  - heat treating, engraving, nails,
- Foods
  - Animal feed, seasonings, snacks
- Machinery
  - Mowers, HVAC, assembly equipment
- Medical Devices & Supplies
  - Pacemakers, gurneys, filters
- Measurement Systems
  - Gages, Vision Systems, CMM
- Paper Products
  - Boxes, gift wrap, diapers
- Pharmaceuticals
  - Prescription, over-the-counter
- Rubber & Plastic Products
  - Tires, hoses, bags, pipes
- Transportation & Parts
  - Cars, trucks, boats, components
- Various Retail Goods
  - Toys, clothing, sporting goods

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SERVICE

- Construction
  - Buildings, Infrastructure, roofing
- Consulting
  - Management, Scientific, technical
- Educational
  - Training, K-12, Secondary
- Financial & Insurance
  - Banks, Mortgages, Brokers
- Government /Public Admin
  - Judicial, security, fire protection
- Healthcare
  - Blood banks, diagnostic labs
- Information Services
  - Publishing, archiving
- Inspection Services
  - Residential, Power plants, Electrical
- Retail
  - Department Stores, Auto Dealers
- Social Services
  - Relief Services, Vocational Rehab
- Scientific / Technical
  - Testing Services, Engineering Firms

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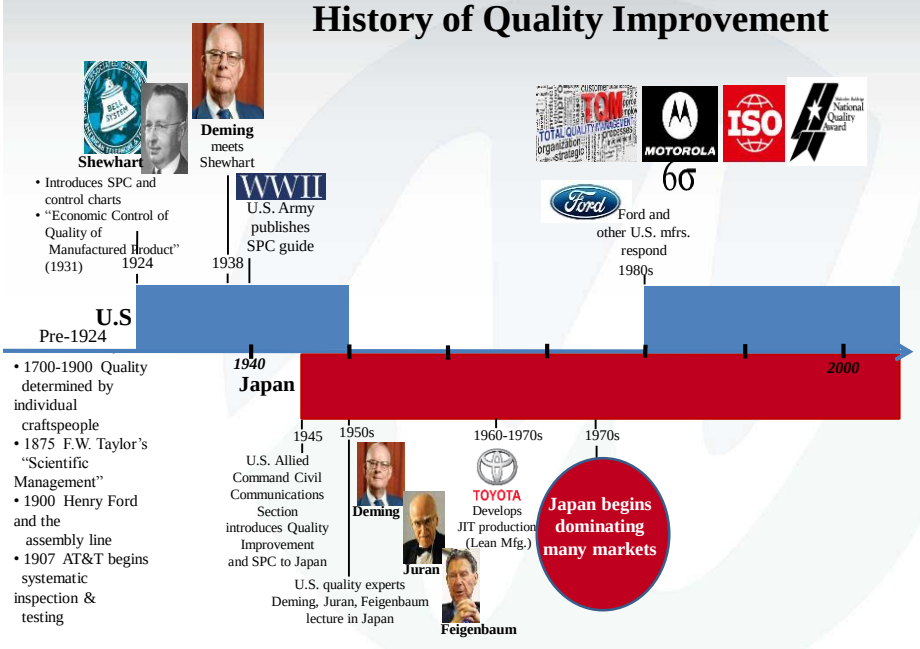
History of Quality

- Quality has been around since beginning of time
  - Apprentice; Craftsman; Master Craftsman

History of Quality Improvement



Sources: SPC: *Decision Support for the Plant Floor*, (Kline and Company, 1989), SW 2-2; *Intro to Statistical Quality Control* (Wiley, 2013), 10-11.

History of Quality

- Quality has been around since beginning of time
  - Apprentice; Craftsman; Master Craftsman
- Industrial Revolution
  - assembly line; scientific management (~1900-1907)

Henry Ford - Automation

https://www.youtube.com/watch?v=8PdmNbqtDdI

Frederick Taylor – Scientific Method

https://www.youtube.com/watch?v=dsnMjVBYNE8

Taylor – Scientific Management

- Scientific management consisted of four principles:
  - Replace rule-of-thumb work methods with methods based on a scientific study of the tasks.
  - Scientifically select, train, and develop each employee rather than passively leaving them to train themselves.
  - Provide "Detailed instruction and supervision of each worker in the performance of that worker's discrete task".
  - Divide work nearly equally between managers and workers, so that the managers apply scientific management principles to planning the work and the workers actually perform the tasks.
- Management plans, workers perform tasks

History of Quality

- Quality has been around since beginning of time
  - Apprentice; Craftsman; Master Craftsman
- Industrial Revolution
  - assembly line; scientific management
- World War II (~1945)
  - Walter Deming; Joseph M. Juran

HISTORY OF QUALITY

Edward W. Deming – 14 Management

https://www.youtube.com/watch?v=gpBUZZnoZTI

Walter Deming
14 Quality Management Principles

1. Create constancy of purpose for improving products and services.
2. Adopt the new philosophy.
3. Cease dependence on inspection to achieve quality.
4. End the practice of awarding business on price alone; instead, minimize total cost by working with a single supplier.
5. Improve constantly and forever every process for planning, production and service.
6. Institute training on the job.
7. Adopt and institute leadership.

Walter Deming
14 Quality Management Principles

8. Drive out fear.
9. Break down barriers between staff areas.
10. Eliminate slogans, exhortations and targets for the workforce.
11. Eliminate numerical quotas for the workforce and numerical goals for management.
12. Remove barriers that rob people of pride of workmanship, and eliminate the annual rating or merit system.
13. Institute a vigorous program of education and self-improvement for everyone.
14. Put everybody in the company to work accomplishing the transformation.

HISTORY OF QUALITY

Joseph Juran - Trilogy

Https://www.youtube.com/watch?v=aD7aLRKv1pg

Juran's Trilogy

- Juran first to write about the cost of poor quality
  - Without change there will be constant waste
  - During change there will be increased costs
  - After improvement margins higher and costs recouped
- Cross-functional management:
  - Quality Planning
  - Quality Control
  - Quality Improvement

History of Quality

- Quality has been around since beginning of time
  - Apprentice; Craftsman; Master Craftsman
- Industrial Revolution
  - assembly line; scientific management
- World War II
  - Walter Demming; Joseph M. Juran
- 1980's Total Quality Management (TQM)
  - Management approach to long–term success through customer satisfaction.
  - All members of an organization participate in improving processes, products, services, and the culture in which they work.
  - Continuous Improvement is fundamental

TQM – Eight Principles

- Strategic and systemic approach
  - Quality integrated as component in overall strategic plan
- Continual improvement
  - Analytically and creatively find ways for competitiveness and efficiency
- Fact-based decision making
  - Collect and analyze data for decision making and predication based on history
- Communications
  - Effective communication maintains morale and motivation

TQM – Eight Principles

- Customer-focused
  - Customer ultimately determines level of quality
- Total employee involvement
  - All participate in working toward common goals
- Process-centered
  - Defined steps, monitor performance to detect variation
- Integrated system
  - Processes linked for defining and implementing business strategy

PROFESSIONAL FRAMEWORK

Quality Assurance and Quality Control Process Flow

Manufacturing/Service Processes

What is a process?

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

* The Memory Jogger ™ 9001:2008

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Manufacturing/Service Processes

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Processes

Three Types of Processes

- Management
- Business
- Support

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Types of Processes

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

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Types of Processes

- Management
  - Provide direction and governance for an organization.
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- **Business**
  - Core Competencies as experienced by external customers
    - Value creating
- Support

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Types of Processes

- Management
  - Provide direction and governance for an organization.
    - organizational goals
    - develop and deploy strategy to attain goals
    - Establish/manage organization designs and performance goals.
- Business
  - Core Competencies as experienced by external customers
    - Value creating
- **Support**
  - sustain the organization.
    - customers internal customers (within the organization)

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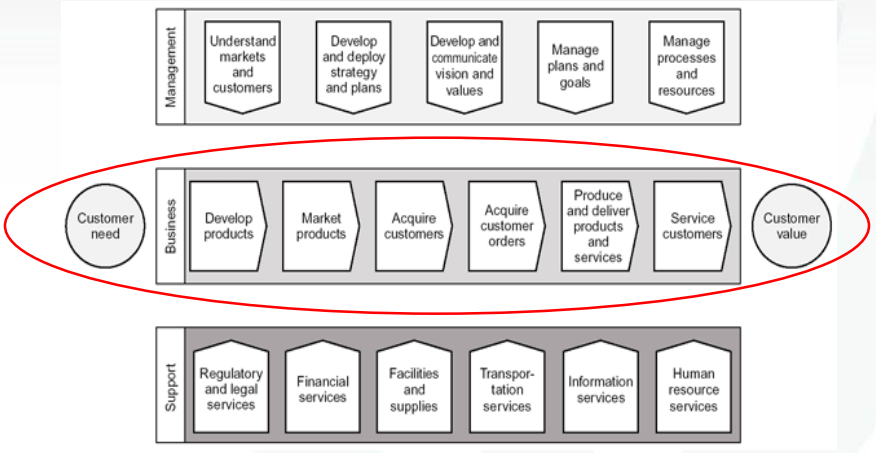
Types of Processes



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

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BUSINESS PRACTICES

- Quality System
  - Regulatory Requirements
  - Customer Requirements
- Lean Six Sigma
  - Two separate business tools
  - Support the Quality System

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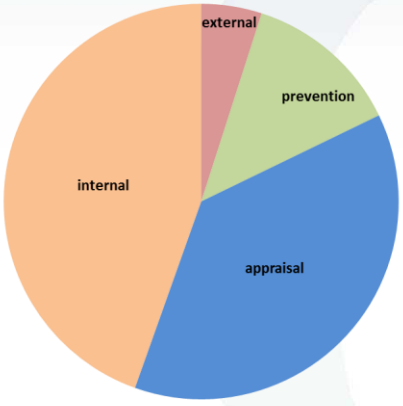
BUSINESS PRACTICES

- **Quality System**
  - **Regulatory Requirements**
  - **Customer Requirements**
- Lean Six Sigma
  - Two separate business tools
  - Support the Quality System

Why have a Quality System

- *Quality is an important component of cost of goods sold.*
- *Lack of quality can lead to product and company failure.*

COST OF QUALITY



- Internal
  - Scrap, Rework
- Appraisal
  - Material Receipt Measurement
  - In-process/Final Inspection
- Prevention
  - Improvement, Planning
- External
  - Returns, Warranty

QUALITY SYSTEMS

- Quality is a product (or service) with the *features and characteristics* which determine *desirability* and can be *controlled* to *meet certain basic requirements.*
- Quality System
  - Say what you do
  - Do what you say
  - Write it all down
  - Act on the Difference

Quality is determined by the Customer (end-user) based on their expectation and needs.

BUSINESS PROCESSES

- Quality System
  - Regulatory Requirements
  - Customer Requirements
- **Lean Six Sigma**
  - **Two separate business tools**
  - **Support the Quality System**

– Lean Manufacturing
  - Production Management Strategy
  - Reduces (eliminates) waste
  - Focused on creating the most value with the least amount of work

"The Machine That Changed the World"
Daniel Jones, Daniel Roos, and James Womack (1990, reprinted 2007)

LEAN MANUFACTURING

- Vocabulary
  - Value: desired characteristics provided to the customer at the right time, place and cost
  - Muda (waste): activity that creates no value but consumes resources
    DOWNTIME

MUDA (Waste)

D defects
O overproduction
W waiting
N non-utilized/under utilized talent
T transportation
I inventory
M motion
E excess processing

BUSINESS PROCESSES

- Quality System
  - Regulatory Requirements
  - Customer Requirements
- Lean Six Sigma
  - Two separate business tools
  - Support the Quality System
  - Lean Manufacturing
    - Production Management Strategy to reduces (eliminate) waste
  - Six Sigma
    - Business Management Strategy
    - Identifying (removing) defects
    - Minimizing process variability

Developed by Motorola (1986)
Jack Welch made business strategy at General Electric (1995)

BUSINESS PROCESSES

- Six Sigma
  - DMAIC: define, measure, analyze, improve, control
  - Structured investigation process
  - Utilizes quality management and statistical methods
- Design for Six Sigma (DFSS)
  - DMADV: define, measure, analyze, design, verify
  - Structured design process (Relevant to complex system/product synthesis)
  - Determines needs of customer and drives to product solutions
- Program focus
  - DMADV = process *generation*
  - DMAIC = process *improvement*

QUALITY SYSTEM

- Method of doing business
  - Regulatory Requirements
    - US Food & Drug Administration
    - Europe, Japan, Canada, etc.
  - Customer Requirements
    - ISO (International Organization of Standards)
    - Specifications, etc.

QUALITY SYSTEM

- Method of doing business
  - Regulatory Requirements
  - Customer 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)
- Quality Department
  - Voice of the Customer
  - Regulatory Review
  - Support Function

QUALITY ASSURANCE VS QUALITY CONTROL

- *Quality Assurance (QA)* plans, develops, documents processes that optimize objectives
  - Reviews and Evaluates
  - Systems based (oversight)
- *Quality Control (QC)* evaluates and respond to non-conformities
  - Measures & Releases
  - Manufacturing floor

QUALITY ASSURANCE

- System Oversight
  - Standards Maintenance
  - Regulatory Review
- Document Control
  - Maintain records
  - Change Control
- Auditing
  - Internal Monitoring
  - Supplier Approval / Review
- Regulatory Department
  - Maintain Agency documents (filings)
  - Up-to-date on Regulations
  - Communicate changes

QUALITY ASSURANCE VS QUALITY CONTROL

- *Quality Assurance (QA)* plans, develops, documents processes that optimize objectives
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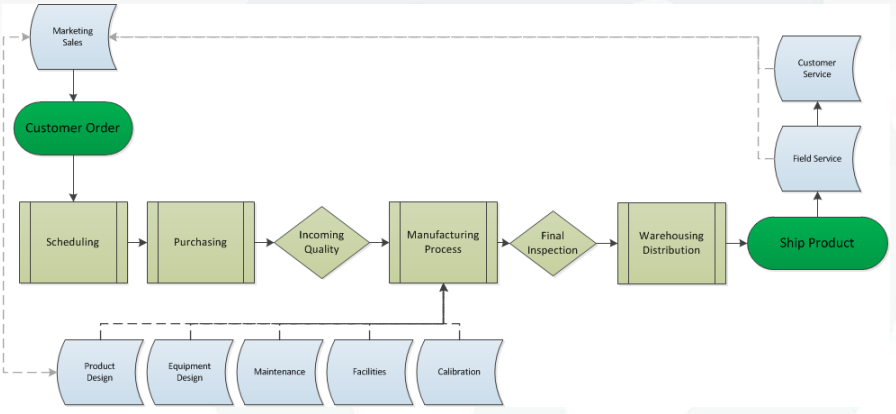
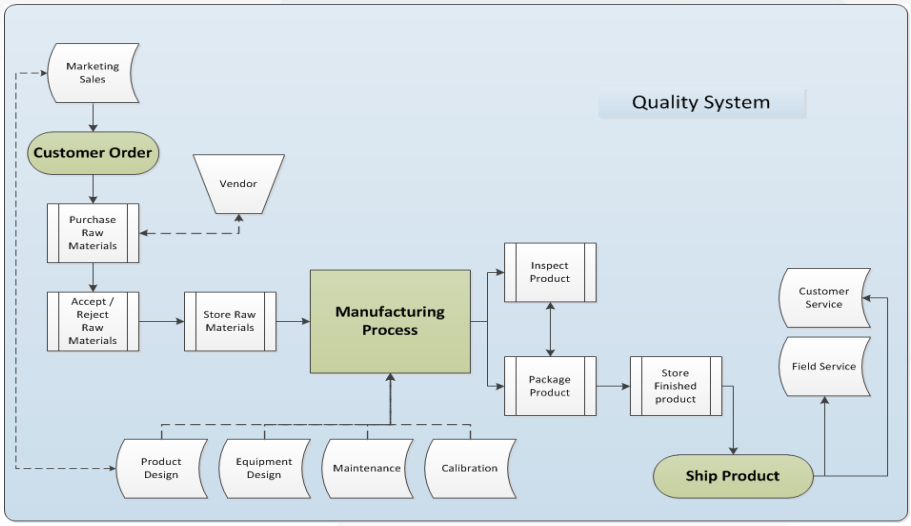
QUALITY CONTROL

- Incoming Quality
  - Material/Component Evaluation
    - Identity testing
    - Dimensional measurements
    - Physical testing
- Production Floor
  - Start-up of process(es)
  - In-process monitor
- Product Release
  - Final Inspection
  - Document (Batch/Lot Record) Review

MANUFACTURING PROCESS (GENERAL)



PROCESS FLOW - MANUFACTURING



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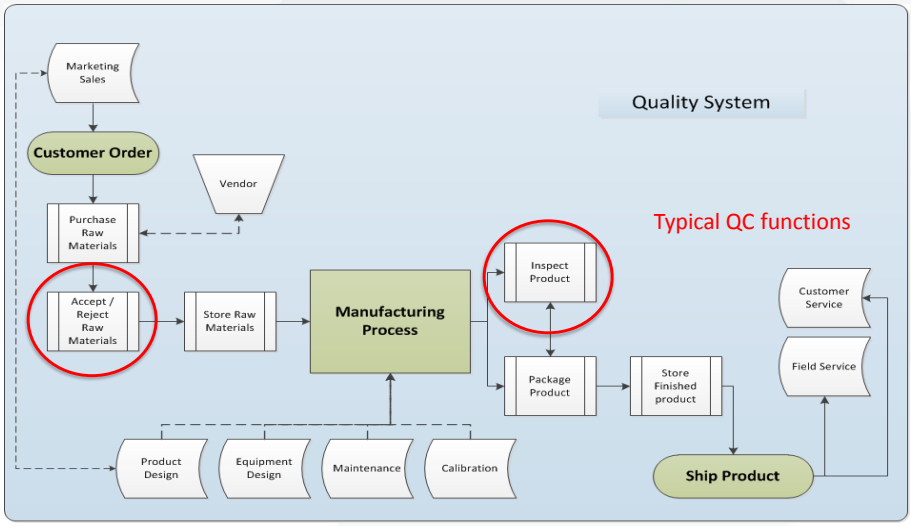

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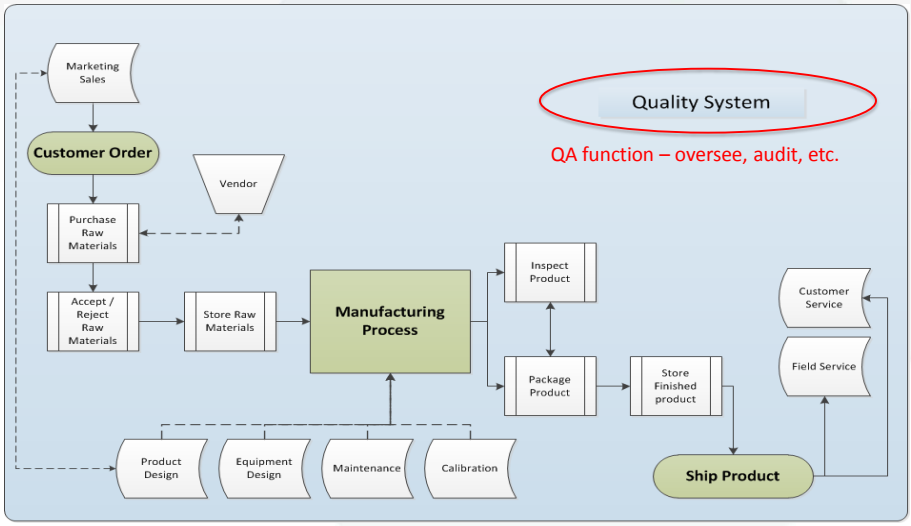


PROFESSIONAL PRACTICES

Ethics

Confidentiality

Teamwork (Conflict Resolution)

Time / Project Management

Communication

PROFESSIONAL PRACTICES

- Company's Code of Ethics
  - Adopted by companies to enable employees to:
    - Understand difference between 'right' and 'wrong'
    - Apply understanding to their business decisions.
  - Implies documents at three (3) levels:
    - Codes of Business Ethics
    - Codes of Conduct for Employees
    - Codes of Professional Practice

CODES OF PROFESSIONAL PRACTICE

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

INTEGRITY - ETHICS

- American Society for Quality Code of Ethics (ASQ.org)
  - **Fundamental Principles**: ASQ requires its members and certification holders to conduct themselves ethically by:
    - Being honest and impartial in serving the public, their employers, customers, and clients.
    - Striving to increase the competence and prestige of the quality profession, and
    - Using their knowledge and skill for the enhancement of human welfare.

American Society for Quality Code of Ethics (ASQ.org)

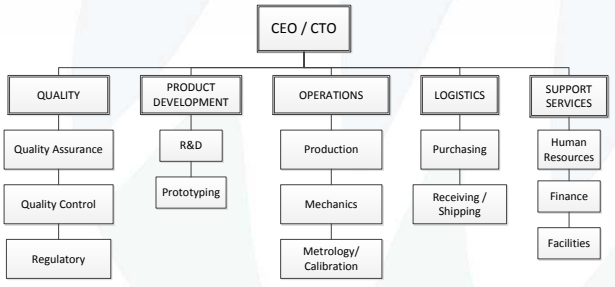
- Members and certification holders are required to observe the tenets set forth below:
  - **Relations With the Public**
    - Article 1 – Hold paramount the safety, health, and welfare of the public in the performance of their professional duties.
  - **Relations With Employers, Customers, and Clients**
    - Article 2 – Perform services only in their areas of competence.
    - Article 3 – Continue their professional development throughout their careers and provide opportunities for the professional and ethical development of others.
    - Article 4 – Act in a professional manner in dealings with ASQ staff and each employer, customer or client.
    - Article 5 – Act as faithful agents or trustees and avoid conflict of interest and the appearance of conflicts of interest.
  - **Relations With Peers**
    - Article 6 – Build their professional reputation on the merit of their services and not compete unfairly with others.
    - Article 7 – Assure that credit for the work of others is given to those to whom it is due.

INTEGRITY - ETHICS

- Quality Assurance & Quality Control
  - Voice of the Customer
    - Is the product manufactured properly?
    - Does the product function as expected?
    - Was the product manufactured using the correct materials
  - Regulatory review
    - Does the product/service meet the Regulatory requirements (i.e. government, UL, etc.)
    - Does the product meet the Customer regulatory expectations?
  - Support function
    - Work with manufacturing, purchasing, etc. to meet Customer and Regulatory requirements

INTEGRITY - ETHICS

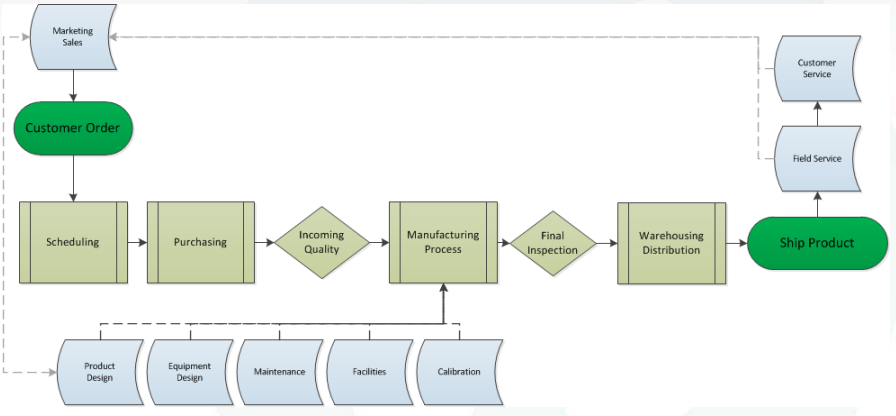
- Quality typically alternate reporting structure
  - Avoid conflict of interest
  - Required by FDA



…"Being honest and impartial in serving the public…."
…"Using their knowledge and skill for the enhancement of human welfare…."

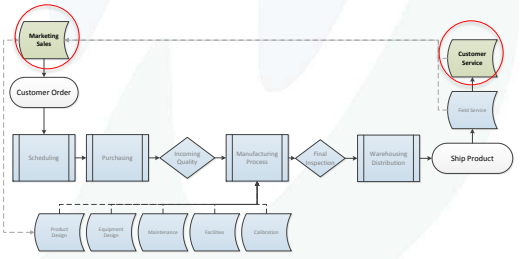
Quality is not just Quality's Responsibility

MANUFACTURING PROCESS (GENERAL)



Quality is not just Quality's Responsibility

- Marketing / Sales
  - Translate Customer requirements
  - Contract review
- Customer Service
  - Technical support
  - Complaints



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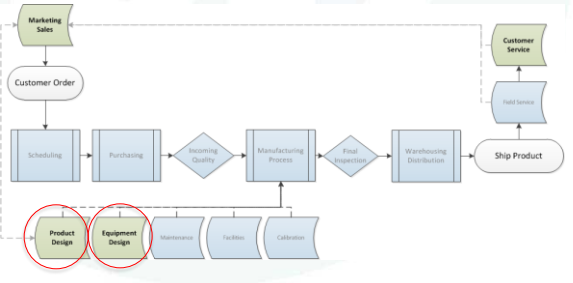
Quality is not just Quality's Responsibility

- Marketing / Sales
- Customer Service

- Engineering (design, process, manufacturing)
  - Quality is built into product, not inspected in
  - Process needs to be repeatable
  - Manufacturing maintains equipment, looks for improvements



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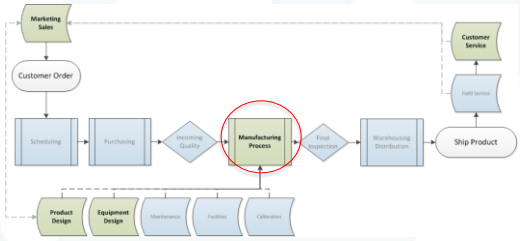
Quality is not just Quality's Responsibility

- Marketing / Sales
- Customer Service
- Engineering (design, process, manufacturing)

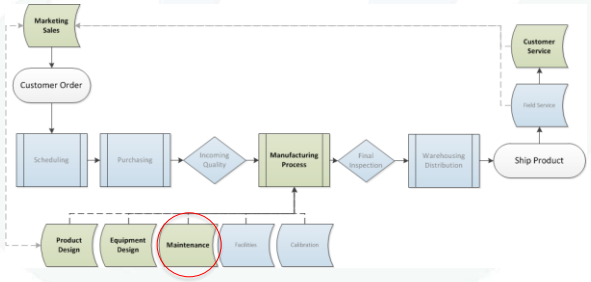
- Manufacturing/Production
  - In-process testing
  - Timely data recording
  - Following procedures



Quality is not just Quality's Responsibility

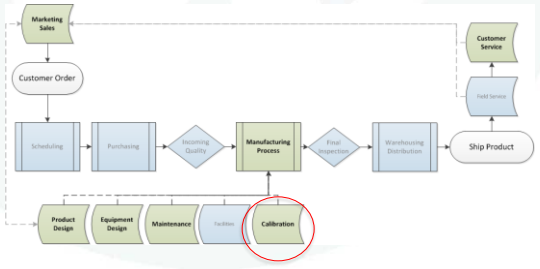
- Marketing / Sales
- Customer Service
- Engineering (design, process, manufacturing)
- Manufacturing/Production

- Maintenance
  - Equipment PM
  - Spare Parts



Quality is not just Quality's Responsibility

- Marketing / Sales
- Customer Service
- Engineering (design, process, manufacturing)
- Manufacturing/Production
- Maintenance
- Calibration (Metrology)
  - Measurement Equipment
  - Production/Assembly Gages, scales, etc.



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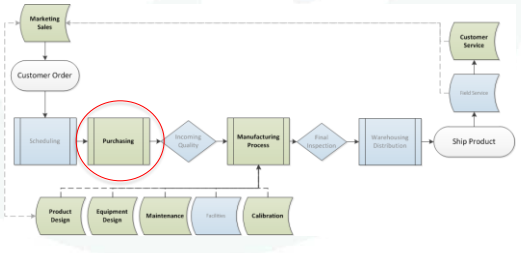
Quality is not just Quality's Responsibility

- Marketing / Sales
- Customer Service
- Engineering (design, process, manufacturing)
- Manufacturing/Production
- Maintenance
- Calibration
- Procurement / Purchasing
  - Supplier approval
  - Alternate Vendors
  - Raw Material Specification(s)



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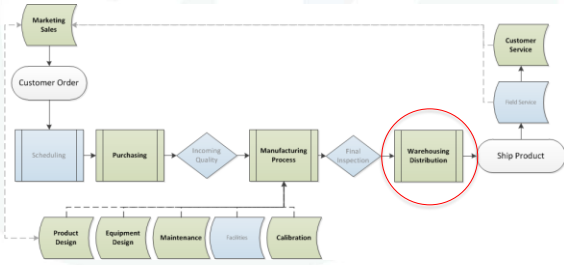
Quality is not just Quality's Responsibility

- Marketing / Sales
- Customer Service
- Engineering (design, process, manufacturing)
- Manufacturing/Production
- Maintenance
- Calibration
- Procurement / Purchasing
- **Packaging / Shipping**
  - Product protection
  - Stacking processes



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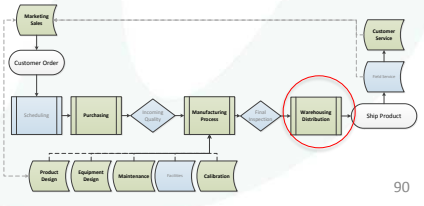
Quality is not just Quality's Responsibility

- Marketing / Sales
- Customer Service
- Engineering (design, process, manufacturing)
- Manufacturing/Production
- Maintenance
- Calibration
- Procurement / Purchasing
- Packaging / Shipping
- **Storage / Warehouse**
  - Environmental (i.e. cold storage, dry, etc)
  - Stacking
  - Delivery to production (material transfer)



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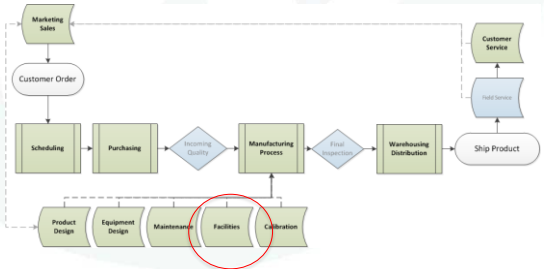
Quality is not just Quality's Responsibility

- Marketing / Sales
- Customer Service
- Engineering (design, process, manufacturing)
- Manufacturing/Production
- Maintenance
- Calibration
- Procurement / Purchasing
- Packaging / Shipping
- Storage / Warehouse
- **Facilities**
  - Controlled Environments
  - Clean Rooms
  - HVAC



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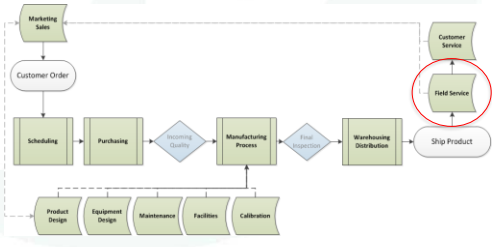
Quality is not just Quality's Responsibility

- Marketing / Sales
- Customer Service
- Engineering (design, process, manufacturing)
- Manufacturing/Production
- Maintenance
- Calibration
- Procurement / Purchasing
- Packaging / Shipping
- Storage / Warehouse
- Facilities
- **Field Service**
  - Customer Expectations
  - Customer Requirements
  - Technical Assistance



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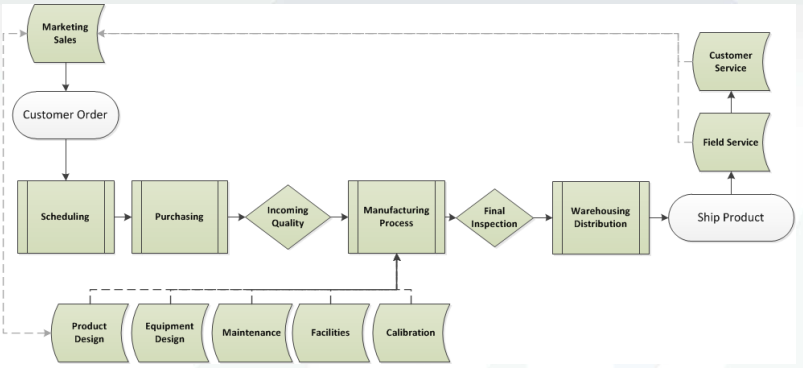
QUALITY IS EVERYONE's RESPONSIBILITY



- Marketing / Sales
- Customer Service
- Manufacturing/Production
- Maintenance
- Calibration
- QA / QC
- Engineering
- Procurement / Purchasing
- Packaging / Shipping
- Storage / Warehouse
- Facilities
- Field Service

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QUALITY SYSTEMS

ISO 9001
FDA – 21CFR Requirements

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REVIEW

- 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)

QUALITY SYSTEMS

- International Organization of Standardization (ISO)
  - ISO 9001:2015 Quality Management Systems – Requirements
  - ISO 13485:2016 Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
  - ISO/IEC 17025:2005 General Requirements and Competencies of Testing and Calibration Laboratories
- ISO/TS 16949:2009 Quality Management Systems –Particular Requirements for the Application of IS0 9001:2008 for Automotive Production and Relevant Service Part Organizations
  - AIAG (AITF) – Automotive Industry Action Group (Automotive International Task Force)
- AS9001C International Aerospace Quality System Standard
  - IAQG (International Aerospace Quality Group)

QUALITY SYSTEMS

- ISO 9001:2015 Quality Management Systems – Requirements
- ISO 13485:2016 Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
- ISO/IEC 17025:2005 General Requirements and Competencies of Testing and Calibration Laboratories
- ISO/TS 16949:2009 Quality Management Systems –Particular Requirements for the Application of IS0 9001:2008 for Automotive Production and Relevant Service Part Organizations
- AS9001C International Aerospace Quality System Standard
- ISO 22000:2005 Food Safety Management Systems – Requirements for any organization in the food chain
- ISO E14001:2004 Environmental Management Systems – Requirements with Guidance for Use

QUALITY SYSTEMS

- US Food & Drug Administration (FDA)
  - 21CFR (Code of Federal Regulations)
    - Part 210/211 Pharmaceuticals
    - Part 600/601/610 Biologics
    - Part 820 Medical Device
  - International Counterparts
    - Japan – Pharmaceutical & Medical Device Agency
    - Europe – European Directives
    - Canada –Health Canada

QUALITY SYSTEMS

- Most common in this area (North Central Massachusetts)
  - ISO 9001:2015E
    - General manufacturing, including design
    - Also used by Service companies (i.e. healthcare, etc.)
  - ISO 13485:2016
    - International medical device
  - US FDA cGMP
    - 21CFR Part 820 (Medical Device)
    - 21CFR Part 210/211 (Pharmaceutical)
      - cGLP (Laboratory Practices) 21CFR Part 58
      - cGCP (Clinical Practices) 21 CFR Part 312
    - 21CFR Part 600/601/610 (Biologics)

ADDITONAL STANDARD

- ISO 14001:2015 Environmental Management Systems
  - not a Quality System, but often also implemented in conjunction with ISO 9001:2015
    - Most recent revisions ensure commonality among systems including PDCA and risk/opportunity evaluations.
  - Used for
    - Minimize how Organization operations (processes) negatively affect the environment (e.g. air, land, water)
    - Comply with applicable laws, regulations and other environmentally oriented requirements
    - Continually improve both
  - Provides assurance that environmental impact is being measured and improved.

wikipedia.org

Reduce – Reuse - Recycle

QUALITY SYSTEMS

- ISO
  - 9001:2015: General Quality Management Systems
  - 13485:2016 Medical Device Manufacture
- US FDA
  - 21CFR Part 210/211 Pharmaceutical
  - Part 820 Medical Device

ISO is voluntary

FDA is mandatory

ISO 9001:2015E

- Quality Management Systems Standard

  "… designed to help organization ensure they meet the needs of customers and other stakeholders while meeting statutory and regulatory requirements related to a product…"
- Third party certification bodies provide independent confirmation
  - Accreditation organizations authorize certification bodies

Accreditation - Exemplar Global (formerly RABQSA)
Certification – LRQA (Lloyds Registrar Quality Assurance LTD)
BSI (British Standards Institute Group)

GENERAL QUALITY PRINCIPLES

- Customer Focus
- Leadership
- Engagement of People
- Process Approach
- Improvement
- Evidence-based decision making
- Relationship management

REFERNCE: ISO 9001:2015

QMS – PRINCIPLES (ISO 9001:2015)

- Customer Focus
  - understand current and future customer needs
  - meet customer requirements
  - strive to exceed customer expectations

  Organizations depend on their customers.
- Leadership
- Engagement of People
- Process Approach
- Improvement
- Evidence-based decision making
- Relationship management

QMS – PRINCIPLES (ISO 9001:2015)

- Customer Focus
- Leadership

  Leaders establish unity of purpose and direction of the organization. They should create and maintain the internal environment in which people can become fully involved in achieving the organization's objectives.
- Engagement of People
- Process Approach
- Improvement
- Evidence-based decision making
- Relationship management

QMS – PRINCIPLES (ISO 9001:2015)

- Customer Focus
- Leadership
- Engagement of People

  People at all levels of an organization and their full involvement enables their abilities to be used for the organization's benefit
- Process Approach
- Improvement
- Evidence-based decision making
- Relationship management

QMS – PRINCIPLES (ISO 9001:2015)

- Customer Focus
- Leadership
- Engagement of People
- Process Approach

  Desired result is achieved more efficiently when activities and related resources are managed as a process

- Improvement
- Evidence-based decision making
- Relationship management

QMS – PRINCIPLES (ISO 9001:2015)

- Customer Focus
- Leadership
- Engagement of People
- Process Approach
- Improvement

  Continual improvement of the organizations overall performance should be a permanent objective of the organization

- Evidence-based decision making
- Relationship management

QMS – PRINCIPLES (ISO 9001:2015)

- Customer Focus
- Leadership
- Engagement of People
- Process Approach
- Improvement
- Evidence-based decision making

  Effective decisions are based on the analysis of data and information
- Relationship management

QMS – PRINCIPLES (ISO 9001:2015)

- Customer Focus
- Leadership
- Engagement of People
- Process Approach
- Improvement
- Evidence-based decision making
- Relationship Management

  An organization and its suppliers are interdependent and a mutually beneficial relationship enhances the ability of both to create value

Manufacturing/Service Processes

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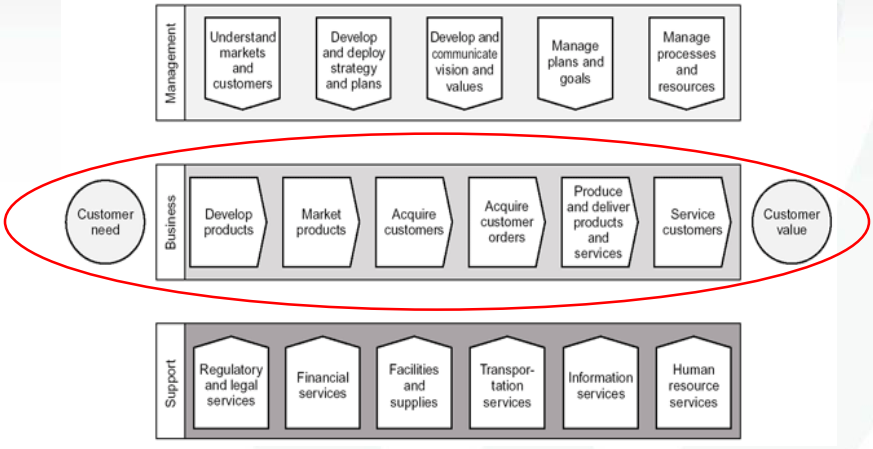
Types of Processes



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

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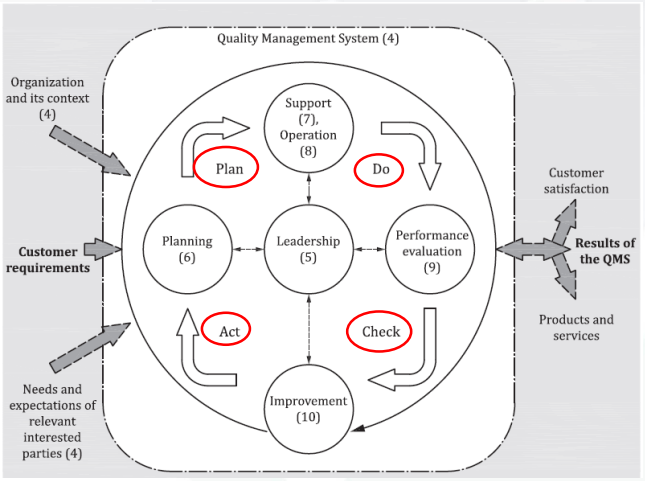
Quality System Process Overview

ISO 9001:2015



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Quality Management System Overview

ISO 9001:2015 --

- Section 4.0 Context of the organization
- Section 5.0 Leadership
- Section 6.0 Planning
- Section 7.0 Support
- Section 8.0 Operation
- Section 9.0 Performance evaluation
- Section 10.0 Improvement

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ISO 9001:2015E

- 4.0 Context of the Organization
  - Determine internal/external issues that can impact or are relevant to strategic direction of the organization
  - Include interested parties (regulators, suppliers, subcontractors, etc.)
  - Overall QMS system scope, documents and records

* Reference ISO 9001:2015(E)

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ISO 9001:2015E

- 5.0 Leadership
  - Management commitment, integration of the QMS into business processes
    - Customer Focus
    - Quality Policy
  - Organizational roles, responsibilities, authorities

* Reference ISO 9001:2015(E)

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ISO 9001:2015E

- 6.0 Planning
  - Address business /product risks and opportunities
  - Quality (business) objectives
  - Changes
    - Controlled, address adverse consequences, resources, responsibilities & authorities

* Reference ISO 9001:2015(E)

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ISO 9001:2015E

- 7.0 Support
  - Resources: personnel, infrastructure, environment, monitoring/measuring devices, intellectual property (organizational knowledge)
  - Training, Awareness, Communication, Documented Information

* Reference ISO 9001:2015(E)

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ISO 9001:2015E

- 8.0 Operation
  - Contract review, purchasing, design control/validation, process control/product release, product traceability, handling & storage, change control, control of non-conforming
- 9.0 Performance Evaluation
  - Statistical methods, inspection/testing, audits, management review,

* Reference ISO 9001:2015(E)

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ISO 9001:2015E

- 10.0 Improvement
  - Select opportunities and implement necessary actions to meet customer requirements and enhance customer satisfaction
  - Corrective Actions for non-conformity (root cause)
  - Continual improvement

* Reference ISO 9001:2015(E)

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ISO 13485:2016

- Previously similar to ISO 9001:2008
  - General Requirements
  - Resource Management
  - Product Realization
  - Measurement, Analysis & Improvement
- Specific requirements in select areas
  - Handout for comparison to ISO 9001:2015 revision
  - Emphasis on regulatory requirements & efficacy

FOOD & DRUG ADMINISTRATION (FDA)

- Federal agency; US Division of Health & Human Services

  "… protect and promote public health through regulation and supervision of
  - *Food safety, tobacco products, dietary supplements*
  - *Prescription, over-the-counter pharmaceuticals, vaccines, biopharmaceuticals, blood transfusions*
  - *Medical devices, electromagnetic radiation emitting devices*
  - *Animal foods & feed, veterinary products…"*

  Center for Biologics Evaluation & Research (CBER)
  Center for Devices and Radiological Health (CDRH)
  Center for Drug Evaluation and Research (CDER)

CODE OF FEDERAL REGULATIONS (CFR)

- CFR is the codification of the general and permanent rules and regulations (sometimes called administrative law)
- The titles are broken down into:
  Chapters, Parts , Sections , and Paragraphs

Example: 21 CFR 820.30(d) (1)
would read Title 21, Part 820, Section 30, Paragraph (d)(1)

CODE OF FEDERAL REGULATIONS (CFR)

Title 1	General Provisions
Title 2	Grants and Agreements
Title 3	The President
Title 4	Accounts
Title 5	Administrative Personnel
Title 6	Domestic Security
Title 7	Agriculture
Title 8	Aliens and Nationality
Title 9	Animals and Animal Products
Title 10	Energy
Title 11	Federal Elections
Title 12	Banks and Banking
Title 13	Business Credit and Assistance
Title 14	Aeronautics & Space (aka Federal Aviation Regulations)
Title 15	Commerce and Foreign Trade
Title 16	Commercial Practices
Title 17	Commodity and Securities Exchanges
Title 18	Conversation of Power & Water Resources
Title 19	Customs Duties
Title 20	Employee's Benefits
Title 21	Food and Drugs
Title 22	Foreign Relations
Title 23	Highways
Title 24	Housing & Urban Development
Title 25	Indians
Title 26	Internal Revenue (aka Treasury Regulations)
Title 27	Alcohol, Tobacco & Firearms
Title 28	Judicial Administration
Title 29	Labor
Title 30	Mineral Resources
Title 31	Money and Finance: Treasury
Title 32	National Defense
Title 33	Navigation & Navigable Waters
Title 34	Education
Title 35	Reserved (Formerly Panama Canal)
Title 36	Parks, Forests, and Public Property
Title 37	Patents, Trademarks, and Copyrights
Title 38	Pensions, Bonuses & Veterans Relief
Title 39	Postal Service
Title 40	Protection of Environment
Title 41	Public Contacts and Property Management
Title 42	Public Health
Title 43	Public Lands: Interior
Title 44	Emergency Management & Assistance
Title 45	Public Welfare
Title 46	Shipping
Title 47	Telecommunication
Title 48	Federal Acquisition Regulations Systems
Title 49	Transportation
Title 50	Wildlife & Fisheries

cGXP

- cGXP -- Current Good [ ] Practices
  - Manufacturing *(GMP)*
    - Pharmaceutical
    - Medical Device
  - Laboratory *(GLP)*
  - Clinical *(GCP)*

cGMP – Current Good Manufacturing Practices

***"…** practices required in order to conform to guidelines recommended by agencies that control authorization and licensing for manufacture and sale of … drug products, and active pharmaceutical products. These guidelines provide minimum requirements that a … manufacturer must meet to assure that the products are of high quality and do not pose any risk to the consumer or public …"*

(Wikipedia.com)

cGMP – Pharmaceutical 21CFR210/211

- Subpart A: General Provisions
- Subpart B: Organization & Personnel
- Subpart C: Buildings & Facilities
- Subpart D: Equipment
- Subpart E: Control of Components, Drug Product Containers & Closures
- Subpart F: Production & Process Controls
- Subpart G: Packaging & Labeling Controls
- Subpart H: Holding & Distribution
- Subpart I: Laboratory Controls
- Subpart J: Records & Reports
- Subpart K: Returned & Salvaged Goods

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=210

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=211

cGMP – Medical Device 21CFR820

- Subpart A: General Provisions
- Subpart B: Quality System Requirements
- Subpart C: Design Controls
- Subpart D: Document Controls
- Subpart E: Purchasing Controls
- Subpart F: Identification & Traceability
- Subpart G: Production & Process Control
- Subpart H: Acceptance Activities
- Subpart I: Nonconforming Product
- Subpart J: Corrective & Preventive Action
- Subpart K: Labeling & Packaging Control
- Subpart L: Handling, Storage, Distribution & Installation
- Subpart M: Records
- Subpart N: Servicing
- Subpart O: Statistical Techniques

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=820

cGLP – Good Laboratory Practices for Non-Clinical Studies

"Good Laboratory Practice (GLP) embodies a set of principles that provides a framework within which laboratory studies are planned, performed, monitored, recorded, reported and archived. These studies are undertaken to ***generate data by which the hazards and risks to users, consumers and third parties, including the environment, can be assessed*** *… GLP helps assure regulatory authorities that the data submitted are a true reflection of the results obtained during the study and can therefore be* ***relied upon when making risk/safety assessments****. "*
(Wikipedia.com)

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cGLP – 21CFR 58 Laboratory Practices

"… These studies are undertaken to generate data by which the hazards and risks to users, consumers and third parties, including the environment, can be assessed … GLP helps assure regulatory authorities that the data submitted are a true reflection of the results obtained during the study and can therefore be relied upon when making risk/safety assessments. " (Wikipedia.com)

- Subpart A: General Provisions
- Subpart B: Organization & Personnel
- Subpart C: Facilities
- Subpart D: Equipment
- Subpart E: Testing Facilities Operation
- Subpart F: Test and Control Articles
- Subpart G: Protocol for & Conduct of a Nonclinical Laboratory Study
- Subpart H: (reserved)
- Subpart I: (reserved)
- Subpart J: Records & Reports
- Subpart K: Disqualification of Testing Facilities

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cGCP – Current Good Clinical Practices

*"… GCP enforces tight guidelines on **ethical aspects of a clinical study.** High standards are required in terms of comprehensive documentation for the clinical protocol, record keeping, training, and facilities, including computers and software… GCP guidelines include protection of human rights for the subjects and volunteers in a clinical trial. It also provides **assurance of the safety and efficacy of the newly developed compounds**…" (Wikipedia.com)*

cGCP – Current Good Clinical Practices

"… GCP guidelines include protection of human rights for the subjects and volunteers in a clinical trial. It also provides assurance of the safety and efficacy of the newly developed compounds…" (Wikipedia.com)

- ICH Guidance for Industry --
  E6: Good Clinical Practice (Consolidated Guidance)
  - Glossary (Definitions)
  - Principles of ICH GCP
  - Institutional Review Board/ Independent Ethics Committee
  - Investigator
  - Sponsor
  - Clinical Trial Protocol & Protocol
  - Investigator's Brochure
  - Essential Documents for Conduct of a Clinical Trial

(ICH = International Conference on Harmonization of Technical Requirements; Europe, Japan & United States)

cGCP – Current Good Clinical Practices

"… GCP guidelines include protection of human rights for the subjects and volunteers in a clinical trial. It also provides assurance of the safety and efficacy of the newly developed compounds…" (Wikipedia.com)

- ICH Guidance for Industry --
  E6: Good Clinical Practice (Consolidated Guidance)

- FDA adopted ICH E6, requirements are throughout 21CFR
  - Part 11 – Electronic Records & Signatures
  - Part 50 – Protection of Human Subjects
  - Part 54 – Financial Disclosure
  - Part 56 – Institutional Review Boards
  - Part 812 – Investigational Device Exemptions
  - Part 814 – Premarket Approval of Medical Devices

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cGXP

- cGXP -- Current Good [ ] Practices
  - Manufacturing *(GMP)*
    - Pharmaceutical
    - Medical Device
  - Laboratory *(GLP)*
  - Clinical *(GCP)*

Comparison chart hand-out

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QUALITY SYSTEMS

- ISO 9001:2008: General Quality Management Systems
- ISO 13485:2003 Medical Device Manufacture
- 21CFR Part 210/211 Pharmaceutical
- 21CFR Part 820 Medical Device

– 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)

Say What you do - DOCUMENTATION

DOCUMENTATION

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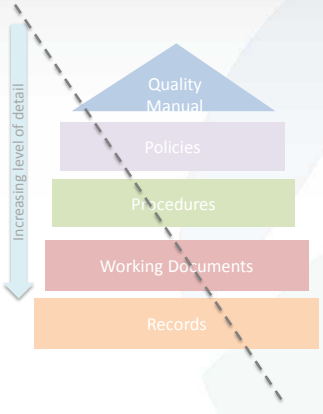
DOCUMENTATION



NOTE: ISO 9001:2015 revision no longer follows this model

Now refers to "Documented Information"

maintain documented information is equivalent to procedure

retain documented information is equivalent to records

Existing quality management systems built on original model – therefore, detail still provided

ISO 13485:2016 (medical devices) and 21CFR 210/211 (pharma) and 820 (medical devices) do specify where procedures are required

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DOCUMENTATION

- Quality Manual

  high level document providing overview of business operation and quality system

Note: No longer an explicit requirement for ISO 9001:2015

- Policies

  provide general guidelines by which company conducts the various manufacturing (service) operations

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DOCUMENTATION

- Procedures – operational detail regarding how business has implemented policies and provide general information on day-to-day operations. (SOP)
- Working Documents

  detailed steps to carry-out specific task(s)
  - Work instruction
  - Test Methods
  - Product / Process / Raw material Specifications
  - Protocols
  - Etc.

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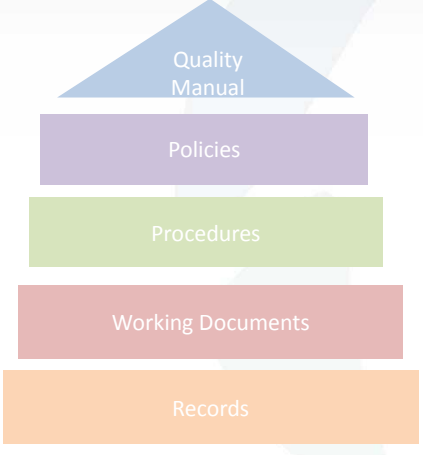
DOCUMENTATION

- Quality Manual – high level document providing overview of business operation and quality system
- Policies – provide general guidelines by which company conducts the various manufacturing (service) operations
- Procedures – operational detail regarding how business has implemented policies and provide general information on day-to-day operations. (SOP)
- Working Documents – detailed steps to carry-out specific task(s).
- Records

  documented results of completing tasks
  - Quality
  - Business

Do what you say - TRAINING



TRAINING

- Qualifications
  - Job Description
  - Resume
- Read and understand
- On-the-job Training (OJT)

Comprehension & Effectiveness

Write it all down - RECORDS

QUALITY RECORDS

- Manual
  - Forms
  - Lab Notebooks
- Electronic
  - Automated systems
  - Validations (Reports)
  - Email

QUALITY RECORDS

- Create permanent , official record of operation(s) conducted.
- Do not omit or falsify data
- Good Documentation Practices (GDP)
  - Terminology used in Pharmaceutical and Medical Device industries.
    - Standards by which documents are created and maintained.
    - Not codified by FDA, but are considered cGMP
  - ISO 9001:2015E & ISO 13485:2016 also have requirements for legibility and document handling

GDP – Recording Data Summary

- Data recording shall be timely and complete
- Recorded in permanent/indelible ink (blue/black)
- Data shall be concise, accurate and legible
- All data/records (pages) shall be included
- Follow company's format for date and time
- For Critical Entries, have an independent verification
- Follow company's format for initials and signatures

GDP – Data Correction Summary

- For incorrect data entries
  - Use a single line-out, leaving original data entry legible
  - Sign and date, with rationale for change
  - Do not use correction tape or fluid
- Do not transcribe data, original data shall be maintained.
- When there is insufficient space for the correction rationale use a reference symbol at the point of the correction.

QUALITY RECORDS

- Create permanent , official record of operation(s) conducted.
- Do not omit or falsify data
- Good Documentation Practices (GDP)
  - legibility and document handling
- Electronic Records
  - 21CFR Part 11 for Pharmaceutical (Bio-)& Medical Device
  - Validated system and Electronic Signature
    - Replaces hand written signature
    - Unique login and password combination
      - Will change often

AUDITING

Principles

REVIEW

- ISO 9001:2015 General Quality System
  - Context of the organization; Leadership; Planning; Support
  - Operation; Performance Evaluation; Improvement
- ISO 13485:2016 Medical Devices
  - General Requirements; Management Responsibilities
  - Resource Management; Product Realization
  - Measurement, Analysis & Improvement
- cGXP -- Current Good (Manufacturing, Laboratory or Clinical) Practices
  - 21CFR 820 (Medical Device cGMP)
  - 21CFR 210/211 (Pharmaceutical cGMP)
  - 21CFR 58 (Nonclinical Laboratory Studies cGLP)
  - ICH E6 (Clinical Studies cGCP)

AUDIT

- Definition (Merriam-Webster dictionary)

  Audit (noun): a methodical examination and review
  - Financial (accounting)
  - **Quality Management**
  - Project Management
  - Energy Conservation
  - Forensic
  - Etc.

AUDIT

- a methodical examination and review
- Quality Management Audit – WHY?
  - Provide feedback for improvement
- Sources
  - Regulatory Inspections (new products, on-going surveillance)
  - ISO Registrar
  - Customer
  - Internal

1st Party Audit - Organization audits themselves Internal Audit
2nd Party Audit – Customer audits (supplier audits) External Audit
3rd Part Audit - Registrar (Regulatory) audits External Audit

INTERNAL AUDIT - References

- ISO9001:2015

Section 9 Performance Evaluation

9.2 Internal Audit

9.2.1 "The organization shall conduct internal audits at planned intervals to provide information on whether the quality management system:

a) conforms to:

1. the organization's own requirements for its quality management system;
2. The requirements of this International Standard

b) is effectively implemented and maintained……"

INTERNAL AUDIT - References

- ISO 13485:2016

  Section 8 Measurement, analysis and improvement

  8.2.4 Internal Audit

  "The organization shall conduct internal audits at planned intervals to provide information on whether the quality management system:

  a) conforms to planned and documented arrangements, requirements of this International Standard, quality management system requirements established by the organization, and applicable regulatory requirements.

  b) is effectively implemented and maintained……"

- 21CFR Part 820, Subpart B Quality System Requirements

  820.22 "Each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine if the effectiveness of the quality system…"

CUSTOMER AUDIT – References

- ISO9001:2015

  Section 8.4 Control of externally provided processes, products and services

  8.4.1 General

  "…organization shall determine and apply criteria for the evaluation, selection, monitoring of performance and re-evaluation of eternal providers based on their ability to provided….in accordance with requirements."

CUSTOMER AUDIT – References

- ISO13485:2016

  Section 7 Product Realization

  7.4 Purchasing

  7.4.1 Purchasing Process

  "… organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements…"

  "…organization shall plan the monitoring and re-evaluation of suppliers…."

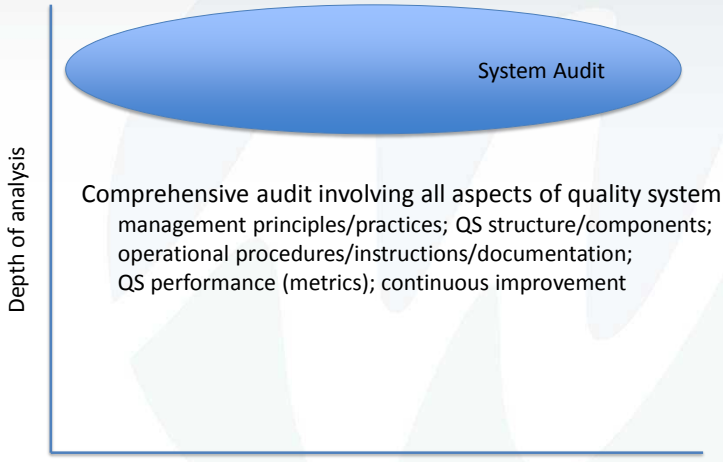
- 21CFR Part 820 Subpart E Purchasing Controls

  820.50(a) "… Each manufacturer shall establish and maintain the requirements, including quality requirements, that must be met by suppliers, contractors, and consultants…"

AUDIT

- a methodical examination and review
  - QMS audits provide feedback for improvement
- Sources
  - Regulatory Inspections
  - ISO Registrar
  - Customer
  - Internal
- Types
  - System
  - Process
  - Product

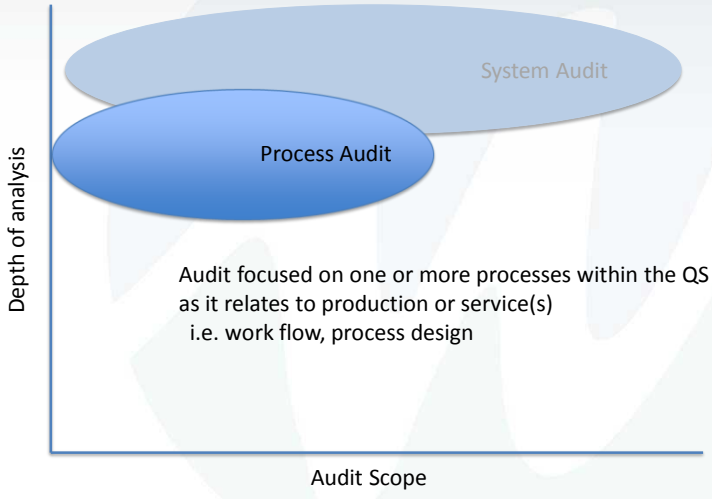
AUDIT TYPES



Comprehensive audit involving all aspects of quality system (QS):
management principles/practices; QS structure/components;
operational procedures/instructions/documentation;
QS performance (metrics); continuous improvement

Certified Quality Technician Handbook, 2nd Edition, ASQ press

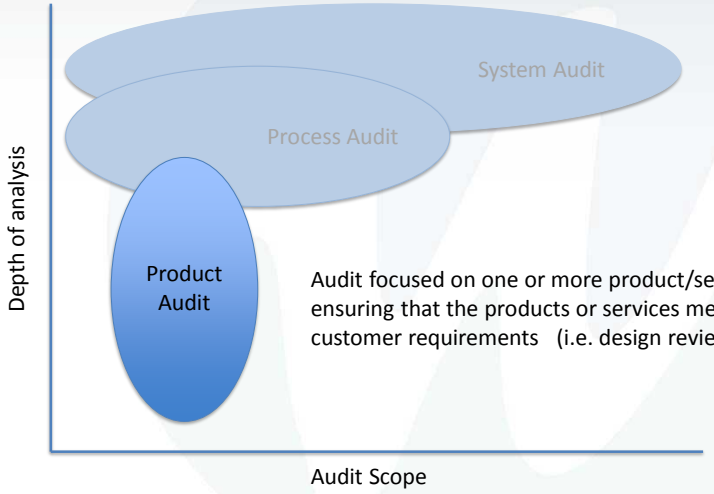
AUDIT TYPES



Audit focused on one or more processes within the QS
as it relates to production or service(s)
i.e. work flow, process design

Certified Quality Technician Handbook, 2nd Edition, ASQ press

AUDIT TYPES



Audit focused on one or more product/service ensuring that the products or services meet the customer requirements (i.e. design review)

Certified Quality Technician Handbook, 2nd Edition, ASQ press

PARTICIPANTS

- Auditee
  - Person/organization being audited
    - » Company
    - » Division
    - » Department
      - Manager / Supervisor
      - Employee
- Auditor
  - Person/organization conducting the audit
    - Lead
    - Team Member
    - Observer

PARTICIPANTS

- Auditee: Person/organization being audited
- Auditor: Person/organization conducting the audit
- Client
  - Person/organization requesting the audit (may be Auditee)
- Interested Party
  - Stakeholder to the audit process or results

ROLES & RESPONSIBILITIES

- Client: Requests the audit and uses the results.
  - Selects the auditor
  - Determines reference standard
  - Specifies type and time/duration

- FDA – determines new product/facility compliance with regulations
- Registrar – determines compliance with standard
- Customer – reviews supplier systems as relates to their needs/requirements
  - ✓ May send own personnel or external firm
- Quality Assurance – internal monitoring of quality system

ROLES & RESPONSIBILITIES

- Auditor: Conducts the audit
  - May be individual or team
  - Maintain objectivity and avoid bias
  - Comply with confidentiality requirements
- Audit Team
  - Lead Auditor
    - » Communicates audit requirements
    - » Manages audit activities and team
    - » Reports the results
  - Team Member
    - » Conducts activities as directed by Lead
    - » Provides documented evidence for report
    - » Similar qualifications to Lead, but not as experienced

ROLES & RESPONSIBILITIES

- Audit Team
  - Lead Auditor
    - » Communicates audit requirements
    - » Manages audit activities and team
    - » Reports the results
  - Team Member
    - » Conducts activities as directed by Lead
    - » Provides documented evidence for report
    - » Similar qualifications to Lead, but not as experienced
  - Observer
    - » Accompanies team but not part of audit
    - » Cannot interfere or influence conduct of audit
    - » Internal audit – trainee

Note: teams may also have “subject matter expert (SME)”

ROLES & RESPONSIBILITIES

- Client: Requests the audit and uses the results.
- Auditor: Conducts the audit
- Auditee: Accommodates the audit and provides
  - Access to facilities, processes, products, documentation
  - Resources necessary
  - Guides (staff members) to accompany Auditor(s)
    - » Establish contacts/timing
    - » Ensures safety/security rules followed
    - » Witness on behalf of Auditee
    - » Clarify / assist in collecting information
  - Follow-up actions as required by Audit Report

AUDIT ACTIVITIES

- Initiate
- Audit Plan (Preparation)
- Conduct the Audit
- Audit Report
- Corrective Action / Follow-up
- Closure

AUDIT ACTIVITIES

- Initiate
  - Purpose / Scope
    - » System
    - » Process
    - » Product / Project
  - Date (Timing) / Duration
    - » Internal versus External

AUDIT ACTIVITIES

- Audit Plan (Preparation)
  - Dependent on complexity and scope
    - » Internal vs. external
  - Team
  - Schedule
    - » Multiple days
    - » Areas for review
    - » Assures personnel available
  - Document Review
    - » Previous audit reports
    - » Quality Manual, Procedures
  - Checklists
    - » Company SOP for supplier and/or internal
    - » Develop questions based on document review
    - » Objective Evidence
      - Documentation
      - Records

AUDIT ACTIVITIES

- Initiate
  - Purpose / Scope; Timing
- Audit Plan (Preparation)
  - Team; Schedule; Document Review; Checklists
- Conducting the Audit
  - Internal versus External
    - » Not out to "get someone" or "find problems"
    - » Respect time
    - » Confidentiality

PROFESSIONAL PRACTICES

Ethics
Confidentiality
Teamwork (Conflict Resolution)
Time / Project Management
Communication

CODES OF PROFESSIONAL PRACTICE

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

CONFIDENTIALITY

- What's the big deal?
- Trade Secret:
  - A formula, practice, process, design, instrument, pattern or compilation of information
  - Not generally known or reasonably ascertainable
  - Require reasonable measures to protect the information
  - Enables a company to obtain an economic advantage over competitors
- Intellectual Property:
  - Copyright
  - Patent
  - Trademark

CONFIDENTIALITY

- What's the big deal?
  - Trade Secret:
  - Intellectual Property
- Financial Data
  - Accounting Records
  - Sales Figures / Market Share
- Personal Information
  - Health
  - Family

AUDIT ACTIVITIES

- Initiate
- Audit Plan (Preparation)
- **Conduct the Audit**
- Audit Report
- Corrective Action / Follow-up
- Closure

AUDIT ACTIVITIES

- Conducting the Audit
  - Internal versus External
  - Opening Meeting
    - » Sign-in for Attendees
    - » Daily schedule
      - Specifics of interest
      - Forward or Backward process
      - Flexible based on Auditee availability
      - Logistics
    - » For internal may be prior to actual audit
  - Follow the Process / Interviewing
    - » Forward
    - » Backward

AUDIT - INTERVIEWING

- Open vs Closed questions
  - Closed requires yes or no – or very specific info i.e. name
- Probing questions – five ways to "probe"
  1. Open question
     - Goes beyond yes/no
  2. Pause (they will fill silence)
  3. Reflective or Mirroring
  4. Paraphrasing
  5. Summary Question

Be friendly, open, make eye contact, put the person at ease

AUDIT ACTIVITIES

- Conducting the Audit
  - Documenting Observations, Findings, etc.
    - » Compliment the good
    - » Explore Improvement opportunities
    - » Sample plans
    - » Objective evidence
      - Training Records
      - Lot / Batch Records
      - Purchase orders; receipts
      - Procedures
      - Observing Personnel
    - » Note taking
      - Meeting attendees
      - Name, title of person interviewed
      - Part Number, Lot Number,
      - Equipment ID number
      - Procedure title, document number, revision

AUDIT ACTIVITIES

- Conducting the Audit
  - Internal versus External
  - Opening Meeting
  - Follow the Process / Interviewing
  - Documenting Observations, Findings, etc.
  - Closing Meeting
    - » Sign-in for Attendees
    - » No surprises
    - » Review the good and the opportunities
      - Discussion and consensus
    - » Timing for Report

AUDIT ACTIVITIES

- Audit Report
  - Clear, complete, concise
  - Fact based
  - Positive Tone
  - Content
    - » Audit Type
    - » Objectives
    - » Audit Team
    - » Standards & Reference documents used
    - » Attendees (Opening/Closing/Guides)
    - » Results
      - Positives
      - Non-conformities
    - » Distribution & Approvals

AUDIT ACTIVITIES

- Corrective Action / Follow-up
  - Auditee Responsible
    - » Prepares Corrective Action plan
    - » Submits to Auditor for consensus
    - » Implements within agreed timeframe
  - Auditor verifies completion/effectiveness during subsequent audit
    - » External vs Internal monitoring

- Closure
  - Corrective Actions assigned & agreed to
    - » Approvals
  - Internal / External
    - » Internal per SOP
    - » External per Customer SOP / requirements
    - » Registrar - after verification at next visit
    - » Regulatory – per notification; dependent on complexity & severity