

Instructor

Cheryl Marzec

- Owner of Marzec & Associates, business & quality standards consulting
- 20 yrs experience in the quality field
- 30 yrs experience in course development & teaching
- Certified Quality Auditor since 1994
- Former RAB & IRCA certified Lead Auditor
- Phone - 801.277.4515, cell – 801-520-3625
- Email – marzec@comcast.net



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Course Certification

Upon successful completion of this course students receive a Certificate of

- Certifies an individuals mastery of the course material
- Certification issued by Salt Lake Community College



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Quality Improvement Assoc. (CQIA)

Understands quality tools and their uses and participates in quality improvement projects

Requirements

- Two years of work experience or an associate degree as a minimum
- Pass a three-hour, written exam consisting of 100 multiple-choice questions
- Recertify every three years



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American Society for Quality (ASQ)

- World's leading authority on quality
- A professional association advancing learning, quality improvement, and knowledge exchange to improve business results, and to create better workplaces and communities worldwide
- A champion of the quality movement offering technologies, concepts, tools, and training to quality professionals, quality practitioners, and everyday consumers, encouraging all to Make Good Great®



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American Society for Quality (ASQ) cont.

- ASQ members have [informed and advised](#) the U.S. Congress, government agencies, state legislatures and other groups and individuals on quality-related topics.
- Administers the United States' premier quality honor—the [Malcolm Baldrige National Quality Award](#), which annually recognizes companies and organizations that have achieved performance excellence
- Contact: www.asq.org, 800.248.1946



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ASQ Certifications

Formal recognition by American Society for Quality (ASQ) that an individual has proficiency within, and a comprehension of, a specified body of knowledge

It is peer recognition, not registration or licensure



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ASQ Certifications

Biomedical Related Certifications

- [Biomedical Auditor](#)
- [HACCP Auditor](#)
- [Pharmaceutical GMP Professional](#)
- [Quality Improvement Associate](#)



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CQIA Prep

- Ensure you have two-years minimum working experience
- Learn the Body of Knowledge (BoK) for the CQIA
- Register for the exam



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CQIA Cost & Dates

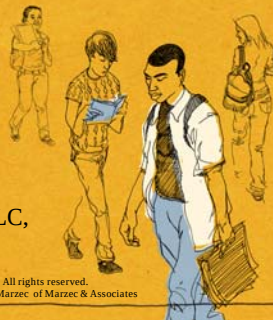
- ASQ-Member - \$155
- Non-Member - \$335
(includes ASQ membership)
- Active US or Canadian Military - \$105

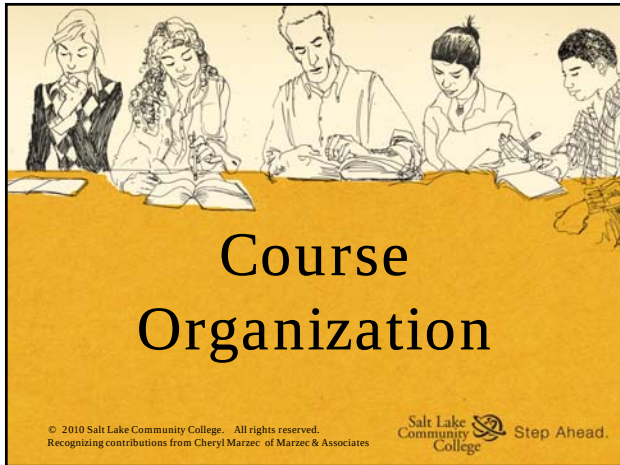
Exam

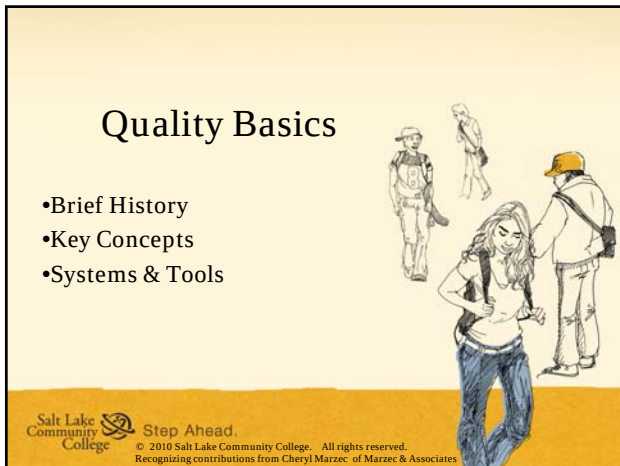
- Given bi-annually in SLC, each December & June

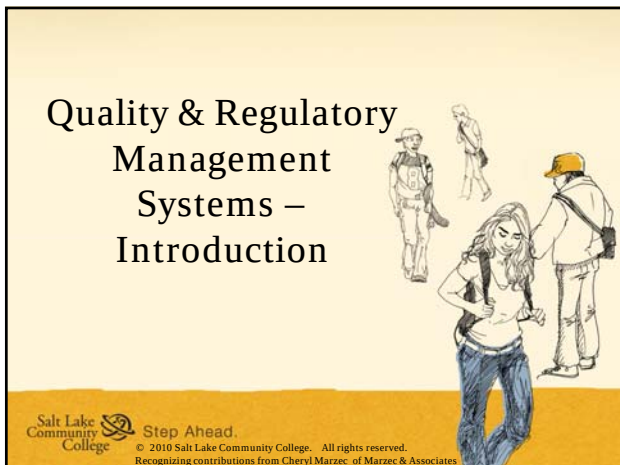


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Teams



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Continuous Improvement



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Quality Management Systems (QMS) & Reg's – Nuts & Bolts



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Project Presentation





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Project & Presentation

- Pick a topic & get instructor approval
- Select a problem & use quality tools to resolve
 - Analyze a team on which you participate; determine how could the course information help improve the team
- Present a quality leaded & their philosophy
- Present an aspect of a QMS or QSR



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Project & Presentation

- Develop 15-20 minute presentation
 - Student handouts are helpful
 - Presentation may be interactive
- Presentations will be given during the last few class sessions
- Students will participate in presentation critiques



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Final Exam

Material Covered:

- Class text book, including CD
- Class presentations
- ISO 9000 Standards
- FDA Regulations



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Quality Basics

- Brief History
- Key Concepts
- Systems & Tools



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Define Quality

- How would you define quality?



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Some Definitions

- Degree to which a set of inherent characteristics fulfills requirements
- Conformance to characteristics
- Fitness for use
- Meeting customer needs
- Exceeding customer expectations
- Superior to competitors
- "I'll know it when I see it"



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Brief History



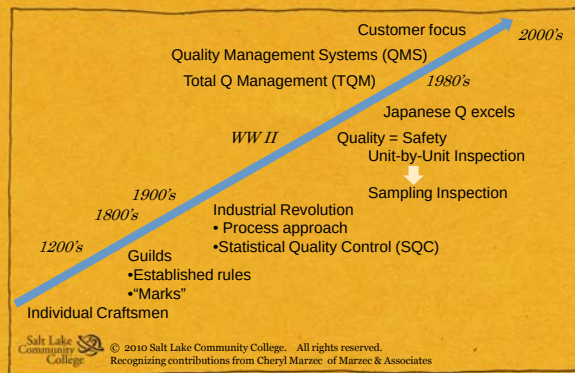
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Brief History of Quality



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Guilds

- Developed strict rules for product & service Q
- Flaws "marked" by inspectors
- Craftsman "marked" goods they made with second mark to track origin of goods
- Eventually "mark" came to represent craftsman's reputation



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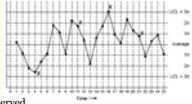


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Walter Shewhart

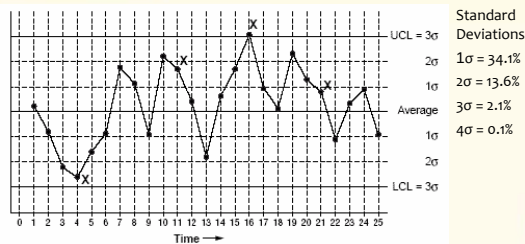


- Bell Labs needed improved reliability of buried equipment
- Dr. Shewhart
 - Developed concept of statistical control
 - Developed control charts
 - Differentiated common cause vs. special cause
- By eliminating special cause:
 - Predict output
 - Manage process economically



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Control Chart



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W. Edwards Deming



- US Dept of Agriculture (USDA) & Census Bureau, statistician
- Dr. Deming
 - Assisted US, WW II effort w/ statistical control
 - Sent to Japan by USDA to aid in post war recovery
 - Major influence in Japan's transformation from "Japanese junk" to high quality products



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W. Edwards Deming



- Deming's "version of the national anthem, which addresses people's inability to hit all the notes, serves as a metaphor for one of his points for management:
- Don't blame the singers (workers) if the song is written poorly (the system is the problem); instead, rewrite the music (fix the system). In life and in art, Deming simply wanted to make it easier for people to sing."



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Joseph M. Juran

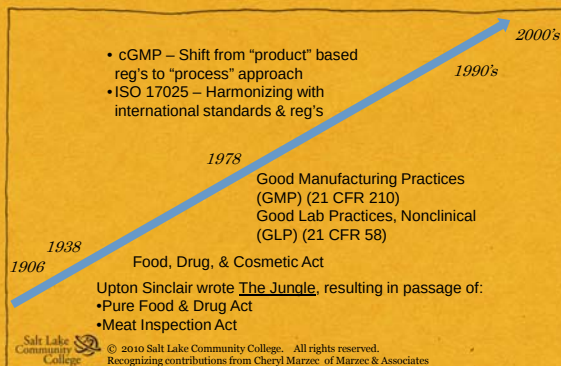


- **Total quality** not just product quality
- Dr. Juran
 - Taught Japanese managers quality principals in 1950's
 - Predicted quality of Japanese goods would overtake US's by mid-1970's
 - Wrote THE book on quality Juran's Quality Handbook



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Laboratory Regulation



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Key Concepts



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Planning

Organizational Planning

Strategic

Long-range strategies

Tactical

Strategy → Action

Operational

Day-to-day operations

Quality Planning

- Dependant on the output of each phase or organizational planning
- Focus on meeting customer's requirements

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Employees



Involved Employee

- Brings issues to management's attention
- Seeks approval to make changes

Empowered Employee

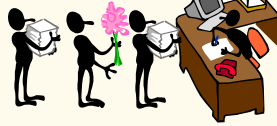
- Have authority to take action, within boundaries



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Employees

Job Enlargement



Job Enrichment



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Variation – Special Cause

Special cause (15% of variations)

- Something unexpected resulted in variation
Ex. – Increased demand for product. Product didn't ship to the customer on time.
Shipping dock was closed due to vandals breaking into the shipping area & damaging loading equipment.
- Process modification not required



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Variation – Common Cause

Common cause (85% of variations)

- Process operating as designed; variation is natural part of the process
Ex. – Increased demand for product. Product shipped to the customers on time.
Temporary over-time authorized to meet demand.
- Process remained in control



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Variation – Out-of-Control

Common cause (85% of variations)

- Process operating as designed; variation is natural part of the process
Ex. – Increased demand for product. Product didn't ship to the customers on time. Failure to anticipate increased demand.
- Change to process may be needed, w/ management's support



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Variation – Tampering

Common cause (85% of variations)

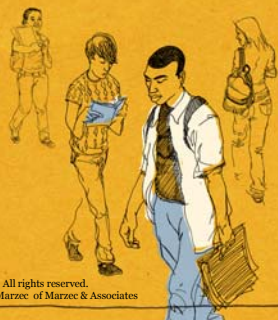
- Process operating as designed
Ex. – Increased demand for product. Product didn't ship to the customers on time. Temporary help brought in. Didn't understand processes; slowed production even more.
Change was not adequately evaluated before implementation



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Marble Exercise

- Why collect data, analyze it, & make changes in a controlled manner?
- This exercise will help illustrate the reasons why.

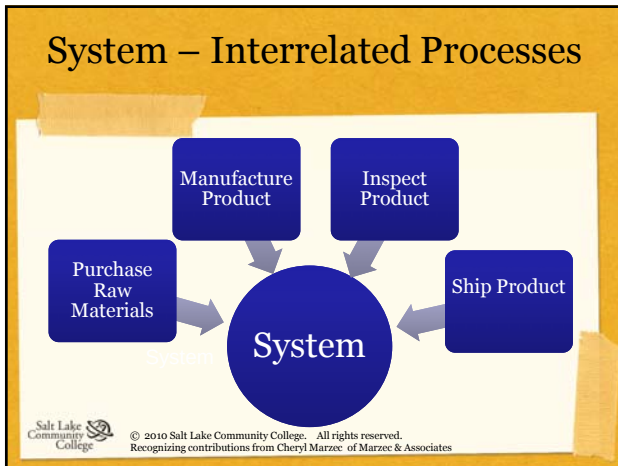


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Systems & Processes



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Quality Systems Today

Quality Mega Tools	Process or System Approaches
• Total Quality Management (TQM) • Lean Manufacturing (Lean) • Six Sigma (6σ) – Developed by Motorola, Baldrige winner	• ISO 9000 Quality System Management – <i>Achievable by any company</i> • Malcolm Baldrige National Quality Award (MBNQA) – <i>Achievable by very few</i>

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Quality & Regulatory Management Systems Introduction



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Quality Systems

- Total Quality Management (TQM)
- Lean Manufacturing (Lean)
- Six Sigma (6σ)

Process or System Approaches

- **ISO 9000 Quality System Management**
- Malcolm Baldrige National Quality Award (MBNQA)

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Regulatory Systems

FDA , CFR Title 21,
Part 58 Good
Laboratory Practice
for nonclinical
Laboratory Studies

FDA , CFR Title 21,
Subchapter H –
Medical Devices, Part
820 Quality System
Regulation

or
cGMP

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What is TQM?

Popularized in the 1980's

Organization-wide approach to quality

Goal – provide world-class products/services to customers, internal & external

- Identify a problem
- Assemble a team
- Define the problem
- Use quality tools to develop solution(s)
- Implement solution(s)



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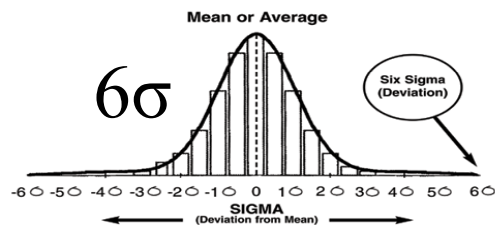
TQM Pitfalls

- Who identifies the problem?
- Team may find good solution, but typically no formal mechanism for implementing change
- People based, not process based



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Six Sigma

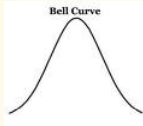


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Six Sigma

6 σ

- Developed by Motorola
- Widespread industry use today
- Quality measure striving for near perfection (>3.4 defects / 10^6)
- Provides organizations tools to improve capability of their processes



Two project methods – DMAIC & DMADV



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Six Sigma Attributes

- Decisions based on data, not assumptions & guesswork
- Focus of achieving measurable & quantifiable financial returns
- Emphasis on management leadership & support
- Special infrastructure of champions, “Black Belts”, to lead & implement



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DMAIC – Existing Processes

Define project goals & customer (internal & external) deliverables



Measure the process to determine current performance



Analyze & determine the root cause of defects



Improve the process by eliminating defects



Control the future process performance



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DMADV

Define project goals & customer (internal & external) deliverables

Measure the process to determine current performance

Analyze & determine the root cause of defects

Design the process to meet customer needs

Verify the design performance & ability to meet customer needs



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When to Use DMADV

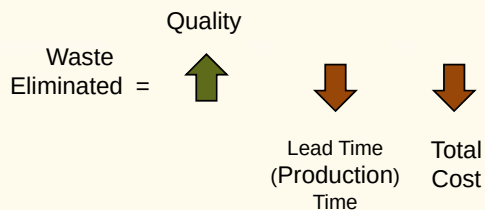
Product or process doesn't already exist, but there is a need

Existing product or process has been optimized, but doesn't meet customer specification or 6σ



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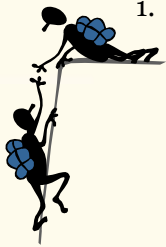
Lean Results



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Lean Enterprise Goals

1. Improve Quality



Understand what customers
require & expect
Design processes to meet
them



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Lean Enterprise Goals

2. Eliminate Waste

- Over Production
- Waiting
- Unnecessary Transport
- Extra Processing
- Excess Inventory
- Extra Motion
- Defects

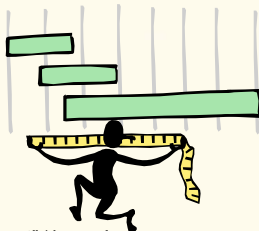


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Lean Enterprise Goals

3. Reduce Lead Time

- Cycle Time
- Batch Delay
- Process Delay



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Lean Enterprise Goals

4. Reduce Total Costs

- Variable – Cost of **doing** business (manufacturing, raw materials, transportation, etc.)
- Fixed – Cost of **being** in business (design, advertising, overhead, etc.)



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Delicate Balance

Just-in-time (JIT)–
Reducing inventory,
but maintaining a
smooth work flow

Getting the right things,
to the right place,
at the right time,
in the right quantity



Pitfall – Not a
process
approach



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Baldrige Purpose



- Stimulate American companies
- Recognize companies that improve product/service quality

- Establish guidelines & criteria for self evaluation
- Provide models (winning companies) for managing for high quality



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Baldrige Criteria

- Leadership
- Strategic planning
- Customer & market focus
- Measurement, analysis, & knowledge management
- Human resource focus
- Process management
- Results

Can be used by any organization to improve quality



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Malcolm Baldrige



- Secretary of State during early 1980's
- Proponent of quality management as key to US prosperity & long-term strength
- Helped draft early version of the award
- Professional team roper
- Installed in the National Cowboy Hall of Fame
- Died in a rodeo fall, 1987



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Baldrige & ISO 9000 Similarities

- Came into being in 1987
- Provided a framework for improving quality
- Process based
- Elevated the status of quality



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Why ISO 9000 ?

- Standard, not an award
- Internationally recognized
- Foundation for QMS
- ISO 9001 structure used by many standards
- Common quality language



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ISO 9000 QMS Principles

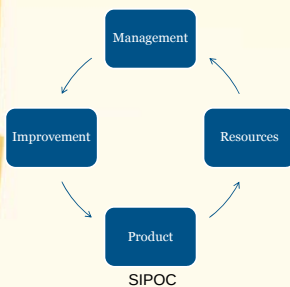
- Customer orientation
- Leadership
- Involvement
- Process management
- System management
- Continual improvement
- Fact-based decisions
- Close supplier relationships



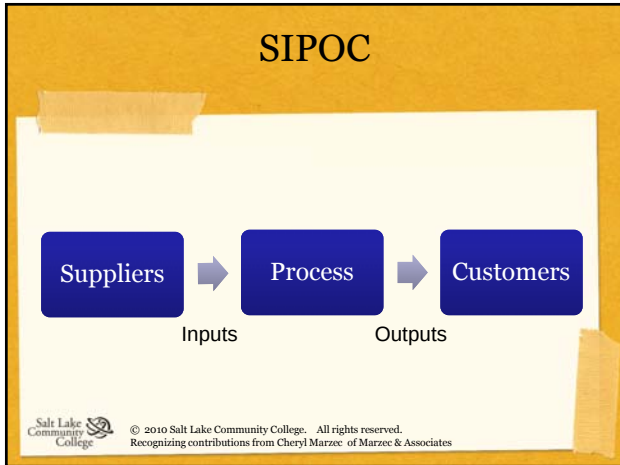
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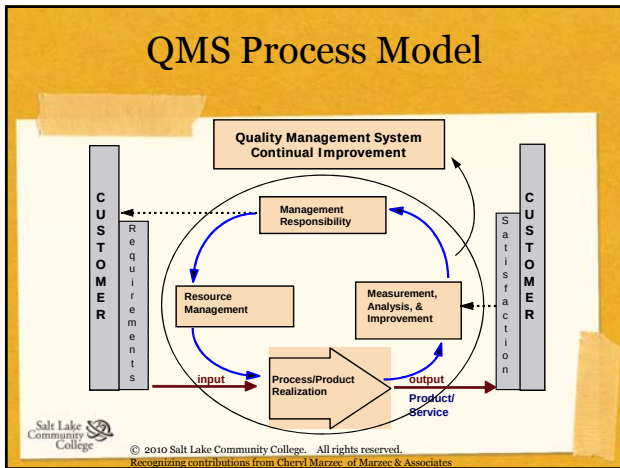
QMS Characteristics

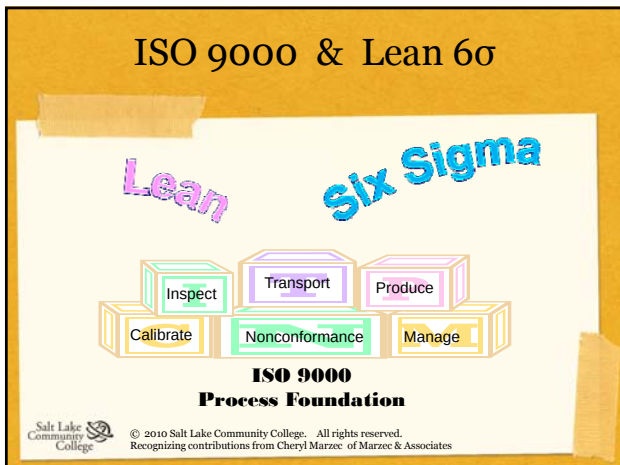
- Systematic approach to quality
- Not just for manufacturing organizations
- Not just inspection-based
- Includes all aspects of an organization



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Understanding Teams



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A Team Is:

Group of organized individuals working toward a common objective

Small number of people equally accountable for accomplishing a task or goal

Small number of people w/ complementary skills committed a common purpose

Combines individuals' knowledge, experience, skills, & attitude in a synergistic effect

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A Team Is Not:

An organizational work unit

A crowd of people or informal gathering

A club, association, or society

An organization's management

Staff meetings, conferences, seminars, or courses

Unless the above are functioning as a TEAM

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Why Initiate a Team?

- Process improvement
- Complete a project
- Solve a problem
- Produce a special event
- Investigate a discrepancy
- Participate in a competitive sport



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Purposes of a Team

The objective involves more than one organization or function (Purchasing, Inspection, Stores)

A degree of isolation from the rest of the organization will help maintain focus on the objective or problem (long term project)

People w/ specific training & experience need to be on-call when a need or problem arises that requires their skills (proposals, design reviews)



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How Long Should a Team Meet?

- Predetermined period
- Resource availability
- Purpose of the team
- Progress being made
- Value of the planned outcome
- Effectiveness of the team



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It Doesn't Last Forever!



- Company policy may limit the a team may exist
- Comradeship may develop so team finds reasons to continue after the project is complete



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Team Types



- **Natural Team** – work group, department, or function w/ a common purpose or function
- **Process Improvement Team (PIT)** – Focus on writing, revising, or improving a process
- **Cross-Functional Team** – May be a PIT focused more on overall processes within an entire organization



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More Team Types

- **Project Team** – Formed to complete a specific mission (implement ISO 9001, create a new product/service/facility)
- **Self-Directed Teams (Self-Managed)**– Groups authorized to make decisions about issues within the bounds of their authority (Safety, quality, scheduling, equipment/standards maintenance)
- **Virtual Teams** – Hybrid team that works electronically



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Team Value

No team should be formed unless its purpose supports the organization's strategies, plans, & objectives



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Team Roles & Responsibilities



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Team Member Roles

- **Champion** - Advocate who initiates a concept or idea for change
- **Sponsor** – Backer who supports the team
- **Team Leader** – Change agent who:

Staffs the team	Entrusted to lead
Participates	Communicates w/ mgt
Takes responsibility	Has authority
Handles logistics	Responsible for records



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Team Member Roles (cont.)

- **Facilitator** – Helper/advisor who:
 - Observes team processes & suggests changes to Leader
 - Intervenes when multiple conversations develop
 - Prevents individual from dominating the team
 - Assists Leader in closing discussions
 - May provide team with training



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Team Member Roles (cont.)

- **Time Keeper** – Monitor who helps team keep track of time
- **Scribe** – Note taker who records critical data & formal minutes (if required), & distributes it
- **Team Members** – Participants/SMEs who work together to bring about change or improvement

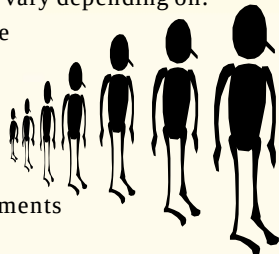


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Team Size

Ideal size ~5, but will vary depending on:

- Urgency of outcome
- Organization size
- Team type
- Mission
- Org's culture
- Regulatory requirements
- Etc.



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Perils & Pitfalls

- Team mission not linked to organizations strategic direction or goals
- Lack of management commitment
- Members lack the needed competence
- Inadequate leadership
- No team building
- Nonexistent or inadequate rules
- And many, many more



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What Makes a Team Work?

- All members agree on the expected outcomes
- Members accept their assigned responsibilities
- Members have access to what is needed to get the job done; information isn't hoarded
- Members are clearly committed & understand their roles
- Team conflict managed
- Members feel they make a difference



Etc.



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Team Formation & Group Dynamics



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Forming a Team

- Formal charter
 - Purpose
 - Sponsor
 - Approval & funding
 - Criteria for member selection
 - Methods & technology
 - Degree of autonomy & empowerment boundaries
 - Constraints
 - Beginning & end time/point



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Forming a Team (cont.)

- Applicable project planning & management tools
- Implemented tracking, measuring, & reporting procedure
- Criteria for risk assessment, contingency plans, & periodic assessments
- Means to recognize, reinforce, & reward the team for good work



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Selecting Team Members

- Selection can make or break a team
- Look at knowledge & past achievements
- Get referrals from others

Refer to Table 4.1, pg 48, of The Quality Improvement Handbook for roles, responsibilities, & performance attributes



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Team Stages – 1. Forming

Forming – Members are trying to establish their position on the team

- Be clear about the purpose of the team
- Identify members roles
- Establish criteria for acceptable behavior



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Team Stages – 2. Storming

Storming – Members are still acting as individuals; defenses are still up; uncertainty may still exist

- A good team leader can be vital to keep the team focused on their goal rather than redefining it



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Team Stages – 3. Norming

Norming – Members shift from dwelling on personal agendas & address the objectives of the team; the team gets rolling

- Potential danger that members may withhold ideas for fear of reintroducing conflict
- A good facilitator can use various tools & techniques for drawing members out



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Team Stages – 4. Performing

Performing – Members understand the strengths & weaknesses of each member; progress is clear & achievement of the goals & objectives in sight

Note: a team may drop back to an earlier stage if something disturbs its growth



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Team Barriers



- Conflict can occur at any point in a team, but is more common during the “forming” & “storming” stages
- Conflict can be positive as a sign of change or movement
- Approach conflict as an opportunity to learn & move forward



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The End



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Exercise/Quiz

1. Think of a team you've participated on recently
2. Complete the information on the Team Exercise sheet.
3. This exercise will be due at the beginning of the next class



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Tools



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Tools

- | | |
|--------------------------------|------------------------|
| * Affinity diagram | Arrow Diagram |
| * Audit | Benchmarking |
| * Brainstorming | Cause & Effect Diagram |
| * Check sheets | Consensus |
| Continuous Quality Improvement | |
| * Control Chart | Cost of Quality |
| Design of Experiments | * Five Whys |
| * Flowchart | Focus Group |

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Tools (cont.)

- | | |
|--------------------------------|-----------------|
| Force-Field Analysis | Gant Chart |
| * Histogram | Matrix Analysis |
| Matrix Diagram | Multi Voting |
| Nominal Group Technique | |
| * Pareto Diagram | * PDCA or PDSA |
| Poka-Yoke | |
| Process Decision Program Chart | |
| Quality Function Deployment | |

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Tools (cont.)

- * Radar Diagram Relations Diagram
- Resource Allocation Matrix
- * Run Chart Scatter Diagram
- Stratification Total Quality Management
- * Tree Diagram



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Affinity Diagram

Gathering & grouping ideas

- Creatively generate large number of ideas/issues
- Organize & summarize natural groupings
- Understand the essence of a problem
- Identify breakthrough solutions



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Arrow Diagram (Activity Network Diagram)

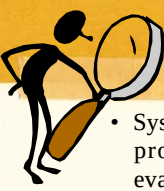
Scheduling sequential & simultaneous tasks

Graphically shows:

- Sequenced plan
- Most efficient path
- Parallel vs. serial tasks
- Realistic project schedule



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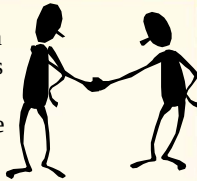
Audits

- Systematic, independent, documented process for obtaining evidence & evaluating it to determine the extent to which audit criteria are fulfilled
- Determine if quality activities & results comply with planned arrangements
- Determine if planned arrangements are implemented effectively

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Benchmarking

An organization compares its own performance for a specific process with the “best practice” of a recognized leader in a comparable process



- Large scale project
- Identify short comings
- Establish baseline or standard to measure its progress

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Brainstorming

Creating bigger & better ideas

- Method for creatively & efficiently generating a high volume of ideas on a topic
- Free of criticism & judgment



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Cause-&-Effect Diagram (Fishbone or Ishikawa Diagram)



Find & Cure causes, NOT symptoms

- Identify, explore, & graphically show all possible causes of a problem to discover its root cause(s)



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Check Sheets

Counting & accumulating data

- Systematically record & compile data so patterns & trends can be detected

Reason	Day					
	Mon	Tues	Wed	Thurs	Fri	Total
Wrong number						20
Info request						10
Boss						19
Total	12	6	10	8	13	49



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Consensus

Group decision making

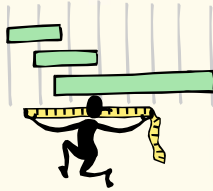
- Everyone must agree with the groups decision
- If anyone desents, group continues to work toward agreement or something they can "live with & support"



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Continuous Quality Improvement (CQI)

- Managed approach to improving & maintaining quality
- CQI uses most of the quality tools at one time or another

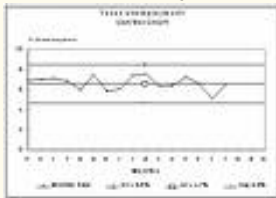


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Control Charts

Recognizing sources of variation

- Measures sequential or time-related process performance & variability



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Cost of Quality

Method for determining extent to which an organizations resources are used for activities that prevent poor quality

- **Prevention costs** – incurred to prevent or avoid quality problems
- **Appraisal costs** – associated with measuring & monitoring quality activities
- **Internal failure costs** – incurred to remedy defects discovered before delivery to customer
- **External failure costs** – incurred to remedy defects discovered by customers



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Design of Experiments

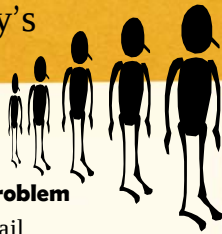
Structured way to characterize processes

- Strategy for planning research:
 - Identify key characteristics impacting quality
 - Run a limited number of tests
 - Collect & analyze data
- Managers can use knowledge to build quality in at earliest stages of design



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Five Why's



Determining root causes of a problem

1. Describe the problem in detail
2. Ask why it happens
3. If answer isn't the root cause, ask why again
4. Continue to ask until the root cause(s) is identified, about five times

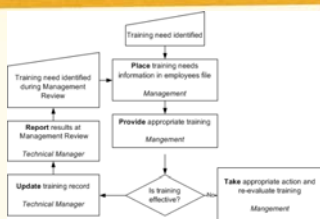


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Flow Charts

Picturing the process

- Identifies flow or sequence of steps
- Defines process boundaries
- Creates common understanding of a process
- Can be applied to anything



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Focus Group

- Customer-oriented approach for collecting information
- Participants, unfamiliar with each other, meet to discuss & share ideas about an issue
- Helpful for understand beliefs & perceptions of population represented by the group



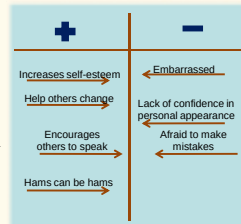
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Force Field Analysis

Positives & negatives of change

- Used to identify forces & factors that support or work against the solution
- Positives can be reinforced
- Negatives eliminated or reduced

Ideal state: To speak confidently & clearly in any situation



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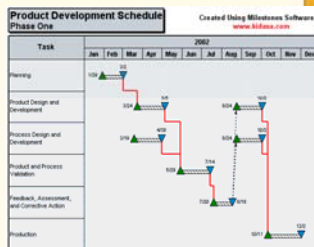
Gantt Chart/Activity Network

Plan & control work

Used to identify:

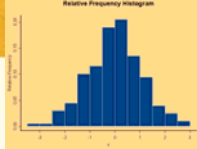
- Critical tasks
- First task to complete
- Next task to complete
- Tasks that can be started simultaneously
- Task durations

Monitor progress



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Histograms



Process centering, spread, & shape

- Summarizes data gathered over time
 - Graphically presents its frequency distribution
- Interpret by asking:
- Process performance w/in specified limits?
 - Does process exhibit wide variation?
 - If action is needed, what action is appropriate?



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Matrix Diagram & Analysis

Finding Relationships

- Systematically identify, analyze, & rate presence & strength of relationships between two or more sets of information

Customer requirement Process	Polite service	Menu	Quick service	Clean
Waiting on tables	Strong		Strong	Medium
Buying		Strong		
Janitorial	Weak			Strong
Food preparation		Medium	Strong	

May be multidimensional matrix



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Multi Voting

Highest priority items

- Avoids a win-lose situation
- Separates “vital few” from “useful many”
- Most useful with large groups & long lists
- Tabulate w/ Check Sheet

10 team members have
5 votes each

Color Choices	1 st vote	2 nd vote
Pink		
Green		
Blue		
Red		
Tan	I	
Purple		
Orange		
Salmon		
Gold		



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Nominal Grouping Technique

Ranking for consensus

- Come to consensus quickly
- Shows relative importance of issues, problems, or solutions
- Everyone has an equal voice

Each team member ranks colors 1-5

Color Choices	Ranking	Total
Pink	4+3+2+2+5	16
Blue	2+2+4+1+1	10
Gold	3+5+2+3+4	17
Red	1+1+3+5+2	12
Purple	5+4+5+4+3	21

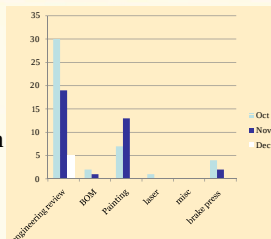


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Pareto Charts

Focus on key problems

- 20% of sources cause 80% of any problem
- Graphic representation of an event frequency
- Focus on items of greatest importance
- Progress is highly visible

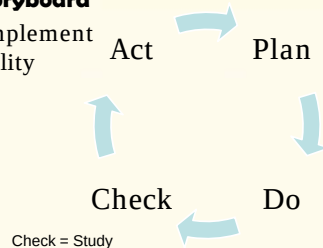


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PDCA

Improvement storyboard

- Key steps to implement & evaluate quality improvement



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PDCA (cont.)

Plan

- Select problem/process to address first
- Describe the improvement opportunity (problem)
- Describe current process (collect data)
- Describe all possible causes (root cause analysis)
- Develop solution & action plan



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PDCA (cont.)

Do

- Implement solution or process change; often done in a limited or controlled environment

Check or Study

- Review & evaluate the result; is solution having the intended result

Act

- Reflect & act on lessons learned; celebrate success

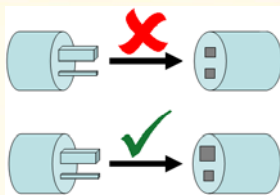


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Poke-Yoke

Mistake proof

- Create process that prevents mistakes
- E.g., part fits into assemble only one way; impossible to place in assemble any other way

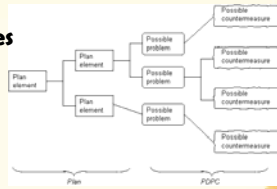


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Process Decision Program Chart

Anticipate outcomes & prepare countermeasures

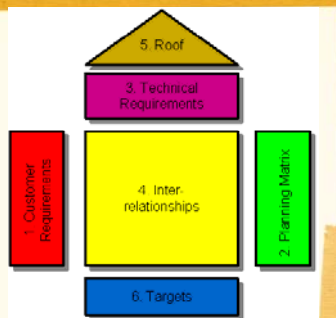
- Method for identifying possible problems so countermeasures can be developed, which lead to the best solution



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Quality Function Deployment (House of Quality)

Transform Voice of Customer into design specifications

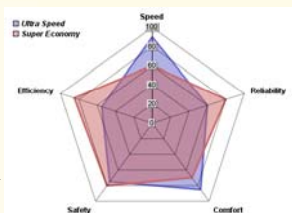


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Radar Charts

Rating performance

- Makes strengths & weaknesses visible on one graph
- Captures different perceptions of team members



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[illegible]

Resource Allocation Matrix

Finding Relationships

- Variation on the matrix chart
- Useful for planning the allocation of resources



A black stick figure is depicted in a dynamic pose, resembling a ballerina. It has one leg extended to the side and another bent, with its arms raised in a graceful arc. It is wearing a large, multi-layered pink tutu. The figure is positioned on the right side of the slide.

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Run Charts

- Line graph used to observe data for trends or patterns over time

Month	Value (%)
Jan	60
Feb	68
Mar	72
Apr	65
May	55
Jun	62
Jul	70
Aug	85
Sep	78
Oct	82
Nov	75
Dec	88

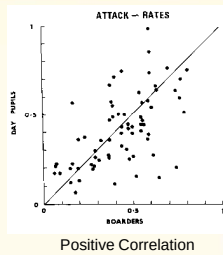
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Scatter Diagram

Measuring relationships between variables

- Shows possible correlation between changes observed in two variables
- May have positive, negative, or no correlation

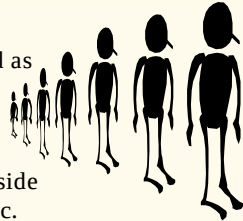


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Stratification

Separate & analyze data from many sources

- Complaint data collected as a single figure
- More useful to break in meaningful categories; office staff, field reps, inside salesmen, accounting, etc.



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Total Quality Management

Set of management practices

- Approach to quality management that emphasizes thorough understanding by everyone
- Not a tool, but utilizes many tools

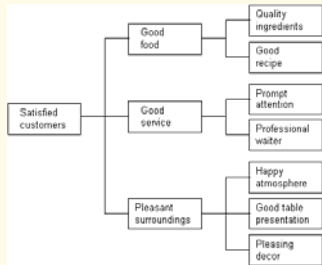


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Tree Diagrams

Mapping tasks for implementation

- Break a broad goal into increasing levels of detailed actions



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Continuous Improvement



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Incremental & Breakthrough Improvement



Two different fundamental improvement philosophies

1. Improvement is achieved gradually, one step at a time
2. Throw out the old and in with the new, process reengineering

Goal – eliminate waste



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Incremental Improvement

1. Select a process
2. Define the process
3. Map the main flow
4. Add decision points & alternative paths
5. Add check points
6. Analyze the flow
7. Prioritize problems
8. Redo process map
9. Do desktop walk through
10. Modify process map
11. Review changes & get approvals
12. Institute changes
13. Review results
14. Change if needed
15. Next process please



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Breakthrough Improvement

1. Have strong, committed leaders support
2. Form high-level, x-functional team
3. Create macro-level process map
4. Select one major process to reengineer
5. Form x-functional reengineering team
6. Examine customers' requirements & wants
7. Understand current process from customer's perspective



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Breakthrough Improvement

8. Brainstorm fulfilling customer's needs
9. Create breakthrough process
10. Test-drive new process w/ small group
11. Collect feedback
12. Modify process & communicate changes
13. Plan controlled rollout
14. Implement rollout
15. Evaluate effectiveness of redesign



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Improvement Cycle

- Action, taken as the result of organized, planned effort that makes a process better
- Not just fire fighting or crisis management
- Cycle has two parts
 - Process simplification
 - Plan – Do – Check – Act



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Improvement Cycle - Simplify

Process simplification

1. Select process & establish improvement objective
2. Organize the “right” team
3. Flowchart current process
4. Simplify process & make changes
5. Develop data collection plan & establish baseline
6. Is process stable? If no, go to Step 5
7. Is process capable? If yes, go to Step 14



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Improvement Cycle - PDCA

Plan – Do – Check – Act

8. Perform root cause analysis
9. Plan process change implementation
10. Modify data collection plan, if necessary
11. Test change & collect data
12. Is process stable? If no, remove change
13. Did process improve?
14. Is further improvement feasible?



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Problem Solving Process

1. Define problem
2. Collect, analyze, & prioritize data; perform root cause analysis
3. Identify possible solutions
4. Select best solution
5. Develop action plan
6. Implement solution
7. Evaluate effectiveness of solution

Corrective Action
in ISO 9001 terms



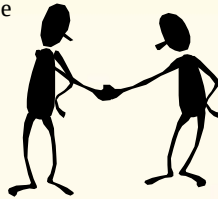
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Customer - Supplier Relationships

Internal Customers – Those within the organization

External Customers – Those served by or who receive products from the organization

These relationships are covered further in ISO 9001



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Tools Exercise, In Class

Tools we'll use:

- PDCA
- Flowchart
- Brainstorming
- Check Sheet
- Radar Chart



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Tool Selector Chart, Page vi

- Working with Ideas
- Working with Numbers
- Working in Teams



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How the Jogger is Organized

- Why use it?
- What does it do?
- How do I do it?
- Tips
- Variations
- Examples



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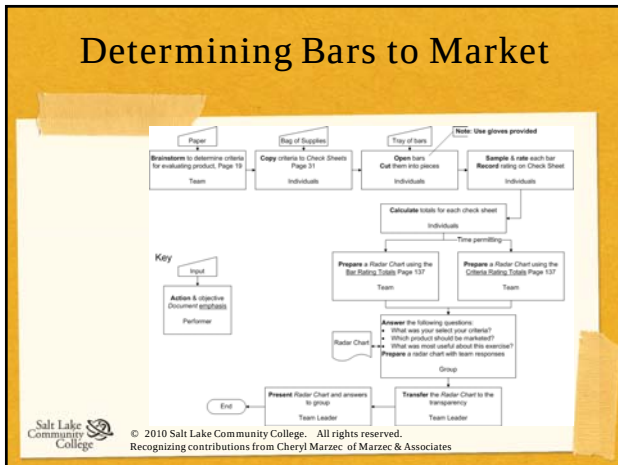
Marketing Problem

- Use Plan – Do – Check – Act, page 115
- Which product has the best chance of success?
 - Determine analysis criteria - Brainstorming
 - Collect data – Check Sheets
 - Analyze – Radar Charts
 - Develop a plan



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Determining Bars to Market



Breakthrough Improvement

1. Have strong, committed leaders support
2. Form high-level, x-functional team
3. Create macro-level process map
4. Select one major process to reengineer
5. Form x-functional reengineering team
6. Examine customers' requirements & wants
7. Understand current process from customer's perspective

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Brainstorming, Page 19

- Structured – Page 20
- Unstructured – Page 21
- Tip – Write ideas on Post-Its, organize an Affinity Diagram to determine criteria – Page 12



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Check Sheet, Page 31

- Determine scale team will use
- Each person:
 - Create a check sheet
 - Record rating criteria down left side
 - Record bar types across top
 - Sample products
 - Record results
 - Total results



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Radar Chart, Page 137

- Construct chart
- Use stickers to mark individuals' bar ratings on spokes
- Determine team rating
- Interpret results
- Prepare transparencies with team rating



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Validity of Bar Ratings (option)

- Prepare second Radar Chart
- Mark maximum & minimum ratings on each spoke
- Shade the area between ratings
- What does the shaded area (variation) tell you about the validity of each bar rating?



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Validity of Criteria (option)

- Prepare Radar chart as before substituting criteria ratings for bar ratings
- What does the shaded area (variation) tell you about the validity of each criteria rating?



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So, now what?

Use these tools

Review the “Tool Selector Chart” next time you have occasion to use tools

Try new tools

Try variations of your usual tools



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Quality Management Systems (QMS) & Reg's – The Nuts & Bolts



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Document Types

ISO	FDA
Requirements documents	Regulations
Guidelines	Guidelines
Technical Reports	Points to consider



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US & International Standards

International (includes Canada)	US
International Laws	Laws
ISO 17025:2005 – General Requirements for the Competence of Testing & Calibration Laboratories CAN-P-4E (Canadian adoption)	FDA, CFR 21, Part 58 – Good Laboratory Practice for Nonclinical Laboratory
ISO Guide 25 – General Requirements for the Competence of Testing & Calibration Laboratories (Obsoleted by ISO 17025)	N/A
ISO 13485:2003 – Quality Management Systems – Requirements for regulatory purposes	FDA, CFR 21, Part 820 – Quality System Regulations for Medical Devices



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ISO 9001 Structure



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ISO 9001 Structure

1. Scope
2. Normative References
3. Terms & Definitions
- 4. Management system**
- 5. Management requirements**
- 6. Resource requirements**
- 7. Product & service realization**
- 8. Measurement, analysis, & improvement**



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4. Quality Management System



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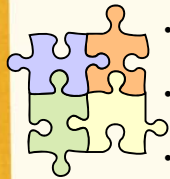
4. Quality Management System

- Identify needed processes
- Determine sequence & interaction
- Develop methods to determine process effectivity
- Ensure resources & info are available to support processes
- Monitor, measure, & analyze processes
- Implement actions to achieve planned results
- Continually improve processes



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Document Puzzle



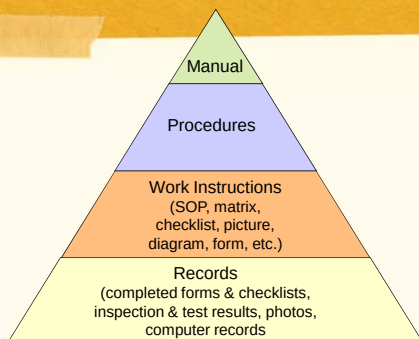
- Write a short manual about your company
- Prepare & implement procedures & work instructions (SOP)
- Maintain records that verify you did what you were supposed to do
- Monitor & ,measure your processes so you can improve them

If it isn't recorded, it didn't happen!



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QMS Documents



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ISO Required Processes

- Control of Records
- Production & Service
- Monitoring & Measuring Devices
- Nonconforming Product/Service
- Corrective Action
- Preventive Action
- Other procedures are "as needed"



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FDA Document Organization

Part 58, GLP

- A. General Provisions
Any thing goes from here
- B. Organization & Personnel

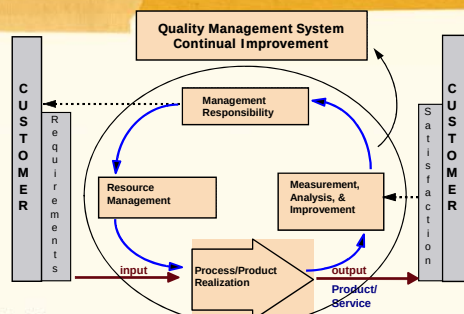
Part 820, cGMP

- A. General Provisions
Any thing goes from here
- B. Quality System Req's



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QMS Process Model



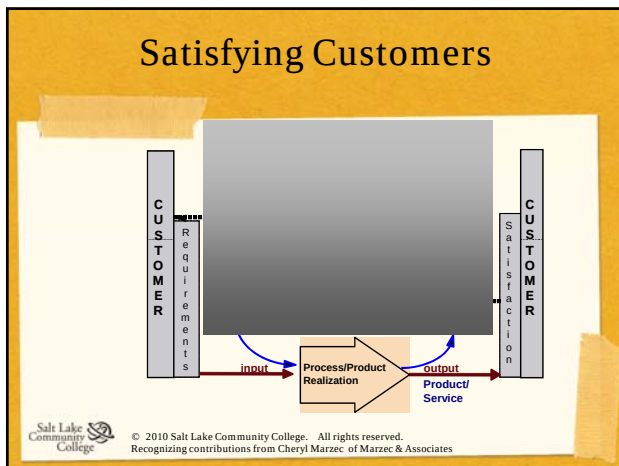
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Customer Satisfaction

Addressed in various sections

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Satisfying Customers



Providing Products & Service Customer's Want



Customer Requirements

What do your customers want?
Are their requirements being met?

- Top Management – ensure customer requirements are identified & met?
- Departments – determine quality objectives & requirements for product
 - Include requirements not stated, but necessary
 - Address statutory & regulatory requirements
 - Include any pertinent requirements

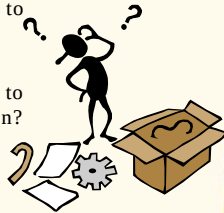


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Customer Satisfaction

• Was your customer satisfied?

- How is customer feedback gathered, analyzed, and used to continually improve?
- Is management reviewing customer feedback & using it to improve customer satisfaction?



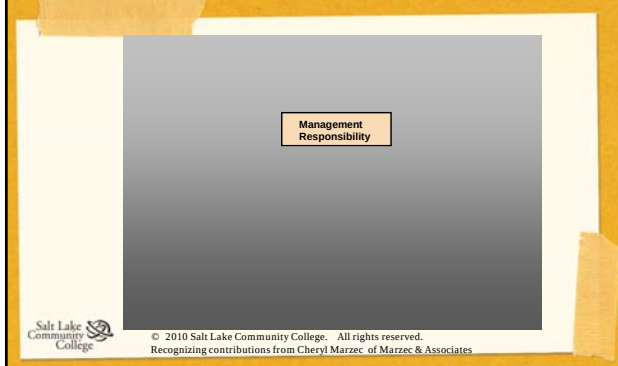
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5. Management Responsibility



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5. Management Responsibility



Management Responsibility



Mgt. Responsibility (cont.)

- Commitment to QMS & continual improvement
- Define authority, responsibility, & communication
- Focusing on the customer

★ Improve Communication

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Mgt. Responsibility (cont.)

- Hold periodic Mgt. Reviews of QMS
 - Customer feedback Changes
 - Audit results Corrective actions
 - Process performance Product conformity
- Purpose
 - Improve processes
 - Improve products
 - Identify needed resources



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6. Managing Resources



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6. Resource Management

Resource
Management



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Resource Mgt. (cont.)

Ensure the organization has adequate resources to:

- Implement the quality system
- Continually improve its effectiveness
- Improve customer satisfaction

Are employees competent & trained?



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Resource Mgt. (cont.)

Ensure organization has adequate resources

- Infrastructure – workplace, equipment, software, supporting services, etc.
- Work Environment – safety, ergonomics, culture, temperature control, noise, cleanliness, etc.



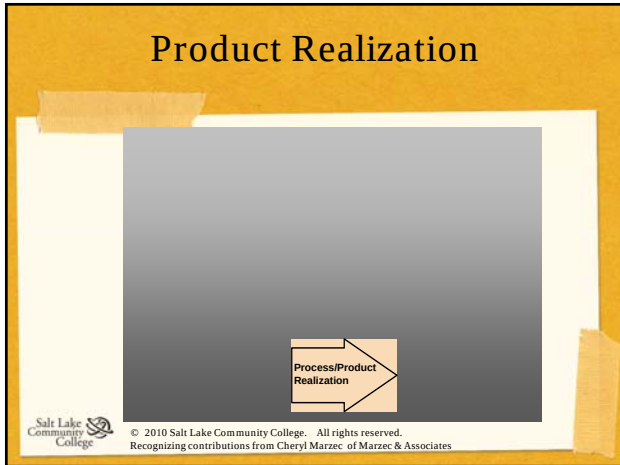
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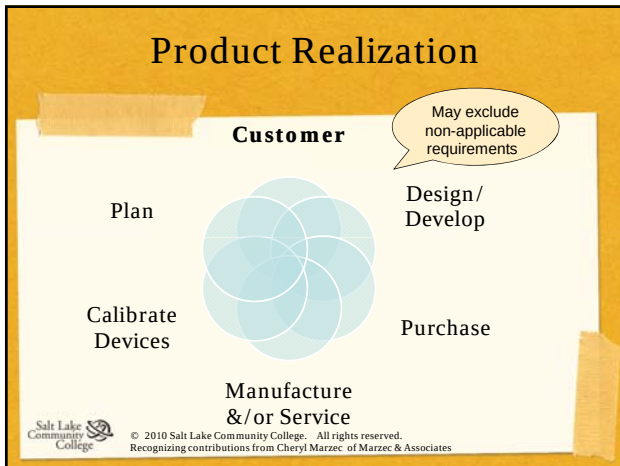
7. Product Realization

Producing Products & Providing Services



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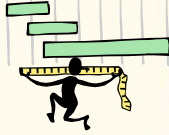




7.1 Planning

Some questions to answer:

- What are the quality objectives & requirements?
- Have we established processes, identified documents, & provided resources?
- How about verification, validation, monitoring, inspection & test activities?
- What records to we need to keep?



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7.2 Customer Related Processes

Some more questions to answer:

- Have we determined ALL the product/customer requirements?
- Have requirements been reviewed & any issues resolved?
- Is there a record of the review?
- Do we have an effective way of communicating with the customer?



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7.3 Design & Development

Design & Development Requirements

- Planned
- Inputs determined *
- Outputs provided so D&D can be verify
- Reviews performed as planned *
- Verification to ensure input req's are met *
- Validation of it's intended use *
- Changes reviewed & approved *



* Records maintained



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Research to D & D



Research

May or may not result in a product



Design & Development

Results in a product



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D & D



Planning
(User Needs)

Review &
Approval

Design Inputs

Verification

Design Outputs

Validation

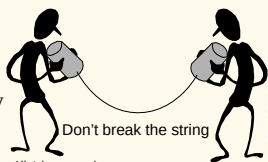
Product



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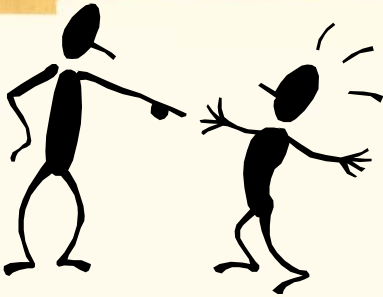
7.4 Purchasing (Includes Supplier Qualification)

- Good communications between supplier & company *imperative*
- Suppliers must meet be “qualified” to ensure they can meet the same stringent requirements as the company
 - Qualified
 - Monitored
 - Re-qualified periodically



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You are responsible for your suppliers work!



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7.4 Purchasing

Purchasing info must include, as appropriate:

- Requirements for product, procedure, processes, or equip. approve.
- Personnel requirements
- QMS requirements



Inspection & test activities implemented to ensure purchased product meets requirements



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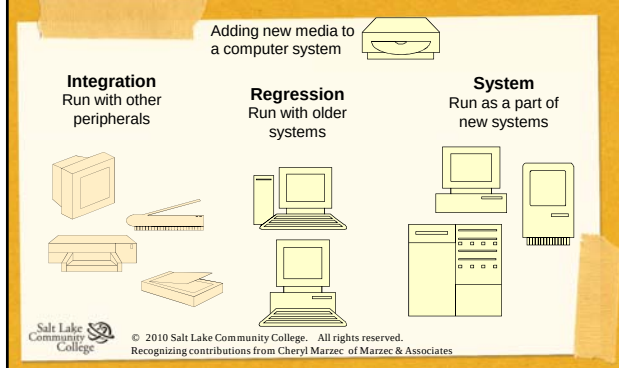
Inspection / Test

- Identify inspection/test points
 - Receiving inspection of raw goods & materials
 - In-process inspections at appropriate points
 - Final inspection
- Types of inspection/test
 - Regression
 - Integration
 - System



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Types of Test



7.5 Production & Service

- Maintain control of production & service
- Validate processes where results can't be verified *
- Identify & trace throughout production
- Customer property must be protected while on site; if unsuitable for use, notify customer *
- Preserve conformity of product until delivered to the customer

* Records maintained as per 4.2.4



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7.6 Calibration

- Calibrate devices according to schedule *
- If device is out of calibration: *
 - Identify product that could have been affected
 - Ensure produce conforms to requirements

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8. Measuring, Analyzing, & Improving



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8. Measurement, Analysis, & Improvement



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Measurement,
Analysis, &
Improvement

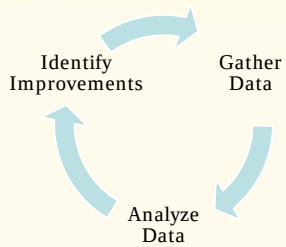
How do we do this?

- Gather data– customers, nonconforming product, audits, monitoring & measuring products & processes
- Analyze data
- Continually improve
 - Corrective actions
 - Preventive actions



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How do we do this?



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8.2 Monitoring & Measurement

- Gather information on customer perception; did we met their req's
- Perform internal audits *
- Monitor & measure processes; are desired results being achieved
- Monitor & measure product characteristics; are product req's met (e.g., inspections & tests) *

* Records maintained
as per 4.2.4



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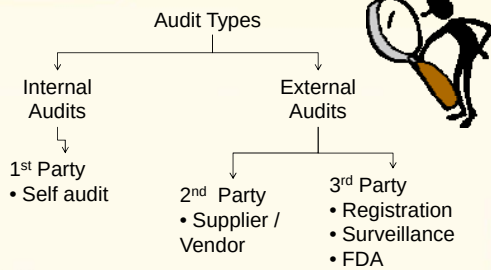
Audits

- Systematic, independent, documented process for obtaining objective evidence, to determine whether requirements are being met.



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Audits Types



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Regulatory Inspections (Audit)

1. Customer complaints or reported adverse reactions
2. Voluntary recalls
3. Deviations from product quality or product claim found by FDA
4. Manufacturing problem with raw materials or packaging components
5. Submission of a new drug application (NDA), biologic license, or premarket approval (PMA)
6. Current GMP inspection of manufacturing operations
7. Approval of a sterile product manufacturing operation



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8.3 Nonconformances

- If product doesn't conform to req's, is it identified & controlled to prevent its unintended use or delivery
 - Determine its disposition *
 - Eliminate the nonconformity
 - Accept under concession
 - Take action to preclude its original intended use
- * Records maintained as per 4.2.4



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8.4 Analyze Data

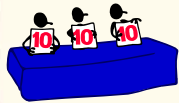
- Gather, collect & analyze data to ensure the QMS is effective
- Data includes:
 - Customer Satisfaction
 - Conformity to product req's
 - Characteristics & trends; opportunities for improvement
 - Suppliers

* Records maintained as per 4.2.4



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8.5 Improvement



Continually improve the effectiveness of the QMS through:

- Quality policy
- Quality objectives
- Audit results
- Analysis of data
- Corrective & preventive actions
- Management review



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Corrective Action

Goal – Eliminate the cause of nonconformity (N/C)

- Review nonconformity
- Take immediate action to contain the N/C
- Determine root cause of the N/C
- Develop & implement plan to eliminate the N/C
- Record the results of actions taken
- Verify the actions are effective



Timely Action!



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Preventive Action

Goal – Eliminate the potential nonconformity (N/C)

- Review potential nonconformity
- Develop & implement plan to prevent the N/C
- Record the results of actions taken
- Verify the actions are effective



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Improve Your System

Quality Management System
Continual Improvement



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The End



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