QUALITY PROCESS MANAGEMENT
Purpose

■ Introduce you to quality processes
■ What are the goals of quality processes
■ How can quality processes be applied for system development and design
■ How does this benefit regulatory requirements
Why Improve Quality?

- Better
  - Customer satisfaction
  - Safety
  - Costs
  - Yields (defects and waste)
  - Repeat business
  - More revenue
  - More profit
  - Competitive position

- Productivity
- Market Image
- Adaptability
- Job Security
- Employee morale
- Shareholder Value
- Innovation
Brief Timeline of Quality

Prior to 1910s
- Sporadic Inspection: Primary approach to quality
- Large impact on war effort (poor quality of weapons and armor in not solved by inspection)

WWI – 1950s
- Statistical and mathematical techniques developed and used
  - Sampling
  - Process Control Charts

1950s-1960s
- Post WWI Japan led quality control movement
- Goal: Zero defects
- Reliability and quality became part of engineering and development process
- TQM: Total Quality Management
Quality Today

- Emphasis is on strategic quality management
  - *quality is not an accident but is rather part of a plan and everyone’s responsibility*
- Internationally recognized importance
  - ISO 9001
- Various maturity models have been created to assess the ability of an organization to use repeatable processes and produce quality repeatable results
- It is always better to prevent a defect from occurring
  - *if you can’t do that, it is better to find the defect before your customer does*
  - *if your customer finds a defect, your quality processes are probably not working*
W Edwards Deming

- Adapted quality manufacturing work, originated by Walter A. Shewhart of Bell Labs, to wide scale production and management
- Recruited by post war reconstruction Japan and taught Japan’s chief executives that improving quality reduces expenses while increasing productivity and market share
- Techniques applied widely by Japanese industries; experienced previously unheard-of levels of quality and productivity at fraction of costs of US industries
- Rejected by US industry for decades
- Ford Motors first to adopt his management principals in the early 1980s
**PDSA Cycle:** The New Economics, 1993

- **Plan**
  - Begin with the end in mind
  - Establish the objectives/processes necessary to deliver results in accordance with the expected output/goals.

- **Do**
  - Execute the plan
  - Collect data

- **Study**
  - If Study phase confirms goals, Plan becomes baseline and cycle repeats

- **Act**
  - Compare actual results to expected results

Variations known as PDCA Cycle (Plan, Do, Check, Act) or Shewhart Cycle

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Dave Saunders, Galen Robotics
Results of PDSA Quality Cycle

Plan
Do
Study
Act

Continuous Improvement

Plan
Do
Act
Study

Updated Standards

Standard

Time

Quality

Illustration Adapted from Johannes Vietze

11/8/16  Dave Saunders, Galen Robotics
Six Sigma: Analytical Approach to Reduce Variation

**Sigma** = \( \sigma = \text{Deviation} \)

( Square root of variance )

![Diagram showing standard deviation and sigma levels]

- Between +/- 1\( \sigma \): 68.27% result: 317300 ppm outside (deviation)
- Between +/- 2\( \sigma \): 95.45% 45500 ppm
- Between +/- 3\( \sigma \): 99.73% 2700 ppm
- Between +/- 4\( \sigma \): 99.9937 % 63 ppm
- Between +/- 5\( \sigma \): 99.999943 % 0.57 ppm
- Between +/- 6\( \sigma \): 99.9999998 % 0.002 ppm

11/8/16 Dave Saunders, Galen Robotics
# 3 Sigma vs 6 Sigma

<table>
<thead>
<tr>
<th><strong>A 3 sigma Company</strong></th>
<th><strong>A 6 sigma Company</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Spends 15~25% of sales dollars on cost of failure</td>
<td>Spends 5% of sales dollars on cost of failure</td>
</tr>
<tr>
<td>Relies on inspection to find defects</td>
<td>Relies on capable process that don’t produce defects</td>
</tr>
<tr>
<td>Lacks disciplined approach to gather and analyze data</td>
<td>Uses Measure, Analyze, Improve, Control and Measure, Analyze, Design</td>
</tr>
<tr>
<td>Benchmarks against their competition</td>
<td>Benchmarks against the best in the world</td>
</tr>
<tr>
<td>99% is good enough</td>
<td>99% is unacceptable</td>
</tr>
</tbody>
</table>

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Lean Manufacturing (Lean Production)

- Management system that emphasizes
  - creating value for customers
  - continuous improvement
  - eliminating waste within a system
- Focused on customer value
- Elimination of waste (Muda)
  - Waste through overburden (Muri)
  - Waste through uneven workloads (Mura)
- Derived mostly from the Toyota Production System (TPS)

7 Muda
- Transport
- Inventory
- Motion
- Waiting
- Overproduction
- Over Processing
- Defects

Only the last turn of a bolt tightens it — the rest is just movement.
— Shigeo Shingo
Lean Six Sigma

- Lean moves the mean and Six Sigma reduces the variance
- Combines the statistical/analytical nature of Six Sigma with waste reduction and production improvement of Lean
FMEA: Failure Mode & Effect Analysis

- A tool used to identify and evaluate failure modes in a process or design
  - Help determine the causes of those failures
  - Help prioritize risks
  - Help develop mitigation strategies or change design to eliminate risk
  - Informs safety requirements, directions for use, parts tolerances, Standard Operating Procedures, critical features and even basic functionality

If this happens Then What
Types of FMEAs

- Design FMEA (DFMEA) – Product focused
- Process FMEA (PFMEA) – Process focused
Starting Point of FMEA: The Point

- What is the point/purpose/objective of the “thing”?  
- How can it be clearly defined?  
- Brakes  
  - Stop a car  
  - Slow a car  
  - Hold a car in position
FMEA Steps (High Level)

Define Failure Mode  Identify Root Cause(s)  Analyze  Act

Do this before starting to develop any part of your solution e.g., Look at a current medical procedure today. What failure modes exist? Do the mitigation strategies may be the features of a new product.
FEMA Steps

1. Identify modes of failure (Look at all realistic potential problems) e.g., car won’t stop, phone won’t turn on

2. Identify consequences & related systems for each mode e.g., car merged with wall, can’t play Clash of Clans

3. Rate severity for each effect (S) [1-10]

4. Identify potential root causes for each failure mode (Be specific) e.g., brake pads worn out, battery dead

5. Rate probability of occurrence of each root cause (O) [0 – 1]

6. Identify process controls and indicators (existing indicators and mitigators) e.g., iPhone popup for battery at 20%, brakes squeal, fuse blows

7. Rate detectability (D) of each mode/root cause [1-10]

8. Calculate Risk Priority Number (S*O*D) and criticality (S*O)

9. Use design to mitigate high-risk or highly critical failures, and reassess to ensure goals have been achieved e.g., Car doesn’t stop because brake pads are kaput and now it’s too late; add indicator to your design (#6)
Risk Assessment

- Green – no action required
- Yellow – develop a risk mitigation plan to lower probability or severity and monitor e.g., brakes squealing, audible indicator
- Red – develop risk mitigation and execute immediately e.g., hard hats, safety goggles, seat belts, safety barriers, ”force fuses”, no drinks in the robot lab
FMEA Severity Ranking

<table>
<thead>
<tr>
<th>Rating</th>
<th>Description</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>Dangerously high</td>
<td>Failure could injure a customer or employee</td>
</tr>
<tr>
<td>9</td>
<td>Extremely high</td>
<td>Failure would create noncompliance with federal regulations</td>
</tr>
<tr>
<td>8</td>
<td>Very high</td>
<td>Failure renders the unit inoperable or unfit for use</td>
</tr>
<tr>
<td>7</td>
<td>High</td>
<td>Failure causes a high level of customer dissatisfaction</td>
</tr>
<tr>
<td>6</td>
<td>Moderate</td>
<td>Failure results in a subsystem or partial malfunction of the product</td>
</tr>
<tr>
<td>5</td>
<td>Low</td>
<td>Failure creates enough of performance loss to cause the customer to complain</td>
</tr>
<tr>
<td>4</td>
<td>Very Low</td>
<td>Failure can be overcome with modifications to the customer's process or product, but there is minor performance loss</td>
</tr>
<tr>
<td>3</td>
<td>Minor</td>
<td>Failure would create a minor nuisance to the customer, but the customer can overcome it without performance loss</td>
</tr>
<tr>
<td>2</td>
<td>Very Minor</td>
<td>Failure may not be readily apparent to the customer, but would have minor effects on the customer’s process or product</td>
</tr>
<tr>
<td>1</td>
<td>None</td>
<td>Failure would not be noticeable to the customer and would not affect the customer’s process or performance</td>
</tr>
</tbody>
</table>
# Occurrence Ranking

<table>
<thead>
<tr>
<th>Rating</th>
<th>Description</th>
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<tbody>
<tr>
<td>10</td>
<td>Very High: Failure is almost inevitable</td>
<td>More than one occurrence per day or a probability of more than 3 occurrences in 10 events</td>
</tr>
<tr>
<td>9</td>
<td>High: Failures occur almost as often as not</td>
<td>One occurrence every three to four days or a probability of 3 occurrences in 10 events</td>
</tr>
<tr>
<td>8</td>
<td>High: Repeated failures</td>
<td>One occurrence per week or a probability of 5 occurrences in 100 events</td>
</tr>
<tr>
<td>7</td>
<td>High: Failures occur often</td>
<td>One occurrence every month or 1 occurrence in 100 events</td>
</tr>
<tr>
<td>6</td>
<td>Moderately high: Frequently failures</td>
<td>One occurrence every three month or 3 occurrences in 1,000 events</td>
</tr>
<tr>
<td>5</td>
<td>Moderate: Occasional failures</td>
<td>One occurrence every six month to one year or 5 occurrences in 10,000 events</td>
</tr>
<tr>
<td>4</td>
<td>Moderately low: Infrequent failures</td>
<td>One occurrence per year or 6 occurrences in 100,000 events</td>
</tr>
<tr>
<td>3</td>
<td>Low: Relatively few failures</td>
<td>One occurrence every one to three years or &lt;5 occurrences in 100,000 events</td>
</tr>
<tr>
<td>2</td>
<td>Low: Failures are few and far between</td>
<td>One occurrence every three to five years</td>
</tr>
<tr>
<td>1</td>
<td>Remote: Failures are unlikely</td>
<td>One occurrence in greater than five years</td>
</tr>
</tbody>
</table>
Types of Process Controls

- Prevent the cause or failure mode from occurring, or reduce the rate of occurrence
- Detect the cause & lead to corrective action
- Detect the failure mode
## Detection Ranking

<table>
<thead>
<tr>
<th>Rating</th>
<th>Det. Rate</th>
<th>Description</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>&lt;80%</td>
<td>Absolute Uncertainty</td>
<td>The product is not inspected or the defect caused by failure is not detectable</td>
</tr>
<tr>
<td>9</td>
<td>60%</td>
<td>Very Remote</td>
<td>Product is sampled, inspected and released based on Acceptable Quality Level (AQL) sampling plans</td>
</tr>
<tr>
<td>8</td>
<td>65%</td>
<td>Remote</td>
<td>Product is accepted based on no defects in a sample</td>
</tr>
<tr>
<td>7</td>
<td>70%</td>
<td>Very Low</td>
<td>Product is 100% manually inspected in the process</td>
</tr>
<tr>
<td>6</td>
<td>75%</td>
<td>Low</td>
<td>Product is 100% manually inspected using go/ no-go or either mistake proving gages</td>
</tr>
<tr>
<td>5</td>
<td>80%</td>
<td>Moderate</td>
<td>Statistical Process Control (SPC) is used in process and product is final inspected offline</td>
</tr>
<tr>
<td>4</td>
<td>65%</td>
<td>Moderately High</td>
<td>SPC is used and there is immediate reaction to out-of-control conditions</td>
</tr>
<tr>
<td>3</td>
<td>90%</td>
<td>High</td>
<td>An effective SPC program is in place with process capabilities ($C_{pk}$) greater than 1.33</td>
</tr>
<tr>
<td>2</td>
<td>95%</td>
<td>Very High</td>
<td>All product is 100% automatically inspected</td>
</tr>
<tr>
<td>1</td>
<td>99.99%</td>
<td>Almost Certain</td>
<td>The defect is obvious or there is 100% automatic inspection with regular calibration and maintenance of the equipment</td>
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RealKaizen.com
Handy Template
(Download at realkaizen.com)

<table>
<thead>
<tr>
<th>Analysis</th>
<th>Action</th>
<th>Results</th>
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<tbody>
<tr>
<td>Procedure</td>
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<tr>
<td>FMEA Doc (original)</td>
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<tr>
<td>Prepared By</td>
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<td>Potential Failure Modes</td>
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<td>Potential Effects of Failure</td>
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<td>Recommendations</td>
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<td>Responsibility and Target Completion Date</td>
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