Six Sigma is the next step in the evolution of management and quality practices. It builds on previous stages: TQM, Deming, SPC and much more. While much will be familiar, it has new elements:

“What accounts for the clearly superior performance these companies have achieved?”
Lessons of Six Sigma

1. Tie to Business Goal (Six Sigma Quality, Reduce Cost, Regulatory Compliant …)

2. Not Just Tools but Processes for Achieving Results:
   - Six Sigma Improvement Process
   - Six Sigma Design Process

3. Dedicated Resources

4. Not Just Training but a Deployment Strategy
Six Sigma

- Six Sigma is about the rapid deployment of the Six Sigma tools and processes into an organization and the effective use of these tools to achieve key business initiatives:
  - Scrap and cost reduction
  - Quality improvements (Six Sigma Quality)
  - Time to market and cycle time reductions
Six Sigma Improvement - MAIC

**Measure**

1. Determine CTQ Characteristics
2. Establish Measures and Goals
3. Identify Gaps in Performance
4. Separate into Mistake Proofing and Variation Reduction
5. Develop Measureable Outputs
6. Validate Measurement System
7. Evaluate Stability and Capability of Outputs

**Analyze**

1. Determine CTQ Characteristics
2. Establish Measures and Goals
3. Identify Gaps in Performance
4. Separate into Mistake Proofing and Variation Reduction
5. Develop Measureable Outputs
6. Validate Measurement System
7. Evaluate Stability and Capability of Outputs

**Improve**

8. Reduce Errors Using Mistake Proofing
9. Improve Stability by Identifying Causes of Shifts
10. Improve Average by Adjusting Key Inputs
11. Reduce Variation by Identifying VIP and Robust Design
12. Verify Capability of Outputs
13. Perform Other Testing
14. Implement Controls

**Control**

15. 20 25 30 35 Seal Strength
20 175 150 Dwell Time (sec)
1.0 70 36.0 37.0 38.0 Torque (in-lb)
5.6 1.7 1.4 2.0 Temperature (°F)
© Copyright 2000, Taylor Enterprises Inc.
### Six Sigma Problem Solving - MAIC

<table>
<thead>
<tr>
<th>Measure</th>
<th>Analyze</th>
<th>Improve</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Describe the Problem</td>
<td>(4) Identify Potential Causes</td>
<td>(9) Determine Best Solution</td>
<td>(12) Implement Solution</td>
</tr>
<tr>
<td>(2) Determine When Problem Started</td>
<td>(5) Analyze Existing Data</td>
<td>(10) Pilot Solution</td>
<td></td>
</tr>
<tr>
<td>(3) Measure Problem Magnitude</td>
<td>(6) Construct List of Verified Facts</td>
<td>(11) Verify Solution Works</td>
<td></td>
</tr>
</tbody>
</table>

### FACTS

- (1) All Machines
- (2) Second Shift
- (3) Certain Codes
- (4) Started 8/22
- (5) Steadily Worse
- (6) All Operators

### Causes to Facts Table

<table>
<thead>
<tr>
<th>Cause</th>
<th>Fact 1</th>
<th>Fact 2</th>
<th>Fact 3</th>
<th>Fact 4</th>
<th>Fact 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>O</td>
<td>X</td>
<td>X</td>
<td>O</td>
<td>A</td>
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<tr>
<td>2</td>
<td>X</td>
<td>O</td>
<td>A</td>
<td>A</td>
<td>O</td>
</tr>
<tr>
<td>3</td>
<td>O</td>
<td>O</td>
<td>A</td>
<td>A</td>
<td>O</td>
</tr>
<tr>
<td>4</td>
<td>X</td>
<td>A</td>
<td>X</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>5</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>X</td>
</tr>
</tbody>
</table>

### Control Plan

- **Code**
  - A
  - B
  - C
  - D
  - E
  - F
  - G
  - H

### Other Charts and Graphs

- **OC Curve**
- **Seal Strength**
- **Subgroup**
- **Machine Method Man**
- **Torque vs. Radius**
- **Upper and Lower Control Limits**

### Additional Details

- **Collect Additional Data Until Root Cause Identified**
- **Measure**
  - IS
  - IS NOT
  - What
  - Where
  - When
  - Extent

- **Analyze**
  - (4) Identify Potential Causes
  - (5) Analyze Existing Data

- **Improve**
  - (9) Determine Best Solution
  - (10) Pilot Solution

- **Control**
  - (11) Verify Solution Works

**Note:** All information is based on the content provided in the image. Additional context or details may be necessary for a complete understanding.
Design for Six Sigma - IDOV

**Identify**

1. Define Customer Requirements
   - VOC

2. Establish Measures and Standards
   - Requirements Definition

3. Identify Potential Failure Modes
   - FMEA

4. Mistake Proof
   - Go-no go gage

5. Develop Measureable Outputs
   - Sampling Plan

6. Validate Measurement System

**Design**

7. Candidate Inputs

8. Key Inputs

9. Characterize Behaviors of Key Inputs

10. Discover Variable Relationships

11. Set Targets and Tolerances

**Optimize**

12. Verify Capability of Outputs

13. Perform Other Testing

14. Implement Controls

---

**Validate**

- SOC Curve
- Life Testing
GHTF Annex A (pages 12-20) describe the tools useful for validation and their roles:

- Statistical Process Control (SPC)
- Acceptance Sampling
- Designed Experiments
- Mistake Proofing
- FMEA
- Robust Design and Tolerance Analysis
- Statistical Methods (confidence intervals, hypothesis testing, ANOVA, regression)
Validation Tools

<table>
<thead>
<tr>
<th>IQ</th>
<th>OQ</th>
<th>PQ</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Risk Assessment</td>
<td>(4) Develop Measurable Outputs</td>
<td>(10) Process PQ Testing</td>
</tr>
<tr>
<td>(2) Mistake Proof</td>
<td>(5) Validate Measurement System</td>
<td></td>
</tr>
<tr>
<td>(3) Equipment Challenge Testing</td>
<td>(6) Determine and Characterize Key Inputs</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(7) Determine Variable Relationships</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(8) Finalize Control Plan</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(11) Product PQ Testing</td>
</tr>
</tbody>
</table>

**FMEA**

<table>
<thead>
<tr>
<th>Item</th>
<th>Function</th>
<th>Failure Mode</th>
<th>Causes</th>
<th>Effects</th>
<th>O</th>
<th>S</th>
<th>D</th>
<th>RPN</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Control Plan**

<table>
<thead>
<tr>
<th>Item</th>
<th>Function</th>
<th>Failure Mode</th>
<th>Causes</th>
<th>Effects</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Control Plan

• In GHTF Guidance Document:
  • “One output of process validation is a control plan.”
  • “The final phase of validation requires demonstrating that this control plan works.”

• We will learn about the elements that make up a control plan

• Control Plan to be completed prior to OQ Limit Testing
FMEA

- Evaluates risks associated with the process and its control plan – column on FMEA form
- Helps identify where improvements are needed
- Used to determine if the process is ready for the final phase of validation
- We will briefly outline what an FMEA is and how it fits into the validation process
# Process FMEA Form

## Failure Modes and Effects Analysis

**Product or Process:** Hot / Cold Cup  
**Division or Dept.:** TE  
**Team Leader:** Wayne Taylor  
**Date Completed:** 10/3/00

<table>
<thead>
<tr>
<th>Item or Step</th>
<th>Function</th>
<th>Potential Failure Mode</th>
<th>Potential Effect(s) of Failure</th>
<th>S</th>
<th>Potential Root Cause(s) of Failure</th>
<th>O</th>
<th>Current Controls</th>
<th>D</th>
<th>RPN</th>
<th>C/A Required?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Body</td>
<td>Holds 12 ounces</td>
<td>Small</td>
<td>Some customers may complain doesn't hold enough</td>
<td>6</td>
<td>Diameter, Cpk = 1.5</td>
<td>2</td>
<td>Set-up check</td>
<td>5</td>
<td>60</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Height, Cpk = 1.1</td>
<td>5</td>
<td>Control chart</td>
<td>3</td>
<td>90</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Large</td>
<td>Customer may complain cup is too large or heavy</td>
<td>5</td>
<td>Diameter, Cpk = 1.5</td>
<td>2</td>
<td>Set-up check</td>
<td>5</td>
<td>50</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Height, Cpk = 1.1</td>
<td>5</td>
<td>Control chart</td>
<td>3</td>
<td>75</td>
<td></td>
</tr>
<tr>
<td>Insulates</td>
<td>Thin</td>
<td></td>
<td>Drink gets cold too fast</td>
<td>7</td>
<td>Thickness, Cpk = 1.3</td>
<td>4</td>
<td>Mold qualification, Sampling plan</td>
<td>4</td>
<td>112</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Too conductive a material</td>
<td>Drink gets cold too fast</td>
<td>7</td>
<td>Property of material not subject to change</td>
<td>1</td>
<td>None</td>
<td>10</td>
<td>70</td>
<td></td>
</tr>
<tr>
<td>Withstands being dropped</td>
<td>Thin</td>
<td></td>
<td>Burns customer, stains carpet, must replace cup</td>
<td>10</td>
<td>Thickness, Cpk = 1.3</td>
<td>4</td>
<td>Mold qualification, Sampling plan</td>
<td>4</td>
<td>160</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Brittle</td>
<td></td>
<td>Burns customer, stains carpet, must replace cup</td>
<td>10</td>
<td>Material property makes subject to cracking or shattering</td>
<td>6</td>
<td>None</td>
<td>10</td>
<td>600</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Statistical Requirements

Part 820-Quality Systems Regulations

Subpart 0, 820.250 Statistical Techniques

(a) Where appropriate, each manufacturer shall establish and maintain procedures for identifying valid statistical techniques required for establishing, controlling, and verifying the acceptability of process capability and product characterization.

(b) Sampling plans, when used, shall be written and based on a valid statistical rationale. Each manufacturer shall establish and maintain procedures to ensure that sampling methods are adequate for their intended use and to ensure that when changes occur the sampling plans are reviewed. These activities shall be documented.
Valid Statistical Techniques

- Recognized Technique
- Properly Applied
- Assumptions are Met
Areas of Application

- **Establish** – Tools for identifying and understanding key variables, for reducing variation and
  - Designed Experiments (Screening Experiment, Response Surface Study, Taguchi Methods)
  - Capability Studies, Analysis of Variance, Variance Components
  - Robust Design Methods, Tolerance Analysis

- **Control** – control plan for
  - Statistical Process Control (Control Charts)
  - Manufacturing Sampling Plans

- **Verify** –
  - Validation/Verification Sampling Plans (Capability Studies)
  - Gauge R&R
Establish – Setting Specs

• Translate Customer Requirements into Product, Process and Material Requirements
  • Assumes customer requirements are identified and translated into verifiable specifications
  • Must identify key product/process/material parameters that must be controlled
  • Must understand the effect these key parameters have
  • Must understand ability to control these key parameters
  • Use all this to establish targets and tolerances on these parameters
Establish – Setting Specs

WIRE
- Roller Speed
- Head Speed
- Temperature
- Melt Index

MOTOR
- Voltage
- Number Windings
- Wire Diameter
- Tightness Windings

PUMP
- Flow Rate
- Radius of Piston
- Stroke Length
- Motor Speed
- Valve Backflow

Dr. Wayne Taylor – www.variation.com
Pump Case Study

- The Requirement:
  - Flow Rate of 10 ± 1 ml/min

- The Concept:
  - Piston and Valves
Identify Key Parameters

- R: Radius of Piston
- L: Stroke Length
- S: Motor Speed
- B: Back Flow

I/O SYSTEM

- F: Flow Rate

- DOE – Screening Experiment
Effect of Key Parameters

\[ F = (16.388 \pi R^2 L - B) S \]

- DOE – Response Surface Study
Control of Key Parameters

<table>
<thead>
<tr>
<th>Inputs</th>
<th>Initial Targets</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Piston Radius (R)</td>
<td>---</td>
<td>0.0005”</td>
</tr>
<tr>
<td>Stroke Length (L)</td>
<td>---</td>
<td>0.0017”</td>
</tr>
<tr>
<td>Motor Speed (S)</td>
<td>---</td>
<td>0.17 rpm</td>
</tr>
<tr>
<td>Back Flow (B)</td>
<td>0.05</td>
<td>0.005 ml</td>
</tr>
</tbody>
</table>

- Capability Studies
# Initial Design

- Designer has freedom to select targets for R, L and S.

<table>
<thead>
<tr>
<th>Inputs</th>
<th>Initial Targets</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Piston Radius (R)</td>
<td>0.1</td>
<td>0.0005”</td>
</tr>
<tr>
<td>Stroke Length (L)</td>
<td>0.5</td>
<td>0.0017”</td>
</tr>
<tr>
<td>Motor Speed (S)</td>
<td>48.2</td>
<td>0.17 rpm</td>
</tr>
<tr>
<td>Back Flow (B)</td>
<td>0.05</td>
<td>0.005 ml</td>
</tr>
</tbody>
</table>
Tolerance Stack-up

Predicted Performance

Initial Design

Flow Rate - (F)

Statistical Tolerance

Characteristic | Value
--- | ---
Average: | 9.9981
Standard Deviation: | 0.27638
Cp: | 1.21
Cc: | 0.00
Cpk: | 1.20
Def. Rate (normal): | 297 dpm
Z-Score (short-term): | 3.43
Sigma Level: | 3.43

Interval for Values = (8.7544, 11.242) +/- 4.5SD
One way of predicting the variation is by performing a simulation.
There are many ways to achieve a 10 ml/min flow rate. One minimizes the variation. The design minimizing the defect rate is:

<table>
<thead>
<tr>
<th>Inputs</th>
<th>Initial Targets</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Piston Radius (R)</td>
<td>0.1737</td>
<td>0.0005”</td>
</tr>
<tr>
<td>Stroke Length (L)</td>
<td>0.4094</td>
<td>0.0017”</td>
</tr>
<tr>
<td>Motor Speed (S)</td>
<td>17.06</td>
<td>0.17 rpm</td>
</tr>
<tr>
<td>Back Flow (B)</td>
<td>0.05</td>
<td>0.005 ml</td>
</tr>
</tbody>
</table>
Optimal/Robust Design

Predicted Performance

Robust Design

Flow Rate - (F)

Statistical Tolerance

Characteristic Value
Average: 9.9964
Standard Deviation: 0.15055
Cp: 2.21
Cc: 0.00
Cpk: 2.21
Def. Rate (normal): 0.0000313 dpm
Z-Score (short-term): 6.54
Sigma Level: 6.54

Interval for Values = (9.3189, 10.674) +/- 4.5SD
Robust Design - Adjust Targets

Seal Strength

Dwell Time
Tighten Tolerances

Relationship Between Input and Output

Variation of Input

Transmitted Variation

Dr. Wayne Taylor – www.variation.com
Tolerance Sensitivity Analysis

Flow Rate
Interval for Values = (9.3189, 10.674) +/- 4.5SD

Transmitted Variation

Inputs
S B R L Total

Percent Reduction Transmitted Variation Table Plot for Input

Options Print Copy Help Lock
Review: Establish – Setting Specs

● Collect 5 Key Pieces of Information:

1. Identify customer requirements
2. Translate into verifiable specifications
3. Key product/process/material parameters that must be controlled (screening experiment)
4. Understand effect these key parameters have (response surface study)
5. Understand ability to control these key parameters (capability studies on parameters)

● Establish targets and tolerances on these parameters (tolerance stack-ups, robust design, tolerance sensitivity analysis)
Control – Maintaining Specs

- Statistical Process Control (Control Charts)
- Manufacturing Sampling Plans
- 100% Inspections
- Mistake Proofing
- Close Loop Feedback
Verify – Demonstrating Specs Met

- Validation/Verification Sampling Plans (Capability Studies)
- Gauge R&R
# Validation Tools

## IQ

### (1) Risk Assessment

### FMEA

<table>
<thead>
<tr>
<th>Item</th>
<th>Function</th>
<th>Failure Mode</th>
<th>Causes</th>
<th>Effects</th>
<th>O</th>
<th>S</th>
<th>D</th>
<th>RPN</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>LSL</td>
<td>Lid falls off</td>
<td>Loose lid</td>
<td>Burn</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>27</td>
</tr>
<tr>
<td>2</td>
<td>USL</td>
<td>Body diameter too small</td>
<td>Component too small</td>
<td>Burn</td>
<td>2</td>
<td>2</td>
<td>4</td>
<td>16</td>
</tr>
<tr>
<td>3</td>
<td>LSL</td>
<td>Lid falls off due to improper clamping</td>
<td>Improper clamping</td>
<td>Burn</td>
<td>2</td>
<td>2</td>
<td>4</td>
<td>16</td>
</tr>
<tr>
<td>4</td>
<td>USL</td>
<td>Body diameter too small</td>
<td>Component too small</td>
<td>Burn</td>
<td>2</td>
<td>2</td>
<td>4</td>
<td>16</td>
</tr>
</tbody>
</table>

## OQ

### (4) Develop Measurable Outputs

#### LSL

- Torque
- Temperature

- USL

#### K = 20

- Torque
- Temperature

#### K = -20

- Torque
- Temperature

### (5) Validate Measurement System

#### OC Curve

- Percent Defective

### (6) Determine and Characterize Key Inputs

#### Seal Strength

### (7) Determine Variable Relationships

#### Dwell Time (sec)

- Temperature
- Hot Bar (°F)

### (8) Finalize Control Plan

#### Control Plan

<table>
<thead>
<tr>
<th>Item</th>
<th>Function</th>
<th>Failure Mode</th>
<th>Causes</th>
<th>Effects</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>LSL</td>
<td>LSL</td>
<td>Lid falls off due to improper clamping</td>
<td>Loose lid</td>
<td>Burn</td>
<td>Change clamping</td>
</tr>
<tr>
<td>USL</td>
<td>USL</td>
<td>Body diameter too small</td>
<td>Component too small</td>
<td>Burn</td>
<td>Increase component size</td>
</tr>
</tbody>
</table>

## PQ

### (10) Process PQ Testing

#### LSL

#### USL

#### Seal Strength

#### OC Curve

- Percent Defective

### (11) Product PQ Testing

#### Failure Rate

- Years

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