“Using Lean Six Sigma To Improve a Risk Management Process”

ASQ Temecula; June 17, 2010
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Proposed Agenda

How do we narrow in on something meaningful?

1. **Define what we mean by LSS and RM Process**
   - Lean (L), Six Sigma (SS), LSS, DFSS
   - Risk Management

2. **Define the scope of our project**
   - Efficacy, efficiency, accuracy, consistency
   - Evolutionary vs. revolutionary

3. **Simulate a project**
   - Typical steps, tasks, and reports

4. **Lessons Learned**
   - + / -

**Short Exercises:**
1. NGT Survey – 3 min
2. NGT Multi-vote Project – 2 min
3. Open disc.: Simulation – 30 min
4. Lessons Learned Disc. – 5 min
Nominal Group Techniques (NGT)

Affinity Diagrams, Multi-voting, Tree diagrams, Mind mapping, Un-inhibited group discuss, Café/town hall mtgs, Unusual settings, etc.

Affinity Diagram for Pizza

<table>
<thead>
<tr>
<th>Product Category</th>
<th>Service Category</th>
<th>Cost Category</th>
<th>Features Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extra value</td>
<td>45 min max wait</td>
<td>Lower price</td>
<td>More toppings</td>
</tr>
<tr>
<td>Delivered Hot</td>
<td>Friendly Drivers</td>
<td>Deals available</td>
<td>&gt; Crust Types</td>
</tr>
<tr>
<td>Post-it Notes</td>
<td>Quick ordering</td>
<td>$0 Fee Delivery</td>
<td>Proper change</td>
</tr>
</tbody>
</table>

FISHBONE DIAGRAM

- Problem or present solution
- Fishbone
- Problem or cause
- Find root cause
- Identify potential causes
- Conduct root cause testing
- Identify solutions
- Implement solutions
- Evaluate solutions

- Assessment
- Measurement
- Analysis
- Conclusion
- Recommendations
- Implementation
- Verification
- Evaluation
- Conclusion

World Class Environmental: Green
- Excellent Customer Satisfaction
- Excellent Services Delivery
- Efficient Productivity
- Consistent Client Satisfaction
- Skilled Employees
- Superior Technology
- Low Cost
- High Quality Manufacturing
- Competitive Pricing
- Prompt Delivery
- Excellent Customer Service
- Skilled Employees
- Efﬁcient Manufacturing
- Low Cost
- High Quality
- Prompt Delivery
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- High Q
NGT Brainstorming
– Sticky Notes

Rate 1 low to 10 high:
1. Your dislike/pain for Six Sigma
2. Your dislike/pain for Risk Management
3. Rate your RM experience level (relative to?)
4. Years as a Quality Professional
What do we mean by “Lean Six Sigma”?

Collections of best known methods: Models, methods, and tools

- Visibility
  - SORT
  - STRAIGHTEN
  - SUSTAIN
  - SHINE
  - STANDARIZE

- Value
  - Keep needed items in the correct place to allow for easy and immediate retrieval
  - Keep the workplace neat and clean

- Velocity
  - The method by which "Sort," "Straighten" and "Shine" are made habitual
  - Maintain established procedures

The 3V’s and the 3M’s

- Project Management
  - Define
  - Measure
  - Analyze
  - Improve
  - Control

- Change Management
  - Culture
  - LCPM

- Variation Management
  - Mold Temp vs. Mold Time
• **Definition:** A formal program used to assess, avoid/mitigate, and control all reasonable forms of business / safety risks
  
  – Contains elements listed above in some way, plus teams, measurements (subjective), action triggers / specifications
  
  – Lifespan oriented: making, using, maintaining, & obsolescing
  
  – Prioritized cost to benefit efforts (RPN based)
  
  – Typically concerned with safety & efficacy

Scope of RM Application

• The project can cover concept (market), customer needs, design, intermediate use (i.e. labs, Drs., nurse), end user, mfg. process, equip., services, suppliers, project risks, etc.

• IVD Example from ISO14971:

```
Manufacturer → Process failure (Initiating event) → IVD device malfunction

Laboratory → IVD examination failure → Incorrect or delayed examination result (Hazard)

Physician → Medical diagnosis failure → Incorrect or delayed medical treatment (Hazardous situation)

Patient → Injury or death (Harm)
```
ICH / FDA guidance from 2006

http://www.fda.gov/RegulatoryInformation/Guidances/ucm128050.htm#III
ISPE GAMP5 Computerized systems

- Step 1: Perform Initial Risk Assessment and Determine System Impact
- Step 2: Identify Functions with Impact on Patient Safety, Product Quality, and Data Integrity
- Step 3: Perform Functional Risk Assessments and Identify Controls
- Step 4: Implement and Verify Appropriate Controls
- Step 5: Review Risks and Monitor Controls

Source: Figure M3.1, GAMP 5: A Risk-Based Approach to Compliant GxP Computerized Systems, © Copyright ISPE 2008. All rights reserved. www.ISPE.org.
Kim’s DRAFT Grand RISK Model

- The Acronym RISK can help us remember
- Missing:
  - SAE AS9100
  - AIAG PPAP

<table>
<thead>
<tr>
<th>Tools</th>
<th>(Plan)</th>
<th>(Assess)</th>
<th>(Verify)</th>
<th>(Report)</th>
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</thead>
<tbody>
<tr>
<td>IEC 60812 (Systems Reliability)</td>
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<td>x</td>
<td>x</td>
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<tr>
<td>ISO13485&gt;&gt; 14971 Risk Management</td>
<td>x</td>
<td>x</td>
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<td>ISPE Gamp 5; Computerized Systems</td>
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<td>ICH Q9 Basic RM Facilitation: FlowCharts</td>
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<td>Basic RM Facilitation: Chk.Sht.</td>
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<td>Failure Mode Effects Analysis (FMEA)</td>
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<td>FME&amp; Criticality Analysis (FMECA)</td>
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<td>Fault Tree Analysis (FTA)</td>
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<td>Hazard Operability Analysis (HAZOP)</td>
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<td>Preliminary Hazard Analysis (PHA)</td>
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<tr>
<td>Risk ranking and filtering</td>
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<td>Supporting statistical tools</td>
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<td>HIPPA</td>
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<td>Loss Reduction</td>
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<td>Risk Mitigation</td>
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<td>Claims Management</td>
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<td>Risk Financing</td>
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<td>Regulatory Accreditation Compliance</td>
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<td>Bioethics</td>
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<th>Tools</th>
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<th>(Assess)</th>
<th>(Verify)</th>
<th>(Report)</th>
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<tbody>
<tr>
<td>Overall Risk Acceptability</td>
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<tr>
<td>Verification / DOE</td>
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<tr>
<td>Statistics - Other</td>
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<td>Risk Management Report</td>
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<tr>
<td>On-going Data Gathering</td>
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<tr>
<td>Risk Reviews / Monitoring</td>
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</tbody>
</table>

Unsure of focus for each functional area
What is the scope of the project?

**KN Model: 4 Ways to Improve Any Process**

- **Consistency**
- **Efficiency**
- **Effectiveness**

**Lean Six Sigma (LSS)**

Evolutionary Change

Discuss each area relative to a target & a RM project

- List muda, mura, muri; 17 signature story
- QPFMEA criteria bias story
- Delta customer centered RM story

**Design For Lean Six Sigma (DFLSS); Revolutionary Change**

Political bias > program fail
What is a more reasonable improvement project?
1. Evolutionary RM program **efficiency** (cost / benefit)?
2. Revolutionary RM program **efficiency** (cost / benefit)?
3. Evolutionary team **accuracy** (criteria or process)?
4. Revolutionary team **accuracy** (criteria or process)?
5. Evolutionary team **consistently** (following procedures)?
6. Revolutionary team **consistently** (following procedures)?
7. Evolutionary program **effectiveness** (end result)
8. Revolutionary program **effectiveness** (end result)
Simulated Case Study

**Basic Steps:**
1. Project pick lists
2. Team selection
3. Project kickoff
4. Defining activities
5. Measuring activities
6. Analyzing activities
7. Improving activities
8. Controlling activities
9. Phase gate reviews and celebratory closing meeting
Spaghetti Map

Before
Run Charts

Run Chart of Yield

<table>
<thead>
<tr>
<th>Observation</th>
<th>Yield</th>
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<tbody>
<tr>
<td>1</td>
<td>100</td>
</tr>
<tr>
<td>2</td>
<td>90</td>
</tr>
<tr>
<td>3</td>
<td>80</td>
</tr>
<tr>
<td>4</td>
<td>70</td>
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<tr>
<td>5</td>
<td>60</td>
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<td>6</td>
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<td>7</td>
<td>40</td>
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<td>8</td>
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<tr>
<td>9</td>
<td>20</td>
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<tr>
<td>10</td>
<td>10</td>
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</tbody>
</table>

Number of runs about median: 27
Expected number of runs: 26.49020
Longest run about median: 7
Approx P-Value for Clustering: 0.55736
Approx P-Value for Mixtures: 0.44264

Number of runs up or down: 32
Expected number of runs: 33.66667
Longest run up or down: 3
Approx P-Value for Trends: 0.28651
Approx P-Value for Oscillation: 0.71349
C&E Cascade

Cause = Design
Effect = Env. Exposure

Cause = Env. Exposure
Effect = Moisture

Cause = Moisture
Effect = Corrosion

Cause = Corrosion
Effect = High Resistance

Cause = High Resistance
Effect = Insufficient Current

Cause = Insufficient Current
Effect = Dim Bulb

Cause = Poor Contact (High Resistance)
Effect = Insufficient Current

Cause = Dim Bulb
CpK

Process Capability of 13096, ..., 13524

<table>
<thead>
<tr>
<th>Process Data</th>
<th></th>
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<tbody>
<tr>
<td>LSL</td>
<td>*</td>
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<tr>
<td>Target</td>
<td>*</td>
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<tr>
<td>USL</td>
<td>2500</td>
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<tr>
<td>Sample Mean</td>
<td>820.725</td>
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<tr>
<td>Sample N</td>
<td>24</td>
</tr>
<tr>
<td>StDev(Within)</td>
<td>278.371</td>
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<tr>
<td>StDev(Overall)</td>
<td>268.896</td>
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<table>
<thead>
<tr>
<th>Within</th>
<th>Overall</th>
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<table>
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<tr>
<th>Potential (Within) Capability</th>
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<tr>
<td>Cp</td>
<td>*</td>
</tr>
<tr>
<td>CPL</td>
<td>*</td>
</tr>
<tr>
<td>CPU</td>
<td>2.01</td>
</tr>
<tr>
<td>Cpk</td>
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<th>Overall Capability</th>
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<td>Pp</td>
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<td>PPU</td>
<td>2.08</td>
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<tr>
<td>Ppk</td>
<td>2.08</td>
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<tr>
<td>Cpm</td>
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Observed Performance

- PPM < LSL: *
- PPM > USL: 0.00
- PPM Total: 0.00

Expected Within Performance

- PPM < LSL: *
- PPM > USL: 0.00
- PPM Total: 0.00

Expected Overall Performance

- PPM < LSL: *
- PPM > USL: 0.00
- PPM Total: 0.00
Design Space Optimization
DOE Reports Here

Sampling Methods: Critical Factors And Initial Design

Search for solution Optimization (Approximations)

Robustness Design

Feasible (safe)

Infeasible (failed)

Constraint Boundary

Initial Design

Air Academy DARPA 2006
Three C’s to Inspire Creativity

Comparison

Component of DFSS

Someone somewhere has already solved your problem- Dr. Ellen Domb

Undesired Result (Conflict)

<table>
<thead>
<tr>
<th>Feature to Improve</th>
<th>Weight of moving object</th>
<th>Weight of non-moving object</th>
<th>Length of moving object</th>
<th>Length of non-moving object</th>
<th>Area of moving object</th>
<th>Area of non-moving object</th>
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</thead>
<tbody>
<tr>
<td>Weight of moving object</td>
<td>29.65, 29.65</td>
<td>15.6, 29.65</td>
<td>29.65, 29.65</td>
<td>29.65, 29.65</td>
<td>29.65, 29.65</td>
<td>29.65, 29.65</td>
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<tr>
<td>Weight of non-moving object</td>
<td>29.65, 29.65</td>
<td>15.6, 29.65</td>
<td>29.65, 29.65</td>
<td>29.65, 29.65</td>
<td>29.65, 29.65</td>
<td>29.65, 29.65</td>
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<tr>
<td>Length of moving object</td>
<td>35.28, 35.28</td>
<td>35.28, 35.28</td>
<td>35.28, 35.28</td>
<td>35.28, 35.28</td>
<td>35.28, 35.28</td>
<td>35.28, 35.28</td>
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<tr>
<td>Length of non-moving object</td>
<td>35.28, 35.28</td>
<td>35.28, 35.28</td>
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<td>35.28, 35.28</td>
<td>35.28, 35.28</td>
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<tr>
<td>Volume of moving object</td>
<td>2.26, 29.40</td>
<td>1.7, 4.35</td>
<td>2.26, 29.40</td>
<td>1.7, 4.35</td>
<td>2.26, 29.40</td>
<td>1.7, 4.35</td>
</tr>
</tbody>
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Dr. Ellen Domb

Someone somewhere has already solved your problem- Dr. Ellen Domb
Control Plan
Purpose / Use

Facilitate Risk Based Decision Making

Corrective Action
- Containment
- Direction
- Clarity

Operational Impact

Preventive Action
- Identify Risks
- Promote Dialog
- Tighten Sample Plans

Identify Strengths

Business Efficiency
- Reduce Sample Plans
- Avoid Conflict

Collection of Knowledge
- Becomes a Dashboard

Umbrella Risk Management

Mitigate Collective Risks

Justify Decisions

Regulatory Compliance

D/P/FMEA

Flow Charts & Process Maps

Control Plan
Purpose / Use

File: FTA_ControlPlan_v1_KN_061510  June 15, 2010  KN x 1209
Risk Mgmt. Enablers

- Jan 2010
- 230 comps:
  - 40 life sci.
  - 23% lg.
- Little s/w use

Source: Aberdeen Group, January 2010
Quality Progress Poll
May 2010

QUICK POLL RESULTS
Each month at www.qualityprogress.com, visitors can take an informal survey, and we post the results. Here are the numbers from a recent Quick Poll:
What's the best way to avoid a product recall?
- Identify potential sources of risk 59.6%
- Listen to customer feedback 16.3%
- Good internal communication 12.5%
- Strong social responsibility focus 11.5%
Risk Control Measures

- ISO14971 suggests forming of a list of risk control measures
- Also see the annex solutions
- Reliasoft software contains a related database

<table>
<thead>
<tr>
<th>Product/process</th>
<th>Example devices</th>
<th>Hazard</th>
<th>Inherent safe design</th>
<th>Protective measure</th>
<th>Information for safety</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single use medical device</td>
<td>Catheter</td>
<td>Bio-(cross)-contamination</td>
<td>Self-destruction after use</td>
<td>Obvious indication after first use</td>
<td>Warning against re-use and of the adverse consequence(s) that could arise from any such re-use</td>
</tr>
<tr>
<td>Active implant</td>
<td>Pacemaker</td>
<td>Electric fields</td>
<td>Use of non-electric drives and controls</td>
<td>Use of differential amplifiers and additional filter algorithms</td>
<td>Warning for commonly encountered hazardous situations</td>
</tr>
<tr>
<td>IVD medical device</td>
<td>Blood analyser</td>
<td>Incorrect result due to method bias</td>
<td>Implement traceable calibrators</td>
<td>Provide traceable trueness controls</td>
<td>Inform users of unacceptable deviation from assigned values</td>
</tr>
<tr>
<td>Software</td>
<td>Patient data management</td>
<td>Erroneous data</td>
<td>High integrity software</td>
<td>Use of checksums</td>
<td>Warnings on screen for user</td>
</tr>
<tr>
<td>Steam sterilization</td>
<td>Biopsy device, operation forceps</td>
<td>High temperature (material degradation)</td>
<td>Use of material that is compatible with high temperatures</td>
<td>Pressure and temperature monitoring and recording</td>
<td>Packaging and loading instructions</td>
</tr>
</tbody>
</table>

Figure D.6 — Some examples of risk control measures
$P_1$ is the probability of a hazardous situation occurring.

$P_2$ is the probability of a hazardous situation leading to harm.
Summary of Tips and Tricks

1. Risk management depends upon people
   – Focus on having fun
     • Minimizing the pain (no long meetings)
     – Pre-prioritize (i.e. by area risks)
     • Maximizing the value-add using NGT
     – To pre-prioritize & to select criteria
     • Inspire creativity using the 3C’s model

2. Develop a control plan centric program
   – Many complimentary tools (i.e. FTA, Process maps with threats, FMEA)

3. Remember all the components using RISK