Learning Objectives

• This session is intended for experienced people to discuss / exchange how to better handle the FMEA activities to get the best out of it, by addressing challenges and difficulties.
  – Interactions are encouraged & appreciated

• It’s not intended to teach basics to beginners who have no experience.
Agenda

• Speaker’s Connection to the Topic
• The Challenges and Dilemma
• Which Parts being Difficult
• Tips to Deal With the Dilemma
• Integration with Related Activities
• An Unique Practice
• Takeaways
• Appendix - More Discussions on Confusing Points
Gary Jing’s Background

- ASQ Fellow, MBA, PhD in IE, CQM / CQE
- Founding MBB @ Seagate TCO (1998 - 2005)
- Sr. Mgr., Global LS / Founding MBB @ Entegris (2005 - 2009)
- Global LSS Leader / MBB @ TE – ADC (2009 - 2015)
- CI Director / MBB @ CommScope (2015 - Present)

- US Delegation to ISO TC176 for ISO 9000 Revision
- Editorial Review Board of Six Sigma Forum Magazine
- IQPC/PEX LSS Award Judge Panel
- Development of ASQ BB Certification Program (participant)
- Delphi panel expert for SME/AME/Shingo Lean Certification Program

- Isixsigma DFSS Award (2011), Finalist of IQPC MBB of The Year (2008)
- Two patents in disc drive modeling from his Sigma work

- Series publications on Lean Sigma

Foreword

• FMEA concept and practice can be applied to almost anything.

• Most common ones are on design and production (process), which splits into:
  – Pre (production) release – easier to change design.
  – Post release – harder to change design.
  – Practice will be different b/w the 2 stages.
  – This session focuses on the Pre.
Foreword

- The mechanism of FMEA is quite straightforward, yet to do it well isn’t easy.

So, what are the challenges?

What are the Biggest Challenges?

Scenario 1: Cowboy under OSHA

- Automatic High-Volume "Whoa"
- Flip-Down Sunglasses
- Safety Rope - When Other Systems Fail
- Bird Cage Mask & Safety Goggles
- 180° Rear View Mirror
- Head Lights
- Prescription Safety Goggles to Insure Horse's Good Vision
- Grab Rail
- Safety Switches & Hotline to Insurance Company
- Steel Toed Stirrups
- Safety Net All Around
- 4 Wheels to Keep Horse Upright in Case He Slips - Hence Not Endangering Rider
- Hard Hat with Wide Brim & Ear Protectors
- Padded Back Seat & Head Restraint
- Tail & Directional Lights
- Backup Lights
- Shoulder Harness
- Automatic, Air Filled Chest Protector
- Maps if You Get Lost & Checklist Before Riding
- Blue Tail Fly Repellent
- Seat Belt
- Self Starter (Accessory)
- Knee Pads (Just in Case)
- Quilted Pants
- Dual Cinch
- E.P.A. Emissions Control Systems
- Non-Skid Spark Suppressors
Example: Functions Identified for a Marker Cap

20 “functions” identified.
- Too much for FMEA.
- Focus on NUD (new, unique, difficult) ones instead.
The cost aspect needed for business decision is usually not considered in FMEA (or RCA).
What are the Biggest Challenges?

Scenario 2: Everything is fine.
So, What are the Biggest Challenges in doing FMEA?

Effectiveness & Efficiency

• The quality of FMEA is hard to evaluate.
• No guaranty (or magic wand)
• With huge investment and no guaranty on results, people have the tendency to cut corner.
Typical Ways to Boost FMEA Quality

- **Experience** - Ultimate pursuit
- **Formality (structure)** - Less effective
- **Right Focus** - More effective
- **Quantity** - Trade efficiency

Will be elaborated in the remaining sections.
Different Industries have Different Expectations on FMEA.

- More serious and formal in highly regulated industries
  - Medical Device, Aerospace, Automotive, etc.
  - Can be used as legal documents.
- Less formal in Telecom
  - Ad hoc in many cases.
- Less formal in Six Sigma activities
  - May be customized or use less formal form, e.g. Potential Problem Analysis (PPA).
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Which Parts of FMEA are Difficult?

• Types of Failure Mode (FM)
• Types of Control
  – Prevention or Detection?
• Is it a Cause or Effect?
  – Cause – effect shifting
• Is it a process issue or design issue?
  – Some FMs may belong to both
  – Many process issues can be addressed by design

Interaction between (sub-)structures (IBS)
  – IBS induced issues are hard to capture
Which Parts of FMEA are Difficult?

- **Types of Failure Mode (FM)**
  - Failing to meet the specification
    - Complete failure
    - Too little (partial, uneven or not complete)
    - Too much (over)
    - Intermittent
    - Failure over time
  - Incorrect or inappropriate requirements
    - Wrong, missing, hidden, unstated, assumed)
  - Unintended use, application, or environment
  - Does harm to others
Which Parts of FMEA are Difficult?

- **Is it a Cause or Effect?**
  - Chain of Causation
  - Cause–effect shifting

Is **Electrical Fault** a Cause, FM or Effect?
- It depends, on what level you are looking at:
  - At car level, it’s a cause;
  - At sub-assembly level is a FM;
  - At component level, it’s an effect.
Which Parts of FMEA are Difficult?

• Types of Control
  – Prevention or Detection?
  – One of most confusing items, hard to do it right.
  – Prevention: Focus on preventing failure to occur, affect Occurrence (O).
  – Detection: Focus on preventing effect to occur, affect Detection (D).
  – Different sets for design and process, no overlap.
Prevention vs. Detection Controls

*DFMEA*
- Prevention Controls typically occur prior to finalizing the design and reduce the risk of failures during Product Validation Testing
  - Engineering analysis and evaluation: Anti-overstress feature
  - Tolerance Stack-Up or Statistical Analysis,
  - Finite Element Analysis
- Detection Controls detect the failure mode, typically during Product Validation testing, prior to releasing design for customer orders
  - Examples include Reliability testing and Performance testing conducted as part of product validation testing

*PFMEA*
- Prevention Controls occur prior to manufacturing the product
  - Equipment setup requirements
  - Poka-yoke
- Detection Controls occur after manufacturing the product but prior to shipping product to customers
  - Product testing
  - Inspection
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Poll

Are all of the FMEA columns equally important?  
**Options:** Yes / No

Which ones are most important?

**Options:**
- RPN
- Detection
- Function
- Failure mode
- Action
- Others
Tips on FMEA Efficiency & Effectiveness

Are all of the FMEA columns equally important? Which ones are most important?

1. The most important column in FMEA is potential failure mode (concerns)
   - To identify potential failures as thoroughly & completely as possible.

2. The 2nd most important is the countermeasures (actions) identified
   - To keep risk of FMs at acceptable level.
   - Be conscious on cost.
3. The 3rd is the risk priority number (RPN)
   - To assess the risk, establish priorities and guide responses.
   - Always highly subjective due to lack of data.
   - Frequently mistaken as most important in FMEA.
   - AIAG is moving away from using it.

4. Everything else is in supporting functions
   - To help make better informed decisions in the process.
Redirect Team’s Brain Power to Boost FMEA Efficiency & Effectiveness

Focusing team resource on NUD and the top 2 most important columns can boost efficiency & effectiveness of FMEA.

- The top 2 most important columns (failure mode & countermeasures) can benefit from team the most.
- An experienced lead person or a small subset group can handle the rest well.
Redirect Team’s Brain Power to Boost FMEA Efficiency & Effectiveness

- We can let the whole group focus on brainstorming for the top 2, and let an experienced lead person take care of the rest along with a small sub team.
- Focusing on NUD (new, unique, difficult), easing on ECO (easy, common, old) items, can gain efficiency.
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Integration with Related Activities

• How is FMEA activity connected with others that have similar intent? e.g.
  – Six Sigma
  – Product Development Process (PDP)
  – Dynamic Control Plan (DCP)

• It’ll be much more effective & efficient if systematically integrate FMEA with activities with similar intent.
Integration with Related Activities

• Six Sigma connection
  – Lean Design for Six Sigma (LDFSS), e.g.
  – VOC / requirement management, e.g.
    • Failing to meet requirements is a/the primary mode of failure.
    • How to make sure you identified hidden / latent / implied requirements?
      → LDFSS VOC section.
How is FMEA Integrated with Relevant Activities - Product Development Stage

AIAG is moving to this direction in joint effort with VDA.

Functional Analysis / NUD - New, Unique, Difficult

Pugh Analysis

Process Map

Prototype

Design Review

Design for “X”

DFMEA

PFMEA

VOC / Requirements

Concept Generation

AIAG is moving to this direction in joint effort with VDA.
How is PFMEA Integrated with Relevant Activities - Post Production Release
Agenda

• Speaker’s Connection to the Topic
• The Challenges and Dilemma
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3-Day DFMA / FMEA Joint Event  
- An Unique Practice

- Addresses a host of manufacturing related concerns together, including:
  - Design review
  - Design for “X”
  - Modularity / part reuse
  - Lean manufacturing & assembly
  - Field installation & maintenance
  - FMEA (Design, Process, Application)

Typically done right after the 1st major prototype acquired.

Many of them have similar intent in different angles, to identify and eliminate problems in the future, thus it’s better to join force.
## Activities & Schedule of Joint Event

<table>
<thead>
<tr>
<th>Stage 0 Prep &amp; Kick-off</th>
<th>Pre Event</th>
<th>Day 1 Morning</th>
<th>Day 1 Afternoon</th>
<th>Day 2 Morning</th>
<th>Day 2 Afternoon</th>
<th>Day 3 Morning</th>
<th>Day 3 Afternoon</th>
<th>Post Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead optionally pre-draft QFD &amp; FMEA</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Stage 1 Review Current Design</th>
<th>Pre Event</th>
<th>Day 1 Morning</th>
<th>Day 1 Afternoon</th>
<th>Day 2 Morning</th>
<th>Day 2 Afternoon</th>
<th>Day 3 Morning</th>
<th>Day 3 Afternoon</th>
<th>Post Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>VOC updates, Teardown prototype, touch &amp; feel.</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Stage 2 Brainstorm / Document Concerns</th>
<th>Pre Event</th>
<th>Day 1 Morning</th>
<th>Day 1 Afternoon</th>
<th>Day 2 Morning</th>
<th>Day 2 Afternoon</th>
<th>Day 3 Morning</th>
<th>Day 3 Afternoon</th>
<th>Post Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole team brainstorm, prioritize concerns,</td>
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<tr>
<td>Breakout to document concerns on FMEA, quickly assess risk.</td>
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<table>
<thead>
<tr>
<th>Stage 3 Generate Better Solution</th>
<th>Pre Event</th>
<th>Day 1 Morning</th>
<th>Day 1 Afternoon</th>
<th>Day 2 Morning</th>
<th>Day 2 Afternoon</th>
<th>Day 3 Morning</th>
<th>Day 3 Afternoon</th>
<th>Post Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multiple rounds of ideations on top concerns</td>
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<tr>
<td>Breakout to Consolidate ideas &amp; review counter measures</td>
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<tr>
<td>Breakout to further develop ideas</td>
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<table>
<thead>
<tr>
<th>Stage 4 Finalizing</th>
<th>Pre Event</th>
<th>Day 1 Morning</th>
<th>Day 1 Afternoon</th>
<th>Day 2 Morning</th>
<th>Day 2 Afternoon</th>
<th>Day 3 Morning</th>
<th>Day 3 Afternoon</th>
<th>Post Event</th>
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</tbody>
</table>

*Breakout to review QFD* | *Finalize improvements & FMEA*
Take-aways

• What are the constant struggles with FMEA?
  – Efficiency and effectiveness.
• The most important columns in FMEA are?
  – Failure Mode & Countermeasures (Actions).
• Everything else is in?
  – Secondary supporting role, to help making better informed decisions.
• Focusing the group resource on the?
  – Most important items can significantly improve the efficiency and effectiveness of FMEA.
Questions?

Gary Jing - http://www.linkedin.com/in/ggaryjing
Appendix

More Discussions on Confusing Points
More Discussions on Confusing Points

• What’s the primary intent / ultimate goal of FMEA?
  – To prevent future problems.
    • Choices of actions should build around this goal.
  – Not for investigation / problem solving.
    • FMEA format isn’t suited to show complicated cause-effect relationships.
  – Additional or variation on goals are possible.
More Discussions on Confusing Points

• What’s in the Scope
  – ASQ critical assumption for PFMEA
    • All components coming into the process step are defect-free. – Defective part out of scope.
  – My view
    • Anything that may jeopardize your goal is in scope, incl. defective incoming material.
    • Failures & solutions not limited to current design.
      – May lead to new design, components or process.
    • If FMEA doesn’t lead to design change during development stage, it’s not as effective as it can.
More Discussions on Confusing Points

• Expectation / “standard” on outputs
  – There is no perfect FMEA or outputs for any subjective analyses
  – Different people doing the same subjective analysis will get different results
    • Which is ok → Delphi Theory – Things will converge through iterations.
  → Use your judgment to decide the best practice for you.
More Discussions on Confusing Points

• Could same FM have **multiple effects** with different Severity (S), O and/or D?
  – Possible to any of them.
    • A FM may have multiple causes and/or effects.
    • A cause or effect may associate to multiple FMs.
  – To simplify the analysis, a popular practice is to focus on the most severe effect per FM.
    • There is a chance to miss an effect with lower severity yet higher RPN.
    • That’s a risk to take to trade for efficiency.
More Discussions on Confusing Points

• Can recommended actions lower Severity?
  – A frequently debated item.
  – Two schools of thought w/ opposite views.
  – Ultimately what’s affected is Criticality = SxO.
  – More common to keep S unchanged, only change O, to keep things simple and avoid confusing debate.
More Discussions on Confusing Points

• What training style / format is more effective
  – Standalone training w/ hypothetical example / exercise (e.g. ASQ)?
  – Learn through doing real projects?

• FMEA is evolving
  – AIAG joining VDA* is proposing dramatic changes
    • Emphasize structural analysis (similar to LDFSS)
    • Eliminate RPN
  – Industries will follow suit in the near future.

* VDA - German Association of the Automotive Industry
AIAG/VDA to Emphasize Structural Analysis

AIAG moving toward VDA practice.
AIAG/VDA to Replace RPN by Action Priority (AP)

<table>
<thead>
<tr>
<th>S</th>
<th>O</th>
<th>D</th>
<th>AP</th>
<th>DFMEA Action Priority Logic</th>
</tr>
</thead>
<tbody>
<tr>
<td>9-10</td>
<td>6-10</td>
<td>1-10</td>
<td>H</td>
<td>High priority due to safety and/or regulatory effects that have a high or very high occurrence rating</td>
</tr>
<tr>
<td>9-10</td>
<td>4-5</td>
<td>7-10</td>
<td>H</td>
<td>High priority due to safety and/or regulatory effects that have a moderate occurrence rating and high detection rating</td>
</tr>
<tr>
<td>9-10</td>
<td>4-5</td>
<td>5-6</td>
<td>H</td>
<td>High priority due to safety and/or regulatory effects that have a moderate occurrence rating and moderate detection rating</td>
</tr>
<tr>
<td>9-10</td>
<td>4-5</td>
<td>1-4</td>
<td>M</td>
<td>Medium priority due to safety and/or regulatory effects that have a moderate occurrence rating and low detection rating</td>
</tr>
<tr>
<td>9-10</td>
<td>1-3</td>
<td>7-10</td>
<td>H</td>
<td>High priority due to safety and/or regulatory effects that have a low occurrence and high detection rating</td>
</tr>
<tr>
<td>9-10</td>
<td>1-3</td>
<td>5-6</td>
<td>M</td>
<td>Medium priority due to safety and/or regulatory effects that have a low occurrence rating and moderate detection rating</td>
</tr>
<tr>
<td>9-10</td>
<td>1-3</td>
<td>1-4</td>
<td>L</td>
<td>Low priority due to safety and/or regulatory effects that have a low occurrence and low detection rating</td>
</tr>
<tr>
<td>5-8</td>
<td>8-10</td>
<td>2-10</td>
<td>H</td>
<td>High priority due to the loss or degradation of an essential or convenience vehicle function that has a very high occurrence rating</td>
</tr>
<tr>
<td>5-8</td>
<td>6-7</td>
<td>7-10</td>
<td>H</td>
<td>High priority due to the loss or degradation of an essential or convenience vehicle function that has high occurrence and high detection rating</td>
</tr>
</tbody>
</table>

Using more sophisticated Guidance Table to guide AP, replacing single threshold for RPN.