



COVIDIEN

ASQ Section 1313

May 2010 Meeting

WELCOME!

# Agenda

- 5:30PM – Tutorial – Arnold Miller, “The Responsibility Process”
- 6:00PM – Announcements
- 6:15PM – Main Topic – Rebecca Jessep, Covidien, “Developing Effective FMEAs”
- 7:00PM – Pizza & Networking

# Section Announcements

- THANK YOU TO COVIDIEN FOR TONIGHT'S FACILITIES!
- Congratulations and thank you to the 2010/2011 ASQ Section 1313 Officers:
  - Chair: Rebecca Jessep, Covidien
  - Vice-Chair: Joe Wojniak, Covidien
  - Treasurer: Ewald Schelert, Retired
  - Secretary: Melinda Schnoes, Medtronic
  - Recertification: Larry Deroin, Ball Aerospace
  - Education Chair: John Beachman, Covidien
  - Publicity & VOC: Byron Murray
  - Internet & Website: Arnold Miller
  - Programs: Guy Harris, Sandhill Scientific
  - SMP: Mike Ferraro, Seagate
  - Newsletter: Gerry Naugle, Verify Corp.
- Job Postings: Check <http://asq1313.org/jobs.html>
- Upcoming Events:
  - Boulder ASQ Section 1313 Picnic, Saturday, August 7th, 2010, Midway Park, Broomfield
  - 27<sup>th</sup> September 2010, ASQ Section Meeting – Liz Ryan, “Responsibility without Authority: Influencing”



# Developing Effective FMEAs

Rebecca Jessep, Sr. NPQA Engineer, Covidien

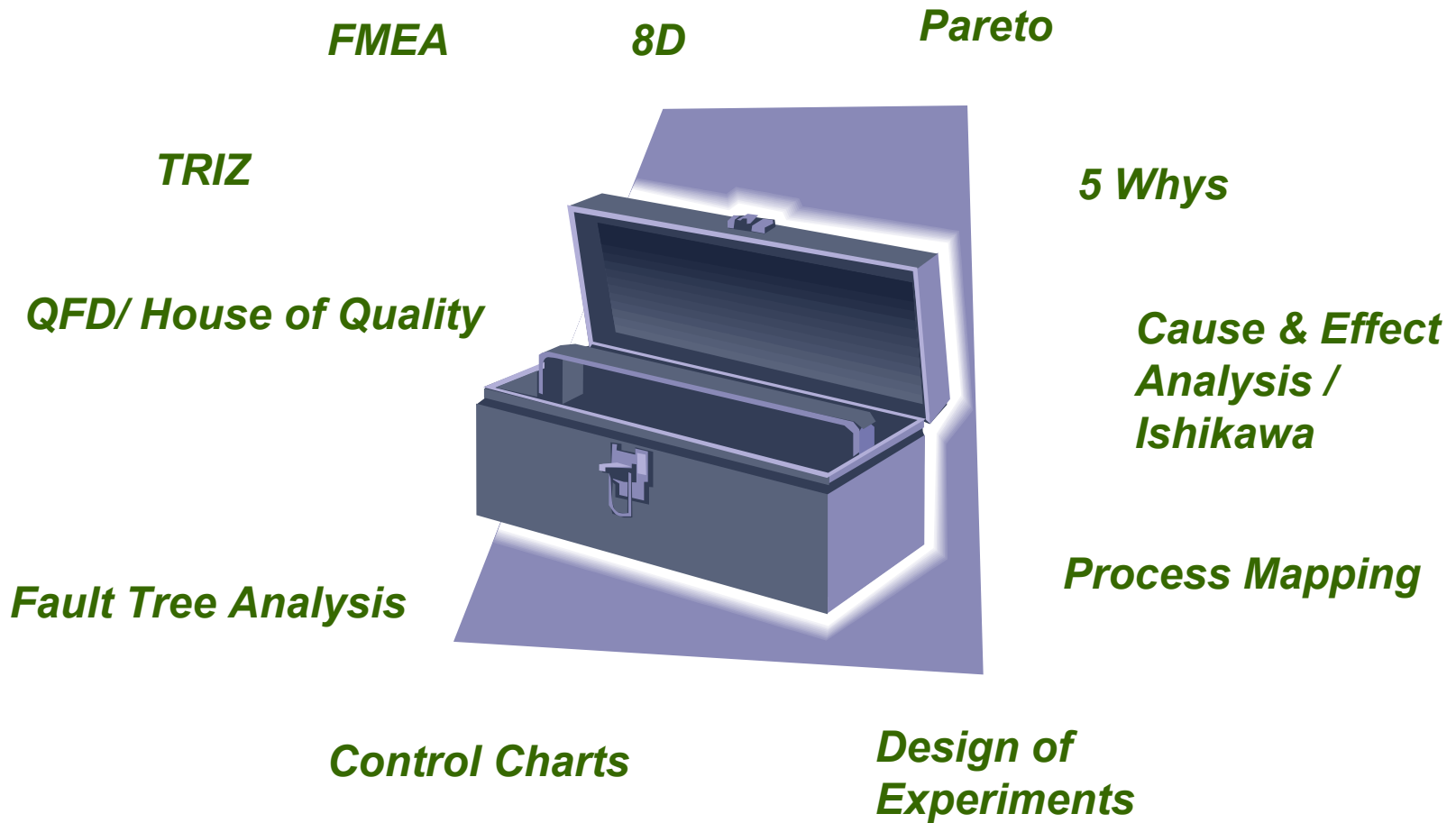
# Take a Stand

- When used appropriately, FMEA is a valuable tool.
- *Do you agree with this statement?*

# Purpose

- What is FMEA?
- Why use FMEA?
- How can FMEA be an effective part of a product development process?
- What are the best practices in using FMEA?

# What is FMEA?



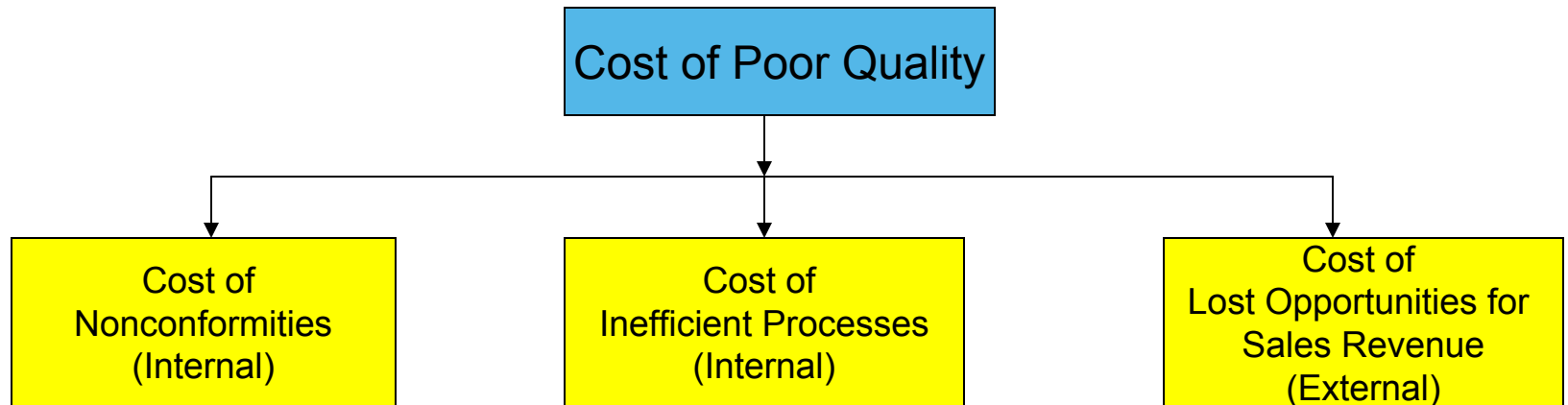
# FMEA Defined

“A systematic method of analyzing and ranking the risks associated with various product failure modes (both real and potential) in order to prioritize the sequence of corrective action.”

- Dailey, 2004

# Business Impact & Opportunity

- Why utilize FMEA early in and throughout development?
  - To mitigate the Cost of Poor Quality
  - “Identify opportunities for reducing customer dissatisfaction and associated threats to sales revenues...” (Juran)



# FMEA Logic - COQ

- Total Quality Cost:
  - Cost incurred by investing in the prevention of nonconformance to requirements.
  - Appraising a product or service for conformance to requirements.
  - Failing to meet requirements
- Prevention Cost:
  - The cost of all activities specifically designed to prevent poor quality in products or services.

## Categories of Quality Costs

<u>Preferential Cost of Quality</u>	<u>Undesirable Cost of Quality</u>
<p style="text-align: center;"><b>1. Prevention</b></p> <ul style="list-style-type: none"> <li>• Incurred to keep failure &amp; appraisal costs to a minimum</li> <li>• Examples:               <ul style="list-style-type: none"> <li>– Quality Planning</li> <li>– FMEA</li> <li>– New Product Review</li> </ul> </li> </ul>	<p style="text-align: center;"><b>3. Internal Failures</b></p> <ul style="list-style-type: none"> <li>• Cost associated with deficiencies discovered before delivery</li> <li>• Examples:               <ul style="list-style-type: none"> <li>– Scrap/rework</li> <li>– 100% sorting/ re-inspection/ retest</li> </ul> </li> </ul>
<p style="text-align: center;"><b>2. Appraisal (Detection)</b></p> <ul style="list-style-type: none"> <li>• Incurred to determine degree of conformance to quality requirements</li> <li>• Examples:               <ul style="list-style-type: none"> <li>– Incoming, in-process inspection &amp; test</li> <li>– Final inspection &amp; test</li> </ul> </li> </ul>	<p style="text-align: center;"><b>4. External Failures</b></p> <ul style="list-style-type: none"> <li>• Cost associated with deficiencies discovered after delivery</li> <li>• Examples:               <ul style="list-style-type: none"> <li>– Complaints/ recalls/ returned materials</li> <li>– Customer defections / customer loss</li> </ul> </li> </ul>

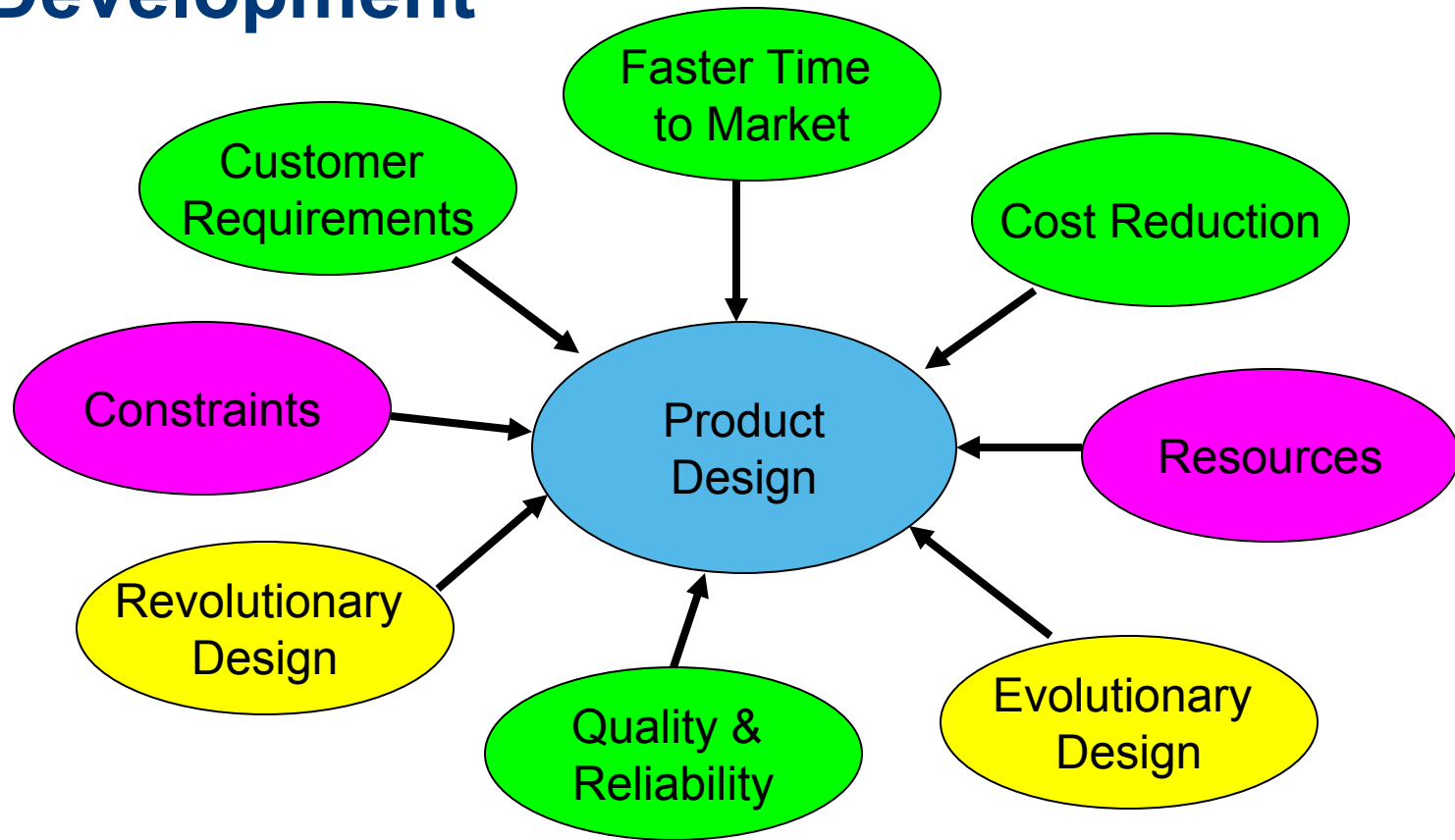
# Business Impact & Opportunity

- Use of FMEA enables a disciplined approach to risk management.
- Results:
  - External results =
    - Improved company image
    - Increased user satisfaction
  - Internal results =
    - Lower overall development costs
    - Shortest cycle time
    - Real time visibility of product maturity
    - Optimal Quality (mitigation of costs for repairs)

# Types & Scope of FMEAs

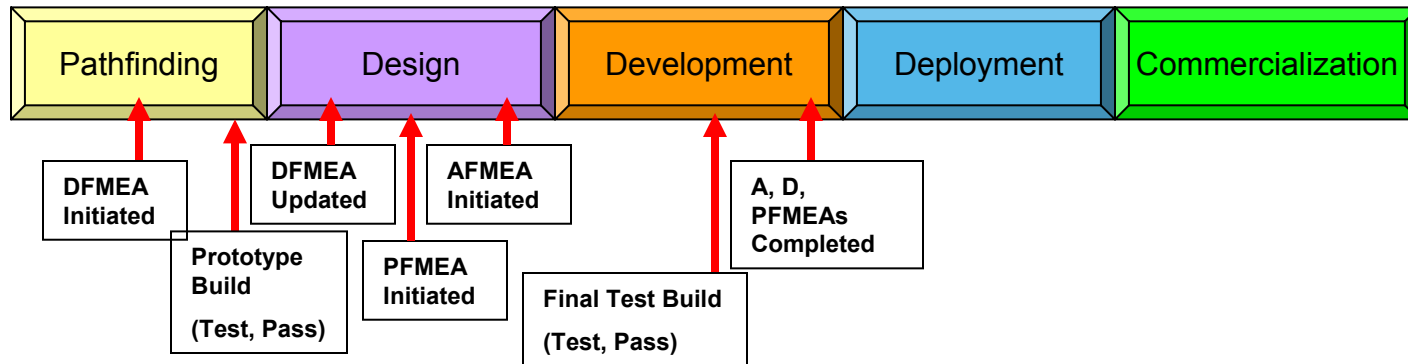
	<b><u>Application FMEA</u></b> <b><u>(AFMEA)</u></b>	<b><u>Design FMEA</u></b> <b><u>(DFMEA)</u></b>	<b><u>Process FMEA</u></b> <b><u>(PFMEA)</u></b>
<b><u>Scope</u></b>	ID & eliminate the impact of risks associated with the user or customer interface in their process.	ID & eliminate the impact of risks associated with the components of a design in the operation of a system.	ID & eliminate the impact of risks associated with the assembly/manufacturing/service process.
<b><u>Failure Mode Focus</u></b>	User FMEA focused on failure modes caused by the design application.	System/component focus concentrating on the way that the system/component may not meet it's design intent or function.	Process failure focus concentrating on the way that the process step may or may not be performed impacting the overall process or the performance of the output of the process.
<b><u>Effect of Failure Focus</u></b>	The consequence that the failure mode has on the customer and/or user.	The consequence that the failure mode has on the system/component's intended function.	The consequence that the failure mode has on the process and the operation of the end product.
<b><u>Example</u></b>	Overheating of the surgical device creates a potential for patient burn.	Shorted resistor causes the temperature of the system to exceed design limits.	Solder volume not controlled. Resistors in series with excess solder resulting in overlapping solder filets. Solder short detected during visual inspection resulting in rework required in the process.

# Environment Surrounding Product Development



# Timing of Application is Everything

- Example: Product Development Cycle Time & Cost Model Analysis
  - Scenario 1:
    - FMEA is initiated in Pathfinding, effectively utilized.
    - Product follows predefined project milestones & launches on time.
    - Defects are designed out of the product and process up front & verified through standard DOE planning in Development with reduced high cost design iterations (Ideal state)



- Estimated **prevention cost of quality for DFMEA = \$90,000**  
(labor only) (5 engineers) x (6 weeks full time) x (\$75/hour)

# Timing of Application is Everything

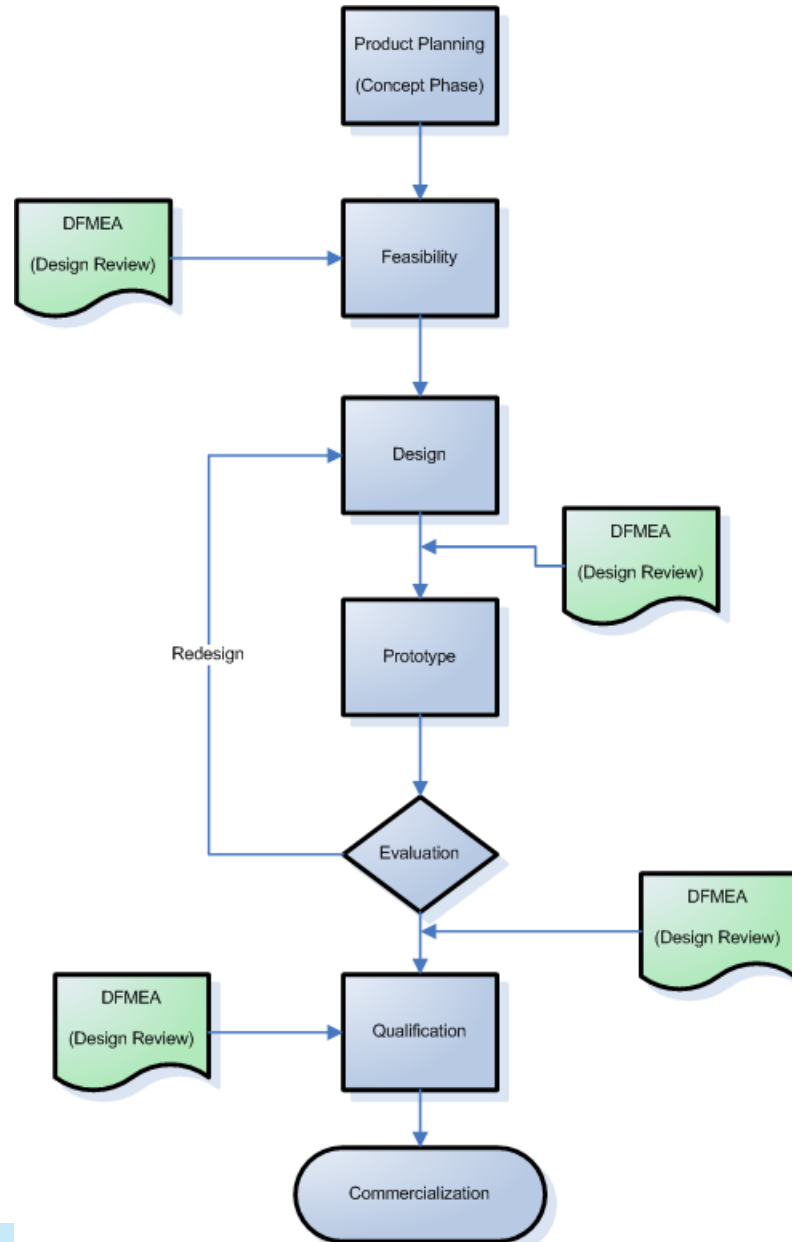
- Example: Product Development Cycle Time & Cost Model Analysis
  - Scenario 2: FMEA is not done adequately or not completed at all. Resulting design has a Field Action.



- Example **cost of poor quality** = \$750,000 (labor & materials)

**Cost of poor quality is ~9X that of prevention cost of quality**

# Timing is Everything – DFMEA Example



# FMEA Best Practices

<u>Best Practice</u>	<u>Description</u>	<u>Benefit</u>
Strategic Planning	At the planning stage for the entire project, define the tools that will be used to identify and mitigate failure modes. Define the resources required, including a schedule with estimated dates & duration of working meetings.	Enables the project manager to incorporate the time required to complete the FMEA Activities into the master project schedule. Resources allotted.
Just in Time Training	Train the team, including all participants, on the methodology of FMEA at the start of the first meeting.	Aligns and involves all team members on the expectations allowing team members to focus on the input to the FMEAs.
Facilitator	<ul style="list-style-type: none"> <li>-Should be an expert in the FMEA process.</li> <li>- Focuses on the team's process more than its product. Pays attention to the effectiveness of the team.</li> <li>- Takes responsibility for the significant planning and preparation work.</li> </ul>	Remains a neutral party enabling the team to successfully generate high quality information to populate the FMEA.

# FMEA Best Practices

<u>Best Practice</u>	<u>Description</u>	<u>Benefit</u>
Subject Matter Experts	Utilize the system/product designer, marketing, regulatory, quality, operations/manufacturing personnel, as well as an independent reviewers without a vested interest to participate in the FMEA meetings.	Keep attendee requirements to a minimum for optimum resource utilization.
Structure – Working Meetings	<p>-Meetings should be no more than 2 hours in length.</p> <p>-Ensure that the system is divided into logical partitions that are manageable in size. Review the design and process using functional block diagrams, system design, architecture, and process flow charts.</p> <p>-Use customer return data and internal process failure data from a comparable product or process, or supplier data.</p>	<p>Optimizes the use of resources so that burnout does not occur.</p> <p>Enables a logical approach to systematically review a system or process.</p> <p>Optimizes use of data. Note: Data must be accurate to provide relevance.</p>

# FMEA Best Practices

<u>Best Practice</u>	<u>Description</u>	<u>Benefit</u>
Working Meeting Tools	<p>The working meeting should be focused on generation of high quality information. Focusing on the function of each system/sub-system, component, or process step, and utilizing a white board or Post-it notes,</p> <ol style="list-style-type: none"> <li>1. Start with brainstorming and relevant historical data to generate failure modes.</li> <li>2. Define causes using tools such as 5-whys, brainstorming, or TRIZ .</li> <li>3. Effects: Create C&amp;E matrices, Mind-maps, or use other tools to define cause effects. Effects may be internal or external.</li> <li>4. Controls: Define the existing mechanisms implemented to either prevent the failure mode or minimize the potential to escape to the customer or negatively impact the customer. Preventative controls are most desirable.</li> </ol>	Enables more effective human interaction and makes FMEA sessions more productive to generate higher quality content.

# FMEA Best Practices

<u>Best Practice</u>	<u>Description</u>	<u>Benefit</u>
Severity, Occurrence, and Detection Ranking Definition & Recommended Ranking Scale	<p>Clearly define the individual scales that will be used to rank Severity, Occurrence, and Detection.</p> <p>-Severity: Is linked to the effect and the impact that the effect will have on the customer, user, or function of the device.</p> <p>-Occurrence: Linked to the Cause of Failure. It is the estimated/perceived, or known actual likelihood of the cause to occur leading to the failure mode.</p> <p>-Detection: Linked to the controls. This is the likelihood that the current controls in place will prevent or identify the failure mode or cause.</p>	<p>Define objective scoring criteria that will be applied prior to ranking in the FMEA. This minimizes the subjectivity and time spent on clarification during the ranking process.</p>

# FMEA Best Practices

- SOD Scoring Example (DFMEA):

Rating	Severity	Occurrence	Detection
9	Product failure resulting in hazardous effects highly probable. Compliance with government regulations in jeopardy.	Very high likelihood. Failure is a continuous problem.	Design and/or process detection method is unproven, unreliable or unknown.
7	Failure results in no injury. The product is inoperable with loss of primary Function. High level of customer dissatisfaction.	Moderately high likelihood. Frequent Failures.	N/A
5	Failure creates enough of a performance loss to cause the customer to complain.	Moderately low likelihood. Intermittent failures.	Failure mode is not designed out of system. Detection is in in-process control/in-process testing during manufacturing or verification &/or validation testing.
3	Product is non-conformant. Average customer notices the defect as a minor nuisance that can be overcome without product performance loss.	Very low likelihood	N/A
1	None. Failure would not be noticeable to the customer.	Extremely unlikely	Failure mode is designed out of the product.

# FMEA Best Practices

<b><u>Best Practice</u></b>	<b><u>Description</u></b>	<b><u>Benefit</u></b>
Risk Priority Number Mitigation	<ul style="list-style-type: none"><li>-It is recommended to define corrective actions for all items having a Severity ranking of “9” or “10”.</li><li>-Assign corrective actions to the top 20% of the Pareto items from the FMEA.</li><li>-Focus efforts on preventative controls to design out the failure modes.</li><li>-Track action items with an owner and due date to closure on an action item tracker sheet.</li><li>-Link any and all reports back to the specific line items on the FMEA for traceability purposes.</li></ul>	After corrective actions are completed and results analyzed, the team should go back and update the new Severity, Occurrence, and Detection ratings, as appropriate. All information should be documented in the FMEA form for traceability purposes. The FMEA may also be utilized by future project teams as relevant historical information.

# Key Takeaways

## FMEA...

1. Is a tool and should be used as part of your toolbox to incorporate quality throughout product development.
  - Has high return on investment in some and not all types of projects
2. Is considered as a “preferential” cost of quality
3. Planning and Timing of FMEA application and execution is critical.
4. Train and involve team members for optimized understanding of FMEA practices
5. Identify, train, and utilize facilitators in companies to promote standard FMEA practice
6. Optimize resources and effectively structure working meetings
7. Define objective Severity, Occurrence, and Detection rankings
8. Define and follow through on corrective actions