

What would FMEA 3.0 be?

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Collaborative Processes



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*Every adversity, every failure,
every heartache carries
with it the seed on
an equal or
greater benefit*

- Napoleon Hill



***But it is better to fail early in development
where the pain isn't as great***

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Failure Mode Effects Analysis (FMEA)

Item / Function	Potential Failure Mode	Potential Effect(s) of Failure	S V Classification	Potential Cause(s) of Failure	O C C	Current Design Controls (Prevention)	Current Design Controls (Detection)	D E T R I P T N	Recommended Actions	Responsibility & Target Completion Date	Action Results			
											S O R	E F F	T H R	
Provide the correct level of friction between brake pads assembly and wheel rim to enable stop bicycle in the required distance, under all operating conditions.	Low friction between brake pads assembly and wheel rim to enable stop bicycle in the required distance, under all operating conditions.	Bicycle wheel does not stop down when the brake lever is pulled, potentially resulting in accident.	10	Cable Brake cable to inadequate lubrication or poor routing	4	Design review of brake system	Bicycle system durability test # 755	2	00	Modify bicycle assembly design to include periodic brake cable lubrication				
				Incorrect design (brake pads)	2			3	00	Modify bicycle assembly design to include design material (Steel, Invar, etc.) to increase of brake pad and wheel rim				
				Cable breaks	6	Cable material selection based on ANSI #303C		Bicycle system durability test # 756	4	00	1. Re-evaluate cable OHS from cable supplier etc. 2. Add Periodic PFMEA review. 3. Based on result of Cable DFMEA, develop cable strength test.			
				Brake Lever breaks	3	Design review of brake system		Bicycle system durability test # 755	1	00				
Brake system to stop bicycle system	Brake system does not stop down when the brake lever is pulled, potentially resulting in accident.	Bicycle wheel does not stop down when the brake lever is pulled, potentially resulting in accident.	10	Selected brake pad material does not supply required friction to wheel	2			2	00	Add brake test / adequate time				
				Brake cable wire	4			Bicycle system	3	00	1. Develop test			



Types: FMECA, DFMEA, PFMEA,...

FMEA Example

Function	Failure Mode	Potential Effects	Severity	Severity x Occurrence x Detection		
Ball point delivers ink to paper	Non consistent ink delivery to paper	Intermittent, incomplete lines.	7			
			7			
	Potential Causes	Prevention Controls	Occurrence	Detection Control	Detection	Risk Priority Number
	Ball diameter variations	Tolerance Specification	1	Process Control XYZ	2	14



One of the more popular tool for risk management

Personal Risk Management



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Group Risk Management

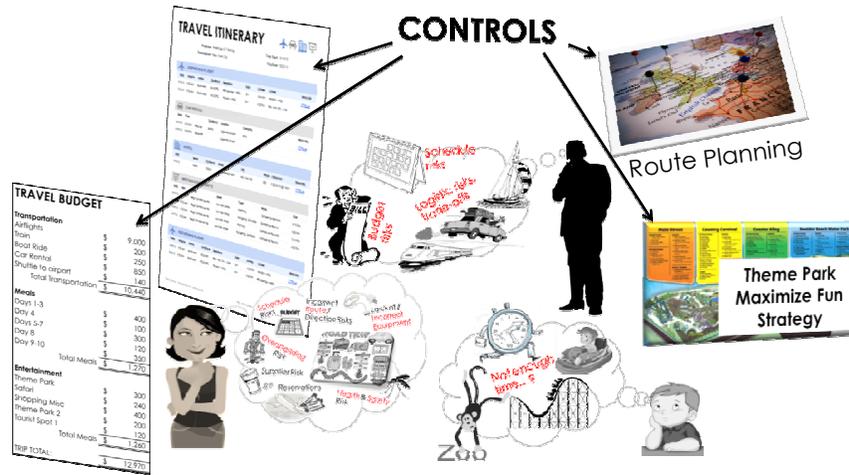


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Group Risk Management



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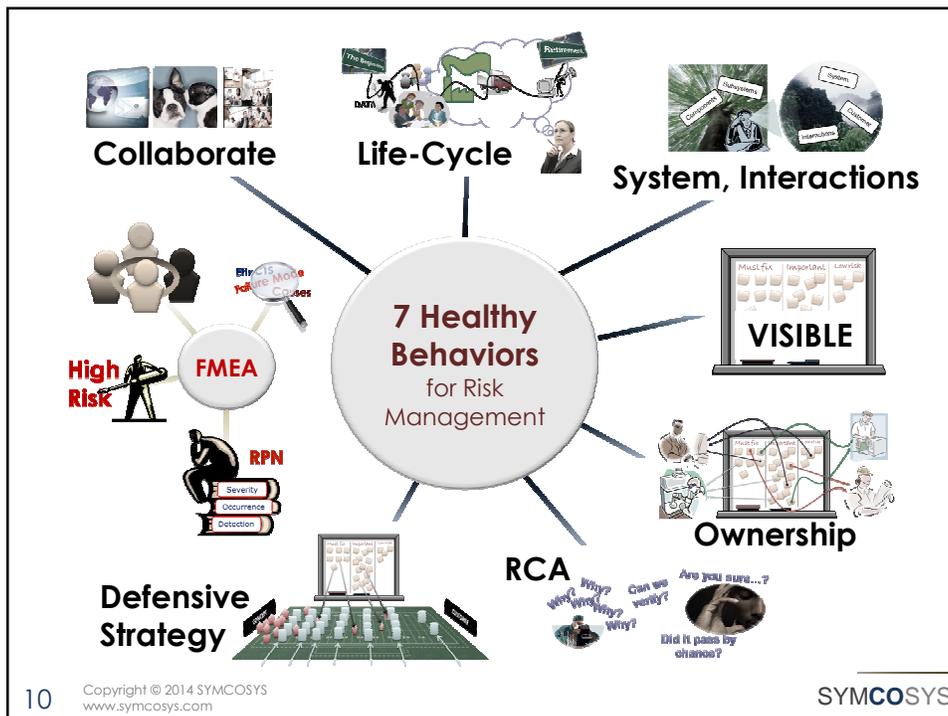
Risk Management Overview



Identify, Assess, Prioritize



Eliminate, Minimize,
Control, Transfer



Why FMEA - Overview?

Severity × Occurrence × Detection = Risk Priority Number

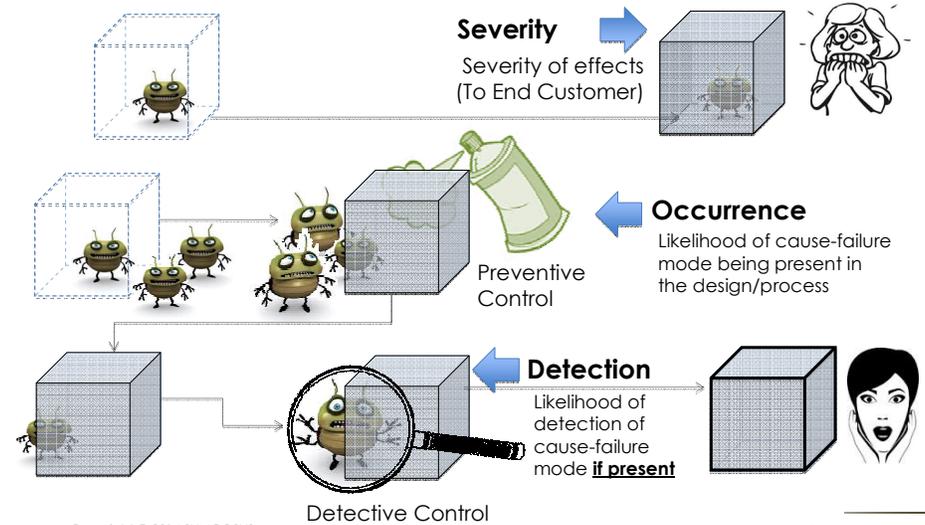
Item / Function	Potential Failure Mode	Potential Effect(s) of Failure	SEV	Potential Cause(s) of Failure	OCC	Current Design Controls (Prevention)	Current Design Controls (Detection)	DET	Recommended Actions	Responsibility & Target Completion Date	Action Results
Provide the correct level of friction between brake pad assembly and wheels to enable stop bicycle in the required distance, under all operating conditions.	Insufficient friction between brake pads and wheels during heavy rain conditions.	Bicycle wheel does not clear down when the brake lever is pulled potentially resulting in excessive.	10	Cable brake line to inadequate lubrication or poor routing Excessive brake master cylinder pressure	4	Design review of brake system	Bicycle system durability test of 750	2	Verify bicycle durability testing on cable master cylinder cable rack for lubricating		
				Cable brake	6	Cable material selection based on AMSI #MSL	Bicycle system durability test of 750	4	Require cable OEMs / PA on cable supplier approval - Update PPE's parts. Based on results of Cable PPE's develop cable strength IC		
				Brake Lever Brakes		Design review of brake system	Bicycle system durability test of 750	1			
				Selected brake pad material does not apply required friction to	1			1	if bench test to evaluate required brake pad friction		
								2	Develop new brake cable		

Reduce Risk, Improves Design & Controls

Structure for assurance

Risk Ratings – How it works

(Independent)

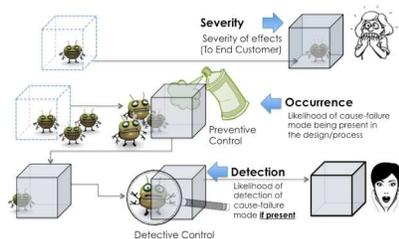


Risk Ratings – DFMEA Example

SEVERITY		OCCURRENCE		(Poor) DETECTION	
10	Hazard, non-compliance	10	Very High	10	Cannot Detect
9		9	1 in 3	9	
8	Primary Function Affected	8	High	8	
7		7			
6	Secondary Function Affected	6	Moderate	6	
5		5		5	Moderate
4	4	4			
3	Fit, Finish, Squeak / Rattle	3	Low	3	
2		2	1 in 1 Million	2	1 in 1 Million
1	No effect	1	Fully Prevented	1	Will Detect

Risk Ratings – How it helps

It breaks down the risk to its elements – better chance to identify risk reduction strategies.



And it helps prioritize risks

Examples of Risk Reduction Strategies

SEVERITY	<ul style="list-style-type: none"> • Eliminate failure mode • Redundancy • Compensating provisions
OCCURRENCE	<ul style="list-style-type: none"> • Eliminate failure mode • Thorough reviews • Analysis / Calculations • Redundancy
(Poor) DETECTION	<ul style="list-style-type: none"> • Design for testability • Improve test/analysis • Increase sample size • Apply higher stresses/environments

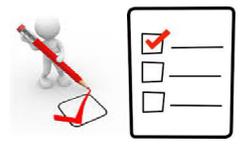
FMEA can be of value... BUT

For many organizations, the following are the things that make FMEAs feel **forced, unnatural** and perceived as a "**checklist**" activity:



Meetings are tedious

FMEA Output: Action items



Completing tasks
⊘ risk reduction

FMEA can be of value... BUT

For many organizations, the following are the things that make FMEAs feel **forced, unnatural** and perceived as a "**checklist**" activity:

Playing Catch Up.

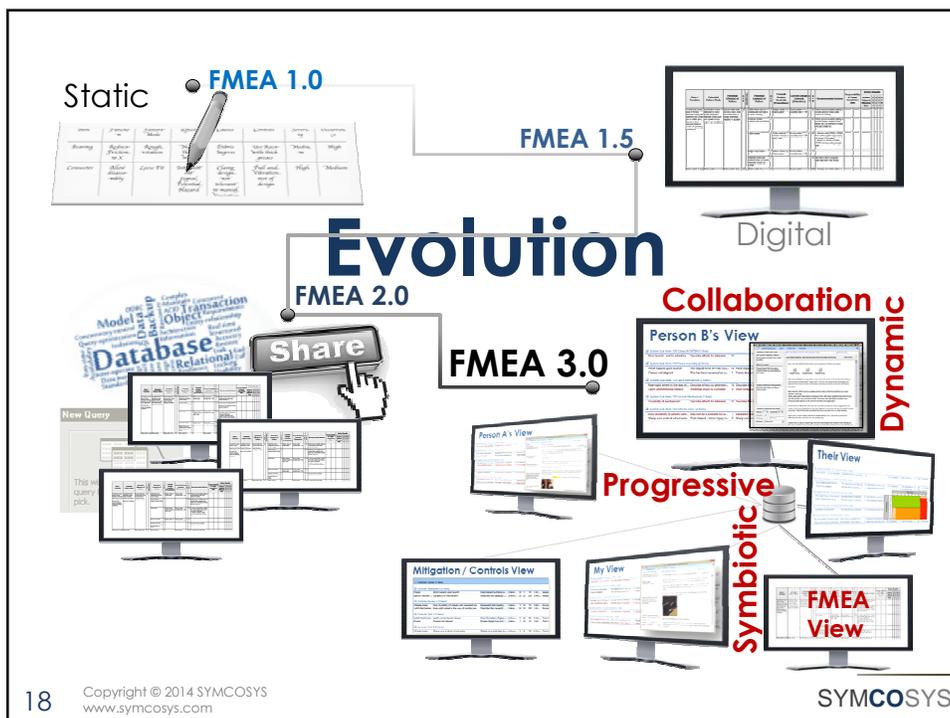


Limited scrutiny of CONTROLS



What we've covered

- Brief intro into FMEA
- Risk Management
- Why FMEA and Risk Ratings
- FMEA Challenges
- ...*The future of FMEA*



Collaborative Risk Assessment & Management

Progressive FMEA

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Each failure has many 'owners' *With different perspectives*



Engineer: The problem is this... and the fix is...

Test owner: Why didn't my test detect this?



Manufacturing QA: Production controls that will Prevent?



FMEA Facilitator: Root cause? Severity? Likelihood? Detection?



Manager: Will this affect our project?



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Progressive FMEA Example

Function	Failure Mode	Potential Effects	Severity	Potential Causes	Prevention Controls	Occurrence	Detection Control	Detection	Risk Priority Number
Ball point delivers ink to paper	Non consistent ink delivery to paper	Intermittent, incomplete lines.	7	Ball diameter variations	Tolerance Specification	1	Process Control XYZ	2	14
			7	Debris ingress affecting ink flow	Special 'Tip' design and tight tolerances	2	Debris ingress test	6	84
			7	Insufficient pressure applied by user	Usage force study	4	Ink delivery Design of Experiments	4	112

Test guy: "I don't think the current debris test verifies this risk adequately. I suggest..."

Progressive FMEA Example

Function	Failure Mode	Potential Effects	Severity	Potential Causes	Prevention Controls	Occurrence	Detection Control	Detection	Risk Priority Number
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			7	Debris ingress affecting ink flow	Special 'Tip' design and tight tolerances	2	Debris ingress test + Step Stress	6	84
			7	Insufficient pressure applied by user	Usage force study	4	Ink delivery Design of Experiments	4	112

+ Step Stress

Engineer: "Test guy and I decided to make some modifications... by step stressing..."

Progressive FMEA Example

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			7	Debris ingress affecting ink flow	Special 'Tip' design and tight tolerances	7	Debris ingress test <i>+ Step Stress</i>	3	147
			7	Insufficient pressure applied by user	Usage force study	↑	↑	↑	↑

+ Step Stress

Facilitator: "See attached email, we agree detection has improved ... but occurrence..."

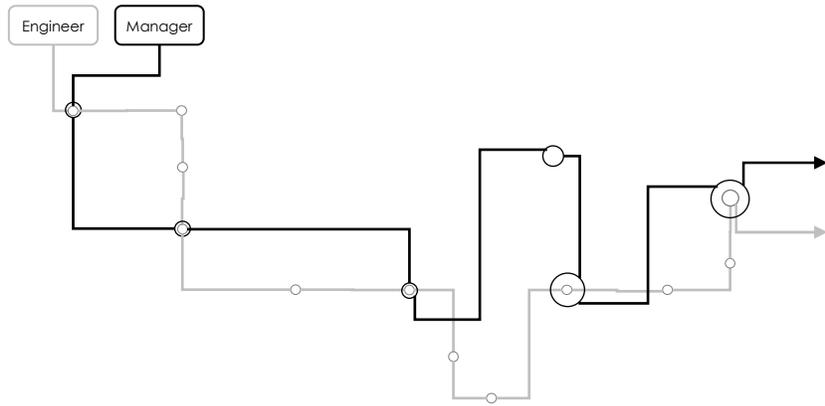
Progressive FMEA Example

Function	Failure Mode	Potential Effects	Severity	Potential Causes	Prevention Controls	Occurrence	Detection Control	Detection	Risk Priority Number
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			7	Insufficient pressure applied by user	Usage force study	↑	↑	↑	↑

+ Step Stress

Engineer: "We've identified a potential fix... working on it..."

Risk Management Interactions

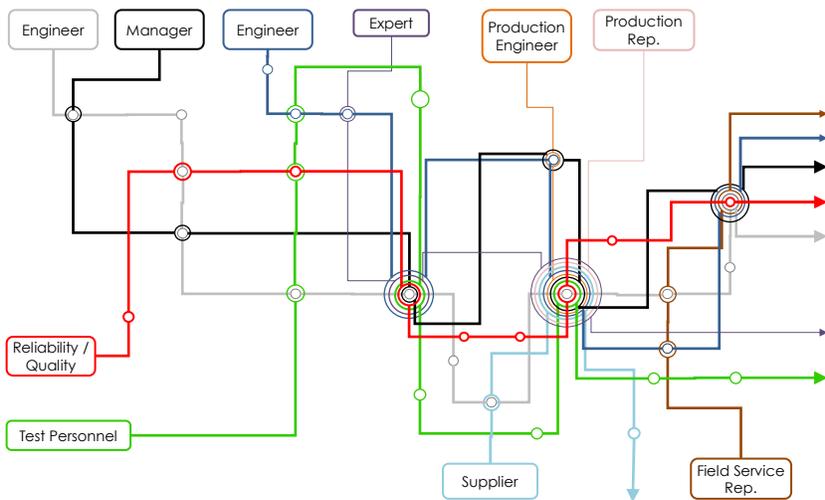


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Risk Management Interactions



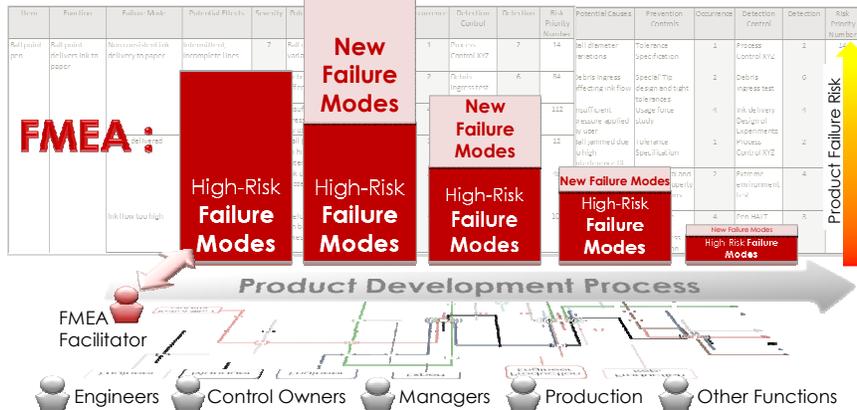
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Aim: Good Capture & Management of Risk

VISUAL INDICATORS:



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Progressive FMEA's AIM:

Is NOT to complete FMEAs to reduce risk,

but ...to foster interaction and collaboration to reduce risk, guided by FMEA fundamentals.

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Risk ratings changes for each Failure Mode “as it happens”.

Guilty until proven/justified approach, doesn't use RPN_i & RPN_r

Progressive FMEA

Is the progressive risk analysis and management of each failure mode, as it evolves through the risk discovery and reduction process;

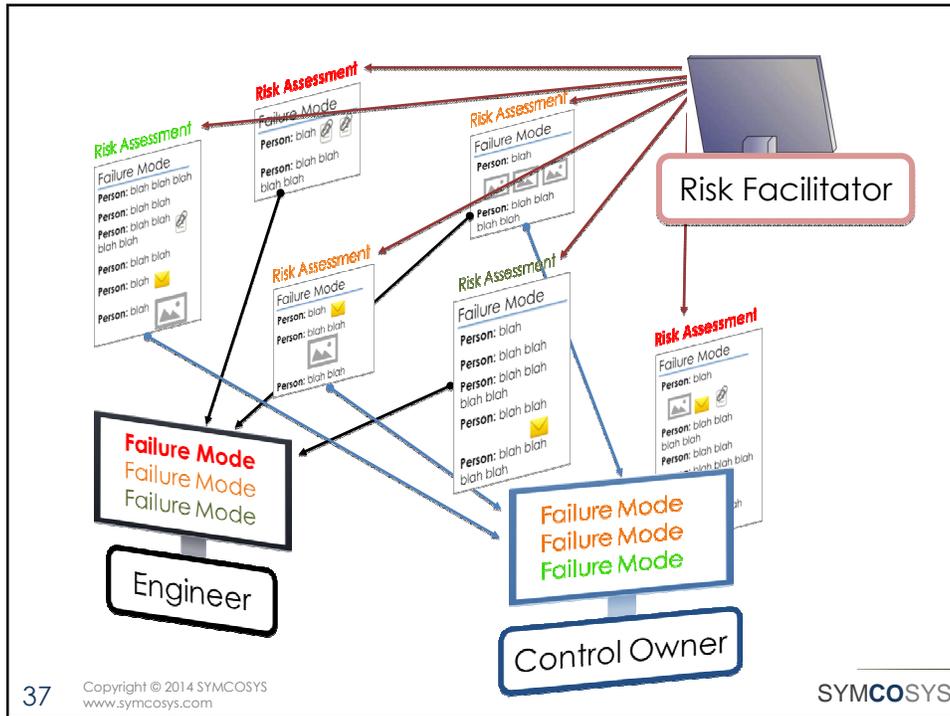
based on collaborative development of captured and organized information, from cross functional team members led by constantly visible risk metrics and dynamic facilitation.

Progressive FMEA

Can be implemented using **MS Outlook™**, **MS SharePoint™** or your own system.

The screenshot displays a Progressive FMEA interface. On the left, a table lists failure modes with columns for Failure Mode, Effects, Cause(s), PreventiveControls, DetectionControls, RPN, and Status. One failure mode, 'Pinch hazard upon launch', is highlighted. A red box labeled 'FMEA' points to this entry. To the right, a detailed view of this failure mode is shown, including its RPN (700) and SdC (70). Below this, there are sections for 'Effects to Customer', 'Detection Controls/Mitigations', and 'Prevention Controls/Mitigations'. A discussion thread is visible, with comments from users like 'RE consumer product safety mag' and 'Bob 19 Feb', discussing the impact force and safety requirements. A red box highlights the discussion area. The text 'Conversations, Clues, Information & Dynamic Facilitation' is overlaid on the discussion area.

Progressive FMEA Forum Live DEMONSTRATION



Benefits

Of the Progressive FMEA process



- **Prevent cost of poor quality** – Through improved interactions and collaboration to reduce risk based on FMEA fundamentals.
- **Increased information capital** – More than just an FMEA sheet – Very rich in information. Highly Re-usable.
- **Higher ROI on time spent** – Lean practice of FMEA

Thank You



**Any
Questions?**

