Failure Mode and Effect Analysis (FMEA)

MASTERING RISK MANAGEMENT WITH THIS SIMPLE, EFFECTIVE APPROACH

Learning Objectives

- Understand the intent of an FMEA
- Identify the contents of an FMEA
- Interpret the outcomes of an FMEA
- Distinguish between the three different types of FMEA that are most useful
- Explain to others why FMEA is a tool they should adopt to decrease stress associated with “What if?”
- Apply FMEA instruction as you execute an FMEA for one of your processes

Agenda

- Definition of FMEA
- History of FMEA
- FMEA Execution
- Three ways to use FMEA
- Why FMEA in the Laboratory?
- FMEA in practice

Definition of FMEA

- Failure Modes and Effects Analysis
  - A risk identification and management tool that allows the user to understand potential risks and document a plan for active mitigation.
  - A tool used to clearly document potential failure modes allowing visibility and knowledgeable communication to ensure highest quality of a new design, process, department, etc.
  - Assesses the Severity (S) of a potential failure, the potential rate of Occurrence (O) of the cause of that potential failure and the ability to Detect (D) the failure and/or cause. The Risk Priority Number (RPN) is the result of multiplying S x O x D and provides us with quantitation of the risk. RPN should be low.
  - Important to look at all the high ratings in addition to the overall RPN.
  - Recommend using 1,5 and 9 rating scale for S, O and D

Side Note: Definition of FMECA

- Failure Modes and Effects and Criticality Analysis (FMECA)
  - Provides added component of criticality for the end user.

History

- Developed by American military in 1940’s
- Nuclear and aerospace industries soon after
- NASA
- Ford Motor Company implemented FMEA in design process in 1970’s
- Incorporated into standards for automotive production and suppliers in 1993.
- Any industry demanding high levels of reliability and quality.

FMEA Tool and Execution

Failure Modes and Effects Analysis (FMEA)

Process Name/Subject: **Department:** **Date:**

Process Area Process Step Improvement	Process Input / Critical Input	Potential Failure Mode	Potential Failure Effect	SEV	Potential Causes	OCC	Current Controls	DET	RPN	Actions Recommended	Responsible	Actions Taken	SEV	OCC	DET	RPN
What is the focus of this Failure?	This column adds detail as needed to identify the focus of the Failure Modes.	How could the Input Fail? How could the specific process Fail? How could the Improvement Fail? List each potential Failure on a new line/row	What is the impact on the Critical to Quality outputs / customer needs? List each Effect on a new line/row	How severe is a Failure to the customer?	What are the potential causes of the Failures? List each Cause on a new line/row	How often does the cause of the Failure Mode occur?	What controls/ mistake proofing processes are in place to avoid the Cause or Failure? List each Control on new line/row	How easy is it to detect either Failure or Cause?	Calculation	What are the actions for reducing the occurrance of the Cause, or improving detection?	JRM	What actions were done? Recalc. RPN				

Area of Focus

Process Area Process Step Improvement	
What is the focus of this Failure?	This is where we identify the Process, Product, Design or Improvement we are working with to identify associated Risks.

Area of Focus – More Detail

Process Area Process Step Improvement	Process Input / Critical Input	
What is the focus of this Failure?	This column adds detail as needed to identify the focus of the Failure Modes.	This column may or may not be filled out depending on the level of detail. There may be a Department you are working with and this is the Assay or Process within that department. If further detail beyond what you put in column 1 is not required then no need to put anything here.

Identifying Potential Failure Modes

Process Area Process Step Improvement	Process Input / Critical Input	Potential Failure Mode
What is the focus of this Failure?	This column adds detail as needed to identify the focus of the Failure Modes.	How could the Input Fail? How could the specific process Fail? How could the Improvement Fail? List each potential Failure on a new line/row

This is where it begins.
What could go wrong with this process, product, etc.? In some cases you know it can go wrong because it has. You definitely put those things down as well as things that people think could go wrong. Right now we don't need to know how often they would. That will come up later.
Put each new failure mode in a new row.
Don't discount what anyone has to say. You don't want to miss anything.
Very important to ask the people upstream and downstream to ensure you understand how this process, product, etc. is or could affect other areas, processes.

How Does it Affect the Customer?

Process Area Process Step Improvement	Process Input / Critical Input	Potential Failure Mode	Potential Failure Effect
What is the focus of this Failure?	This column adds detail as needed to identify the focus of the Failure Modes.	How could the Input Fail? How could the specific process Fail? How could the Improvement Fail? List each potential Failure on a new line/row	What is the impact on the Critical to Quality outputs / customer needs? List each Effect on a new line/row

Now think about how this failure could, and perhaps already does, affect the end user/customer. In some cases we consider Lab Administration the customer. In nearly 100% of the cases the Patient and/or Physician will be this customer.
List every effect in a new row.

How Badly will it Affect the Customer?

Process Area Process Step Improvement	Process Input / Critical Input	Potential Failure Mode	Potential Failure Effect	S E V
What is the focus of this Failure?	This column adds detail as needed to identify the focus of the Failure Modes.	How could the Input Fail? How could the specific process Fail? How could the Improvement Fail? List each potential Failure on a new line/row	What is the impact on the Critical to Quality outputs / customer needs? List each Effect on a new line/row	How severe is a Failure to the customer?

Severity (S) Rating:
If/when this failure does happen how bad/severe will it be to the customer? What is the severity of the Effect?
Example: Rating of 1 = Not bad, Customer will not complain, but may mention it.
Rating of 5 = The Customer lets us know and they are not happy. No major negative health outcome.
Rating of 9 = Major negative health outcome. The Customer may not be able to be the one who makes contact.

Note: Each organization should agree on their own rating scales to keep understanding of the ratings consistent among all users.

What May Cause this Failure?

Process Area Process Step Improvement	Process Input / Critical Input	Potential Failure Mode	Potential Failure Effect	S E V	Potential Causes
What is the focus of this Failure?	This column adds detail as needed to identify the focus of the Failure Modes.	How could the Input Fail? How could the specific process Fail? How could the Improvement Fail? List each potential Failure on a new line/row	What is the impact on the Critical to Quality outputs / customer needs? List each Effect on a new line/row	How severe is a Failure to the customer?	What are the potential causes of the Failures? List each Cause on a new line/row

List the thing(s) that may be the cause of the Failure Mode identified.
Place each new cause in a new row.

How Often Might Those Causes Occur?

Process Area Process Step Improvement	Process Input / Critical Input	Potential Failure Mode	Potential Failure Effect	S E V	Potential Causes	O C C
What is the focus of this Failure?	This column adds detail as needed to identify the focus of the Failure Modes.	How could the Input Fail? How could the specific process Fail? How could the Improvement Fail? List each potential Failure on a new line/row	What is the impact on the Critical to Quality outputs / customer needs? List each Effect on a new line/row	How severe is a Failure to the customer?	What are the potential causes of the Failures? List each Cause on a new line/row	How often does the cause of the Failure Mode occur?

Occurrence (O) Rating:
How often does the Cause of each Failure Mode occur?
Example: Rating of 1 = We think it could happen but it will be extremely rare.
Rating of 5 = It could happen 50% of the time.
Rating of 9 = It is likely to happen very often.

What is in Place to Prevent Failure?

Process Area Process Step Improvement	Process Input / Critical Input	Potential Failure Mode	Potential Failure Effect	S E V	Potential Causes	O C C	Current Controls
What is the focus of this Failure?	This column adds detail as needed to identify the focus of the Failure Modes.	How could the Input Fail? How could the specific process Fail? How could the Improvement Fail? List each potential Failure on a new line/row	What is the impact on the Critical to Quality outputs / customer needs? List each Effect on a new line/row	How severe is a Failure to the customer?	What are the potential causes of the Failures? List each Cause on a new line/row	How often does the cause of the Failure Mode occur?	What controls/ mistake proofing processes are in place to avoid the Cause or Failure? List each Control on new line/row

Is there anything in place or have you already actively planned and/or designed something to act as a Control to help ensure this Failure Mode does not happen? If yes, that is what goes in this column.

Many people say they have policies or SOPs acting as controls. Those are considered controls. They are not necessarily high-value controls for this purpose.

List each different Control in a new row.

Will You Know If the Failure Happens?

Process Area Process Step Improvement	Process Input / Critical Input	Potential Failure Mode	Potential Failure Effect	S E V	Potential Causes	O C C	Current Controls	D E T
What is the focus of this Failure?	This column adds detail as needed to identify the focus of the Failure Modes.	How could the Input Fail? How could the specific process Fail? How could the Improvement Fail? List each potential Failure on a new line/row	What is the impact on the Critical to Quality outputs / customer needs? List each Effect on a new line/row	How severe is a Failure to the customer?	What are the potential causes of the Failures? List each Cause on a new line/row	How often does the cause of the Failure Mode occur?	What controls/ mistake proofing processes are in place to avoid the Cause or Failure? List each Control on new line/row	How easy is it to detect either Failure or Cause?

Detection (D) Rating:
If the Failure does occur will you be able to detect it? If yes, how easily and when? Before or after the Customer does?
Example: Rating 1 = When it goes wrong we'll know it right away before the Customer has an opportunity to see it.
Rating 5 = When it goes wrong we will probably be able to see and act on it internally before the Customer knows it happened.
Rating 9 = We will not find the Failure. The Customer or their representative will most likely be the one to let us know.

Interpreting the Risk

Process Area Process Step Improvement	Process Input / Critical Input	Potential Failure Mode	Potential Failure Effect	S E V	Potential Causes	O C C	Current Controls	D E T	R P N
What is the focus of this Failure?	This column adds detail as needed to identify the focus of the Failure Modes.	How could the Input Fail? How could the specific process Fail? How could the Improvement Fail? List each potential Failure on a new line/row	What is the impact on the Critical to Quality outputs / customer needs? List each Effect on a new line/row	How severe is a Failure to the customer?	What are the potential causes of the Failures? List each Cause on a new line/row	How often does the cause of the Failure Mode occur?	What controls/ mistake proofing processes are in place to avoid the Cause or Failure? List each Control on new line/row	How easy is it to detect either Failure or Cause?	Calculation

RPN = Risk Priority Number
This is a simple calculation – S x D x O
You want the RPN to be low. When you see your RPNs you will make the decision of what has the highest risk and needs to be acted upon.
In addition to the RPN review all ratings of 9 to ensure you aren't discounting a low to medium RPN that has, for example, Severity of 9.

High Risk - Planning

This section allows you to plan for mitigation if there are identified Failure Modes that you have decided show intolerable risk levels. Important to document the Plan and then follow up with what actually was done. The new S, O & D Ratings are completed when actions are completed to get new RPN. Continue the sheet with more actions if RPN still not within your specifications.

Actions Recommended	Responsible	Actions Taken	SEV	OCC	DET	RPN
What are the actions for reducing the occurrance of the Cause, or improving detection?	Who will be responsible to ensure actions are taken?	What actions were done? Recalc. RPN				

Simplified

- How could “It” go wrong?
  - Remember to think about what could happen upstream and downstream along with immediate area.
- What will or could happen when it goes wrong?
- If that happens what would be the most likely cause(s)?
- Do we have anything in place to prevent those cause(s)?
- If it happens can we detect it and when will we know?

Important Rules to Execute FMEA

- Execute in one room with a Group/Team
- PLAN for the right people to participate
  - Upstream representation
  - Downstream representation
  - Process representation
  - Big picture

Three Ways to Use FMEA

1. Assessment of the Value Stream
   - Areas or processes with highest risk potential
2. Individual New Design, Process, Department, etc.
   - Where are the potential risks that we need to take care of before the design is complete?
   - What risks do we need to be aware of and plan to mitigate?
3. Confirming process changes are lowest possible risk.
   - Process improvements can cause more problems then they fix.

Three Ways to Use FMEA

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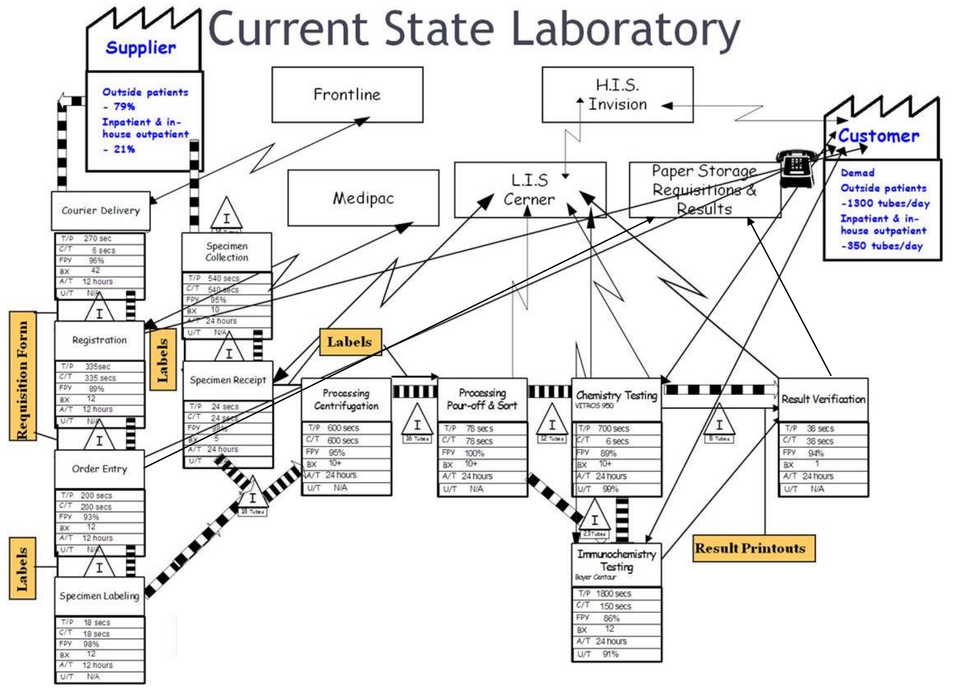
Assessment of the Value Stream

- Question: Where are the highest areas of risk in our Clinical Laboratory?
- Review the Value Stream Map (VSM):
  - Samples/Products waiting
  - Information – type and number of connections
  - High process times
  - Cycle times not meeting takt time
  - Multiple process steps within a department with wait times between them.



Example of Value Stream FMEA

Section of Value Stream	Area of focus	Potential Failure Mode	Potential Failure Effect	S E V	Potential Causes	O C C	Current Controls	D E T	R P N
What is the focus of this Failure?	This column adds detail as needed to identify the focus of the Failure Modes.	How could the Input Fail? How could the specific process Fail? How could the Improvement Fail? List each potential Failure on a new line/row	What is the impact on the Critical to Quality outputs / customer needs? List each Effect on a new line/row	How severe is a Failure to the customer?	What are the potential causes of the Failures? List each Cause on a new line/row	How often does the cause of the Failure Mode occur?	What controls/ mistake proofing processes are in place to avoid the Cause or Failure? List each Control on new line/row	How easy is it to detect either Failure or Cause?	Calculation
Processing Department	Registration, OE and Labeling separate steps with wait in between each	Lost specimen	Patient redraw	5	Employees not following standard	1	Standard work	5	25
Processing Department	Registration, OE and Labeling separate steps with wait in between each	Lost specimen	Late Dx	5	Too many touches	9	None	5	225
Processing Department	Registration, OE and Labeling separate steps with wait in between each	Mislabeled specimen	Incorrect results - wrong Dx	9	Multiple patient labels to choose from	9	None	9	729
Processing Department	Registration, OE and Labeling separate steps with wait in between each	Mislabeled specimen	Incorrect results - wrong Dx	9	Similar names	5	"Name Alert"	9	405
Processing Department	Registration, OE and Labeling separate steps with wait in between each	Mislabeled specimen	Incorrect results - wrong Dx	9	Employee not well trained	1	Labeling section of Training	9	81
Processing Department	Registration, OE and Labeling separate steps with wait in between each	Increased TAT	Late Dx	5	Specimens waiting between steps	9	None	1	45
Processing Department	Registration, OE and Labeling separate steps with wait in between each	Increased TAT	Patient misses daily discharge time	9	High volume time of day	5	None	1	45

Three Ways to Use FMEA

1. Assessment of the Value Stream
   - Areas or processes with highest risk potential
2. Individual New Design, Process, Department, etc.
   - Where are the potential risks that we need to take care of before the design is complete?
   - What risks do we need to be aware of and plan to mitigate?
3. Confirming process changes are lowest possible risk.
   - Process improvements can cause more problems then they fix.

Specific Design, Process, Department, etc.

- What risks may be associated with current processes, products, departments, etc.?
- What could happen to this new design (process or product) or as a result of this new design?

Example of FMEA for New Design

New Design/Product or Offering	Area of focus	Potential Failure Mode	Potential Failure Effect	SEV	Potential Causes	OCC	Current Controls	DET	RPN
What is the focus of this Failure?	This column adds detail as needed to identify the focus of the Failure Modes.	How could the Input Fail? How could the specific process Fail? How could the Improvement Fail? List each potential Failure on a new line/row	What is the impact on the Critical to Quality outputs / customer needs? List each Effect on a new line/row	How severe is a Failure to the customer?	What are the potential causes of the Failures? List each Cause on a new line/row	How often does the cause of the Failure Mode occur?	What controls/ mistake proofing processes are in place to avoid the Cause or Failure? List each Control on new line/row	How easy is it to detect either Failure or Cause?	Calculation
DNA Testing		Incorrect billing	Patient overcharged - Refund required	5	New - improper or not enough information/training	5		5	125
DNA Testing		Incorrect billing	Patient undercharged - Low reimbursement	5	New - improper or not enough information/training	5		5	125
DNA Testing		Incorrect billing	Review by government agency	9	New - improper or not enough information/training			5	0
DNA Testing		Low order frequency	Product wastage - expensive	9	Low physician awareness	5		5	225

Example of FMEA with Current Process Step

Process	Area of focus	Potential Failure Mode	Potential Failure Effect	SEV	Potential Causes	OCC	Current Controls	DET	RPN
What is the focus of this Failure?	This column adds detail as needed to identify the focus of the Failure Modes.	How could the Input Fail? How could the specific process Fail? How could the Improvement Fail? List each potential Failure on a new line/row	What is the impact on the Critical to Quality outputs / customer needs? List each Effect on a new line/row	How severe is a Failure to the customer?	What are the potential causes of the Failures? List each Cause on a new line/row	How often does the cause of the Failure Mode occur?	What controls/ mistake proofing processes are in place to avoid the Cause or Failure? List each Control on new line/row	How easy is it to detect either Failure or Cause?	Calculation
Phlebotomy	In patient AM Draw	Patient not in room	Increased TAT	5	No coordination betw departments	1	None	5	25
Phlebotomy	In patient AM Draw	Cannot get blood	Increased TAT	5	New Phleb	5	None	5	125
Phlebotomy	In patient AM Draw	Cannot get blood	Increased TAT	5	Patient type - Transplant, etc.	5	None		
Phlebotomy	In patient AM Draw	Cannot get blood	Late Dx	9	New Phleb	5	None	9	405
Phlebotomy	In patient AM Draw	Cannot get blood	Late Dx	9	Patient type - Transplant, etc.	5	None	9	405
Phlebotomy	In patient AM Draw	Mislabeled specimen	Incorrect results - wrong Dx	9	More than 1 patient's labels with the Phleb	9	None	9	729
Phlebotomy	In patient AM Draw	Mislabeled specimen	Incorrect results - wrong Dx	9	Phleb not trained	1	Labeling section of Training	1	9

Three Ways to Use FMEA

1. Assessment of the Value Stream
   - Areas or processes with highest risk potential
2. Individual New Design, Process, Department, etc.
   - Where are the potential risks that we need to take care of before the design is complete?
   - What risks do we need to be aware of and plan to mitigate?
3. Confirming process changes are lowest possible risk.
   - Process improvements can cause more problems then they fix.

Confirmation of Low Risk Process Changes

- Process Improvement Projects results in multiple opportunities to make changes.
- Long hours are put in planning for implementation.
- Always conduct a thorough risk analysis prior to planning any change.
- Mitigate risks to ensure change provides all benefits assumed.

Example of FMEA for Change

Solution / Process Change	Area of focus	Potential Failure Mode	Potential Failure Effect	SEV	Potential Causes	OCC	Current Controls	DET	RPN
What is the focus of this Failure?	This column adds detail as needed to identify the focus of the Failure Modes.	How could the Input Fail? How could the specific process Fail? How could the Improvement Fail? List each potential Failure on a new line/row	What is the impact on the Critical to Quality outputs / customer needs? List each Effect on a new line/row	How severe is a Failure to the customer?	What are the potential causes of the Failures? List each Cause on a new line/row	How often does the cause of the Failure Mode occur?	What controls/ mistake proofing processes are in place to avoid the Cause or Failure? List each Control on new line/row	How easy is it to detect either Failure or Cause?	Calculation
Deliver Clinic specimens not requiring processing directly to testing areas vs. stopping in Processing		No record of specimen receipt in Testing	Increased TAT	5	Specimen not scanned into LIS to show receipt in Testing	1	Specimen Drop Zones in Testing areas with dedicated LIS	1	5
Deliver Clinic specimens not requiring processing directly to testing areas vs. stopping in Processing		No record of specimen receipt in Testing	Extra time required by both Testing and Processing personnel to find.	5	Specimen not scanned into LIS to show receipt in Testing	1	Specimen Drop Zones in Testing areas with dedicated LIS	1	5
Deliver Clinic specimens not requiring processing directly to testing areas vs. stopping in Processing		No record of specimen receipt in Testing	Decreased confidence in Processing personnel	5	Specimen not scanned into LIS to show receipt in Testing	1	Specimen Drop Zones in Testing areas with dedicated LIS	1	5
Deliver Clinic specimens not requiring processing directly to testing areas vs. stopping in Processing		No record of specimen receipt in Testing	Decreased confidence in Processing personnel	5	Specimen not scanned into LIS in correct location	1	Specimen Drop Zones in Testing areas with dedicated LIS	1	5
Deliver Clinic specimens not requiring processing directly to testing areas vs. stopping in Processing		Specimens do not get to correct location	Increased TAT	5	Testing location training not adequate	1	Well designed and labeled rack system at each Clinic and Testing Drop Zone	1	5
Deliver Clinic specimens not requiring processing directly to testing areas vs. stopping in Processing		Specimens do not get to correct location	Extra time required by Processing personnel to pick up and deliver to correct location	5	Testing location training not adequate	1	Well designed and labeled rack system at each Clinic and Testing Drop Zone	1	5
Deliver Clinic specimens not requiring processing directly to testing areas vs. stopping in Processing		STAT and other samples in Processing delayed while Processor is delivering	Increased TAT for non-Clinic specimens	5	Processing schedule not providing for 1 person always in Processing while 1 is delivering	1		1	5
Deliver Clinic specimens not requiring processing directly to testing areas vs. stopping in Processing		STAT and other samples in Processing delayed while Processor is delivering	Increased TAT for non-Clinic specimens	5	Processing personnel at break, lunch or other non-processing area when delivery person is delivering	1	Schedule to ensure coverage in both Processing and Delivering Route at all times. Breaks and lunches set between delivery times or when more than 2 people are scheduled.	1	5
Deliver Clinic specimens not requiring processing directly to testing areas vs. stopping in Processing		Patients waiting to be drawn in OP Drawing Room	Patient satisfaction low	9	Schedule doesn't have enough people to cover Processing, Delivery and OP Drawing Room	1	Schedule should have coverage with OP Drawing Room patients waiting minimal amount of time. Low frequency of patients	1	9
Deliver Clinic specimens not requiring processing directly to testing areas vs. stopping in Processing		Patients waiting to be drawn in OP Drawing Room	Increased TAT for OP Drawing Room Patients	5	Schedule doesn't have enough people to cover Processing, Delivery and OP Drawing Room	1		1	5
Deliver Clinic specimens not requiring processing directly to testing areas vs. stopping in Processing		Specimen Drop Zones not large enough to accommodate all racks and specimens	Specimes lost or dropped on floor	9	Drop Zones not designed well	1	Pilot phase will test Drop Zone designs. Feedback from Processing and Testing departments will be solicited on regular basis	1	9
Deliver Clinic specimens not requiring processing directly to testing areas vs. stopping in Processing		Specimen Drop Zones not large enough to accommodate all racks and specimens	Specimes lost or dropped on floor	9	Drop Zones not changed by the Testing area personnel without consultation with PI Team and Processing.	5		1	45

Best Reasons to Use FMEA in Laboratory

1. Prevention vs. Reaction
   - Decrease number of Fire Fighting events
- Help choose meaningful improvement projects
- Keep the whole Value Stream top of mind
- Encourage employees to think about risk, resulting in better quality outcomes overall.
- Inspectors LOVE to see risk analysis as part of the regular protocol of the lab.

Reasons People Stray away from FMEA

- Intimidating
- Longgggggggggggggggggg
- Not sure what it really means or how to use it.

Let’s Do It

- Choose one of your
  - Processes
  - Offerings
  - New ideas or improvements you’re thinking of implementing
- To the best of your knowledge right now execute the FMEA. This will give you a good start to finish with the right group at your lab.

Thank you

Enjoy the Conference!