

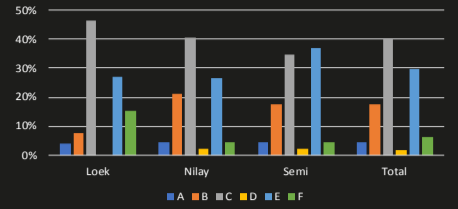
Results Workshop 1 | The "Perfect FMEA"

Question 1

What is your motivation to use the FMEA methodology for risk inventory?

- A We have a legal obligation
- B Our customer demands we do FMEA's
- C It is our company policy and part of our product development plan
- D We only do FMEA's when we have time
- E We like the structural approach
- F Other

	Loek	Nilay	Semi	Total
A	4%	5%	4%	4%
B	8%	21%	17%	18%
C	46%	41%	35%	40%
D	0%	2%	2%	2%
E	27%	27%	37%	30%
F	15%	5%	4%	6%



- Issues with previous products
Focus on prevention
- Commercial perspective
Early identify feasibility
- Increase customer satisfaction or sales
Avoid reoccurring engineering
- Better understanding quality of the customer
- Set scope
Decrease risk and increase quality
- Advanced development Projects
Input for design for diagnostics
- Input for better diagnostics and conditioning based maintenance

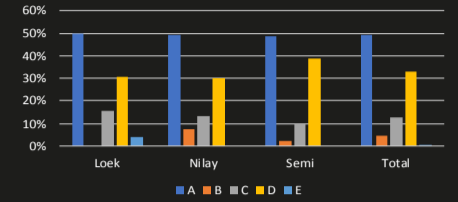
Main Take-Away Post-Its
FMEA is risk management plus more

Question 2

What is your opinion about the end results of a performed FMEA?

- A It gives me a good insight of the possible risks of the Design /Process
- B The FMEA does not bring new insights ; it is often a summary of things we already knew
- C The quality of the FMEA content differs a lot . It is difficult to formulate a clear Failure mode, Cause and Effect
- D We take notice of recommended actions and give follow up
- E Other

	Loek	Nilay	Semi	Total
A	50%	48%	49%	49%
B	0%	7%	2%	4%
C	15%	13%	10%	13%
D	31%	30%	39%	33%
E	4%	0%	0%	1%



- Output is various
- Good for communication
- Knowledge transfer

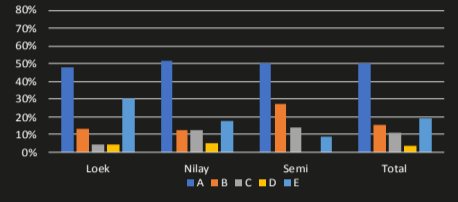
Main Take-Away Post-It
FMEA end result serves more than the primary purpose

Question 3

When do you decide to perform an FMEA on your design or process?

- A We decide to perform only FMEA's on critical parts/ processes , based on the opinion of the project team/PL/ Architect etc.
- B We use a criteria list when to perform FMEA's, when not
- C We do an FMEA only on request of our (external) customer
- D We do not use FMEA's
- E Other

	Loek	Nilay	Semi	Total
A	48%	52%	50%	50%
B	13%	13%	27%	16%
C	4%	13%	14%	11%
D	4%	5%	0%	4%
E	30%	18%	9%	19%



- Only new designs with critical components via CTQ flowdown
- Always FMEA for lessons learned/improve New requirements
- Always for re-use and interfaces
Always unless argued
- Tool for design maturity
New products for manufacturing process
- Focus on new introduced processes
Unclear decision management
- FMEA needs to be used for all designs and processes
Rough dFMEA
- For all electro-mechanical functions
In advanced developments projects

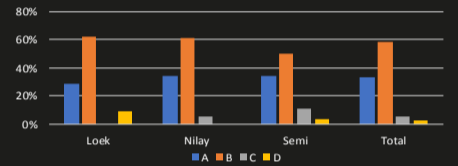
Main Take-Away Post-Its
Various reasons to start performing a FMEA

Question 4

How do you select your "brainstorm" team?

- A We invite the project team (architect, project engineers)
- B We invite relevant participants, based on the scope (subjects) of the FMEA
- C We have no defined strategy how to set up a brainstorm team
- D Other

	Loek	Nilay	Semi	Total
A	29%	34%	35%	33%
B	62%	61%	50%	59%
C	0%	5%	12%	6%
D	10%	0%	4%	3%



- Only SME's to limit resources
- Overview of all potential participants
- Discuss with Lead Engineer what/who is required
- Single person approach

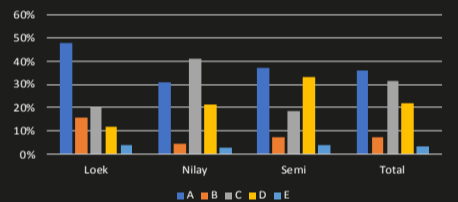
Main Take-Away Post-Its
FMEA participants composition varies

Question 5

How important is the brainstorm location?

- A We sit together in one room (group dynamic)
- B We use remote online videocall (Teams, Facetime etc.)
- C We combine remote and classroom
- D If possible (depending on the subject), near the subject, on the Gemba.
- E Other

	Loek	Nilay	Semi	Total
A	48%	31%	37%	36%
B	16%	4%	7%	7%
C	20%	41%	19%	32%
D	12%	21%	33%	22%
E	4%	3%	4%	3%



- Adapt to possibilities
Timezone
- Access to shopfloor
Adapt choice to scope
- Social aspects underestimated
Use recordings
- Go to Gemba, actual process, prototype, demonstration
- Go to Gemba, risk of working on currency issues operator specific
- Unimportant
- Remote from desk disturbs colleagues

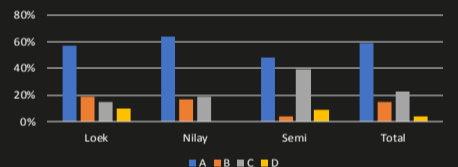
Main Take-Away Post-Its
Various meaning, preference to are near the subject (Gemba and/or Product

Question 6

How do you guide the brainstorm?

- A We use an FMEA facilitator /moderator to guide the brainstorm process
- B We use subject matter experts to motivate the team
- C We leave it to the brainstorm team
- D Other

	Loek	Nilay	Semi	Total
A	57%	64%	48%	59%
B	19%	17%	4%	15%
C	14%	19%	39%	23%
D	10%	0%	9%	4%



- If done ones with facilitator, then prefer facilitator
- Facilitator allows participants to stay in comfort zone
- What if insufficient resources/no facilitator?
- Risk biased facilitator if engineer facilitates
- Moderator
- Decision of PL if facilitator should be used or SA/LE moderators

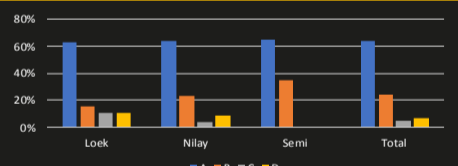
Main Take-Away Post-Its
FMEA to be guided by a facilitator is strongly preferred

Question 7

How do you rank the results of the brainstorm session(s)?

- A We use a ranking table with the RPN score (SOD number)
- B We use a ranking table with the AP score (High/Medium/ Low)
- C We have our own ranking method
- D Other

	Loek	Nilay	Semi	Total
A	63%	64%	65%	64%
B	16%	23%	35%	24%
C	11%	4%	0%	5%
D	11%	9%	0%	7%



- Detection excluded; only SxO
- Tables are company specific
- Distinguish risk types: customer and legal
- Used common sense on RPN-values
- Significant/critical
- Also ranking on severity and occurrence

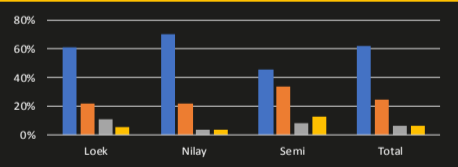
Main Take-Away Post-Its
Ranking is considered per company

Question 8

How to mitigate the defined actions?

- A Based on a ranking threshold (RPN/ AP Score)
- B Based on expected improvement (less impact if risk occurs , higher yield etc.)
- C Based on other priorities
- D Other

	Loek	Nilay	Semi	Total
A	61%	70%	46%	62%
B	22%	22%	33%	25%
C	11%	4%	8%	7%
D	6%	4%	13%	6%



- Also use: resources, cost/benefit, etc.
- Focus on safety in medical products
- High severity and high risk items need actions

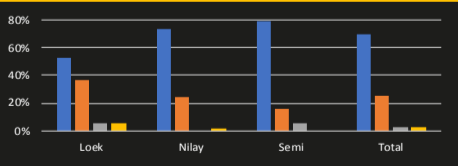
Main Take-Away Post-Its
Mitigations are based on RPN-scores, but additional aspect can be included

Question 9

Should we re-rank the defined risks (reduced risk impact of the implemented solution)?

- A Always
- B Sometimes, depending on the criticality of the risk
- C Never
- D Other

	Loek	Nilay	Semi	Total
A	53%	73%	79%	70%
B	37%	24%	16%	25%
C	5%	0%	5%	2%
D	5%	2%	0%	2%



- Need follow-up actions before re-ranking
- Issue resolution not part of scrum
- After RMM assessment the risk might go down, but not always

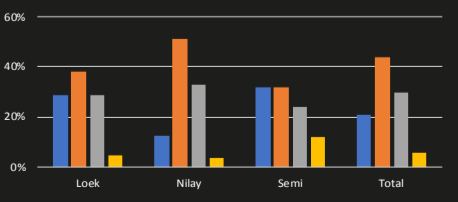
Main Take-Away Post-Its
Actions required prior to re-ranking.
Note: Access if mitigation action cause new risks

Question 10

How are FMEA-results from the past, integrated in the development of new products/processes?

- A We don't use historical data, we always start from scratch; previous FMEA are not traceable
- B Historical FMEA's plus the results, are stored in a dedicated folder somewhere
- C FMEA's are treated as living documents
- D Other

	Loek	Nilay	Semi	Total
A	29%	13%	32%	21%
B	38%	51%	32%	44%
C	29%	33%	24%	30%
D	5%	4%	12%	6%



- Old versus new FMEA
- Master Living FMEA too big to handle how to disseminate knowledge
- FMEA is > 20 years product doc in medical
- Risk engineer disturb structure

Main Take-Away Post-Its
It look like this is still an uncultivated topic.