Questions and Answers from the APQP4Wind Webinar – A Closer Look at FMEA, the tool for Risk Management

June 2nd, 2020

Morning Webinar (09:00-10:00 CEST)

Question 1 (Q1): In an organization, who do you think is responsible for deriving the customer specified characteristics from?
Answer 1 (A1): This question was answered in the webinar, please find the recordings here: www.apqp4wind.org/webinars or go to: https://youtu.be/0rvUnyzgyrs

Q2: Is it mandatory to use PFMEA format from APQP Workbook or we can develop our own format?
A2: This question was answered in the webinar, please find the recordings here: www.apqp4wind.org/webinars or go to: https://youtu.be/0rvUnyzgyrs

Q3: If we are the design authority, and our product is not custom design for a specific customer, how the DFMEA will provide the customer special characteristics to us? Or better to ask, how do we get the customer special characteristics?
A3: This question was answered in the webinar, please find the recordings here: www.apqp4wind.org/webinars or go to: https://youtu.be/0rvUnyzgyrs

Q4: Is it mandatory to consider all the process element in to control plan or only special characteristic?
A4: This question was answered in the webinar, please find the recordings here: www.apqp4wind.org/webinars or go to: https://youtu.be/0rvUnyzgyrs

Q5: What methods do you suggest for initiating the cultural change?
A5: This question was answered in the webinar, please find the recordings here: www.apqp4wind.org/webinars or go to: https://youtu.be/0rvUnyzgyrs

Q6: When suppliers are not ready to share the complete FMEA as per their policy, what solution do we accept? Shall we get the 1st page only as the evidence of document existence?
A6: It is common practice to accept reviewing the FMEA on site when a supplier regards the FMEA as critical organization -knowledge. I can imagine after COVID 19 that showing in teams/skype could also be an option. If the customer must have "solid" evidence you might agree putting a fraction of the FMEA in the PPAP, ex the 5 highest risk or alike.

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Q7: The evaluation of the 'Action Results' rankings should be done after all measures are executed or we should estimate the results of the actions proposed?
A7: First estimate as basis for decision , then evaluate again after implementation and first results.

Q8: Should we consider mitigation of risks on basis of RN matrix or RPN itself?
A8: RN matrix.

Q9: Some of the organization have defined RPN number to act. Below that no action is required. Is it okay?
A9: It was and is not a recommended best practice, you should use the RN matrix mainly, which makes the previous prioritizing: "First Severity, then occurrence" operational.

Q10: In an organization, who do you think is responsible for deriving the customer specified characteristics from DFMEA and customer requirements?
A10: If you follow the APQP4Wind organization set up the leader of the Product Quality Planning Team should make sure this happens. It could well be delegated to sales rep in the group, or even better it could happen "automatically" by your Quality Management System.

Q11: Is a DFMEA necessary if the delivered product is standardized?
A11: Yes, any product should be covered by a DFMEA also a commodity / standard product (catalogue part). The DFMEA will then be generic but will need update if the product is customized for the specific application.
(See also the DFMEA answer for Q3 given in the APQP4Wind Morning Webinar)

Q12: I have the same question about reevaluation of risks after mitigation actions are defined, when should it be done? After their implementation or during FMEA creation?
A12: *See the answer for Q2 given in the APQP4Wind Morning Webinar*

Q13: How to calculate sampling size for MSA in case of wind turbine components manufacturing?
A13: You cannot calculate. The recommended set up for Type 2 is full scale, but the tool works for reduced number of parts, repetition, and operators also to accommodate to practical limitations if present. The "price" for reducing is statistical uncertainty increasing.

Q14: Is there a method for managing our confidence or uncertainty when doing the FMEA scoring?
Q14: Practice and experience. And be aware that the first scoring should be updated as knowledge is gained with verification and validation activities or true out the life cycle of the product as knowledge are building. So, the first scoring is only the first and if it is not fully correct there are plenty of opportunities to update it.

Q15: Is PFMEA a required for all risk items (Low, Medium, High)? According to APQP4Wind guideline?
A15: According the PPAP scoping matrix p 49 it might be agreed that it is not required for low

risk items. PFMEA is however a process risk analysis and does not always need to be part specific (e.g. It might exist already).

Q16: Can you share your thoughts and advice on Software DFMEAs?
Q16: No, there are very many applications available to support the process. But what the best fit for you company and organization would be, do fully depend on the need, situation, and other applications it should be working together with.

Q17: Who is responsible for periodical review and update of PFMEA?
A17: To be decided in your system. But review should happen as a step in your change management (as applicable) including changes initiated from claim, warranty, and field failures.

Q18: Is capacity analysis part of PFMEA?
A18: As concept, no. But if you identify critical to process characteristic then you must proof capable on the t characteristic.

Q19: How can we get the FMEA handbook?
A19: You can buy the FMEA book from BV – See the mail address at the commercial slide.

Q20: Are the new changes of AIAG/VDA changes applicable for APQP4WInd? If yes will there be revision of APQP4Wind Manual?
A20: It is not for us as training providers to decide, however I believe that there is no need to update the APQP4Wind Manual for that purpose alone and right now.
The adherence to AIAG/VDA is not a wind requirement for now.
The AIAG/VDA provides more guideline in methodology for conducting the FMEA than the shorter APQP4Wind, but no conflict as I see it.
The action priority thinking is well aligned, you might find minor difference in the results of the action priority (but not more that you can handle in your QM system in case you supply both Wind and Automotive).

Q21: Please can you give us some thoughts on software DFMEAs?
A21: No, there are very many applications available to support the process. But what the best fit for you company and organization would be, do fully depend on the need, situation and other applications it should be working together with.

Q22: Where can we find solid information about the new version of FMEA?
A22: https://www.aiag.org/ or at https://www.vda-qmc.de/
You can also attend relevant training for the new FMEA method by many quality focused training providers.

Q23: If a customer require a catalogue product but also include a Customer Requirements Doc. is it supplier responsibility to review & be sure that this product fulfills all customer requirements, right? If catalogue part cannot fulfill, it should be customized..."

A23: Yes, if a customer requires a catalogue part but also include extended requirements and specifications you must ensure that you part fulfills all requirements. If not, you must make the customer aware about the discrepancy. If you want to customize your product or only offer your standard product is your decision if you clearly state and difference.