A Closer Look at …

Failure Mode & Effect Analysis (FMEA)
- The Tool for Risk Management

June 2\textsuperscript{nd}, 2020
1. Welcome
2. Webinar Instructions
3. Risk Management
4. Failure Mode and Effect Analysis
   • Design Failure Mode & Effect Analysis (DFMEA)
   • Process Failure Mode & Effect Analysis (PFMEA)
5. Implementation - Do's and Don'ts
6. A look into the future of Risk Management and FMEA
7. Q&A Session
8. Thank you!
Welcome by the General Manager of APQP4Wind
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- Secretariat
- Company Members
- Training Providers
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Read more about how to become a member on [www.apqp4wind.org](http://www.apqp4wind.org)
Training Providers

- World-wide training setup
- Carefully selected training Suppliers
- Mandatory training courses to become an approved APQP4Wind Supplier
- Seller of APQP4Wind Manual

Contact our Training Providers here
Status on Global Implementation of APQP4Wind

- 2300 course participants
- 650 companies with certified employees
- 4500 Manuals sold worldwide
Global Training Deployed in 34 countries

- Denmark
- Turkey
- Sweden
- United Arab Emirates
- Norway
- Czech Republic
- Finland
- Serbia
- Germany
- South Africa
- Netherlands
- India
- Switzerland
- China
- Belgium
- South Korea
- Austria
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Webinar Instructions

• Duration: 45 minutes

• You are welcome to write questions in the chat function during the presentation

• Questions will be answered in the Q&A session

• The webinar will be recorded and published on the APQP4Wind website along with the presentation material

• You will receive an e-mail with links to both the recordings and presentation material after the webinar
Presenters

Bent Weibel, Senior Lead Auditor, DNV GL

With a background of more than 30 years of international experience in management and quality functions in automotive, renewable energy, medical device and certification do I have a solid knowledge and experience base to assess, support and lead the development of quality in product-, process- and business-related processes.

Ivan Mikkelsen, Lead Auditor and Product Manager, Bureau Veritas

With a background in a business- and statistical education, more than 30 years of experience in quality and management functions in automotive, renewable energy, packaging and certification, and many years experience in providing training, I am focused on how systems and risk management help companies to develop competence and meet their strategies in a global market.
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RISK MANAGEMENT

– The Mother Connecting it All
Risk Management in the Wind Industry

Types of risk facing a project

• STRATEGIC - Fit of project to direction – understand market needs

• FINANCIAL - Business case, investment, profitability, robustness

APQP4Wind - responses

• Voice of the customer

• Kick off meeting

• Feasibility review
Risk Management in the Wind Industry

Types of risk facing a project

- **TIME** - Prepare and deliver design and process on time
- **TECHNICAL** – Product risk related to design and manufacturing process

APQP4Wind - responses

- Product Quality Plan
- Special characteristics
- DFMEA
- PFMEA
APQP4Wind: Risk - Control by use of FMEA

- **Customer Requirements**
  - General agreements, technical specifications, drawings etc.

- **Customer Specified Special Characteristics**

- **DFMEA**
  - The DFMEA responsibility and control depends on type of the project. In case of Manufacture to Specifications/Material Processing Supplier, Customer makes and controls DFMEA.
  - The special characteristics communicated by Customer to Supplier as part of Customer requirements as a minimum. In case of a Design Responsible Supplier it is Supplier’s responsibility to make and control DFMEA.

- **PFMEA**
  - Process ID

- **Control Plan**
  - Process ID

- **MSA**
  - Process ID

- **Work Instructions**
  - Process ID

- **Process Capability**
  - Process ID

All documentation generated should have a unique identifier, e.g., process ID. This ensures consistency throughout the documentation and issues Customer requirements and operational data/documents.
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FAILURE MODE & EFFECT ANALYSIS

- Robust Products and Processes
Failure Mode & Effect Analysis - (FMEA)

What is the FMEA

Failure Mode and Effects Analysis, FMEA is an analytical methodology used to ensure that potential problems have been considered and addressed throughout the product and process development process.
Failure Mode & Effect Analysis - (FMEA)

Current Control

1. Identify the function and it’s requirements
2. Identify the failure mode, it’s effect and severity (Sev.)
3. Identify the cause mechanism and occurrence (Occ.)
4. Identify preventive and detection controls (Det.)
5. Rank the risks by their Risk Number (R.N.)

Action Result

6. Identify actions to eliminate or mitigate the risk / R.N. to an acceptable level
7. Assign responsibility and set due dates
8. Follow up and have the actions implementation verified for effectiveness

<table>
<thead>
<tr>
<th>Item/Function</th>
<th>Requirements</th>
<th>Potential Failure Mode</th>
<th>Potential Effect(s) of Failure</th>
<th>Sev</th>
<th>Class</th>
<th>Potential Cause(s)/Mechanism(s) of Failure</th>
<th>Current Design Controls</th>
<th>Controls Prevention</th>
<th>Det</th>
<th>R.N.</th>
<th>R.P.N.</th>
<th>Recommended Actions</th>
<th>Responsibility &amp; Target Date</th>
<th>Action Results</th>
<th>Action Serv Taken</th>
<th>Occ</th>
<th>Def</th>
<th>R.N.</th>
<th>R.P.N.</th>
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How to prioritize actions

Prioritization helps the design team and organization to define focus areas and initiate actions to eliminate or take the risk to an acceptable level:

• Give priority to
  • Safety Special Characteristics then
  • Product Special Characteristics and
  • Process Special Characteristics

• Drive the risks from the Red to the Yellow and Green area

• WE ADD VALUE BY DRIVING ACTION

• BE QUALITATIVE IN YOUR ASSESSMENT OF THE FMEAs
DFMEA and PFMEA in the APQP4Wind framework

<table>
<thead>
<tr>
<th>APQP4Wind Phases</th>
<th>Plan and define program</th>
<th>Product design and development</th>
<th>Product design verification</th>
<th>Process Design and Development</th>
<th>Process verification</th>
<th>Product and process validation</th>
<th>PPAP approval and update</th>
</tr>
</thead>
<tbody>
<tr>
<td>DFMEA</td>
<td>Start FMEA planning in concept phase before product development begins. Information flow from DFMEA to PFMEA. The DFMEA and PFMEA should be executed during the same period to allow simultaneous optimization</td>
<td>Start DFMEA when the design concept is well understood</td>
<td>Complete DFMEA analysis prior to release of design specification for quotation</td>
<td>Complete DFMEA actions prior to start of production tooling</td>
<td>Update DFMEA and PFMEA in case of changes to product or processes</td>
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</tr>
<tr>
<td>PFMEA</td>
<td>Start PFMEA when the production concept is well understood</td>
<td>Complete PFMEA analysis prior to final process definitions</td>
<td>Complete PFMEA action and update prior to PPAP</td>
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DFMEA

DFMEA, Design Failure Mode and Effects Analysis is aimed at identification of and prevention and mitigation of:

• Safety and or regulatory concerns
• Product malfunctions
• Reduced product performance and life
• Customer dissatisfaction

DFMEA Output

• Visualization of systems, sub-systems, their interaction, potential failure and effects to:
  • Enable product design improvements
  • Enable design of robust manufacturing and assembly processes
• Identification of design functions and characteristics for the verification and validation plans
• Identification of Special Characteristics
  • Critical to Safety and Critical to Function
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Process Failure Mode & Effect Analysis - (PFMEA)

PFMEA

PFMEA, Process Failure Mode and Effects Analysis is aimed at identification of and prevention and mitigation of:

• Process related failures and their effect
• Non-conformance and quality cost
• Loss of capacity and delivery delays
• Customer dissatisfaction

PFMEA Output

• Visualization of process and sub-processes, their interaction, potential failure and effects to:
  • Enable process design Improvements to ensure robust manufacturing and assembly processes
  • Identification of process inspections for the control plan
  • Identification of process variables on which to focus process control
  • Identification of Special Characteristics
  • Critical to Process
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BOOSTERS & PITFALLS IN FMEA IMPLEMENTATION
TIMING

DO

• Initiate and process the FMEA along with the progress of the project

• Make sure that the FMEA’s are connected to the control plans

• Make sure that improvements suggested during the FMEA work are collected and addressed

DO NOT

• Wait with FMEA until the product development and/or preparing the process is nearly completed

• Wait with FMEA until the customer start asking for a PPAP
PREPARATION

DO

• Scope what should be in the FMEAs where and when to start and stop

• Spend time to understand the function, intent and risk of the product – ask for inputs

• Ask for/create p-diagram (DFMEA) or process flow chart (PFMEA)

DO NOT

• Rush through the analysis without information or based on assumptions

• Replicate similar analyses without reflection and justification
Preparing the DFMEA Parameter (P) Diagramme

**Mechanical/Chemical specs**
- **Mechanical**
  - Dimensions of parts (Thickness, lengths, geometry, design)
- **Chemical**
  - *Material* - steel quality (type)
  - *Surface treatment* / Hardening
- **Assembly specs.**
  - *Torque* dimensions and specs

**Usage**
- Extreme operation
- Security - stop and idling
- Regular stops - position
- Service: Accessibility, operation, safety, risk of damage
- Interacting liquids

**System Interactions**
- Impact and vibrations from tower, nacelle, and blades

**Inputs**
- **Load types:**
  - Horizontal
  - Vertical
  - Interactions
  - Vibrations

**Main Bearing**

**Noise factors**

**Outputs**
- Adapt loads
- Stabilize rotation
- Reduce and balance friction

**Functional**
- Particles falling of
- Cracks / breaches
  - Increased wear > Premature break down

**Non Functional**
- Leaking grease or oil

**Failure modes**

**Changes over time**
- Fatigue
- Erosion
- Corrosion

**External environment**
- Vibrations
- Flood, earthquake
- Climate variations

**Manufacturing/Assembly**
- Torque
- Dirt, particles

**Piece to piece variation**
- Material-variations
- Part -tolerances

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**Preparing the DFMEA Parameter (P) Diagramme**

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**Preparing the DFMEA Parameter (P) Diagramme**
TEAM DEFINITION

DO

• Set up a crossfunctional team with a qualified and available "driver"

• Motivate and brief the participants as needed

DO NOT

• Let 1-2 quality specialists perform the FMEA alone
COMMUNICATION

**DO**

- Inform and coordinate progress between customer and supplier

- Keep all relevant parties updated concerning Special Characteristics – also when risk changes

- Appreciate openness, even when the topics is concerns

**DO NOT**

- Hold special risks or concerns back for handling yourself
TECHNICAL QUALITY IN EXECUTION

**DO**

- Make sure you are handling as failure modes real challenges /risks for the design/ process
- Do not extend the list with hypothetical issues
- Prioritize special characteristics
- Use knowledge from previous design and existing processes

**DO NOT**

- List only product defects as process failure modes
- Start from scratch for every new product – the processes are most often the same
- Leave the risk analysis up to suppliers providing the manufacturing technology
CULTURE AND LEADERSHIP

**DO**

- Create a top –management mentoring
- Promote good results and team efforts
- Allow learning to take place before expecting breakthroughs

**DO NOT**

- Allow the voices from the project cemetary to decide your priorities ("FMEA does not work here"…)
- Accept key persons neglecting participation
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A LOOK INTO THE FUTURE OF RISK MANAGEMENT & FMEA
A look into the future of Risk Management and FMEA

The FMEA process we know, is under change

What is the focus of the new AIAG and VDA FMEA:

- Introduces a comprehensive Seven-Step Systematic approach
- Introduction of AP, Action Priority – Ranking potential failures into Priority HIGH, MEDIUM and LOW
- Introduction of FMEA-MSR, Monitoring and System Response Linking functional safety ISO 26262 to the FMEA
Key Take Aways

1. Implementing APQP4Wind is a strategic decision.

2. Implementing FMEA is Key to successful implementation of APQP4Wind.

3. Implementing FMEA will often be a cultural change, which is unlikely to happen without meeting resistance and consistent management intent in response.
BUREAU VERITAS| APQP4Wind

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Professional training provider in APQP4Wind worldwide. Bureau Veritas has the experience, know-how and technical expertise to improve your productivity and performance through trainings and workshops.

APQP4Wind trainings has been delivered in Denmark, Germany, Turkey, Hungary, Spain, China, US, South Korea, Japan, India etc.

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Experience in implementing and facilitating FMEA at Wind Power companies incl. OEM’s.

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More info and enrollment

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# DNV GL APQP4Wind Academy

## Trainers
- Highly skilled and competent trainers for delivery of APQP4Wind training world-wide. All trainers have many years of experience in the Wind Industry and lead auditor experience within the Wind Industry
- Local language speaking trainers in: English, Danish, Chinese, Portuguese, French, German
- Number of trainers:
  - Americas: 2
  - Europe: 4
  - APAC: 2

## Classroom and Virtual Training
- APQP4Wind Management Awareness (1 day)
- APQP4Wind Specialist Training (4 days)
- APQP4Wind Internal Auditor (2 days)
- APQP4Wind Awareness Training for Employees and Train-the-Trainer (1/2 day)

## QA Maturity Assessment
- DNV GL have developed the first scheme for Maturity Assessment in the market
- You will receive a high-level assessment of your current compliance to the APQP4Wind requirements
- You will receive a report helping you identify and prioritize areas of improvement

## Info and Training Calendar
- See our global training calendar [www.dnvgl.com/APQP4Wind](http://www.dnvgl.com/APQP4Wind)
- Birgit Lund Nielsen
  - Training Manager
  - Birgit.lund.Nielsen@dnvgl.com

1400 certificates issued
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Time for Questions and Answers