APQP 4 Wind

A Closer Look at …

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

June 2nd, 2020

Agenda

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

Courtesy of LM Wind Power

APQP4Wind Community

Board of Directors

Country Ambassadors

Company Members

Working Group

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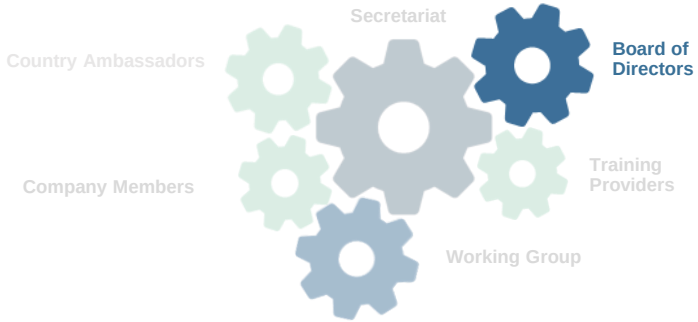

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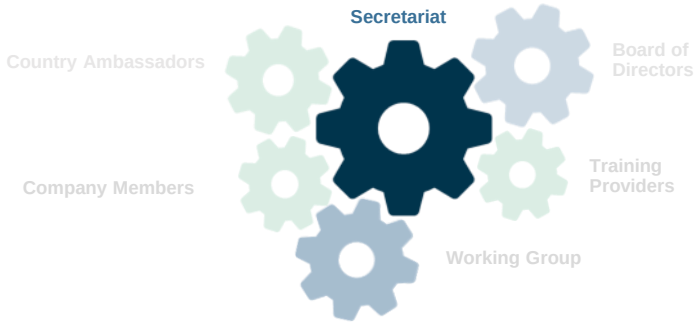

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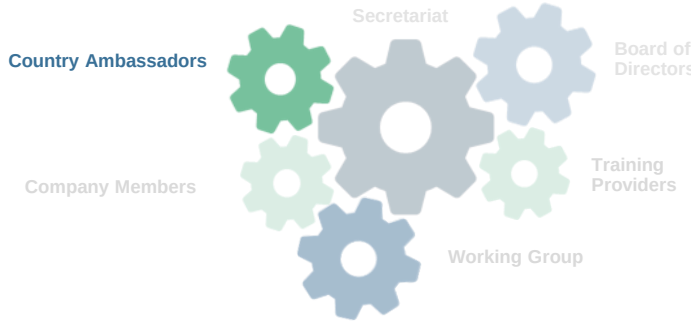

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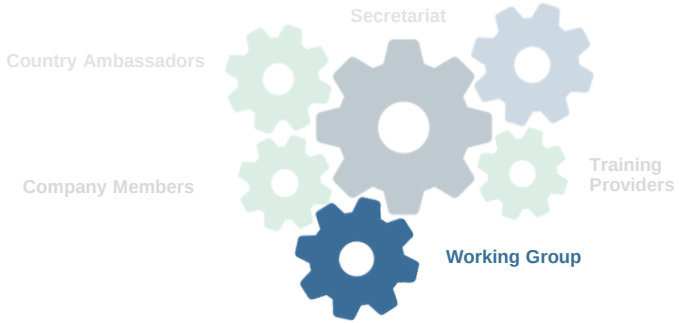

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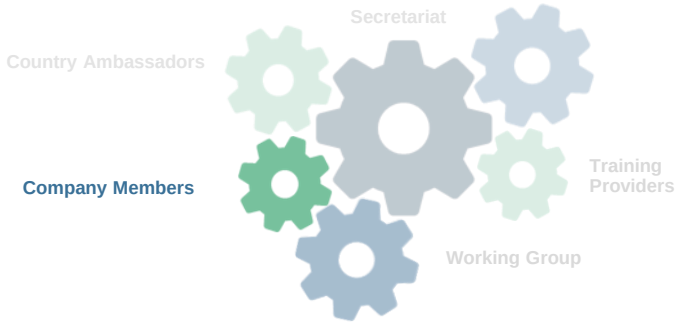

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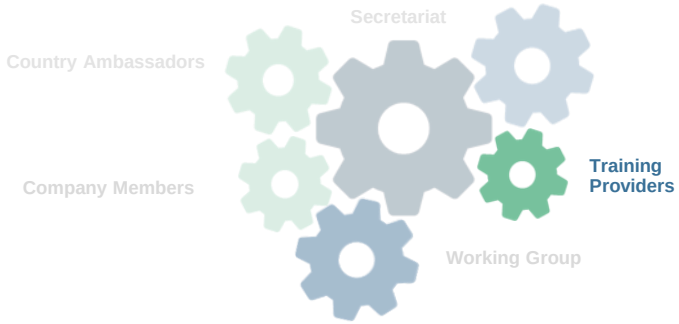
Read more about how to become a member on www.apqp4wind.org

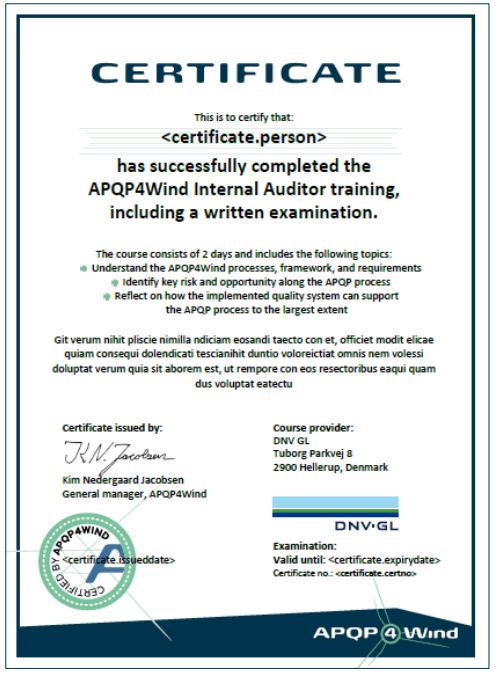
Training Providers



- 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


CERTIFICATE

This is to certify that:

<certificate.person>

has successfully completed the APQP4Wind Internal Auditor training, including a written examination.

The course consists of 2 days and includes the following topics:
- Understand the APQP4Wind processes, framework, and requirements
- Identify key risk and opportunity along the APQP process
- Reflect on how the implemented quality system can support the APQP process to the largest extent

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Certificate issued by:
Kim Nedergaard Jacobsen
General manager, APQP4Wind

Course provider:
DNV GL
Tuborg Parkvej 8
2900 Hellerup, Denmark

DNV·GL

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APQP4WIND CERTIFIED

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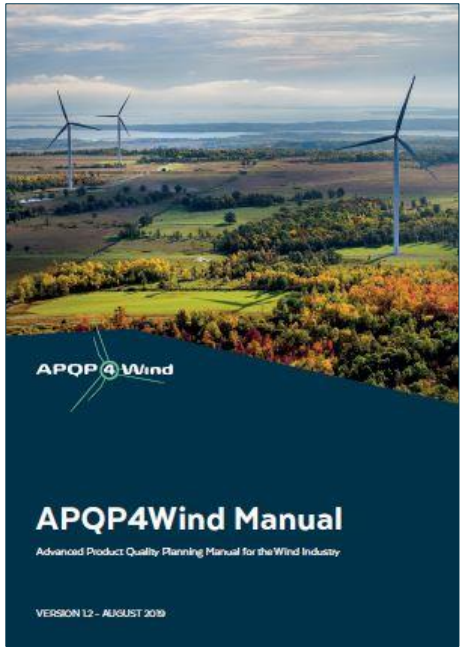
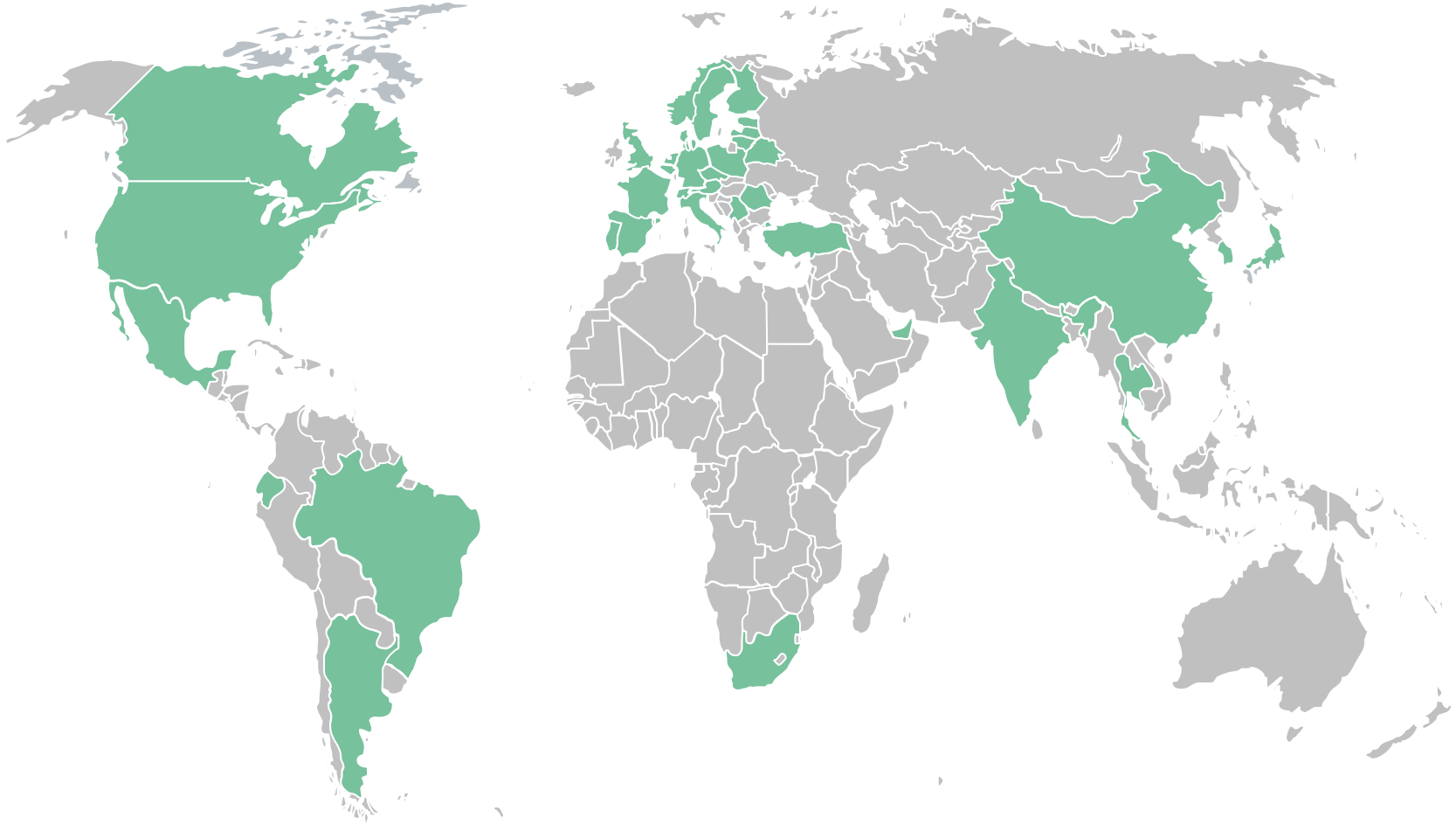
2300 course participants

650 companies with certified employees



4500 Manuals sold worldwide

Global Training Deployed in 34 countries



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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

Courtesy of LM Wind Power

APQP 4 Wind

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

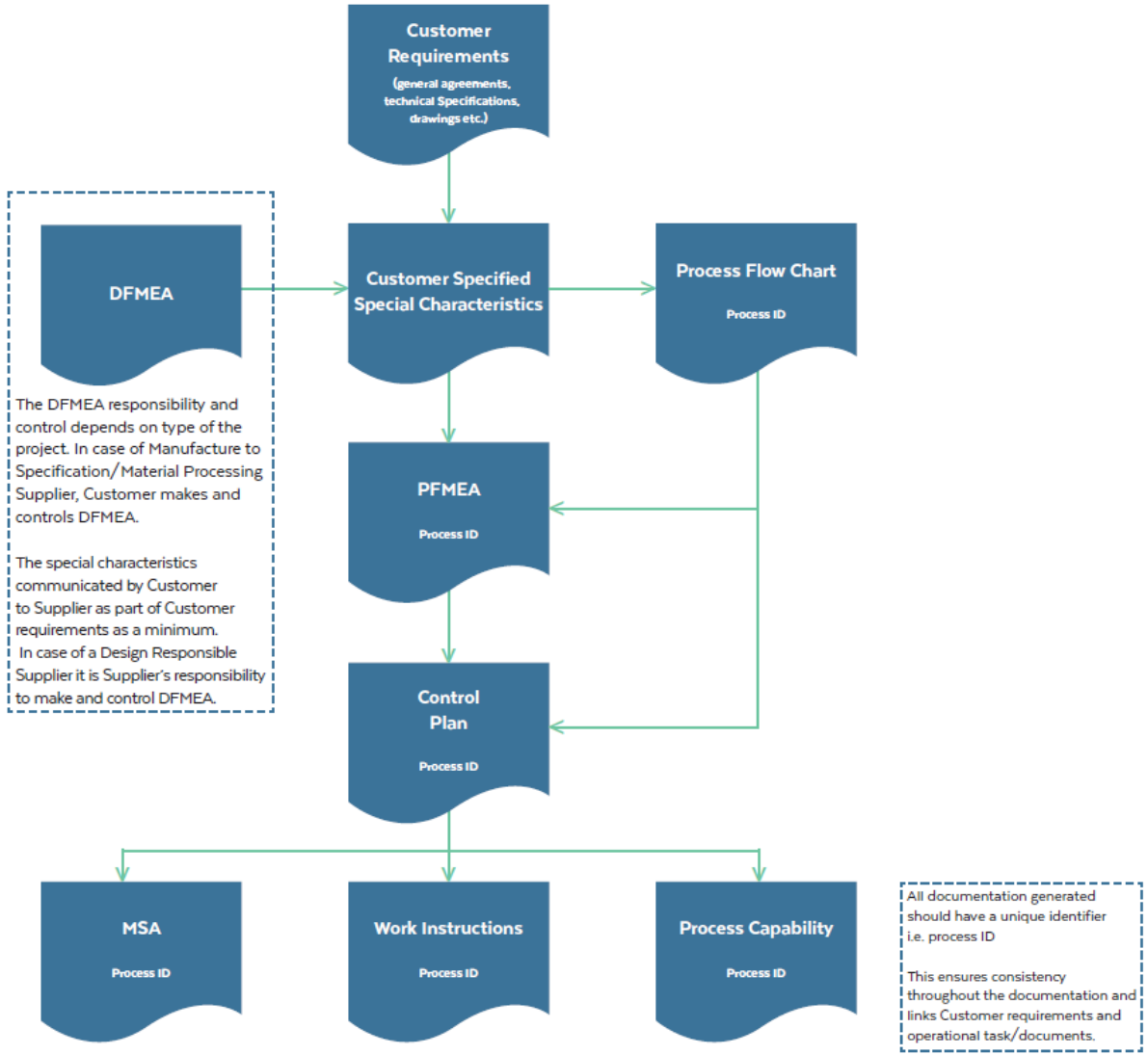
Types of risk facing a project

- 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



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FAILURE MODE & EFFECT ANALYSIS

- Robust Products and Processes

Courtesy of LM Wind Power

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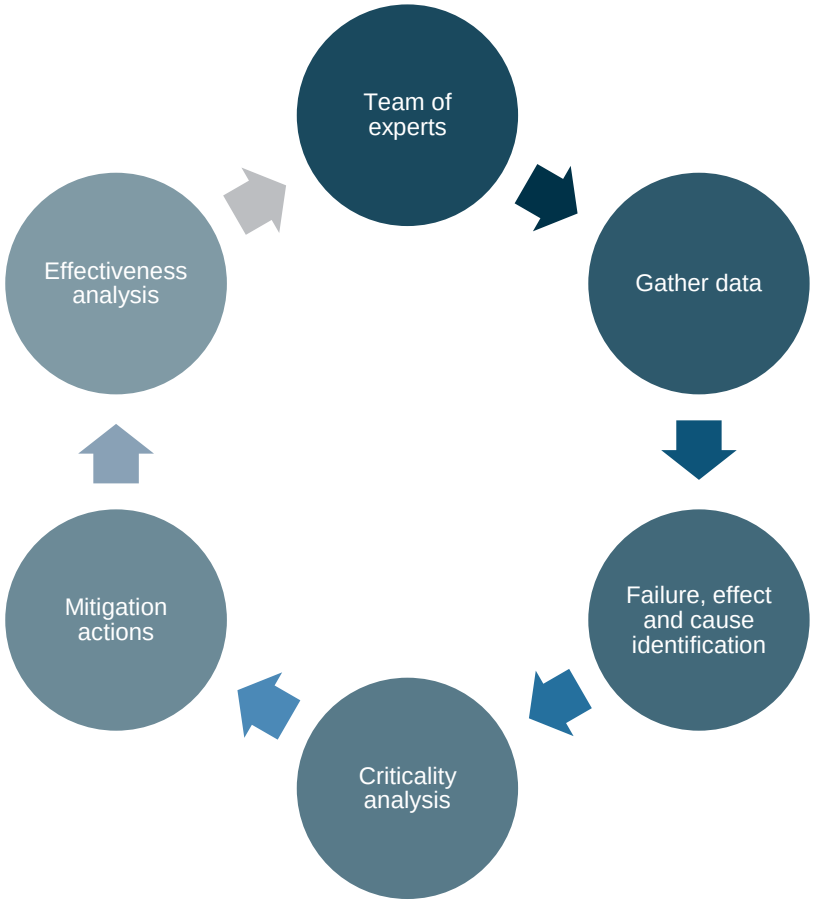
Failure Mode & Effect Analysis - (FMEA)

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 occurance (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

						Current Design Controls								Action Results						
Item/Function	Requirements	Potential Failure Mode	Potential Effect(s) of Failure	Sev	Class	Potential Cause(s)/Mechanism(s) of Failure	Controls Prevention	Occ	Controls Detection	Det	R.N.	R.P.N.	Recommended Actions	Responsibility & Target Date	Actions Taken	Sev	Occ	Det	R.N.	R.P.N.
1.			2.			3.			4.		5.		6.	7.	8.					

Failure Mode & Effect Analysis - (FMEA)

How to prioritize actions

Prioritization helps the design team and organization to define focus areas and iniciate actions to eleminate 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 ASSESMENT OF THE FMEAs

APQP4Wind – Risk Priority Matrix

Label	Criteria
	Severity ≥ 9 and Occurrence > 1 OR The Risk Number, RN ≥ 63 OR The Risk Priority Number, RPN ≥ 505
	Risk number anything between RED and GREEN in below matrix
	The Risk Number, RN ≤ 12

Occurrence \ Severity	1	2	3	4	5	6	7	8	9	10
10	10	20	30	40	50	60	70	80	90	100
9	9	18	27	36	45	54	63	72	81	90
8	8	16	24	32	40	48	56	64	72	80
7	7	14	21	28	35	42	49	56	63	70
6	6	12	18	24	30	36	42	48	54	60
5	5	10	15	20	25	30	35	40	45	50
4	4	8	12	16	20	24	28	32	36	40
3	3	6	9	12	15	18	21	24	27	30
2	2	4	6	8	10	12	14	16	18	20
1	1	2	3	4	5	6	7	8	9	10

Risk Number ..... RN = Severity x Occurrence
Risk Priority Number ... RPN = Severity x Occurrence x Detection

Failure Mode & Effect Analysis - (FMEA)

DFMEA and PFMEA in the APQP4Wind framework

APQP4Wind Phases	Plan and define program	Product design and development	Product design verification	Process Design and Development	Process verifcation	Product and process validation	PPAP approval and update
DFMEA	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	Start DFMEA when the desing concept is well understood	Complete DFMEA analysis prior to release of design specification for quotation		Complete DFMEA actions prior to start of production tooling		Update DFMEA and/or PFMEA in case of changes to product or processes
PFMEA		Start PFMEA when the production concept is well understood	Complete PFMEA analysis prior to final process definitions			Complete PFMEA action and update prior to PPAP	

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Design Failure Mode & Effect Analysis - (DFMEA)

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 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

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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 adressed

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

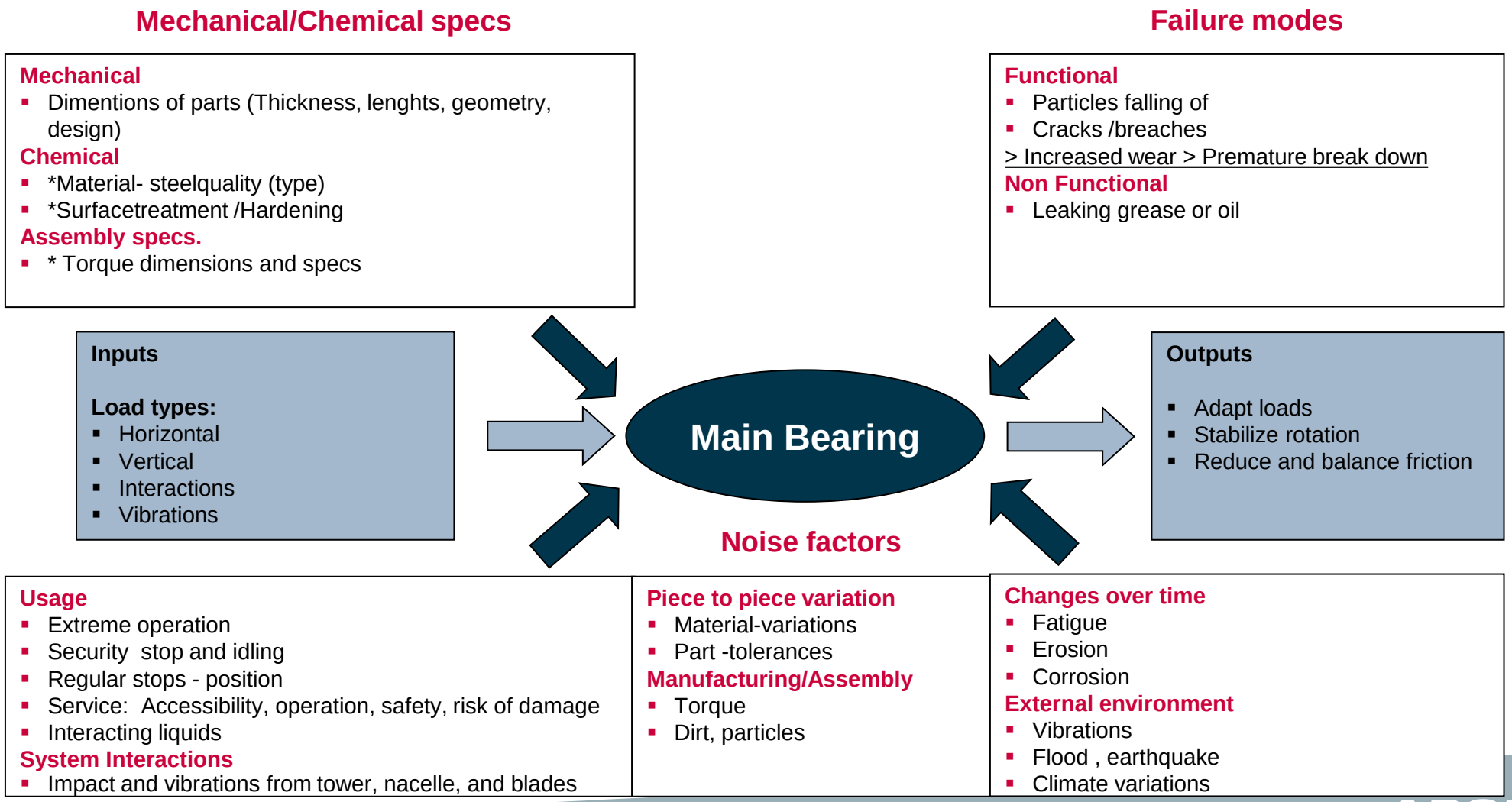
DO

- 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 assumtions
- Replicate similar analyses without reflection and justification

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 hypotetical 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

Courtesy of GE Renewable Energy

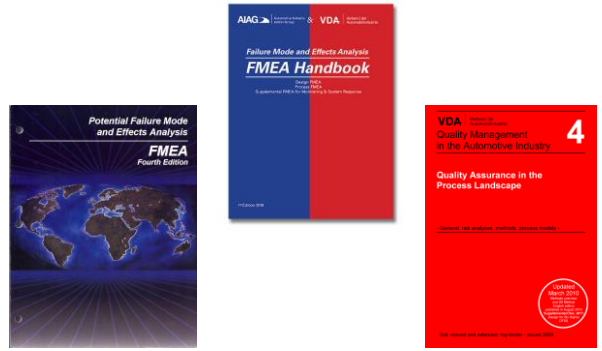
APQP 4 Wind

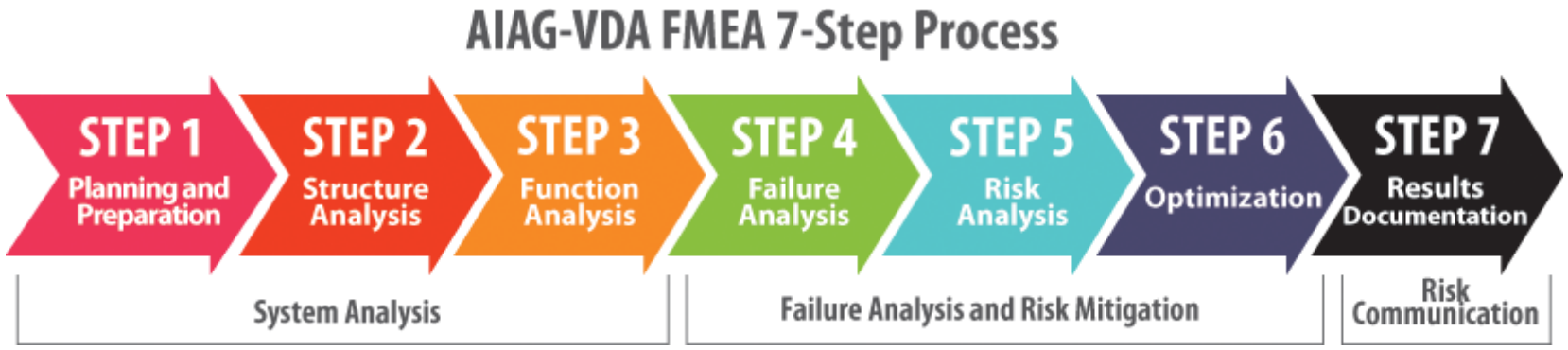
A look into the future of Risk Management and FMEA

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 succesfull 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

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All trainings can be delivered as **open training, in-house or online** *

English, German, Chinese and Danish **native speaking trainers with decades of hands on experience in APQP and its' tools**

* APQP4 Wind Specialist training online is an option during COVID 19. The Specialist training is highly recommended to be face to face

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

Strategic screening workshop to check your companies challenges in the Wind market, and establish actionable first steps towards APQP4Wind is offered

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DNV GL APQP4Wind Academy

1400 certificates issued

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
- Birgit Lund Nielsen
  Training Manager
  Birgit.lund.Nielsen@dnvgl.com

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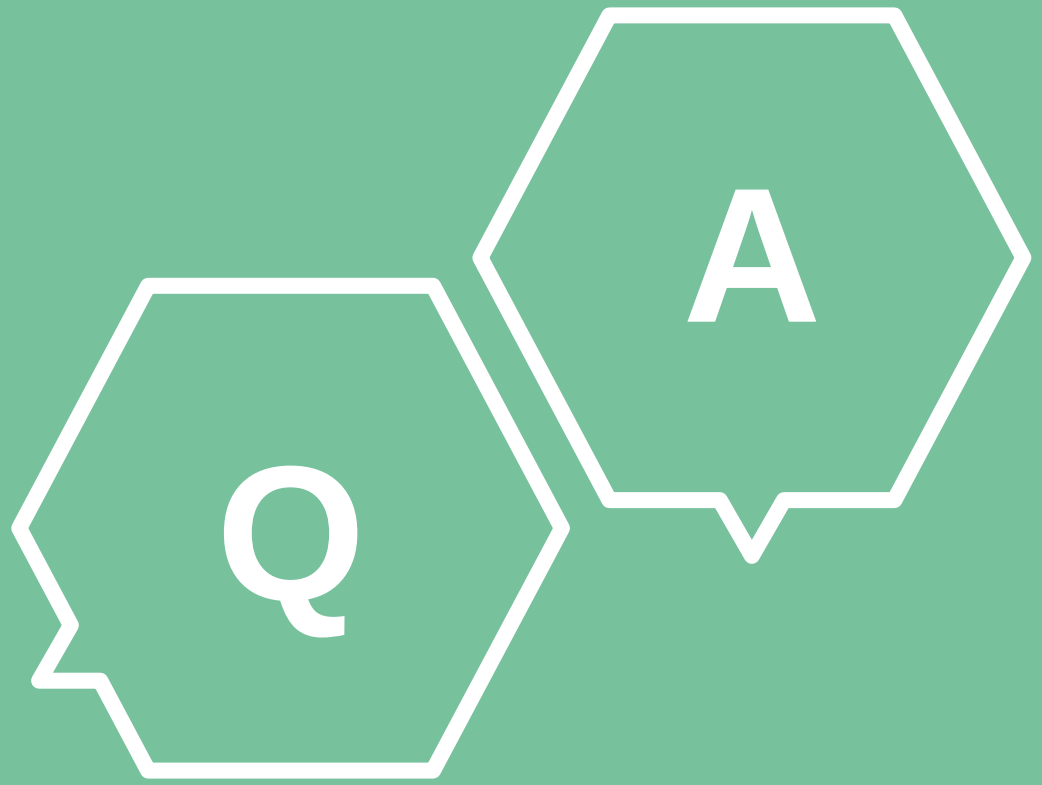
Time for Questions and Answers



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