PROCESS-FMEA

Step 1: Planning and Preparation	Create a project description and a project plan. Define the scope of analysis, team, time and tool.
Step 2: Structure Analysis	Visualize the scope of analysis alternatively as a structure tree or block diagram or digital model.
Step 3: Function Analysis	Formulate and specify functions and function relationships in nets.
Step 4: Failure Analysis	Visualize the error chain for each product function.
Step 5: Risk Analysis	Use your knowledge and assign actions to causes and types of errors. Determine the Action Priority using severity, occurrence and detection.
Step 6: Optimization	Identify risk-reducing actions and evaluate the risk again after their implementation.
Step 7: Results Documentation	Make FMEA data available for reuse. Inform management (reports, key figures, risks, actions).

Guideline for Team Members

- You are an expert: Offer expertise.
- Be there exclusively for the FMEA team meeting and prepare yourself. Your input is important for the success of the team.
- Respect the experts next to you – accept different options.
- The team is counting on you!
- Enquiries are not a sign of incompetence.
- Participate actively.
- Take responsibility.

peak avenue

AIAG & VDA FMEA Alignment

The 7 Steps of Process-FMEA

Evaluation of the Severity Criteria			Evaluation of the Occurrence		Evaluation of the Detection	
10	high	Failure may result in an acute health and/or safety risk for the manufacturing or assembly worker.	extremely high	No prevention controls.	very low	No testing or inspection method has been established or is known. The failure mode will not or cannot be detected.
9		Failure may result in in-plant regulatory noncompliance.	very high	Prevention controls will have little effect in preventing failure cause.		It is unlikely that the testing or inspection method will detect the failure mode. The failure mode is not easily detected through random or sporadic audits.
8	moderately high	100% of the production run affected may have to be scrapped. Failure may result in in-plant regulatory noncompliance or may have a chronic health and/or safety risk for the manufacturing or assembly worker. Line shutdown greater than full production shift; stop shipment possible; field repair or replacement required other than for regulatory noncompliance. Failure may result in in-plant regulatory noncompliance or may have a chronic health and/or safety risk for the manufacturing or assembly worker.			low	Test or inspection method has not been proven to be effective and reliable (e.g. plant has little or no experience with method, gauge R&R results marginal on comparable process or this application, etc.). Human inspection (visual, tactile, audible) or use of manual gauging (attribute or variable) that should detect the failure mode or failure cause.
7		Product may have to be sorted and a portion (less than 100%) scrapped; deviation from primary process; decreased line speed or added manpower. Line shutdown from 1 hour up to full production shift; stop shipment possible; field repair or replacement required other than for regulatory noncompliance.	high	Prevention controls somewhat effective in preventing failure cause.		Test or inspection method has not been proven to be effective and reliable (e.g. plant has little or no experience with method, gauge R&R results marginal on comparable process or this application, etc.). Machine-based detection (automated or semi-automated with notification by light, buzzer, etc.), or use of inspection equipment such as a coordinate measuring machine that should detect failure mode or failure cause.
6	moderately low	100% of production run may have to be reworked off line and accepted. Line shutdown up to 1 hour.			moderate	Test or inspection method has been proven to be effective and reliable (e.g. plant has experience with method; gauge R&R results are acceptable on comparable process or this application, etc.). Human inspection (visual, tactile, audible) or use of manual gauging (attribute or variable) that will detect the failure mode or failure cause (including product sample checks).
5		A portion of the production run may have to be reworked off line and accepted. Less than 100% of the product affected; strong possibility for additional defective product; sort required; no line shutdown.	moderate	Prevention controls are effective in preventing failure cause.		Test or inspection method has been proven to be effective and reliable (e.g. plant has experience with method; gauge R&R results are acceptable on comparable process or this application, etc.). Machine-based detection (semi-automated with notification by light, buzzer, etc.), or use of inspection equipment such as a coordinate measuring machine that will detect failure mode or failure cause (including product sample checks).
4		100% of production run may have to be reworked in station before it is processed. Defective product triggers significant reaction plan; additional defective products not likely; sort not required.			high	System has been proven to be effective and reliable (e.g. plant has experience with method on identical process or this application), gauge R&R results are acceptable. Machine-based automated detection method that will detect the failure mode downstream, prevent further processing or system will identify the product as discrepant and allow it to automatically move forward in the process until the designated reject unload area. Discrepant product will be controlled by a robust system that will prevent outflow of the product from the facility.
3	low	A portion of the production run may have to be reworked in-station before it is processed. Defective product triggers minor reaction plan; addtional defective products not likely; sort not required.	low	Prevention controls are highly effective in preventing failure cause.		System has been proven to be effective and reliable (e.g. plant has experience with method on identical process or this application), gauge R&R results are acceptable. Machine-based automation detection method that will detect the failure mode instation, prevent further processing or system will identify the product as discrepant and allow it to automatically move forward in the process until the designated reject unload area. Discrepant product will be controlled by a robust system that will prevent outflow of the product from the facility.
2		Slight inconvenience to process, operation, or operator. Defective product triggers no reaction plan; additional defective products not likely; sort not required; requires feedback to supplier.	very low			Detection method has been proven to be effective and reliable (e.g. plant has experience with method, error-proofing verifications, etc.). Machine-based detection method that will detect the cause and prevent the failure mode (discrepant part) from being produced.
1	very low	No discernible effect or no effect.	extremely low	Prevention controls are extremely effective in preventing failure cause from occuring due to design or process. Intent of prevention controls - failure mode cannot be physically produced due to the failure cause.	very high	Failure mode cannot be physically produced as-designed or processed, or detection methods proven to always detect the failure mode or failure cause.