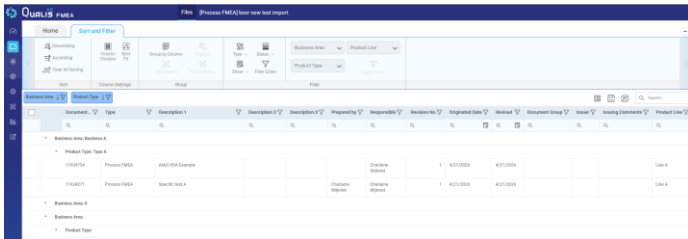




Datalyzer Qualis 4.0 FMEA

Software for Process Flow, Failure Mode
and Effect Analysis and Control Plan



The use of FMEA started in the aviation industry during the 1950's. Today it has wide industrial acceptance. Within many industries it is now mandatory to perform FMEA and apply the associated Control Plan.

As part of the Measure and Analysis Phase, FMEA is a core step in any Six Sigma implementation. In ISO 9001:2015 there is a requirement to implement effective risk management.

FMEA has proven itself in the Aerospace and Automotive Industry and it is the natural choice to meet the risk requirements of ISO 9001:2015. Within the automotive industry the use of FMEA and a Control Plan are required by the IATF 16949 specification as part of the advanced product quality planning framework. Now AIAG and VDA have harmonized approaches, which is implemented in Datalyzer FMEA. In Aerospace Industry, manufacturers need to comply with RM13004.

The different steps in APQP and the use of FMEA and Control Planning are illustrated in the movie on the following webpage

<https://www.Datalyzer.com/products/fmea-software/>



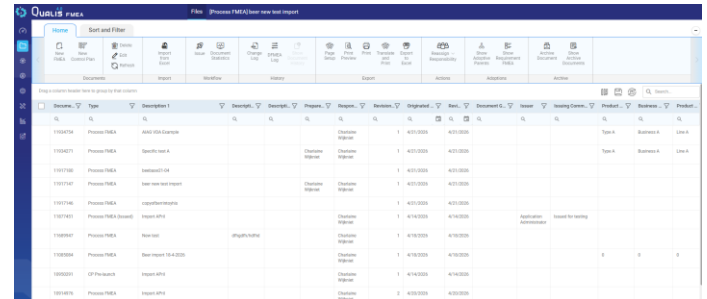
General features

Datalyzer FMEA will operate as a stand-alone or it will link to the Datalyzer SPC module. The program closely follows the methodology defined in industry like IATF16949, RM13004, etc. Datalyzer FMEA is as all Datalyzer modules available in multiple languages. The components of the FMEA module are:

Catalogue

An advanced catalogue offers the option to organize all your documents according to your business structure. Additional filter options always provide you quick access to the right documents

Example catalogue screen



Setup

During the creation of documents users can use standard text or reference FMEAs to speed up the process. Tables for severity, occurrence and detection are established as are classification symbols for special characteristics. This setup work guarantees consistency and saves time when completing the FMEA. Alarm levels for RPN, AP numbers or severity are also defined. Complete user and role management and authentication on multiple levels is implemented.

Process Flow and FMEA

All data entered is displayed as "What you see is what you get". Accordingly, when a team comes together, they can view the development of the Process Flow or FMEA on the screen. The software automatically follows the required structure, so the user is not concerned with formatting the cells and structuring the Process Flow/FMEA. Datalyzer also supports the linking of standard FMEAs. During the creation of a specific FMEA users can simply adopt a standard FMEA considerably reducing the amount of work to create the FMEA.

Analyze FMEAs

You can analyze multiple FMEA documents by sorting, filtering or grouping columns. This way you can quickly organize your FMEAs to get answer questions quickly like: Show me which failure modes have a High Priority for a group of FMEAs, or show me what process steps we have in our company in a specific department.



Example FMEA analyze screen

Document Name	Step / Function	Requirement	Failure Mode	Effect	Risk Class	Potential Cause of Failure	Control Plan	Recommended Action	Responsibility
WFO 100									
WFO 100									
WFO 100									
WFO 100									

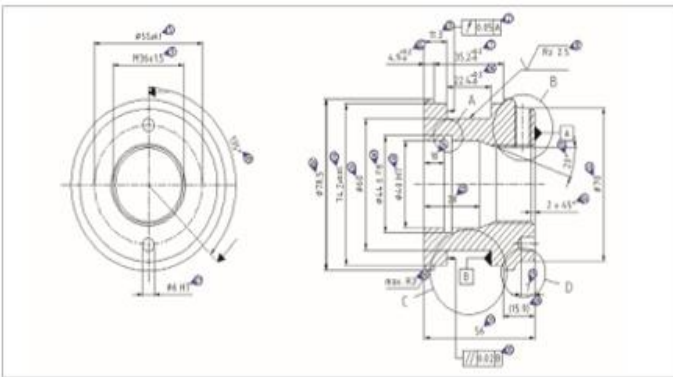
Control Plan

The Control Plan can be linked to the FMEA. The predefined tables for the Control Plan contents can speed up the data entry process.

When the control plan is printed users have an option to translate the content of the control plan. This makes it possible to create the control plan in English for customers and print the Control Plan in another language for operators on the shop floor.

Drawing – Control Plan – SPC

In combination with Ballooning software data from drawings or a 3D model can be imported automatically into the Control Plan. The Control Plan can be shown while creating a SPC chart to ensure the SPC and FMEA/Control Plan constitute an integrated approach or control charts can even be created automatically from the Control Plan.



Open Actions

Actions not completed in any of the FMEAs can be reported in an open action list. From this list you have direct access to the FMEA review and signoff procedure. Datalyzer FMEA supports a regular review and signoff for FMEAs and Control Plans. A notification service will inform users about open actions which are almost due.

The notification service will be used for other messages like informing subscribers that an FMEA is issued.

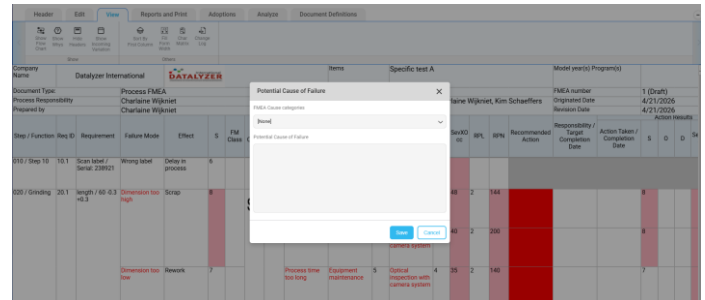
Import and export

Often, companies have already been working with FMEAs and Control Plans in Excel. To facilitate the start-up of Datalyzer FMEA, the Excel FMEAs and Control Plans can be imported into and exported from the database.

Finding the root cause

To assist users in finding the root cause for potential failures, the “5 Why” problem solving and Ishikawa (Fishbone) analysis are integrated into the FMEA. The root cause for the Failure Mode can be investigated with these tools and the “5 Whys” and “Fishbone category” are stored within the FMEA.

Example Datalyzer FMEA data entry screen



AIAG-VDA FMEA Manual

Since 2019 all automotive companies have to re-establish their FMEA methodology based on the harmonization of AIAG and VDA. The 1st edition of the new Handbook AIAG-VDA was released in June 2019. Datalyzer has aligned the software to be compliant to the new methodology and offers training to support companies in the transition towards the new manual

Example Datalyzer FMEA AIAG-VDA format

Step 1: Planning and Preparation	Step 2: Structure Analysis	Step 3: Function Analysis	Step 4: Failure Analysis	Step 5: Risk Analysis
Company Name: Datalyzer International	Process Step: Example function	Function of the Process: Example function	Failure Mode: Example failure	Risk Class: Example risk

RM13004

In 2020, AESQ released the reference manual 13004. Datalyzer FMEA fully complies to RM13004 and in addition also support ITAR and EAR configuration in the system. With the integrated solution for RM13003, RM13004 and RM13006 in more than 20 languages Datalyzer offers a one shop solution for implementation of APQP core tools in Aerospace industry.

Companies often use Excel to create FMEAs. The table below shows the differences between Excel and Datalyzer FMEA to manage your FMEAs.

Function	FMEA in Excel	Datalyzer FMEA
Organize documents	Documents need to be organized in Windows directory structure	Catalogue can be shown according to company organization including various filters
Create FMEA/CP layout	Cells or rows need to be merged or inserted manually to get the correct layout	Layout is created fully automatically
Establish correct FMEA/CP structure	User must know and follow FMEA/CP rules according to the requirements	User is forced to follow the design rules of the FMEA/CP
Select numbers for severity, detection or occurrence	User must know the rules, or this needs to be programmed into a template	User can customize predefined tables which can be used during data entry
Analyze FMEAs (Sort, filter, group)	If cells are merged, you cannot apply filter and sorting anymore in Excel. Analyzing across multiple FMEAs is not possible	Even with correct FMEA structure Datalyzer FMEA still supports filtering, sorting, grouping of columns making it possible to analyze documents even across multiple FMEAs
Enter classification symbols in FMEA	User needs to program classification symbols	User can select from a catalogue
Monitor actions	User needs to monitor actions manually or in a separate system	Actions are automatically visible through an action list and mails can be send
Integrate standard FMEAs in FMEAs per product or customer	FMEAs will be created based on a standard. With changes in the standard all FMEAs using the standard need to be changed manually. User needs to keep track which FMEAs are using which standard	Standard FMEAs are linked to FMEAs per product or per customer. An update of a standard will automatically be updated in all specific FMEAs
Version control FMEA and CP	User needs to implement a system which will be accepted by auditors regarding version control. Almost impossible to prove issued versions are not changed	Issuing versions is done automatically. Impossible to edit an issued version. Historic status and dates are preserved
Link Process Flow, FMEA and CP	User needs to make sure the link between Process Flow, FMEA and CP is maintained	Link between Process Flow, FMEA and CP can be established automatically
Translate document	User needs to translate the control plan	Datalyzer has an option to automatically translate content of an FMEA or control plan to another language. Header fields are standard available in 14 languages
Integration with drawing and SPC	Integration must be established manually by user	FMEA system can be integrated with ballooning and SPC system
Authorization of users	Excel has no authorization options	Datalyzer has complete user management option including authorization rules
Reports about all documents	Cannot be done in Excel	Various reports are possible
Pareto of RPN report sorted on action priority	Cannot be done in Excel across documents	Available in Datalyzer FMEA



Training and Implementation

Very little training is required to use Datalyzer FMEA. The program is so intuitive that you will be up and running in no time. For each specific topic in Datalyzer FMEA there is a full video available. The videos range from generic background about the structure of FMEA to specific videos how to use the FMEA program in specific situations.

The following videos are available:

1. Explanation of FMEA structure

This video explains the relationships between columns in an FMEA document.

2. Document Catalog

This video explains how you can use the catalog screen to access documents in the FMEA module.

3. Process Flow

This video explains the available functionality in the Process Flow.

4. Creating an FMEA

This video explains how you can quickly create an FMEA document in the Datalyzer FMEA program.

5. Export control plan to Datalyzer Spectrum SPC

This video explains how you can create the setup of control charts in the Datalyzer SPC module directly from the Control Plan.

6. Import characteristics into Control Plan

This video explains how you can import information directly from a drawing into the Control Plan using ballooning software.

7. Importing FMEA from Excel

This video explains how you can import FMEAs in Excel directly in the Datalyzer FMEA program.

8. Classification

This video explains how you can use classification and how this more powerful than the use of RPN numbers

9. Action Priority

This video explains how action priority works in the harmonized FMEA method (AIAG-VDA) and how it is implemented in Datalyzer FMEA.

10. Issuing an FMEA

This video explains how the issuing process is supported by the FMEA module.

11. Create a linked Control Plan

This video explains how to create a Control Plan and how the Control Plan can be linked to the FMEA document.

12. Categories

This video explains how you can use categories to store more relevant information in your FMEA screen.

13. Standard and specific FMEAs

This video explains how you can link standard process FMEAs when creating an FMEA for a specific customer and how this can help to strongly reduce the time to manage FMEAs.

www.datalyzer.com/fmeavideo

We can also provide on-site and on-line Software User training. Please contact your account manager or sales@datalyzer.com in order to receive an offer.

General FMEA theory training

If there is limited knowledge within the company, Datalyzer can assist with FMEA training and can assist in the creation of FMEAs. During the training, the following topics will be discussed.

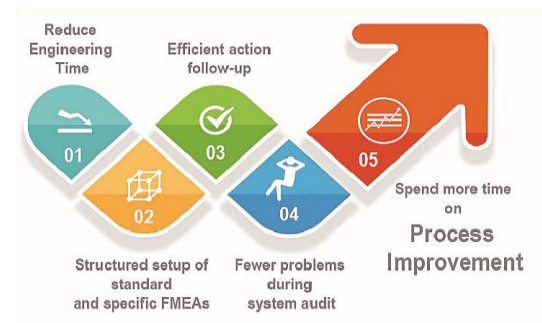
- Introduction FMEA
- Organizing FMEA teams
- Planning training exercises
- FMEA in 15 steps
 1. Scope of the process
 2. Flow charting
 3. Process function requirement
 4. Potential failure mode
 5. Potential effect of the failure
 6. Severity
 7. Classification
 8. Potential causes
 9. Occurrence ranking
 10. Current process controls
 11. Detection
 12. RPN/Action Priority
 13. Recommended actions
 14. Implement recommended actions
 15. Evaluate action results
- Linking FMEA to the Control Plan and SPC
- Feedback from SPC to FMEA
- Evaluation



Results

The result of implementation of Datalyzer FMEA typically is:

- Reduction of engineering time to prepare the FMEA/CP.
- Proper registration of engineering knowledge due to structured setup of standard and specific FMEAs.
- Better follow up of actions possible.
- Professional impression to customers.
- Less problems during customer or system audit.
- Your time is spent improving your process NOT running the FMEA system.



Customer Support

Technical support for the Datalyzer Qualis 4.0 system is available by phone, e-mail or by our automated Support Desk.

- USA: Monday through Friday, 8:30 to 5:30 ET
- Europe: Monday through Friday, 8:30 to 6:30 GMT -1
- Asia: Monday through Friday IST 8:30 to 6:30

Support agreements are renewable annually for a modest fee. Services include new versions upon request and personal telephone, fax or e-mail support and an automated ticket system. Custom software modifications can be quoted individually.

Database Compatibility

Datalyzer Qualis 4.0 software versions are available for use with Microsoft SQL Server databases.

Operating System Compatibility

Datalyzer Qualis 4.0 desk top modules work with the following Microsoft Windows operating systems: Windows 8, 10, 11. Datalyzer Qualis is network-compatible with Windows Server. Citrix® and Microsoft Terminal Services thin client/server configurations can also be used.

The browser version runs on most browsers through IIS and can be installed on premise, in a private cloud or as a SaaS solution.

Associated Modules

- Datalyzer Qualis 4.0 Gage Management System
- Datalyzer Qualis 4.0 APQP
- Datalyzer Qualis 4.0 SPC
- Datalyzer Dashboard Module
- Datalyzer Qualis 4.0 Analytics
- Datalyzer Qualis 4.0 Certificate of Analysis/FAIR

Request a demonstration via www.datalyzer.com.

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www.datalyzer.com

