

DataLyzer® FMEA

Software for Failure Mode and Effects Analysis and Control Planning



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 aerospace and automotive 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 are harmonizing approaches, which DataLyzer® FMEA will embody.

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® Spectrum SPC module. The program closely follows the methodology defined in IATF16949. DataLyzer® FMEA is as all DataLyzer® modules available in multiple languages. The components of the FMEA module are:

Setup

During the setup phase users can add descriptions for the FMEA and standard texts for the control plan to stored lists. Tables for severity, occurrence and detection are established as are classification symbols for special characteristics. This set up work guarantees consistency and saves time when completing the FMEA. Alarm levels for RPN numbers or severity are also defined. The new action priority as a replacement of RPN is already supported. 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 FMEA's. During the creation of a specific FMEA users can simply adopt a standard FMEA considerably reducing the amount of work to create the FMEA.

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 the Elias Ballooning software data from drawings 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 FMEA's 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 of FMEA's and Control Plans. A notification service will inform users about open actions which are almost due.

Import and export

Often companies have already been working with FMEA's in Excel. To facilitate the startup of DataLyzer® FMEA the Excel FMEA's can be imported. It is also possible to export FMEA's and Control Plans to Excel.

Finding the root cause

To assist users in finding the root cause "5 Why" problem solving and the 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" stored within the FMEA.



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 FMEA's.
- 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.



Companies often use Excel to create FMEA's. The table below shows the differences between Excel and DataLyzer® FMEA to manage your FMEA's.

Function	FMEA in Excel	DataLyzer [®] FMEA
Create FMEA/CP layout	Cells or rows need to be merged or inserted	Layout is created fully automatically
	manually to get the correct layout	
Establish correct FMEA/CP structure	User has to know and follow FMEA/CP rules	User is forced to follow the design rules of the
	according to the requirements	FMEA/CP
Select numbers for severity, detection or	User has to know the rules or this needs to be	User can customize predefined tables which can
occurrence	programmed into a template	be used during data entry
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	Actions are automatically visible through an
	separate system	action list and mails can be send
Integrate standard FMEA's in FMEA's per product	FMEA's will be created based on a standard.	Standard FMEA's are linked to FMEA's per product
cq customer	With changes in the standard all FMEA's using	or per customer. An update of a standard will
	the standard need to be changed manually. User	automatically be updated in all specific FMEA's
	needs to keep track which FMEA's are using which	
	standard	
Version control FMEA and CP	User needs to implement a system which will be	Issuing versions is done automatically.
	accepted by auditors regarding version control.	Impossible to edit an issued version. Historic
	Almost impossible to prove issued versions are	status and dates are preserved
	not changed	
Link Process Flow, FMEA and CP	User needs to make sure the link between	Link between Process Flow, FMEA and CP can be
	Process Flow, FMEA and CP is maintained	established automatically
Translate document	User needs to translate the control plan	DataLyzer [®] has option to automatically translate
		content of a a 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

DataLyzer® FMEA software training

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 a 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 screen

4. Creating a FMEA

This video explains how you can quickly create a FMEA document in the DataLyzer $^{\otimes}$ FMEA program

5. 5 Why Analysis

This video explains how 5 Why, cause and effect and FMEA are integrated

6. Categories

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

7. Standard and specific FMEA's

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

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 new harmonized FMEA method (AIAG VDA) and how it is implemented in DataLyzer® FMEA

10. Issuing a FMEA

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

11. Create and link control plan

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

12. 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

13. Import characteristics into Control Plan

This video explains how you can import information directly from a drawing into the control plan using ballooning

14. Importing FMEA from Excel

This video explains how you can import FMEA's in Excel directly in the DataLyzer[®] FMEA program

www.datalyzer.com/fmeavideo



General FMEA training

If there is limited FMEA knowledge within the company, DataLyzer[®] can assist with FMEA training and can assist in the creation of FMEA's. During the training the following topics will be discussed:

- Goals of the training
- 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

Harmonizing FMEA

In 2018 all automotive companies have to re-establish their FMEA methodology based on the harmonization of AIAG and VDA. DataLyzer® is already aligning our software to be compliant to the new methodology and will offer training to support companies in the transition.







Customer Support

Technical support for the DataLyzer® FMEA system is available by phone, fax, e-mail or 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 Software purchases include no-charge updates for six months. Support agreements are renewable annually for a modest

fee. Services include new versions upon request and personal telephone, fax or e-mail support.

Training seminars are available in our offices or on site. Contact your salesperson for more information. Custom software modifications can be quoted individually.

Database Compatibility

DataLyzer[®] Spectrum software versions are available for use with Microsoft SQL Server databases.

Operating System Compatibility

Windows XP SP3, Windows Server 2003 SP2, Windows Vista SP1 or later Windows Server 2008 (not supported on Server Core Role), Windows 7,8, 10, Windows Server 2008 R2 (not supported on Server Core Role) Citrix can be used.

Supported Architectures

x86, x64

Associated Modules

- DataLyzer[®] Spectrum
- DataLyzer® Spectrum Gage Management System
- DataLyzer[®] SPC Wizard (data analysis and training module)
- DataLyzer[®] OEE

Download demonstration versions at www.DataLyzer.com https://www.datalyzer.com/download/trial-buy/

DataLyzer is a registered trademark of DataLyzer International Inc.

Citrix is a trademark of Citrix Systems, Inc. and/or one or more of its subsidiaries, and may be registered in the United States Patent and Trademark Office and in other countries. Novell and NetWare are registered trademarks of Novell, Inc. in the United States and other countries. Oracle is a registered trademark of Oracle Corporation and/ or its affiliates. Microsoft, Excel, SQL Server, Windows NT, Windows, Windows Vista are registered trademarks of Microsoft Corporation in the United States and other countries.

European office

DataLyzer[®] International bv Eindhoven The Netherlands T +31-40-2940980 E sales@datalyzer.com

American office

DataLyzer® International, Inc. Wixom, MI 48393 USA T +1-248-960-3535 T 800-553-4SPC (4772) within the U.S. F +1-248-946-8490 E sales@datalyzer.com UK office DataLyzer[®] International Hull United Kingdom T +44-7498-562750 E sales@datalyzer.com

French office

DataLyzer[®] International Paris T +33-7-67-44-42-52 E sales@datalyzer.com

Asian office DataLyzer® Technologies Pvt Ltd Bangalore India T +91-9740013624 T +91-8026769337 E salesindia@datalyzer.com

www.datalyzer.com

International Distributors

DataLyzer[®] International has a very capable international distributor network. Most distributors have a long term relationship with our company and years of experience with the implementation of SPC, OEE, FMEA and DataLyzer[®] software.

For your local distributor look at www.datalyzer.com/company/reseller/

