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 have harmonized 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://wwwdatalyzer.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 start-up 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.

<table>
<thead>
<tr>
<th>Function</th>
<th>FMEA in Excel</th>
<th>DataLyzer FMEA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Create FMEA/CP layout</td>
<td>Cells or rows need to be merged or inserted manually to get the correct layout</td>
<td>Layout is created fully automatically</td>
</tr>
<tr>
<td>Establish correct FMEA/CP structure</td>
<td>User has to know and follow FMEA/CP rules according to the requirements</td>
<td>User is forced to follow the design rules of the FMEA/CP</td>
</tr>
<tr>
<td>Select numbers for severity, detection or occurrence</td>
<td>User has to know the rules or this needs to be programmed into a template</td>
<td>User can customize predefined tables which can be used during data entry</td>
</tr>
<tr>
<td>Enter classification symbols in FMEA</td>
<td>User needs to program classification symbols</td>
<td>User can select from a catalogue</td>
</tr>
<tr>
<td>Monitor actions</td>
<td>User needs to monitor actions manually or in a separate system</td>
<td>Actions are automatically visible through an action list and mails can be send</td>
</tr>
<tr>
<td>Integrate standard FMEA’s in FMEA’s per product or customer</td>
<td>FMEA’s will be created based on a standard. With changes in the standard all FMEA’s using the standard need to be changed manually. User needs to keep track which FMEA’s are using which standard</td>
<td>Standard FMEA’s are linked to FMEA’s per product or per customer. An update of a standard will automatically be updated in all specific FMEA’s</td>
</tr>
<tr>
<td>Version control FMEA and CP</td>
<td>User needs to implement a system which will be accepted by auditors regarding version control. Almost impossible to prove issued versions are not changed</td>
<td>Issuing versions is done automatically. Impossible to edit an issued version. Historic status and dates are preserved</td>
</tr>
<tr>
<td>Link Process Flow, FMEA and CP</td>
<td>User needs to make sure the link between Process Flow, FMEA and CP is maintained</td>
<td>Link between Process Flow, FMEA and CP can be established automatically</td>
</tr>
<tr>
<td>Translate document</td>
<td>User needs to translate the control plan</td>
<td>DataLyzer® has option to automatically translate content of an FMEA or control plan to another language. Header fields are standard available in 14 languages</td>
</tr>
<tr>
<td>Integration with drawing and SPC</td>
<td>Integration must be established manually by user</td>
<td>FMEA system can be integrated with ballooning and SPC system</td>
</tr>
<tr>
<td>Authorization of users</td>
<td>Excel has no authorization options</td>
<td>DataLyzer® has complete user management option including authorization rules</td>
</tr>
<tr>
<td>Reports about all documents</td>
<td>Cannot be done in Excel</td>
<td>Various reports are possible</td>
</tr>
<tr>
<td>Pareto of RPN report sorted on action priority</td>
<td>Cannot be done in Excel across documents</td>
<td>Available in DataLyzer® FMEA</td>
</tr>
</tbody>
</table>
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 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 FMEA’s 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 new 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 FMEA’s
    This video explains how you can link standard process FMEA’s when creating an FMEA for a specific customer and how this can help to strongly reduce the time to manage FMEA’s.

wwwdatalyzer.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
- Severity
- Classification
- Potential causes
- Occurrence ranking
- Current process controls
- Detection
- RPN/Action Priority
- Recommended actions
- Implement recommended actions
- Evaluate action results
- Linking FMEA to the Control Plan and SPC
- Feedback from SPC to FMEA
- Evaluation

New AIAG-VDA FMEA Manual
In 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 is released June the 3rd 2019. DataLyzer® is aligning the software to be compliant to the new methodology and offers training to support companies in the transition towards the new manual.
Customer Support
Technical support for the DataLyzer® FMEA system is available by phone, e-mail or our Technical 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® Gage Management System
- DataLyzer® SPC Wizard (data analysis and training module)
- DataLyzer® OEE

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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/