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Managing FMEAs with Helix ALM

Abstract

Failure modes and effects analysis (FMEA) helps companies discover the risks that could occur with a product — both built-in risks and issues that might arise because of the way users interact with the product. By conducting FMEAs early on, companies can make more informed decisions about which risks to mitigate, eliminate, or accept. But if developers never see the FMEAs or find them too late in the development lifecycle, it reduces the effectiveness of FMEAs.

This guide discusses how Helix ALM simplifies the FMEA process and makes them more visible early in the development process.

Introduction

According to the old maxim, an ounce of prevention is worth a pound of cure. Adjusted for inflation, that ounce might be worth several tons of cure for companies operating in safety-critical industries. Just ask Baxter, GM, and other companies that have issued massive product recalls due to critical safety defects in their products. The cost of such defects is measured not only in the dollars it takes to fix them but sometimes in lives lost because of it.

For any industry — and particularly for safety-critical ones — it is increasingly important to identify and prevent product errors before the product goes to market. To do that, many companies rely on a process called failure modes and effects analysis (FMEA).

What Role Do FMEAs Play in Product Development?

FMEAs help a company identify hazards that may arise from known risks — both in the design of the product and in the way users interact with it. Depending on the risk and the hazard, the company determines if an FMEA is warranted. Conducting FMEAs early allows the company to make more informed decisions about the risks they discover.

Because FMEAs can significantly reduce the number of defects prior to the product's release, they are particularly beneficial to companies in safety-critical industries where product safety and reliability are especially important.

In addition, FMEAs can help evaluate proposed changes. Companies that treat risk assessment as a one-time event miss the opportunity to evaluate changes and ensure they are not introducing new risks into the product. New risks can occur any time the product design changes — as a result of addressing a previous risk, a new feature request, or any other change.

Finally, when made visible to the testing and quality assurance teams, FMEAs can improve the testing effort by identifying areas of risk that might need additional testing. For example, a requirement calls for additional power to a device for the cleaning cycle only. If used for any other cycle, it may pose a risk to the user. The team might want to change some of the testing to make sure that additional power can't be selected for any of the non-cleaning cycles.

Establishing and maintaining a good FMEA process can strengthen the risk mitigation process and help avoid costly product recalls, regulatory actions, and user harm.

What Reduces FMEA Efficacy?

Although many companies use FMEAs as a risk-prevention strategy, most FMEAs do not have the visibility needed to be effective. Sometimes this is due to the company generating FMEAs after development is completed, in order to comply with auditor requirements or ease customer concerns.

Lack of FMEA visibility can also be due to a lack of communication between the FMEA team and the development, testing, and quality assurance teams. This is often the case when companies use spreadsheets and other manual, document-based methods to perform FMEAs.

Regardless of the reason, the lack of FMEA visibility often results in companies failing to see the business improvement opportunities that FMEAs offer.

This is where automated solutions — such as **Helix ALM** from Perforce Software — can help improve the process as well as streamline information management and reporting throughout the product development lifecycle. With Helix ALM, companies can ensure FMEAs are visible and being conducted properly and thoroughly, leaving no FMEA missed.

How Does Helix ALM Support FMEAs?

While it is possible to perform FMEAs with documents and spreadsheets, using Helix ALM to support the FMEA effort provides added benefits. With Helix ALM, teams can manage the timing of FMEAs, set ownership and define the individuals responsible for specific FMEAs, and most importantly, generate automated traceability reports. And when an FMEA report is needed, it can be easily generated directly from Helix ALM.

MANAGE FMEA TIMING AND ASSIGNMENTS

A company may have an established FMEA process, but that doesn't mean it is actually being followed. With Helix ALM, the SME can set rules to prevent a requirement or set of requirements from being approved or moved forward unless an FMEA is conducted.
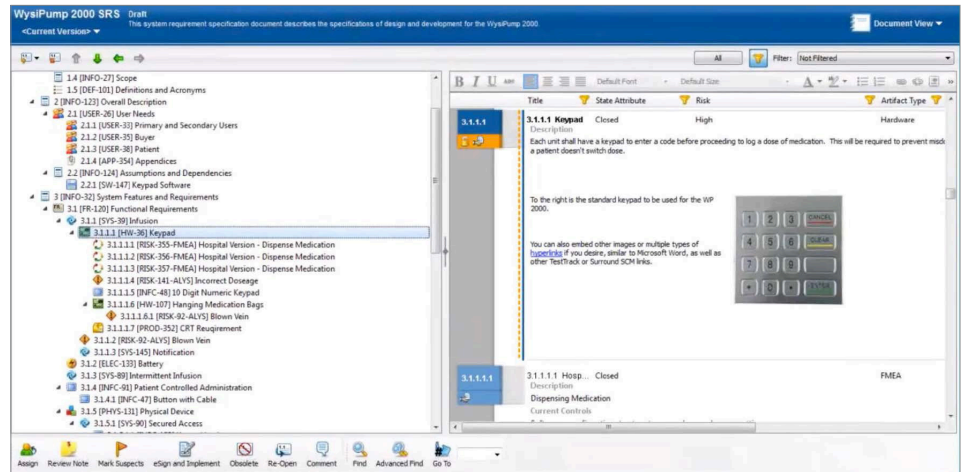

Figure 1: Helix ALM's requirements management tool, showing the FMEAs associated with an infusion pump keypad.

For example, if the SME determines that a certain requirement is high risk, he or she can associate FMEAs with it and require that they be performed before the requirement is approved. When team members view the requirement in Helix ALM, all the associated risk analysis and mitigations will be displayed. The team can see the FMEA mitigation strategy, all the different pieces related to it, and what specific aspects the risk mitigations address.

Helix ALM also allows team members to drill down into individual FMEA artifacts and see the associated information. This includes the Risk Priority Number (RPN) score, which Helix ALM automatically calculates. Helix ALM also automatically sends information to the responsible person when the SME makes an update to a requirement.

With all FMEA information in one place, Helix ALM is a single source of truth for risk management within the project.

SET OWNERSHIP

Helix ALM allows the ownership of an FMEA to be set to a particular individual. Most often, this will be the SME. The owner of an FMEA subsequently has the capability to choose who will work on the FMEA itself.

IMPROVED VISIBILITY THROUGH AUTOMATED LINKING

Helix ALM improves the visibility of FMEA information by automatically linking all artifacts associated with a particular FMEA. For example, it is easy to view an individual requirement associated with an FMEA and immediately know that it's a high-risk requirement.

Figure 3: Helix ALM can generate a list of all FMEA data.

Users can easily see how the risk is being mitigated, because they can drill down into an individual FMEA artifact and see the information linked to it. Helix ALM links to detailed information such as RPN scores, which it calculates automatically based on preestablished formulas.

Likewise, traceability with Helix ALM is an inherent process that doesn't require much overhead. Because most of it is automatic, linking artifacts becomes a natural and almost invisible part of the team's daily work. The value of linking is that there is no question whether a specific FMEA has been completed.

EXPOSES GAPS IN COVERAGE

There are two ways Helix ALM can help users identify requirements without work items and FMEAs that haven't been fully mitigated:

1. By viewing links in requirements or FMEAs
2. By viewing links in the Traceability tab

When viewing a requirement, a triangle indicator on the Traceability tab means at least one artifact is linked to that requirement. The user can click the tab to view the links and verify that a work item was created.

If the Traceability tab does not have a triangle indicator, a work item has not been created from the requirement and the user can click the Add Link… button to add one.

Users can also see requirements with related work items in the Artifacts list window by adding a column that shows if requirements have links. To do this, the user can right-click a column header and select Has Links in the Link Fields list to see if an issue has at least one link of any item type.

In the new column, the user can quickly scan the list window for Yes or No to see the issues that do not have test cases.

DELIVERS VISIBILITY ACROSS THE ENTIRE DEVELOPMENT PROCESS

Helix ALM can be implemented for the entire product development lifecycle, providing end-to-end management of requirements, risk, test cases, and defects. With Helix ALM, managers and teams gain greater visibility into their product development process from a single source of truth.

REVEALS PROCESS ISSUES

In addition to helping manage FMEAs, Helix ALM can also help fix process issues. Helix ALM shows how often each step in the process is touched, updated, or changed in some way.

Helix ALM can also identify issues and test cases that lack requirements, which may indicate unrequested features that developers have added, or features that were requested late in the process. These features may require an FMEA, or at least an assessment by the SME.

ASSISTS IN CLOSING THE LOOP

Once an underlying process or development issue has been identified, and a solution proposed, the team needs a way to ensure the solution corrected the problem. Helix ALM can help here as well.

As mentioned earlier, Helix ALM can generate a list of all FMEA data, including the RPN score associated with each identified risk (see Figure 4). After the mitigation strategy for a risk has been put into use, the team can reassess the severity, occurrence, and detection aspects of the risk. Helix ALM will then calculate the new RPN and automatically notify the SME of the new score.

FMEA + Helix ALM = Powerful Risk Reduction

Helix ALM makes the FMEA process faster and easier by putting vital data just a few clicks away and automating traceability matrices and FMEA reports. With Helix ALM, SMEs can easily manage FMEAs and continually monitor their status as the product moves through the stages of the development cycle. The end result is reduced risk, lower development costs, and faster time to market.

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