One of the fundamental efforts to mitigate risk of product failure is to integrate the systematic FMEA discipline at both the design and process stages. By creating the FMEA at these two early stages, manufacturers significantly reduce the cost impact that a failure can bring further down the production line or out into the market. The FMEA not only becomes the reference point for all failure research but is a living document that is continuously updated to drive quality improvement in product and process development going forward.

Since this practice is pivotal to identifying and mitigating the risk of failure, why do we continue to see reputable manufacturers stumble in the FMEA process?

Many of these organizations are stalled in antiquated spreadsheet systems trying to manage tens of thousands of FMEAs resulting in needless labor cost, data errors, siloed communication and missed opportunities to incorporate “lessons learned” that drive true continuous quality improvement. Failure in managing the FMEA process correctly results in ongoing product issues, recall impacts, litigation and potential fatal outcomes.

What are the solutions that proactive manufacturers are using to drive efficiency and attain the rigor needed from the FMEA process? Discover the steps to move your FMEA process forward to aid in detection of risk and remove inherit failures often found in current FMEA approaches.
QUALITY FMEA EFFORTS

For decades now, most advanced OEM manufacturers have relied on Failure Modes and Effects Analysis (FMEA) for critically assessing both the proposed design of a product (DFMEA) and the subsequent process or production required for its manufacture (PFMEA).

The FMEA process has been designed to identify and mitigate potential risk throughout the design and manufacturing process. Both types of FMEA initiatives discover, rank and record possible quality defects or issues, recommend corrective actions to ensure quality throughout development and beyond, and are valued drivers of continuous improvement.

Yet these independent-but-related FMEAs — design and process — are surprisingly prone to fall out of sync with each other; conclusions and recommendations may be clearly documented in one FMEA without also being transferred to the other.

TRADITIONAL FMEA PROCESS

FMEA activities focus on discovering potential failure points or quality “issues” pertaining to a proposed product’s design or its production. In so doing, both types of FMEAs are considered systematic and rigorous in the investigation and documentation process answering the following:

- What are the potential failures?
- How likely are the potential failures?
- What are the effects of potential failures?
- What preventative actions can/will eliminate (or at least reduce) potential failures?
- Documented detailed written account

IDENTIFICATION: In many cases, the thorough examinations fundamental to a good FMEA may uncover the need for a major design or production change. For example, findings in either type of FMEA may point to a product modification that demands a new distinguishing part number to ensure safety, reliability, functionality and overall quality of the product in question.

AN FMEA CAN REDUCE OR ELIMINATE THE CHANCE OF IMPLEMENTING A CORRECTIVE CHANGE.

– FMEA REFERENCE MANUAL

This all-too-common disconnect can lead to a perpetual broken chain; old issues repeated over and over, products continually fail in the same manner, businesses — and customers — suffer the same fallout. Luckily, this is an unnecessary conflict that can be prevented, restoring once again ultimate trust in the FMEA endeavor that is so fundamental to everyday quality and continuous improvement.

INTEGRATION: FMEAs are used in many industries, particularly for new products or models, or if new technology is involved, or if the product design or manufacturing process is particularly complex. As shown in chart on the next page, both the DFMEA and the PFMEA are traditionally integrated as important “continuous steps” within the flow of information during product development — but many times not fully integrated with each other.
Understandably, the documentation for a DFMEA or PFMEA is not simply created, filed, and forgotten. The ideal FMEA remains valid over the life of the product, continually updated/revised with relevant new information or changes affecting design or production. Think living documents as opposed to leaving documents, and DFMEAs and PFMEAs remain trusted resources going forward. Properly maintained and updated over the lifetime of the product, FMEA documents are highly valued as “THE” primary resource in the event of a quality investigation; they are the first place a quality manager turns to in researching what issues could arise, what is their expected severity, and what is their recommended resolution. In short, well-done and closely managed FMEAs are considered the gold standard for the truth about a product or part.

As well, a project team working on a related new product or model typically consults previous FMEAs for a jumpstart in both new design and new production initiatives.

Awareness of the findings and recommendations laid out in those FMEAs can prevent old errors from repeating. This vital FMEA function helps drives continuous improvement while also increasing efficiency.

Given the crucial roles of both the DFMEA and the PFMEA — and particularly in light of today’s ubiquitous automations that help ensure stellar quality and productivity throughout most of the competitive global market — it is somewhat surprising that FMEAs are still typically created and managed using traditional tools such as voluminous spreadsheets and manual data entry. Unfortunately, systems requiring such intensive human intervention provide no guarantee that valuable “lessons learned” and/or changes due to discoveries documented in one type of FMEA are also replicated in the other FMEA.

Even the most herculean efforts to manually keep both types of FMEAs “in sync” with one another at all times (i.e., sharing new discoveries and recommendations in a timely manner to address — or even prevent — product quality issues) are innately subject to occasional failure. By definition, the treasured validity of each FMEA report actually becomes suspect; neither can be fully trusted.

When product design and production teams remain disjoint in this way, using cumbersome tools without an automated means of sharing their respective FMEA findings, each group may unwittingly end up preserving obsolete or incomplete DFMEA or PFMEA information. Unfortunately, in subsequently consulting these sources, respective decisions on future designs and processes are on a shaky footing. Like any simple “cut-and-paste” error made upfront, this unnoticed scenario can pave the way for serious trouble.
TOP FMEA ISSUES AND SOLUTIONS

The meticulous detail and repetitive nature of working on a comprehensive FMEA, whether for design or process/production, can be grueling and tedious. Complex designs featuring literally thousands of parts and processes, such as for automobile manufacturing, are particularly challenging for FMEA management. In such industries, FMEAs can increase workloads across multiple teams, sometimes even creating additional work that seems downright redundant or “non-value added”. Such drudgery can lead to subtle burnout or “FMEA fatigue”, putting the quality of the FMEA — and hence the quality of the product itself — at risk. For example, when separate (yet related) DFMEA and PFMEA information fails to be exchanged, whether accidentally or because of a simple weakness in communication, consider some of the possible fallout:

ISSUE #1: DFMEA and PFMEA content differs
If FMEA recommendations for changes in product design and/or manufacture are not automatically shared in a reliable and timely manner from one FMEA group to another, the two entities fall out-of-sync. One FMEA dissolves into obsolescence — and it might not be clear which one. Entire departments may be confidently headed in different directions.

EXAMPLE: Suppose an auto manufacturer installs 30,000 parts per vehicle, typically requiring 20,000 DFMEAs and 20,000 PFMEAs to simultaneously track and update design and production details about these parts. Successfully managing this using manual tools such as spreadsheets clearly requires flawless human performance — no errors, no oversights, no tardiness — in every instance and for every part and process. The undertaking is labor-intensive, unreliable, rife with risk, and ultimately doomed to failure no matter how diligent the contributing teams or how well-planned their revision systems.

What happens if an FMEA is not updated at some point? Put simply, consulting an obsolete FMEA can lead to the same quality issue(s) that were previously addressed in the missing information. A disaster may ensue.

SOLUTION: Both FMEAs need to be linked automatically, not with spreadsheets or similar data-entry efforts. The ASI DATAMYTE QDA solution, for example, includes an integrated DFMEA and PFMEA communication path to ensure matching information. When either type of FMEA is updated by its corresponding group, the other group receives an “alert” to do the same. This linking works both ways, i.e., it is “bi-directional”, DFMEA to PFMEA. The seamless automation means that FMEAs stay in sync with minimal effort, and both remain valid resources for future product development and continuous improvement.

ISSUE #2: Finding FMEA data is difficult
Project teams consult related FMEAs from the past to review findings and recommendations that can prevent repeated errors. But searching spreadsheet archives (sometimes having thousands of files) can be highly impractical or even impossible, both in finding the proper file and in filtering data to focus on a specific parameter.
SOLUTION: The content of every FMEA must automatically stay current to prevent top priority safety issues from falling through the cracks. The ASI DATAMYTE QDA solution helps ensure this integrity; DFMEAs and PFMEAs automatically provide alerts to one another as changes occur. With such strong feedback/input integration in place, consulting either FMEA can reliably prevent the recurrence of serious issues of the past.

ISSUE #3: Outdated FMEAs
Consulting a previous FMEA in which crucial content is either missing or incorrect due to an overlooked update is at best pointless — or at worst dangerous — when trying to resolve quality issues.

EXAMPLE: Ongoing quality issues will continue in your plant when a part quality issue has been identified — and addressed in a DFMEA — but it never makes it to the corresponding PFMEA. Production will keep installing the old part and the product will continue to roll off the line with the same quality issue.

SOLUTION: The content of every FMEA must automatically stay current to prevent top priority safety issues from falling through the cracks. The ASI DATAMYTE QDA solution helps ensure this integrity; DFMEAs and PFMEAs automatically provide alerts to one another as changes occur. With such strong feedback/input integration in place, consulting either FMEA can reliably prevent the recurrence of serious issues of the past — and nobody has to intervene first.

CLOSE THE LOOP TO CONTINUOUS QUALITY
When trying to manage FMEA demands with inadequate tools — those that require constant attention and painstaking human intervention, such as voluminous spreadsheets, massive amounts of data entry, hundreds of emails, follow-up meetings and other discussions, and the list goes on — it is clear that certain aspects of traditional FMEAs no longer suit today’s automated manufacturing environments. It is time to extend the helping hand of automation into the world of FMEAs, establishing that absolutely essential link and cohesion between design FMEAs and process FMEAs that has been eluding the world all along.

<table>
<thead>
<tr>
<th>Comparison</th>
<th>QDA</th>
<th>Spreadsheet</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bi-directional updates to Design/Process FMEAs</td>
<td>YES</td>
<td>No</td>
</tr>
<tr>
<td>Automatic revision tracking (history log) of all changes.</td>
<td>YES</td>
<td>No</td>
</tr>
<tr>
<td>Quick search and retrieval of similar FMEAs for “lessons learned”.</td>
<td>YES</td>
<td>No</td>
</tr>
<tr>
<td>Email alert to key individuals when specific changes made.</td>
<td>YES</td>
<td>No</td>
</tr>
<tr>
<td>Automatic reporting sent to key individuals.</td>
<td>YES</td>
<td>No</td>
</tr>
<tr>
<td>Integrated Quality System scalable to your global manufacturing needs.</td>
<td>YES</td>
<td>No</td>
</tr>
<tr>
<td>Reduction in human error due elimination of ‘cut and paste’ approach.</td>
<td>YES</td>
<td>No</td>
</tr>
<tr>
<td>Easy data filtering for quick FMEA analysis without risk of lost data</td>
<td>YES</td>
<td>No</td>
</tr>
</tbody>
</table>

For more information on the company’s solutions, visit www.asidatamyte.com.