

University of Wales Trinity Saint David
School of Engineering

Failure Mode & Effects Analysis Technical Report



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Engineering Applications & Study Skills
(ACMA4007)

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1 Introduction

In the dynamic landscape of the manufacturing sector, understanding and managing risks are crucial for ensuring the safety, reliability, and success of engineering projects.

Engineers play a pivotal role in identifying, assessing, and mitigating the potential risks. It is imperative that engineers adhere to current codes of conduct as a duty of care. By following these codes, they can ensure that their projects are not only ethical, but also safe for public use. To leave no stone unturned, a thorough risk assessment process is implemented, within this investigation includes the use of Failure Mode and Effect Analysis (FMEA).

1.1 Aims

The purpose of this report is to identify possible failures associated with the 10G Open Cap in the Biotage Sfar 10G Column using FMEA (Failure Mode Effects Analysis). With aims to examine the preventative measures that have been established and put into practice to prevent these failures.

1.2 Objectives

1. Explain the need for risk management within the engineering sector and the necessity for codes of conduct.
2. Carry out a Failure Mode and Effect Analysis.
3. Organise an Excel spreadsheet to display results from FMEA.
4. Describe the needed mitigating actions and how they were implemented.
5. Revisit the 4 highest RPN results and further mitigate risks with actions.
6. Analyse all work carried out within the investigation.

2 Literature Review

2.1 Requirement for Risk Management in Manufacturing

The manufacturing sector is characterized by multiple complex processes, machinery, and materials, which make it vulnerable to different types of risks. Therefore, it is crucial to identify and mitigate these risks to ensure the smooth operation of production processes, maintain product quality, adhere to safety standards, and comply with legal regulations. It also prepares the business on minimizing the effects the failure has and allows a contingency plan to be put in place prior to the event.

2.2 Use of FMEA in Mitigating Risks

Failure Modes & Effects Analysis (FMEA) is a widely accepted methodology for systematically evaluating potential failure modes and their effects on a system, process, or product. FMEA aids in identifying critical failure modes, prioritizing risks, and implementing targeted corrective actions. By employing FMEA, engineers can enhance the robustness of their designs, minimize the probability of failures, and improve overall system reliability. Typically, FMEA's risk evaluations is defined by using the RPN (Risk Priority Number), which formulates from multiplying the scores of Occurrence, Severity and Detection.

$$RPN = O \times S \times D$$

2.3 IMechE Code of Conduct

The IMechE Code of Conduct emphasizes the responsibility of engineers to prioritize satisfying all current regulations to ensure their work is ethical and safe. The Institution of Mechanical Engineers follows a set of standards outlined in their royal charter and by-laws document. By-law 30 in this document establishes the central ethical responsibilities for all members of the institution. Below are a few points taken from the document;

- They shall quantify, balance and limit risk in all aspects of professional work, including with those who are working under their authority
- They shall avoid deceptive acts and refrain from corrupt practices.
- They shall comply with obligations for health and safety.

(Institution of Mechanical Engineers, 2021)

This document highlights the importance of adhering to high standards of work to meet engineering institutions' codes of conduct. Following these codes ensures accurate work completion with minimal risk. Other laws and regulations, such as the Health and Safety at Work Act, impose legal obligations on engineers to ensure they are meeting a minimum requirement resulting in a safe working environment.

Under the Management of Health and Safety at Work Regulations 1999, the minimum you must do is:

- a) identify what could cause injury or illness in your business (hazards)
- b) decide how likely it is that someone could be harmed and how seriously (the risk)
- c) take action to eliminate the hazard, or if this isn't possible, control the risk

(HSE, 2024)

3 Methodology

3.1 Process of Conducting FMEA

3.1.1 Scope definition

The FMEA process begins with defining the scope, outlining the boundaries of the analysis. This involves identifying the product or process that needs to be assessed.

3.1.2 Assembling a Cross-functional Team

A diverse team comprising engineers, operators, quality control, research development and safety specialists is crucial for comprehensive risk assessment. This ensures a multidimensional perspective and expertise in different aspects of the design/manufacturing process.

3.1.3 Identifying Failure Modes

The team systematically identifies potential failure modes for each component or process, considering past experiences, historical data, and expert knowledge.

3.1.4 Determining Failure Effects

The consequences of each identified failure mode are evaluated, considering the impact on safety, product quality, and overall system functionality.

3.1.5 Assigning Severity, Occurrence, and Detection Ratings

Numerical scales are used to assign severity, occurrence, and detection ratings for each failure mode, facilitating a quantitative analysis of risks. Show below in Table 1, Table 2 and Table 3.

3.1.6 Calculating Risk Priority Number (RPN)

RPN is calculated by multiplying severity, occurrence, and detection ratings. This prioritizes failure modes for targeted mitigation efforts.

3.1.7 Developing Mitigation Strategies

The team proposes corrective actions to reduce RPN values, addressing the root causes of failure modes and enhancing the overall system robustness.

Within Appendices, there is a more detailed explanation of the process.

3.1.8 FMEA Layout within excel

DFMEA

Process/Product Name: Sfar Cartridge 5G Open Assembly

Responsible: Jordan Hessey

Core Team:

Prepared By: Jordan Hessey

DFMEA Date (Orig.): 14-Jan-24

(Rev.): 001

Biotage

Item	Function / Requirement	Potential Failure Mode	Potential Failure Effects	SEVERITY (1 - 10)	Potential Causes	OCCURRENCE (1 - 10)	Current Design Controls (Prevention)	Current Design Controls (Detection)	DETECTION (1 - 10)	RPN	Action Recommended	Resp.	Actions Taken	Action Results					
														SEVERITY (1 - 10)	OCCURRENCE (1 - 10)	DETECTION (1 - 10)	RPN		
	What is the process step, change or feature under investigation?	In what ways could the step, change or feature go wrong?	What is the impact on the Product if this Failure is not prevented or corrected?		What causes the step, change or feature to go wrong? (How could it occur?)		What controls exist that prevent the failure?	What controls exist that detect the failure?			What are the recommended actions for reducing the occurrence of the cause or improving detection?	Who is responsible for making sure the actions are completed?	What actions were completed (and when) with respect to the RPN?						
3	CAP 5G/10G Open: Encloses media/insert within column and allows column to function under pressure.	Thread incorrect within CAP	Unable to assemble CAP onto barrel correctly	8	Thread start position wrong	3	Research thread sizes	Carry out DVP	5	120	Take DVP results and specify tolerances on technical drawing for supplier & design QC gauge	JH	DVP results investigated to give a know USL and LSL needed for function to operate as needed. Drawing created with desired limits. Gauge designed to capture specific features	8	1	2	16		
					Inside thread diameter too large														
					Inside thread diameter too small														
					Thread pitch wrongly sized														
		Luer Lock Connection out of specification	Unable to connect instrument to CAP	7	Moulded outside diameter too large	3	Research thread sizes		5	105	Take DVP results and specify tolerances on technical drawing for supplier & design QC gauge	JH	DVP results investigated to give a know USL and LSL needed for function to operate as needed. Drawing created with desired limits. Gauge designed to capture specific features	7	1	2	14		
					Moulded outside diameter too small														
					Thread pitch wrongly sized														
			Leakage		9	Moulded outside diameter too small	3		Research thread sizes		5	135	Take DVP results and specify tolerances on technical drawing for supplier & design QC gauge	JH	DVP results investigated to give a know USL and LSL needed for function to operate as needed. Drawing created with desired limits. Gauge designed to capture specific features	9	1	2	18
		Thread pitch wrongly sized																	
		Blockage / reduced flow		5	Moulded inside diameter too small	3	Existing product flowrates considered		5	75							0		
		O-Ring seat	O-Ring doesn't form correct seal leading to leakage	9	O-ring seat too large	2	Compression rates researched for desired pressure		5	90	Take DVP results and specify tolerances on technical drawing for supplier & design QC gauge	JH	DVP results investigated to give a know USL and LSL needed for function to operate as needed. Drawing created with desired limits. Gauge designed to capture specific features	9	1	2	18		
					O-ring seat too small														
					Surface finish too rough		Research surface finishes to find desired finish/fitment											3	54
		Insert taper lock	Incorrect fitment	7	Wrong taper angle	2	Taper fitment choose from standards		5	70								0	
					Surface finish too rough		Research surface finishes to find desired finish/fitment												
		Material Cleanliness	Customer test result void	9	contaminated material	2	Classifications for cleanliness researched		3	54									0
		Material grade / weakness	Customer test result void	9	Incorrect material	2	Material selection based on media compatibility		3	54									0
			Wrong colour	3	Wrong compound used		Discussion within team to decide on correct colour		1	6							0		
		Outside diameter	Fitment issues with instruments & accessories	5	Incorrect moulding	2	All accessories to be considered when choosing outside diameter		6	60									0
		CAP Height Measurement	Fitment issues with instruments	5	Incorrect moulding	2	All accessories to be considered when choosing overall height		6	60									0

Figure 1 - DFMEA Layout (For Illustration purposes only)

3.1.9 Criteria Tables used within DFMEA process

Table 1 - Design Severity Scale (Biotage 2024)

Design Severity Scale		
Adapt as appropriate		
Effect	Severity of Effect on product / customer	Ranking
Hazardous - Without Warning	Failure could injure the customer or an employee.	10
Very High	Failure would create noncompliance with customer requirement	9
High	Failure renders the unit inoperable or unfit for use.	8
Moderate	Failure causes a high degree of customer dissatisfaction.	7
Very Moderate	Failure results in a subsystem or partial malfunction of the product.	6
Low	Failure creates enough of a performance loss to cause the customer to complain.	5
Very Low	Failure can be overcome with modifications to the customer's process or product, but there is minor performance loss.	4
Minor	Failure would create a minor nuisance to the customer, but the customer can overcome it without performance loss.	3
Very Minor	Failure may not be readily apparent to the customer, but would have minor effects on the customer's process or product.	2
None	Failure would not be noticeable to the customer and would not affect the customer's process or product.	1

Table 2 - Design Occurrence Scale (Biotage 2024)

Design Occurrence Scale		
Adapt as appropriate		
Probability of Failure	Occurrence of cause (Design life/reliability of item)	Ranking
Almost Certain	New technology/new design with no history	10
Very High	Failure is inevitable with new design, new application, or change in duty cycle/operating conditions	9
High	Failure is likely with new design, new application, or change in duty cycle/ operating conditions.	8
Moderately High	Failure is uncertain with new design, new application, or change in duty cycle/ operating conditions.	7
Moderate	Frequent failures associated with similar designs or in design simulation and testing.	6
Low	Occasional failures associated with similar designs or in design simulation and testing.	5
Very Low	Isolated failures associated with similar designs or in design simulation and testing.	4
Remote	Only isolated failures associated with almost identical design or in design simulation and testing.	3
Very Remote	No observed failures associated with almost identical design or in design simulation and testing.	2
Absolute Uncertainty	Failure is eliminated through preventative control.	1

Table 3 - Design Detection Scale (Biotage 2024)

Design Detection Scale		
Adapt as appropriate		
Detection	Likelihood of detection by design control	Ranking
Absolute Uncertainty	No known controls available to detect failure mode	10
Very Remote	Very remote likelihood current controls will detect failure mode	9
Remote	Remote likelihood current controls will detect failure mode	8
Very Low	Very low likelihood current controls will detect failure mode	7
Low	Low likelihood current controls will detect failure mode	6
Moderate	Moderate likelihood current controls will detect failure mode	5
Moderately High	Moderately high likelihood current controls will detect failure mode	4
High	High likelihood current controls will detect failure mode	3
Very High	Very high likelihood current controls will detect failure mode	2
Almost Certain	Current controls almost certain to detect the failure mode. Reliable detection controls are known with similar processes.	1

3.2 Justifications for Rankings



Figure 2 - Biotage Sfär Column & Liquid loading through Luer port

Shown in Figure 2 is a Sfär Column assembled and how a sample is loaded through the Cap. Within the DFMEA process, it was decided to break the Column down into subassemblies to truly capture the failure modes within each component.

3 key Potential Failure modes were chosen to focus on as the results of the RPN was the highest;

1. Thread incorrect within CAP
2. Luer lock Connection out of specification
3. O-Ring seat

As shown above in Table 1, Table 2, and Table 3 these are the criteria used to determine the severity, occurrence, and detection within the FMEA carried out. Based on sound engineering discussions and the criteria tables, a realistic ranking value was determined for each element within the FMEA.

Table 4 - Potential Failure Modes and their corresponding scores before mitigating actions

Potential Failure Mode	Potential Failure Effects	Severity (1-10)	Occurrence (1-10)	Detection (1-10)	RPN
Thread incorrect within CAP	Unable to assemble CAP onto barrel correctly	8	3	5	120
Luer Lock Connection out of specification	Unable to connect instrument to CAP	7	3	5	105
	Leakage	9	3	5	135
O-Ring seat	O-ring doesn't form correct seal leading to leakage	9	2	5	90

Table 5 - Potential Failure Modes and their corresponding scores after mitigating actions

Potential Failure Mode	Potential Failure Effects	Severity (1-10)	Occurrence (1-10)	Detection (1-10)	RPN
Thread incorrect within CAP	Unable to assemble CAP onto barrel correctly	8	1	2	16
Luer Lock Connection out of specification	Unable to connect instrument to CAP	7	1	2	14
	Leakage	9	1	2	18
O-Ring seat	O-ring doesn't form correct seal leading to leakage	9	1	2	18

3.2.1 Thread incorrect within CAP

Severity Rating

Deemed inoperable as this is a vital component within the assembly for holding pressure and securing an insert in place.

Likelihood of occurrence

As there are other products very similar to this design within the company, it was decided very unlikely of occurrence.

Likelihood of Detection

Again, with previous designs playing a factor and carrying out DVP (design verification plan) the chances of detecting the failure were moderate.

3.2.2 Luer lock connection out of specification

The Luer lock had multiple failure effects if the potential failure mode were to happen, hence why it has two RPN scores for the two separate effects.

Severity Rating

Being unable to connect with customers machinery, this would cause a high degree of customer dissatisfaction. Leaking on the other hand, would create noncompliance with customer requirements.

Likelihood of occurrence

Very similar design to preexisting designs within biotage, giving a very unlikely chance of the design having these issues.

Likelihood of Detection

Moderate chance of detection as again, coming from very similar designs within biotage and being captured within DVP.

3.2.3 O-Ring Seat

Severity Rating

Scored very high due to creating a noncompliance with customer requirements as their tests couldn't be carried out successfully.

Likelihood of occurrence

Very remote, no observed failures within biotage other products with this failure.

Likelihood of Detection

DVP has a moderate chance of detecting this failure mode.

Risk Priority Numbers

With RPN numbers calculated, this gave indication which modes needed to take precedence for most risk.

1. Luer Lock Connection out of specification – Leakage – 135
2. Unable to assemble CAP onto barrel – 120
3. Luer Lock Connection out of specification – Unable to connect to instrument – 105
4. O-Ring doesn't form correct seal - 90

3.3 Corrective Actions

With all Failure modes, the DFMEA & DVP results were reviewed.

- Review tolerances that can be held
- Pressure the CAP can withstand
- Any leakage detected
- Thread fits

With knowledge gained from the DFMEA & DVP on these results, technical drawings were modified to represent the necessary requirements needed to control the CAP within specifications. Also, with discussions, it was decided that extra controls such as creating QC gauges to check incoming product. This allowed specific features to be captured and giving a high detection rate.

4 Conclusions

In conclusion, the FMEA process is a powerful tool for mitigating risks in the manufacturing sector. By systematically identifying and addressing potential failure modes, engineers can enhance the reliability and safety of systems. The effectiveness of FMEA lies in its ability to provide a structured approach to risk management, aligning with the ethical responsibilities outlined in the IMechE Code of Conduct. However, the tool's effectiveness also depends on the commitment to implementing proposed corrective actions and continuous monitoring of the evolving manufacturing landscape.

The FMEA process uncovered many potential failures within the design looked at in this report, but, with the aid of RPN numbers, allowed a more efficient way of mitigating high risk factors. The results after mitigating actions proved a positive impact on the design and demonstrating the overall effectiveness of FMEA.

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6 Appendices

6.1 How to conduct an FMEA analysis: A step-by-step guide

Lucidchart(2024)

Here's how to get started.

1. Choose a process you want to analyse

First, identify what product or process you want to assess. The FMEA analysis is comprehensive, so you want to focus on a specific process with a narrow scope. If you are already aware of an issue, that's a good place to start.

Pro tip: For complex processes, consider breaking up the project into smaller parts and conducting multiple FMEA analyses.

2. Gather a team

Next, put together a cross-functional team to help conduct a thorough analysis.

Team members should be people who are directly involved in the process you're analyzing. They could come from design, manufacturing, maintenance, sales, or customer service. Include people who are not in management roles to get a clear perspective of the process realities (and challenges) on the ground.

3. Review the process

Review your current process and identify each process component and function. Be specific. Consider what the purpose of the process is and what customers expect it to do.

Once you have your process components mapped out, you can document them in your FMEA diagram.

4. Identify failure modes

Brainstorm all the different ways the process could break down. These are called failure modes. What are the risks? How could each component fail or malfunction?

Keep in mind that failure in one component could cause another failure somewhere else.

Pro Tip: Use sticky notes to list failures underneath each process step to more easily brainstorm and visualize the potential risks.

5. Outline the effects of each potential failure

Once you've listed all the potential failure modes, go through each one and identify all the consequences on the system, process, customer, or organization.

In other words, for each failure mode, ask:

What happens when this function fails?

How does a failure here affect the customer?

Then consider what the root causes are for each failure (your team members are an invaluable resource here). List the causes on your FMEA diagram.

6. Determine the severity of each failure

As noted earlier, FMEA ranks the three assessment criteria on a scale of 1 to 10. The first criterion is severity.

Go through each failure mode and assign it a number based on how serious the issue is, with 1 being insignificant and 10 being catastrophic. Add these rankings to the FMEA diagram.

7. Rank occurrence

Next, you will rank occurrence or the probability of each failure mode to occur. Again, assign a ranking between 1 and 10, with 1 being least likely and 10 being inevitable. Add these rankings to the FMEA table.

8. Rank detection

The last criterion is detection. In other words, what is the likelihood the failure will be detected and acted upon before it happens (or before it is noticed by the customer)?

You'll need to first identify what controls are currently in place to prevent the failure from happening or keeping the problem from reaching the customer.

Once you know what controls are in place, you can rank how likely those controls will prevent detection. Again, rank these probabilities for each failure on a scale of 1-10, with 1 meaning you're certain the failure will be detected and 10 meaning you're certain the failure will not be detected.

9. Calculate the RPN

With each criterion ranked and listed on your FMEA table, you can multiply the rankings to calculate the risk priority number (RPN):

$$\textit{Severity} \times \textit{Occurrence} \times \textit{Detection} = \textit{RPN}$$

The RPN helps you prioritize which failures are most urgent so you can create a strategic plan of action.

10. Create a plan of action based on the risk priorities

With your failure modes mapped out and ranked, you can quickly assess which areas of the process need corrective measures and recommended actions. This might mean making changes to the process or product design or adjusting the measures and controls in place to mitigate risk and detection.

Your specific action plan should focus on the following objectives:

Eliminating failure modes from the process altogether where possible

Minimizing the severity and reducing the occurrence of failure modes

Improving detection of failure modes (i.e., improving controls)

As you map out your plans, note them on the FMEA sheet as well as which team members are responsible for each action.

After implementing these measures, note the results and recalculate the RPN to assess your progress and impact.

6.2 Personal Development Plan

Name – Jordan Hessey

Degree – BEng Advanced Manufacturing Operations

Previous Qualifications – HNC Mechanical Engineering, HNC Electrical & Electronics Engineering

Previous Experience – Qualified Toolmaker, Manufacturing Engineer, Senior Manufacturing Engineer

Goal	Objective	Resources Required	Measurement	Target Date
Become Engineering Manager	Complete Degree and many courses alongside to increase knowledge	University & training institutes	Course Completion	2027
Team Management training	Learn how to correctly manage teams	Manager 1to1, Training institute	Manager input, Course Completion	2027
NEBOSH	Become Highly efficient in knowledge of H&S	Training institute	Course Completion	2027
Machinery Legislative training	Understanding machinery legislation in more depth, able to challenge others	PILZ training facility	Course Completion	2027
Fusion 360 competent	Efficient in the use of Fusion360	Fusion360, Training	Course Completion & use fusion without help	2025

6.3 Technical Poster

Failure Mode & Effects Analysis

Jordan Hessey

School of Engineering

BEng (Hons) Advanced Manufacturing Operations

Introduction

The purpose of this project is to identify possible failures associated with the 10G Open Cap in the Biotage Sfar 10G Column using FMEA (Failure Mode Effects Analysis).

With aims to examine the preventative measures that have been established and put into practice to prevent these failures.

FMEA brief overview

Failure Modes & Effects Analysis (FMEA) is a widely accepted methodology for systematically evaluating potential failure modes and their effects on a system, process, or product. FMEA aids in identifying critical failure modes, prioritizing risks, and implementing targeted corrective actions.

By employing FMEA, engineers can enhance the robustness of their designs, minimize the probability of failures, and improve overall system reliability. Typically, FMEA's risk evaluations is defined by using the RPN (Risk Priority Number), which formulates from multiplying the scores of Occurrence, Severity and Detection.

$$RPN = O \times S \times D$$

Methodology

1. Process of Conducting FMEA

1. Scope definition
The FMEA process begins with defining the scope, outlining the boundaries of the analysis. This involves identifying the product or process that needs to be assessed.

2. Assembling a Cross-functional Team
A diverse team comprising engineers, operators, and safety specialists is crucial for comprehensive risk assessment. This ensures a multidimensional perspective and expertise in different aspects of the design/manufacturing process.

3. Identifying Failure Modes
The team systematically identifies potential failure modes for each component or process, considering past experiences, historical data, and expert knowledge.

4. Determining Failure Effects
The consequences of each identified failure mode are evaluated, considering the impact on safety, product quality, and overall system functionality.

5. Assigning Severity, Occurrence, and Detection Ratings
Numerical scales are used to assign severity, occurrence, and detection ratings for each failure mode, facilitating a quantitative analysis of risks. Show below in Table 1, Table 2 and Table 3.

6. Calculating Risk Priority Number (RPN)
RPN is calculated by multiplying severity, occurrence, and detection ratings. This prioritizes failure modes for targeted mitigation efforts.

7. Developing Mitigation Strategies
The team proposes corrective actions to reduce RPN values, addressing the root causes of failure modes and enhancing the overall system



10G Open Cap attached to the Biotage Sfar 10G Column & a Column being filled through the Luer port.



Corrective Actions

With all Failure modes, the DFMEA & DVP results were reviewed.

- Review tolerances that can be held
- Pressure the CAP can withstand
- Any leakage detected
- Thread fits

With knowledge gained from the DFMEA & DVP on these results, technical drawings were modified to represent the necessary requirements needed to control the CAP within specifications. Also, with discussions, it was decided that extra controls such as creating QC gauges to check incoming product. This allowed specific features to be captured and giving a high detection rate.

Summary of Key Findings

The FMEA process is a powerful tool for mitigating risks in the manufacturing sector. By systematically identifying and addressing potential failure modes, engineers can enhance the reliability and safety of systems. The effectiveness of FMEA lies in its ability to provide a structured approach to risk management, aligning with the ethical responsibilities outlined in the IMechE Code of Conduct. However, the tool's effectiveness also depends on the commitment to implementing proposed corrective actions and continuous monitoring of the evolving manufacturing landscape.

The FMEA process uncovered many potential failures within the 10G Open Cap, but, with the aid of RPN numbers, allowed a more efficient way of mitigating high risk factors. The results after mitigating actions proved a positive impact on the design and demonstrating the overall effectiveness of FMEA.

References

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Figure 3- Technical Poster (Illustration purposes)

Failure Mode & Effects Analysis

Jordan Hessey

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BEng (Hons) Advanced Manufacturing Operations

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FMEA brief overview

Failure Modes & Effects Analysis (FMEA) is a widely accepted methodology for systematically evaluating potential failure modes and their effects on a system, process, or product. FMEA aids in identifying critical failure modes, prioritizing risks, and implementing targeted corrective actions.

By employing FMEA, engineers can enhance the robustness of their designs, minimize the probability of failures, and improve overall system reliability. Typically, FMEA's risk evaluations is defined by using the RPN (Risk Priority Number), which formulates from multiplying the scores of Occurrence, Severity and Detection.

$$RPN = O \times S \times D$$

Methodology

1. Process of Conducting FMEA

1. Scope definition

The FMEA process begins with defining the scope, outlining the boundaries of the analysis. This involves identifying the product or process that needs to be assessed.

2. Assembling a Cross functional Team

A diverse team comprising engineers, operators, and safety specialists is crucial for comprehensive risk assessment. This ensures a multidimensional perspective and expertise in different aspects of the design/manufacturing process.

3. Identifying Failure Modes

The team systematically identifies potential failure modes for each component or process, considering past experiences, historical data, and expert knowledge.

4. Determining Failure Effects

The consequences of each identified failure mode are evaluated, considering the impact on safety, product quality, and overall system functionality.

5. Assigning Severity, Occurrence, and Detection Ratings

Numerical scales are used to assign severity, occurrence, and detection ratings for each failure mode, facilitating a quantitative analysis of risks. Show below in Table 1, Table 2 and Table 3.

6. Calculating Risk Priority Number (RPN)

RPN is calculated by multiplying severity, occurrence, and detection ratings. This prioritizes failure modes for targeted mitigation efforts.

7. Developing Mitigation Strategies

The team proposes corrective actions to reduce RPN values, addressing the root causes of failure modes and enhancing the overall system robustness.



10G Open Cap attached to the Biotage Sfar 10G Column & a Column being filled through the Luer port.



Corrective Actions

With all Failure modes, the DFMEA & DVP results were reviewed.

- Review tolerances that can be held
- Pressure the CAP can withstand
- Any leakage detected
- Thread fits

With knowledge gained from the DFMEA & DVP on these results, technical drawings were modified to represent the necessary requirements needed to control the CAP within specifications. Also, with discussions, it was decided that extra controls such as creating QC gauges to check incoming product. This allowed specific features to be captured and giving a high detection rate.

Summary of Key Findings

The FMEA process is a powerful tool for mitigating risks in the manufacturing sector. By systematically identifying and addressing potential failure modes, engineers can enhance the reliability and safety of systems. The effectiveness of FMEA lies in its ability to provide a structured approach to risk management, aligning with the ethical responsibilities outlined in the IMechE Code of Conduct. However, the tool's effectiveness also depends on the commitment to implementing proposed corrective actions and continuous monitoring of the evolving manufacturing landscape.

The FMEA process uncovered many potential failures within the 10G Open Cap, but, with the aid of RPN numbers, allowed a more efficient way of mitigating high risk factors. The results after mitigating actions proved a positive impact on the design and demonstrating the overall effectiveness of FMEA.

References

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Potential Failure Modes and their corresponding scores before mitigating actions

Potential Failure Mode	Potential Failure Effects	Severity (1-10)	Occurrence (1-10)	Detection (1-10)	RPN
Thread incorrect within CAP	Unable to assemble CAP onto barrel correctly	8	3	5	120
Luer Lock Connection out of specification	Unable to connect instrument to CAP	7	3	5	105
	Leakage	9	3	5	135
O-Ring seat	O-ring doesn't form correct seal leading to leakage	9	2	5	90

Potential Failure Modes and their corresponding scores after mitigating actions

Potential Failure Mode	Potential Failure Effects	Severity (1-10)	Occurrence (1-10)	Detection (1-10)	RPN
Thread incorrect within CAP	Unable to assemble CAP onto barrel correctly	8	1	2	16
Luer Lock Connection out of specification	Unable to connect instrument to CAP	7	1	2	14
	Leakage	9	1	2	18
O-Ring seat	O-ring doesn't form correct seal leading to leakage	9	1	2	18

Explanation of failure modes

1. Thread incorrect within CAP

Severity Rating
Deemed inoperable as this is a vital component within the assembly for holding pressure and securing an insert in place.

Likelihood of occurrence
As there are other products very similar to this design within the company, it was decided very unlikely of occurrence.

Likelihood of Detection
Again, with previous designs playing a factor and carrying out DVP (design verification process) the chances of detecting the failure were moderate.

Severity Rating
The Luer lock had multiple failure effects if the potential failure mode were to happen, hence why it has two RPN scores for the two separate effects.

Likelihood of occurrence
Being unable to connect with customers machinery, this would cause a high degree of customer dissatisfaction. Leaking on the other hand, would create noncompliance with customer requirements.

Likelihood of Detection
Very similar design to preexisting designs within biotage, giving a very unlikely chance of the design having these issues.

Likelihood of Detection
Moderate chance of detection as again, coming from very similar designs within biotage and being captured within DVP.

3. O-Ring Seat

Severity Rating
Scored very high due to creating a noncompliance with customer requirements as their tests couldn't be carried out successfully.

Likelihood of occurrence
Very remote, no observed failures within biotage other products with this failure.

Likelihood of Detection
DVP has a moderate chance of detecting this failure mode.

Risk Priority Numbers
With RPN numbers calculated, this gave indication which modes needed to take precedence for most risk.

1. Luer Lock Connection out of specification - Leakage - 135
2. Unable to assemble CAP onto barrel - 120
3. Luer Lock Connection out of specification - Unable to connect to instrument - 105
4. O-Ring doesn't form correct seal - 90