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The role of failure mode and effects analysis in improving the quality performance of dairy laboratories

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Abstract

Failure modes and effects analysis (FMEA) is a proactive procedure for risk management and quality improvement in laboratories. The FMEA was carried out on pre-analytical stage of ultra-high-temperature milk samples. It was applied at two different stages; in the first phase, the potential failure mode was chosen and the probable risks for failure mode were assessed and analyzed. Risk priority numbers (RPNs) were calculated to evaluate and organize reasons for potential failure and their impacts and identify the risk level. As for the second phase, it encompassed establishing and implementing the proposed action plans and measuring their effects. The uppermost RPN was human errors (504), followed by training (432), incorrect samples handling and transport (336), and insufficient sterilizing of tools (192). Employing the effective improvement action plan significantly decreased the RPN. The FMEA should be utilized as a regular tool to improve processes in laboratories.

Practical applications

The failure modes and effects analysis (FMEA) method is used mainly to minimize errors, improve the quality of pre analytical stage of milk samples in the laboratory, identify potential failures, and develop and prioritize improvement strategies. Corrective actions significantly lower the risk priority numbers values. Besides, FMEA is a preventive tool and it is helpful in risk assessment of processes in dairy laboratories. The FMEA is a frequently-used technique for quality assurance in food industry and numerous manufacturing industries addressing purchasers, governmental requirements, quality control, and safety. Nowadays, the FMEA is being applied in healthcare laboratories, and to attain all-inclusive and fast improvement in safety in non-healthcare industries.

1 | INTRODUCTION

Laboratory holds an important place in the dairy factories. It is very important to carry out many tests for quality control before, during and after different processing stages (raw material control, operations control, hygiene control, and final products' control). There are numerous tests and activities which are performed within the dairy laboratories. These activities comprise of three essential and vital phases as follows: pre-analytical, analytical, and post-analytical stages. All of these activities are susceptible to errors, and these errors are inevitable as it is not possible to entirely get rid of them; however, it is possible to decrease them (Marin, Rivas-Ruiz, Del Mar Pérez-Hidalgo, & Molina-Mendoza, 2014).

According to World Health Organization [WHO] (2011), there is a need for tools that are capable of detecting errors at each stage of testing. It is necessary also to have preventive measures to reduce errors, as the early detection or the avoidance is a step toward ensuring the quality of results and a noteworthy improvement to consistency, safety, reliability, and cost in the laboratory. This can be done by utilizing some tools such as internal quality control (IQC) and external quality assessment (EQA) and failure mode and effect analysis (FMEA) as risk management tools. With increasing workload as well as

Abbreviations: D, detection; EQA, external quality assessment; FMEA, failure modes and effects analysis; HACCP, hazard analysis critical control point; HAZOP, hazard and operability studies; HR, human resources; IQC, internal quality control; KPI, key performance indicators; O, occurrence; QA, quality assurance; QC, quality control; QMS, quality management system; RPN, risk priority number; S, severity; UHT, ultra-high-temperature.

complexities of laboratory testing and consumer health, the traditional technical adopted like IQC) and EQA may not enough to cope with quality management problems for dairy laboratories. We applied failure mode and effects analysis (FMEA), a proactive tool, to reduce errors associated with the process in a dairy laboratory (Jiang, Jiang, Ding, & Liu, 2015). Besides, the using of FMEA is recommended compared with the hazard and operability studies (HAZOP) and hazard and critical control point analysis (HACCP) because these methods can be time-consuming and may not be often practical to implement on a routine basis. They may have a place in biosecurity in assessing existing operational procedures, identifying weaknesses, and anticipating faults, especially when failures are critical (Cross, 2011).

Assessing the risk connected to the identified failure modes, effects and reasons, and prioritizing issues for corrective action identify and accomplish corrective actions to address the most serious concerns (Carlson, 2012).

The FMEA process includes identifying problems/errors and utilizing scales to find out the severity of the problems/errors, the possibility of occurrence, and the chances of detection. From these assessments, a risk priority number (RPN) can be calculated. Problems/errors-free operations will have low RPNs, whereas complex operations will have high RPNs (Chiozza & Ponzetti, 2009).

Xie (2013) indicated that FMEA is "an engineering technique using RPN to prioritize failure modes." The author reported that RPN is a product of three ranked ratings, which are occurrence, severity, and detection. It is calculated as: RPN = O * S * D. Occurrence (O) rating is assigned to the reason of the failure mode to reveal the probability of the cause and the immediate failure mode; severity (S) rating is assigned to the end effect of the failure mode to reveal the seriousness of the end effect and detection (D) rating is assigned to the reason of the failure mode to reveal the difficulty of finding the reason or failure mode. These ratings are quantified by integer numbers between (1 and 10). The RPNs are compared with each other, and failure modes with higher RPNs have greater risk, and corrective actions are taken to lessen their RPNs.

The FMEA method was formalized via the U.S. Armed Forces by the introduction of Mil-P 1629 procedure for carrying out failures mode effects and criticality analysis. The purpose was to categorize failures "according to their impact on mission success and personnel/equipment safety" (United States Military, 1980).

The implementation of FMEA began to extend to other industries and was used in wafer biscuit manufacturing lines in a food corporation. It was utilized as a mean to ensure quality and as a way to improve the operational performance of the manufacturing cycle (Scipioni, Saccarola, Centazzo, & Arena, 2002). It was implemented for risk assessment in Turkish confectionary manufacturing, in which the traditional techniques and tools were intensively employed in the manufacturing process. The implementation of this method improved the safety and quality of the goods (Ozilgen 2012).

Woodhouse (2005) introduced FMEA as a new tool for improving processes to increase patient's safety in a medical lab document. ISO/TS 22367 (2008) defines the use of FMEA in laboratories as a tool that can be used to detect and illustrate medical lab errors by applying the principles of risk management, with reference to pre-examination, examination, and post-examination processes. It was also used as a technique for risk management and quality improvement of clinical laboratories and in increasing awareness and in recognition of probable risky situations of a testing system (Eliza & Minodora, 2015). To the best of our knowledge, this manuscript is the first to advocate for the use of FMEA in dairy laboratories. The key purpose of this study is to encourage the using of FMEA as a tool for improving the quality performance of dairy laboratories.

2 | MATERIAL AND METHODS

The study was conducted at the quality dairy laboratory of factory X during October 1, 2015 to March 30, 2016. This factory is one of the leading factories in the field of producing, manufacturing, and exporting dairy products in Egypt. The factory produces almost 400 tons of products per day. It operates 7 days a week through three shifts. The operations and activities in the dairy lab start with a sampling process and end with result reporting and these activities can be divided into three main phases that is summarized in the flow chart (Figure 1).

According to Mcdermott, Mikulak, and Beauregard (2009), Lago et al. (2012), and Xie (2013), FMEA was performed in two parts; the first part consisted of three steps.

Step 1: Chose a high-risk procedure on which FMEA was performed. The pre-analytical testing stage happens in the laboratory process and it is considered the major source of errors in laboratory. It ranges from 32 to 75% of the total testing errors at this stage (Bonini,

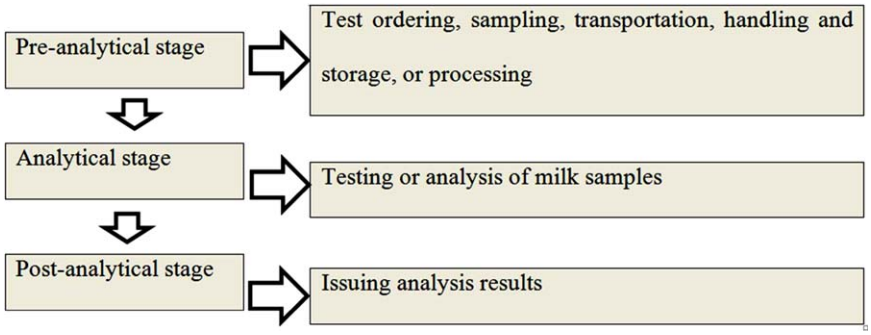

FIGURE 1 Flow chart for dairy laboratory testing stages

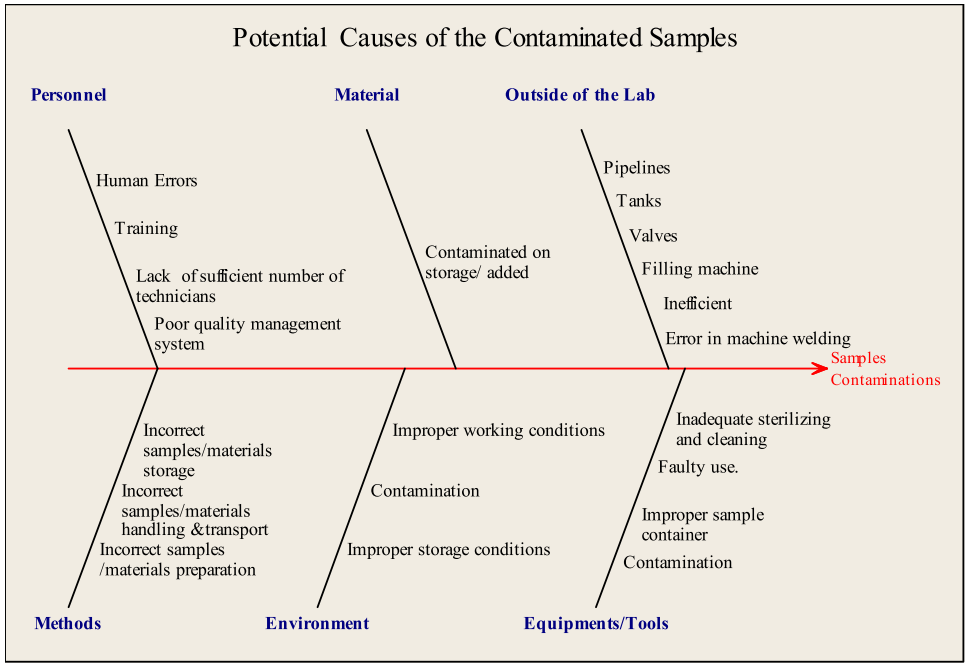

FIGURE 2 Ishikawa diagram analysis of the root causes of the contamination of samples

Plebani, Ceriotti, & Rubboli, 2002). For this reason, FMEA technique was implemented in this stage. The potential failure mode was selected according to impact size (ultra-high-temperature [UHT] milk samples contamination).

Step 2: Brainstormed on the potential effects of failure mode and root causes through meetings with the quality assurance engineers, technicians, quality control engineers, lab manager, and officials. The root causes of the contamination of samples were defined and presented in Ishikawa Diagram (Figure 2). This diagram was created by following the same procedure as Arvanitoyannis and Savelides (2007).

Step 3: Assigned ratings to severity, occurrence, and detection. This step includes, assigning ratings to severity, occurrence, and detection based on a 10-point scale. In the fourth step, all three ratings were multiplied together to get the RPN, which was used to rate the risk priority for reasons of failure mode and to rank the requirement for corrective actions in order to get rid of or decrease the possible causes of failure modes.

The second part of FMEA consists of identifying and carrying out the proposed action plans in order to get rid of or decrease the high risk and recalculate the RPN after carrying out the action plan. The RPN should be considerably decreased or the action taken was not effective in reducing the severity or likelihood of occurrence or detection.

The Microsoft Office program (Microsoft Excel 2010) and Minitab 16 programs were used for the preparation of spreadsheets, calculations, and data analysis.

The cause and effect diagram (Figure 1), allowed us to identify and display all the possible root causes related to contaminated samples in the dairy laboratories. Six main categories identified includes; personnel such as human errors, training, lack of sufficient number of technicians, and poor quality management system; methods such as incorrect samples/materials preparation, incorrect samples/materials handling and transport, and incorrect samples/materials storage; materials such as contaminated on storage/added; equipment/tools such as inadequate sterilizing and cleaning, such as improper storage conditions, contamination, and improper working conditions.

3 | RESULTS AND DISCUSSION

The first part of FMEA technique was carried out at pre-analytical stage by identifying the failure mode: the most common reasons for their occurrence, and their probable effects. Severity (S), occurrence (O), and detection (D) of every risk was calculated in accordance with the FMEA scoring system. Also, the RPN was calculated as shown in (Table 1).

Pareto analysis was used to arrange the RPNs in terms of the extent of its impact. Pareto chart was established by following the methods as suggested by McDermott et al. (2009).

Analysis showed that the highest percentage of RPN was human error's RPN (24.5%) followed by training's RPN (21%), incorrect samples/materials handling and transport RPN (16.3%), and inadequate sterilizing and cleaning of tool RPN (9.3%). It is the improper sample containers that cause the lowest RPN. The rest of the RPNs are shown in Figure 3. It should be noted that the first four RPNs on the left side of the chart represent the Significant Few.

The first part of FMEA and Pareto analysis results clearly showed that the greatest risks and errors were associated with personnel, methods, and tools. So, we focused on finding solutions to improve them so as to promote significant improvement in the accuracy of laboratory analyses and reduce laboratory errors.

An action plan utilizing FMEA was established and it outlined the procedures to be carried out and the one who is responsible for the

TABLE 1 FMEA format for contamination samples in pre-analytical stage (part 1)

Process	Failure mode	Failure effect	S	Cause	O	Control	D	RPN[a]
Pre-analytical stage	UHT milk samples contamination	- Extra expenses as a result of repetitive work - Leads to waste of time, personal effort and materials - Inaccuracy results and reliability failures	8	Human errors	9	Visual inspection	7	**504**
				Training	9	Evaluation reports	6	**432**
				Improper storage conditions	3	Visual check	4	**96**
				Contamination in facilities or lab environment	4	Test swabs	2	**64**
				Incorrect samples/ materials preparation	6	Visual inspection and results	4	**192**
				Incorrect samples/materials handling and transport	7	Visual inspection and results	6	**336**
				Tools contamination	4	Visual check and test swabs	4	**128**
				Proper sample container	1	Visual inspection	1	**8**
				Inadequate sterilizing and cleaning of tools	4	No action	6	**192**
				Material contamination on storage/added	3	Visual check and tests	3	**72**
				Production lines	2	Lab tests (HACCP)	2	**32**

[a]Calculated as: RPN = O * S * D.
D = detection; HACCP = hazard analysis critical control point; O = occurrence; RPN = risk priority numbers; S = severity; UHT = ultra-high-temperature.

implementation of these procedures. Table 2 shows the proposed action plan of improvement in common and the actions taken in addressing it. The new RPN which was obtained through re-evaluation of FMEA showed considerable reduction in RPNs of all the risks.

The contamination of UHT milk samples due to human errors and training were reduced after the implementation of corrective actions to 96 and 64, respectively (Table 2). Ensuring that the job description is compatible with employees' certificates and expertise, providing suitable supervision and ensuring that workers have the required capabilities to achieve the allocated job through establishment of a need's assessment plan are important in reducing errors arising from workers at the pre-analytical stage (ISO/IEC 17025, 2005). Additionally, monitoring personal hygiene of staff and educating them on correct practices reduced the risk of cross-contamination (Ozilgen, 2011). Quality circles of meeting lab personnel and listening to problems, submitting reports to employees regarding their performance and their strengths

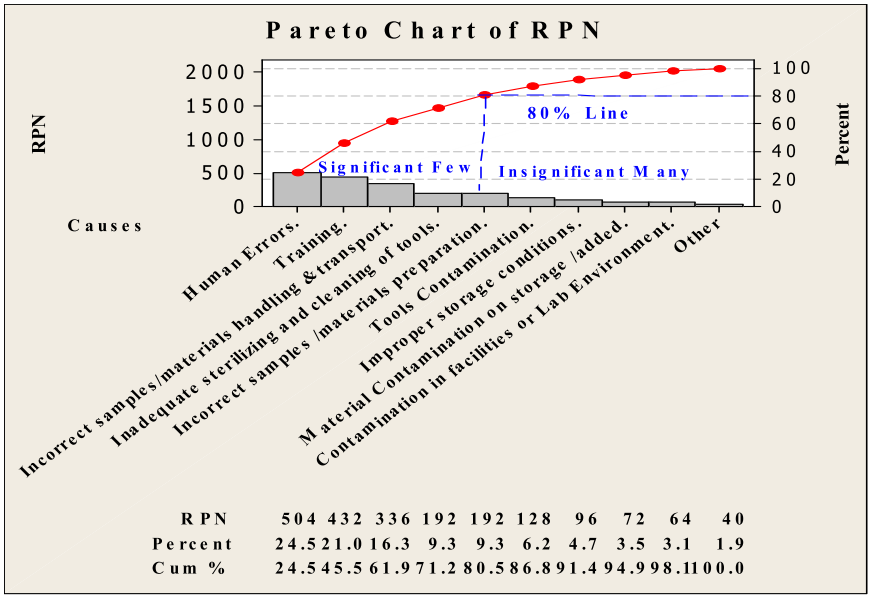

FIGURE 3 Pareto chart of RPN

TABLE 2 FMEA with action plan and new RPN (part 2)

RPN[a]	Action recommended	Responsible	Action taken	S	O	D	RPN[b]
Item (1) RPN = 504 Human errors	Preparing weekly meetings with lab personnel to listen problems and take actions	Lab quality manager	Quality circles	8	3	4	**96**
	Increasing the number of workers commensurate with work load	HR manager and lab quality manager	No action				
	Improving work environment	Security and services department	No action				
	Monitoring actions of employees in their work environment and evaluate their level of productivity and quality	QA engineer	Video surveillance system				
	Ensure that job descriptions are compatible with employees' certificates and expertise	QA engineer and HR manager	Comparing between the job description and qualification of employees				
	- Providing suitable supervision - Monitoring personal hygiene of staff	HR manager	A person was appointed through performance indicators that have been measured				
	Ensuring that workers have the capabilities needed to achieve the allocated job	HR manager and lab manager	Needs assessment plan was established				
	Strengthening the feeling of loyalty to the workplace to achieve the desired objectives	HR manager and lab manager	Connected reward and incentives with good performance - Connected good performance with promotions				
	Feedback: submitting reports to employees regarding their performance, and their strengths and weaknesses, suggesting appropriate solutions to enhance good performance, and correcting any deficiencies	QA and HR manager	All horizontal and vertical communication channels in the factory were improved				
	Creating service facilities for workers to provide an appropriate work environment for them to perform their work efficiently	Security and services department	A land next to the factory was allocated for this purpose				
Item (2) RPN = 432 Training	- Developing and improving training plans - Increasing the skills of the workers (workshops)	HR manager and lab manager	Training programs were improved such as: on the job training, soft skills training and technical training	8	2	4	**64**
	Establishing a special department for KPIs measure for (Measuring workers performance, audit in addition to review)	Chief executive officer and HR manager	KPIs forms were established				
	Pursuing and developing quality control plans	QA manager	Quality control plans were improved and developed				
Item (3) RPN = 336 Incorrect samples/materials handling and transport	Technical training of persons who are responsible for transferring and handling samples on how best to transfer and handle samples and how to preserve them	HR manager and lab manager	Technical tainting programs were improved	8	3	4	**96**

(Continues)

TABLE 2 (Continued)

RPN[a]	Action recommended	Responsible	Action taken	S	O	D	RPN[b]
Item (3) Cont. RPN = 336 Incorrect samples/materials handling and transport	Monitoring the cleanliness of the persons who are responsible for transferring and handling samples and emphasis on wearing of personal protective equipment to prevent the contamination of the samples during handling and/or transportation	Lab manager and QC engineer	Video surveillance system-and a person was assigned for monitoring	8	3	4	**96**
	Ensuring suitable circumstances for transferring and handling samples	QC engineer and lab manager	A person was assigned for checking				
	Re-planning or re-arranging the factory (to reduce the distance between the lab and production line; thus reducing the time required for transport and handling processes and also reducing the problems that may occur during transport)	Security and services departmentand Projects management department	Under study				
Item (4) RPN = 192 Inadequate sterilizing and cleaning	Making sure of the calibration of autoclaves each period	QA engineer	- Calibration records were established - Accredited calibration certificate	8	3	2	**48**
	Designing an instruction booklet of work to clarify the proper steps for cleaning tools and equipment	QC engineer	Work instructors for QMS were designated to clarify the proper methods for cleaning and use of instruments				

[a]RPN = risk priority numbers before improvement processes.
[b]RPN = risk priority numbers after improvement processes; calculated as: RPN = O * S * D.
D = detection; HR = human resources; KPI = key performance indicators; O = occurrence; QA = quality assurance; QC = quality control; QMS = quality management system; S = severity.

and weaknesses resulted in appropriate solutions and enhanced performance. Developing and improving training plans which includes; on job training, soft skills training, and technical training led to increased skills of the workers (ISO/IEC 17025, 2005). Also, corrective actions such as developing the quality control plans and continuous improvement (WHO, 2011), establishing key performance indicators (KPIs) forms for measuring workers performance and audit and review contributed to minimized human errors and training risk.

The potential risk of incorrect sample/materials handling and transportation reduced to 96 after implementing the corrective actions. The corrective actions were monitoring the cleanliness of persons responsible for samples transfer and handling and wearing of personal protective equipment to ensure safe samples. The technical training of persons responsible for material transfer and handling is important to preserve and ensure suitable circumstances for samples transfer and handling (ISO/IEC 17025, 2005; Malhotra, Lal, Prakash, Daga, & Kishore, 2007; Ozilgen, 2011; WHO, 2011).

Designing an instruction booklet to clarify the proper steps for cleaning tools and equipment and ensuring regular calibration of autoclaves (ISO/IEC 17025, 2005) resulted in a reduction of inadequate sterilizing and cleaning risk to 48.

Figure 4 shows the improvement action carried out on human errors and a new RPN of 96, the reduction in RPN was 408 (96–504), with a percentage value of −80.95%. Moreover, the improvement action carried out on training has a new RPN of 64. The reduction in RPN was 368 (64–432) RPN points, with a percentage value of −85.2%. Furthermore, the improvement action carried out on incorrect samples/materials handling and transport has a new RPN of 96. The reduction in RPN was 240 (96–336) RPN points, with a percentage value of −71.43%. Finally, the improvement action carried out on inadequate sterilizing and cleaning has a new RPN of 48. The reduction in RPN was 144 (48–192) RPN points, with a percentage value of −75%.

These results were satisfactory and indicated the success of the corrective actions. Thus, implementing FMEA technique in the dairy laboratory decreased errors and risks associated with activities in the laboratory.

4 | CONCLUSIONS

The FMEA method was utilized to minimize errors, improve the quality of pre-analytical stage of samples of UHT milk inside the dairy laboratory, identify potential failures, and develop and prioritize improvement

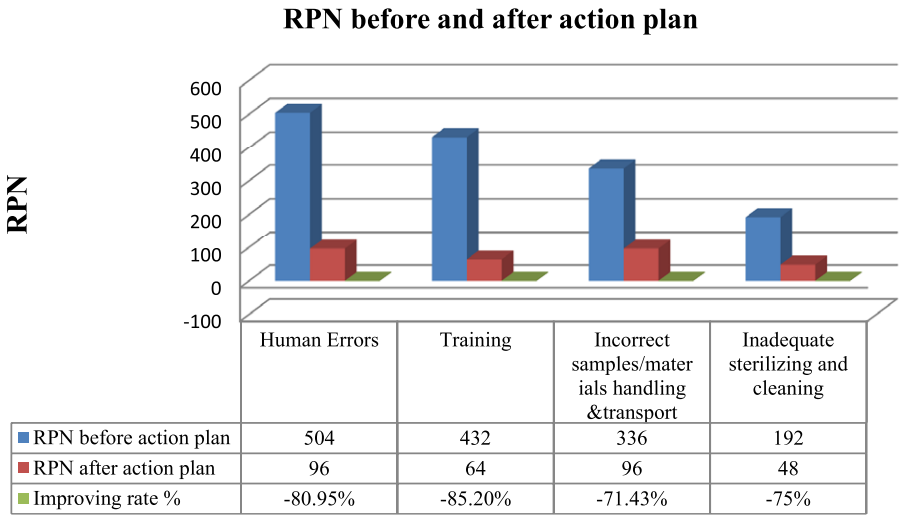

FIGURE 4 RPN before and after action plan

strategies. Through this method, we discovered that human errors, training, incorrect samples/materials handling and transport, and inadequate sterilizing and cleaning were the chief reasons for these failures with the highest RPNs. Suggested corrective actions significantly lowered the RPN values. Results of this study demonstrated the significant use of the FMEA method for risk management in dairy laboratory. In a few words, we can say that FMEA is a preventive tool and also it is a helpful instrument in risk assessment of processes in dairy laboratories and to lessen laboratories errors by utilizing FMEA tool analysis.

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