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Creation and Implementation of Process FMEA with Focus on Risk Reduction for Packaging Process

ASM S. Ullah
St. Cloud State University

Creation and Implementation of Process FMEA with Focus on Risk Reduction for Packaging Process

by

ASM Saif Ullah

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Hiral Shah, Chairperson
Ben Baliga
Balasubramanian Kasi

Abstract

A Twin Cities electronic device manufacturer, with its increasing customers in medical device industry, decided to get certified for ISO 13485:2003 and ISO 14971. As a result of this the company is implementing risk based approach to different process to fulfill the requirement of ISO 13485 and ISO 14971.This capstone project focuses on studying the packaging process and conducting risk analysis on this process. The project includes creating process flow chart, and calculating and managing risk using FMEA for packaging process. FMEA which stands for Failure mode and effect analysis is a proactive tool developed to identify, evaluate and prevent product and/or process failures. The project studies the packaging process and helps identifying different failure modes (FM) for each of the process input, determining effect of each of the FM, identifying causes for the FM, analyzing severity, quantifying occurrences and detectability to each of the FM, calculating risk priority number, assessing risk and mitigating risk according to Risk Management Plan for the company. This includes conducting risk-benefit analysis as well.

Acknowledgements

I have taken efforts in this project. However, it would not have been possible without the kind support and help of many individuals. I would like to extend my sincere thanks to all of them.

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Table of Contents

Chapter Page

List of Tables

List of Figures

Chapter I: Introduction

Introduction

Located in the suburbs of Twin Cities in MN, XYZ Company manufacturers embedded products (which include modules, microprocessors, single-board computers, satellite communications products, development kits and software) and non-embedded products (which include enterprise cellular routers, gateways, wireless communication adapters (ZigBee, Wi-Fi, proprietary RF), serial servers, intelligent console servers, USB connected products, remote display products, cameras, sensors and the #1 selling serial card line in the world.). The plant produces, packs, and ships these products to serve different industries that include energy, government, retail, transportation, medical among many others.

With increasing customers in the medical device industry, management has decided to get certified for ISO 13485:2003. ISO 13485:2003 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services. Obtaining the certification will help the company to initiate and build risk management approach to all of its applicable processes resulting in gaining market with its competitors.

FMEA methodology is a tool to prevent failures or defects and reduce the risk of losing a customer. It can be especially useful when “evaluating a new process prior to implementation and in assessing the impact of a proposed change to an existing

process. This capstone project focuses on studying the packaging process and conducting risk analysis on this process. The project includes creating process flow chart, and calculating and managing risk using FMEA for packaging process.

A detailed discussion on the methodology is discussed in the methodology section.

Problem Statement

Packaging process includes packaging of single unit, unit with accessories, and bulk packaging. No risk analysis is done on this process. Current packaging process is therefore prone to error resulting in product discrepancy and customer dissatisfaction. Since, the process is not analyzed for risk, apart from being error prone, it does not satisfy risk based approach to fulfill the requirement of ISO 13485.

Nature and Significance of the Problem

XYX Company produces Machine to Machine communication device of different sizes and shapes. With nearly $200M annual revenue, and 9.4% growth of hardware products last year, the company currently ships 55,000 SKUs. As a growing company, and increasing customers in the medical device industry, to keep up with growth, and gain more market share among its competitions, the management is focused on getting the plant certified with ISO 13485 and ISO 14971.

As a requirement of ISO 13485 and also as good manufacturing practice (GMP), different operational processes in the plant would need to be managed for risk. Packaging process has not been analyzed for risk. Therefore, the risk in the

packaging process is analyzed and documented creating a baseline for managing risk for the operation. This project helps with the followings:

- Good manufacturing practice
- Foster proactive management, improve operational effectiveness and efficiency
- Improve the identification of opportunities and threats
- Establish a reliable basis for decision making and planning
- Reduce customer complain
- Increase customer satisfaction
- Form a baseline for risk management and continuoFaus improvement
- Increase productivity

Objective of the Project

At a very high level the objective of the project is to establish a baseline for decision making and planning to manage risk for the packaging process by analyzing risk.

The objectives of the project are to understand the packaging process, identity different failure modes (FM) for each of the process input, determine effect of each of the FM, identify causes for the FM, analyze severity, quantify occurrences and detectability to each of the FM, calculate risk priority number, asses risk and mitigate risk according to Risk Management Plan for the company. This also includes conducting risk-benefit analysis as well.

Project Questions/Hypotheses

Questions which are answered with the project completion are listed below:

1. What are the different process steps for packaging process?
2. What are the process inputs for of each of the process step?
3. What are the failure modes of each of the process step?
4. What is the effect of each of the failure modes?
5. What are the severity of the failure effects?
6. What are the different causes of the failure modes?
7. What are the occurrences?
8. What are current controls for failure modes?
9. What are the detectability for each of the current controls?
10. What is the risk (i.e., Risk Priority Number) for each of the failure mode?
11. What are the mitigation and/or control plan for each of the failure mode needing mitigation?
12. What is the new estimated severity upon mitigation action?
13. What is the new estimated new occurrence(s) upon mitigation action?
14. What is the new estimated detection(s) upon mitigation action?
15. What is the new RPN upon mitigation action?

Limitations of the Project

The scope of the project is limited to the packaging process only. Within the packaging process, packaging of single unit is more emphasized. The FMEA process

is limited to calculating current risk priority number (RPN) for each of the failure mode and recommending risk mitigation when the RPN is not acceptable.

Summary

Chapter I included introduction of the project, problem statement, nature and significance of the problem, project objective, questionnaire, and the limitation of the project. Chapter two focuses on the literature review done for the project completion.

Chapter II: Background and Review of Literature

Introduction

All activities of an organization involve risk. The current focus of the U.S. Food and Drug Administration (FDA) on risk-based determination requires that regulated industries dramatically improve their understanding and use of hazard control concepts. An effective quality risk management approach can ensure a high-quality product by providing a proactive means to identify and control potential quality issues during development and manufacturing. Additionally, it can improve decision making if a quality problem arises. Risk management is a complex subject because each stakeholder places a different value on the probability of harm occurring and its severity. As one of the stake holders, the manufacturer makes judgments relating to the safety and performance of a product, including the acceptability of risks (Rodriguez-Perez & Pena-Rodriguez, 2012).

Risk is defined as the combination of the probability of the occurrence of harm and severity of that harm (Rodriguez-Perez, 2012). According to Rodriguez-Perez and Pena-Rodriguez (2012) quality risk management supports a scientific and practical approach to decision making during the life cycle of a product. It provides documented and reproducible methods to accomplish the quality risk management process based on current knowledge about the probability, severity and detectability of the risk. Inadequate or ineffective quality risk management can harm patients, product users, and company value.

Risk Management Phases

Risk management principles should be applied throughout the life cycle of the product and used to identify and address safety issue. Risk management can be divided into phases of activities.

The first phase can be determining acceptable risk levels in the device or the process. Organizations have a policy or procedure to determine risk acceptability criteria for an operation. These criteria are determined from the analysis of a manufacturer's own experience with similar devices or research on what appears to be currently accepted risk by regulators, users, completion and industry.

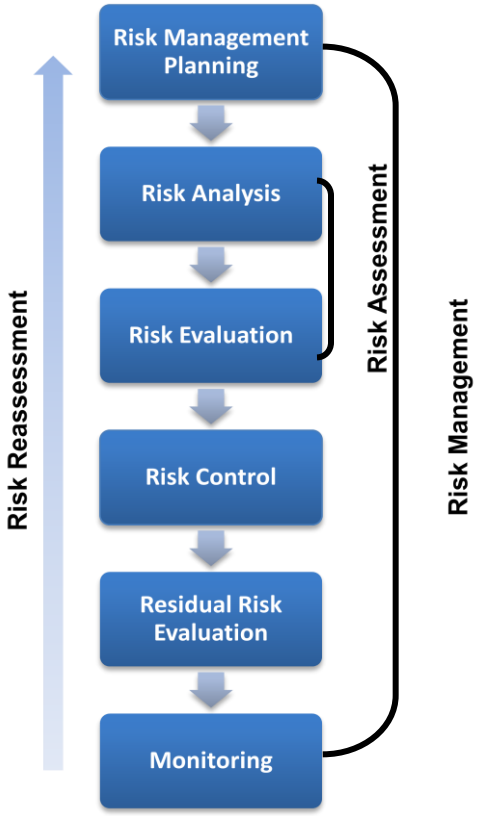


Figure 1: Risk Management Phase

The second phase of this approach is called risk analysis which starts with the identification of hazards which may occur due to inherent properties of the device during normal use or foreseeable misuse. After hazards are identified, risks are estimated for each of the identified hazards using available information.

The third phase comprises of comparison of estimated risk with risk acceptability criteria–which will determine appropriate level of risk reduction if necessary. This phase is also known as risk evaluation. Combination of risk analysis and risk evaluation is called risk assessment.

The fourth phase consists of risk control and monitoring activities. During this phase manufactures take risk mitigation activities to reduce or eliminate risk to meet the organization's acceptable risk criteria, determined in phase one. Risk control activities may begin as early as design input and continue throughout the life cycle (Rodriguez-Perez, 2012).

Risk Management Tools

According to Rodriguez-Perez and Pena-Rodriguez (2012) risk is assessed and managed in a variety of informal ways based on a compilation of observations, trends and other information. That approach can provide useful information that supports the handling of complaints, quality defects, deviations and resource allocation. But with a more formal approach, industry and regulators can assess and manage risk using recognized risk management tools:

- Basic risk management facilitation methods, such as flowcharts and check sheets.

- Failure mode and effects analysis (FMEA).
- Fault tree analysis.
- Hazard analysis and critical control points (HACCP).
- Hazard operability analysis.
- Preliminary hazard analysis.
- Risk ranking and filtering.

FMEA: A Risk Management Tool

The tool that is most widely used for risk assessment is known as Failure mode and effects analysis (FMEA). According to Šolc (2012), the objective of FMEA is to analyze potential defects / faults in a given system in a selected time period of life so that corrective measures can be taken to reduce the risks that come with it gives rise to defects. FMEA is widely used in the manufacturing industries such as automotive, aerospace, and electronics industries to identify, prioritize, and eliminate known potential failures, problems, and errors from systems under design before the product is released. Failure causes are any errors or defects in process, design, or item especially ones that affect the customer, and can be potential or actual (Rhee & Ishii, 2003). In FMEA failure is defined as any undesirable outcome such as production loss, injury or even an accident, and customer is defined as someone or something that receive products or services (Ebrahimipour, Rezaie, & Skokrvi, 2010).The FMEA methodology was developed and implemented for the first time in 1949 by United States Army (Scipioni, Saccarola, Centazo, & Arena, 2002). In the

1950s the increasing attention paid to safety and the need to prevent predictable accidents in aerospace industry led to the development of the FMEA methodology.

Within pharmaceutical and medical products manufacturing, FMEA is the most common and widely accepted tool for risk management. FMEA is discussed as one of the most important tools for risk management in ICH Q9: Quality Risk Management–which serves as a guide for industry by FDA. In section 1.2 FDA writes,

> FMEA provides for an evaluation of potential failure modes for processes and their likely effect on outcomes and/or product performance. Once failure modes are established, risk reduction can be used to eliminate, contain, reduce, or control the potential failures. FMEA relies on product and process understanding. FMEA methodically breaks down the analysis of complex processes into manageable steps. It is a powerful tool for summarizing the important modes of failure, factors causing these failures, and the likely effects of these failures. (Rodriguez-Perez, 2012)

Furthermore, it mentions that FMEA can be used to prioritize risks and monitor the effectiveness of risk control activities (Rodriguez-Perez & Pena-Rodriguez, 2012).

According to Palanichamy (2010) Risk Management Process ISO 14971 requires the manufacturer to establish, document and maintain a risk management process for:

- Reviewing the intended use (intended purpose) of the medical device
- Identification of hazards (known and foreseeable)
- Estimation of the probability of occurrence of harm
- Estimation of the severity of each hazard and its harm
- Evaluation of associated risks (decision making)
- Control of these risks

- Monitoring of the effectiveness of these controls throughout the whole lifecycle of a medical device.

As per ISO 14971:2012 manufacturer shall use one or more of the following risk control options in the priority order listed (Rodriguez-Perez & Pena Rodriguez, 2012):

- Inherent safety by design;
- Protective measures in the medical device itself or in the manufacturing process;
- Information for safety

The risk management process does not end with the design and manufacturing process but also includes applicable sterilization, packaging, labeling, storage, handling/ transport, distribution and market surveillance. The manufacturer shall apply risk management from the initial conception until the ultimate decommissioning and disposal of the product. Therefore, the gathering of postproduction information is a required part of the process. The latest version of ISO 14971:2007 (“Medical devices–Application of risk management to medical devices”) was approved on 5 December 2006 by the Association for the Advancement of Medical Instrumentation (AAMI) and on 1 February 2007 by the American National Standards Institute (ANSI). Finally published in May 2007 as ANSI/AAMI/ISO 14971:2007 (Palanichamy, 2010).

FMEA Methodology

The FMEA method is based on a document that has to be regularly reviewed with experience and production data history in mind. FMEA method can be classified according to the practical purpose for which it is used (Šolc ,2012).

1. Constructional FMEA: This is also known as Design FMEA used for verification of components, features, design and analysis of the design of the product. Evaluates using the outputs of the final product or service features. When creating of constructional FMEA is necessary to ascertain whether it was intended above all errors and have been taken to prevent their effective. Constructional FMEA examines all possibilities of failure of the product regardless of the likelihood of their occurrence and the probability of detection. (Note: May have separate Use FMEA and Design FMEA.)

   Procedural FMEA: Also known as Process FMEA assumes the established causes of errors of constructional FMEA, which is relevant to the process. Procedural FMEA examines all errors and assembly production process and their causes, in the case of logistics as it can be very material flow analysis process or the process of planning, buying and selling. FMEA to solve problems using the so-called systemic approach, that understands the product or process of systemically. It deals with the errors arising in the elements of the process, as well as errors in the input and output of the process and their mutual ties.

2. Systematic FMEA: The aim of the systematic FMEA is to prevent possible errors already in the system design. It uses a matching system used to objectively substantiated decisions on the proposal. Systematic FMEA examines errors along the lines of the product life cycle.

The diagram below depicts different FMEAs in the life cycle of a product:

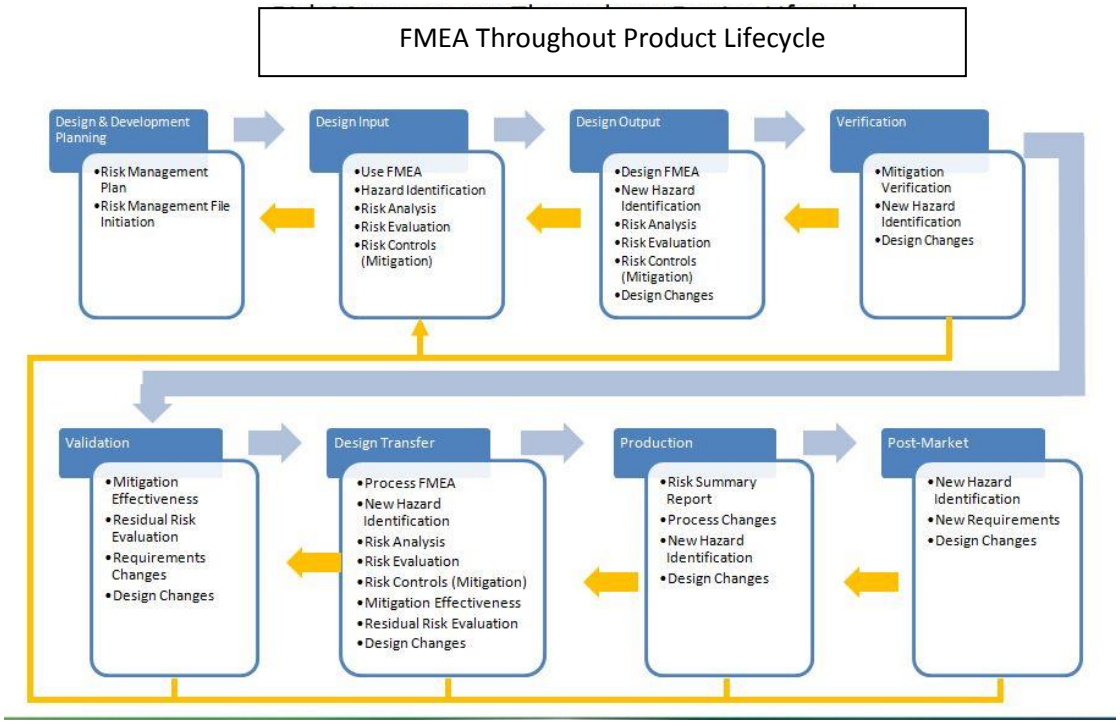


Figure 2: FMEA throughout Product Lifecycle

When deciding on the scope and method of application of FMEA in a particular system in a particular element, it is necessary to consider, for the specific purpose of the method is to be used and in which the temporal phase relative to the total life of the system as well as other activities. It is

necessary to consider the required level of knowledge of adverse events, failures and their consequences. Based on these considerations, it is possible determine the depth of analysis for a particular system level (system, subsystem, part, element). Means of achieving corporate objectives are (Šolc, 2012)

- increase the safety of functions and reliability of the products (detect bottlenecks)
- reduce warranty and service costs,
- shorten the development process,
- start-ups with fewer errors,
- better compliance of the planned terms,
- economical production,
- better service,
- better communication in factory.

When quantifying risk FMEA uses indicator, which gives importance to reciprocity error, probability of detection and probability of failure. This allows comparison of individual mistakes and focus on the most important causes that give rise to error. German standard of the automotive industry VDA 2.4 this ratio indicates how: MR/P–Rate of Risk / Priority or Risk Priority Number (RPN). Risk priority number (RPN) is a result of the severity, occurrence and detection.

There is a preliminary work that the team has to do before to elaborate a FMEA document, that is essentially to gather and analyze some documents, such as the:

- Bill of material (BOM)
- Package construction analysis
- Specific applicable medical standards
- Legal and regulatory requirements
- Quality agreements
- Validation plans

After this first step, the steps to be followed are (source Quality-One):

- RPN & Closure Path 1 Development (Failure Modes)
- Path 2 Development (Causes & Occurrences)
- Path 3 Development (Testing & DV Development)
- Action Priority & Assignment
- Actions Taken / Design Review
- Re-ranking

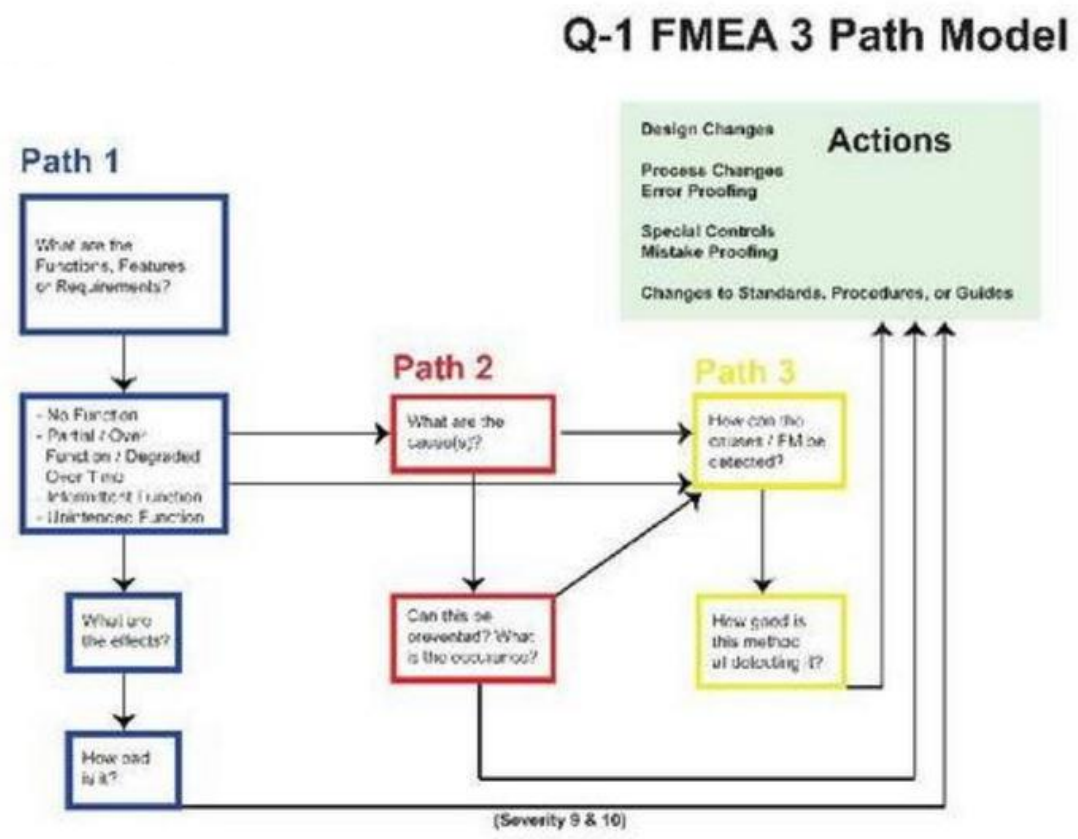


Figure 3: FMEA Path Model

Medical devices developed for human application are used for diagnostic or treatment purposes. They may either be an instrument, an apparatus or a material. Moreover, these devices can be used for daily patient care as well as for medical scientific purposes. Researchers in charge to develop new medical devices are faced with the complex task of making a medical device safe for human use. This implies that the device should be safe and effective. Risk management involves the identification, understand, control, and prevent failures that can result in hazards when people use medical devices (Palanichamy, 2010).

Package design is a key element that must be designed to withstand the rigors of sterilization, transportation and storage. Design testing coupled with process validation provide the basis of a fully validated, effective package. Package design consists of three elements (Pilchik, 2003):

1. Primary package: Contains the device and additional components to protect the device.
2. Secondary package: Usually a folded carton "shelf pack" containing one primary package system. It often contains the labeling information with barcode for patient and device traceability.
3. Tertiary package: Shipping carton containing multiple packages of the device.

Summary

Chapter II included background information and review of literature. Chapter III focuses on methodology, definition of different terms used, and timeline for the project completion.

Chapter III: Methodology

Introduction

This chapter focuses on the methodology used in the project. The chapter concludes with the project timeline.

Methodology

The following procedure is used to conduct the FMEA for packaging process:

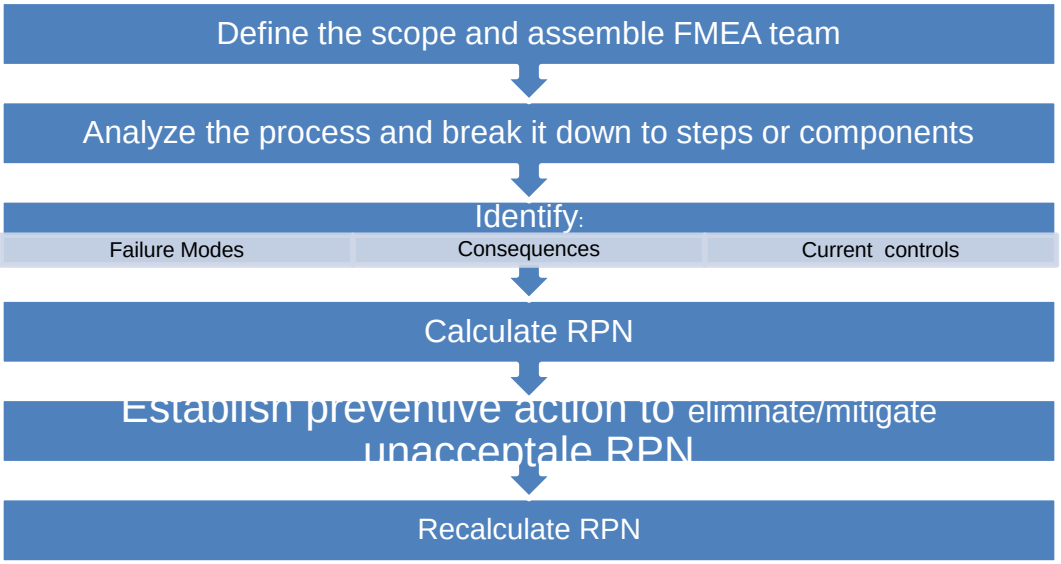


Figure 4: FMEA Procedure for Packaging

All the different terms used in the process flow is described below:

FMEA Team: A cross functional team Involving subject matter experts, manufacturing engineers, packaging lead, quality engineer are formed to conduct FMEA. Training on FMEA are provided to all involved. Appendix B contains the training presentation.

Flow analysis: With the help of flow analysis tools such as flow chart, process chart, and operation chart, the flow of parts and materials are observed in detail

which leads to easier way to sort process inputs and risks associated with each of the process inputs. Each team member is required to be familiar with the process map. It is recommended that each team member physically walk through the process.

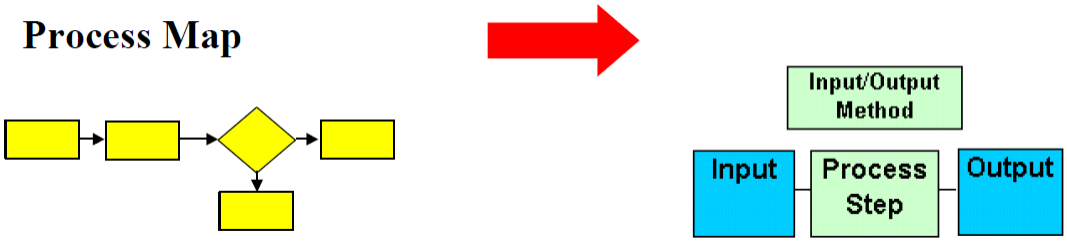


Figure 5: Process Map for Process Input and Process Output

Next steps in the methodology will involve FMEA Matrix and filling in different key inputs to generate RPN. Given below is an FMEA Matrix:

Table 1: FMEA Matrix

[Type] FMEA Matrix

Product / Process / Service: Date:				Team: [names, titles]					Revision Level: Rev of FMEA Reason for Change:					
[Type] Function	Potential Failure Mode	Potential Effect of Failure	Severity (S)	Potential Causes of Failure	Occurrence (O)	Current Controls & Detection Methods	Detection (D)	Initial RPN	Recommended Action Plan	Action Implemented	New Sev. (S)	New Occ. (O)	New Det. (D)	New RPN
Design														
Process														
Use														

Index: Line item numbering for easy reference. It is optional but suggested. (Not shown in matrix.)

[Type] Function: Intended purpose or objective of a specific design, process or service as it relates to a customer need or expectation, regulatory requirement, safety or performance specification. State the function as an action verb. Examples: provide vibration damping, bond Part A to Part B, store ECG waveform data, sharpen instrument cutting edge, etc. For this particular project, this the function will be packaging process.

Potential Failure Mode: From the process map, the process inputs for each of the process steps are found. Failure modes are nothing but different states that would cause the key input to fail. Each of the key input from the process map is then analyzed for possible failure modes. From the past history (i.e., non-conformance record), expert opinion and brain storming of the group a list of failure modes are generated for each of the key process inputs.

Potential Effect of Failure: Effect of failure is the failure mode's impact on the key output variable (i.e. most importantly customer requirement). It is the consequence of the failure on the product safety, design, performance, compliance with regulations, customer satisfaction, etc. Information sources include but not limited to clinical reports, customer complaints, device experience databases (e.g., FDA’s MAUDE), field service and reliability data. Each of the failure mode is analyzed for its potential failure impacts. In cases where there is no source of potential failure

impact, potential effects of failure can also be generated using brainstorm technique. There may be more than one failure effects for each of the failure mode.

Severity (S) of Effect: It is qualitative or quantitative ranking of the seriousness of the failure effect. It is recommended to consider the worst case effect but consider all effects individually. Generally, the severity level can only be reduced through inherent safety by design so the best practice is to address high-severity hazards early in the design. Late design changes are very costly, especially time to market. For packaging FMEA each of the failure effect is ranked for its severity on the basis of the following table:

Table 2: Severity Matrix

Effect	Criteria: Severity of Effect Defined	Ranking
Hazardous: Without Warning	May endanger operator. Failure mode affects safe vehicle operation and / or involves noncompliance with government regulation. Failure will occur **WITHOUT** warning.	10
Hazardous: With Warning	May endanger operator. Failure mode affects safe vehicle operation and / or involves noncompliance with government regulation. Failure will occur **WITH** warning.	9
Very High	Major disruption to production line. 100% of product may have to be scrapped. Vehicle / item inoperable, loss of primary function. Customer very dissatisfied.	8
High	Minor disruption to production line. Product may have to be sorted and a portion (less than 100%) scrapped. Vehicle operable, but at a reduced level of performance. Customer dissatisfied.	7
Moderate	Minor disruption to production line. A portion (less than 100%) may have to be scrapped (no sorting). Vehicle / item operable, but some comfort / convenience item(s) inoperable. Customers experience discomfort.	6
Low	Minor disruption to production line. 100% of product may have to be reworked. Vehicle / item operable, but some comfort / convenience item(s) operable at reduced level of performance. Customer experiences some dissatisfaction.	5
Very Low	Minor disruption to production line. The product may have to be sorted and a portion (less than 100%) reworked. Fit / finish / squeak / rattle item does not conform. Defect noticed by most customers.	4
Minor	Minor disruption to production line. A portion (less than 100%) of the product may have to be reworked on-line but out-of-station. Fit / finish / squeak / rattle item does not conform. Defect noticed by average customers.	3
Very Minor	Minor disruption to production line. A portion (less than 100%) of the product may have to be reworked on-line but in-station. Fit / finish / squeak / rattle item does not conform. Defect noticed by discriminating customers.	2
None	No effect.	1

Potential Cause(s) of Failure: Each of the failure is analyzed for potential failures. Different root cause analysis techniques (cause and effect matrix,

brainstorming, fault tree analysis (FTA)), are used to identify causes and contributing factors for each of the failure. There might be more than one cause of a failure.

Occurrence (O): Qualitative or quantitative ranking of the likelihood that the failure or hazardous situation will occur. Record of customer complaints, non-conformances are good source for ranking occurrences. The following table is referred for ranking occurrences:

Table 3: Occurrence Matrix

Probability of Failure	Possible Failure Rates	Cpk	Ranking
Very High: Failure is almost inevitable	≥ 1 in 2	< 0.33	10
	1 in 3	≥ 0.33	9
High: Generally associated with processes similar to previous processes that have often failed	1 in 8	≥ 0.51	8
	1 in 20	≥ 0.67	7
Moderate: Generally associated with processes similar to previous which have experienced occasional failures, but not in major proportions.	1 in 80	≥ 0.83	6
	1 in 400	≥ 1.00	5
	1 in 2,000	≥ 1.17	4
Low: Isolated failures associated with similar processes	1 in 15,000	≥ 1.33	3
Very Low: Only isolated failures associated with almost identical processes	1 in 150,000	≥ 1.5	2
Remote: Failure is unlikely. No failures ever associated with almost identical processes	≤ 1 in 1,500,000	≥ 1.67	1

Current Control & Detection Methods: This is the process of identifying existing mitigation techniques in place to control the risk, i.e., safety by design, protective measures (design / manufacturing), and safety information. Detection methods might include design / process engineering analysis, simulation or modeling, testing, inspection, design review, etc.

Detection (D): It is qualitative or quantitative ranking of the reliability of detecting a failure or hazardous situation before causing harm. It is recommended not to rely on the customer or user to detect the failure or hazardous situation, e.g.,- the surgical prep / setup team. Detection for packaging FMEA is done on the basis of guidelines from the following table:

Table 4: Detection Matrix

DETECTION EVALUATION CRITERIA		
Detection	**Criteria: Liklihood the existence of a defect will be detected by test content before product advances to next or subsequent process**	**Ranking**
Almost Impossible	Test content detects < 50 % of failures	10
Very Remote	Test content must detect 50 % of failures	9
Remote	Test content must detect 70 % of failures	8
Very Low	Test content must detect 80 % of failures	7
Low	Test content must detect 85 % of failures	6
Moderate	Test content must detect 90 % of failures	5
Moderately High	Test content must detect 95 % of failures	4
High	Test content must detect 97.5 % of failures	3
Very High	Test content must detect 99.5 % of failures	2
Almost Certain	Test content must detect 99.9 % of failures	1

Initial RPN: The risk priority number is a quantified risk level calculated as S x O x D. It is compared to the risk acceptance criteria as stated in the risk management plan or by organization policy. The acceptable RPN for XYZ is less than 70.

Recommended Action Plan: The activity(ies) needed to further control risks by reducing the severity, occurrence and/or detection level. Any failure modes of RPN greater than or equal to 70 must be mitigated with recommended action plan. This requires identifying the needed resources, including responsible person, and due date for each activity.

Action Implemented: Confirmation of the activities completed and the controls actually implemented.

New Severity (S): The estimated severity level following implementation of remedial action. Unless there is a design change the severity would remain same.

New Occurrence (O): The estimated occurrence level following implementation of remedial action.

New Detection (D): The estimated detection level following implementation of remedial action.

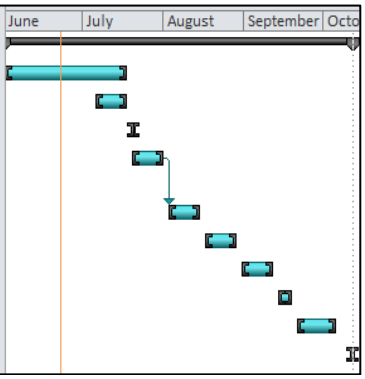
New RPN: The risk priority number resulting from the new product of S x O x D. This value is then again compared to the risk acceptance criteria.

Timeline

The proposed timeline for the project as shown in the Gantt Chart below:

Table 5: Gantt Chart for the Project

	Task	Task Name	Duration	Start	Finish
1		**Capstone Project Timeline**	**96 days**	**Mon 6/1/15**	**Mon 10/12/15**
2		Research Material	35 days	Mon 6/1/15	Fri 7/17/15
3		Study Packaging Process	10 days	Mon 7/6/15	Fri 7/17/15
4		Create Team	1 day	Mon 7/20/15	Mon 7/20/15
5		Identify Failure Modes, Effects, and Causes	10 days	Mon 7/20/15	Fri 7/31/15
6		Quantify RPN	10 days	Mon 8/3/15	Fri 8/14/15
7		Mitigate Risk	10 days	Mon 8/17/15	Fri 8/28/15
8		Risk-benefit analysis	10 days	Mon 8/31/15	Fri 9/11/15
9		Compose report	5 days	Mon 9/14/15	Fri 9/18/15
10		Send report for approval	11 days	Mon 9/21/15	Mon 10/5/15
11		Defense project	1 day	Mon 10/12/15	Mon 10/12/15



Capstone Project Timeline:

1. Research Material: read theory and methodology to solve the problems.
2. Study packaging process: Identify process inputs and process output
3. Create team: Identify key personnel for the FMEA project. For this project, the team consisted of packaging supervisor, one packaging operator, one labeling operator, one quality engineer, and two manufacturing engineers.
4. Kick-off meeting and training: Kick off meeting with the team and train team on FMEA. Training presentation can be located in Appendix B.
5. Create packaging process flow chart.
6. Identify Failure Modes, Effects and Causes: calculate required number of future stations and operators.
7. Measure Risk: Identify severity, measure occurrences and detectability and calculate Risk Priority Number (RPN) for each of the failure mode.
8. Mitigate Risk: Identify the risks that needs to be controlled and make a control plan to mitigate risk

9. Risk Benefit Analysis: Any failure mode, with unacceptable RPN, that could not be mitigated to acceptable risk, will be studied for risk benefit analysis
10. Compose Report: write report with detail result and analysis.
11. Send Report for Approval: send report draft for any necessary changes.
12. Defense Project: present and elaborate project result to Capstone Project Committee.

Chapter IV: Data Presentation and Analysis

Introduction

Chapter IV focuses on the different data (i.e., process flow chart, FMEA, etc.) created for the capstone project. A thorough analysis of data is also done in this chapter.

Data Presentation

The process for packaging is observed. On the basis of the observation a process flow map for packing is created. Given below is the process flow map for packaging process.

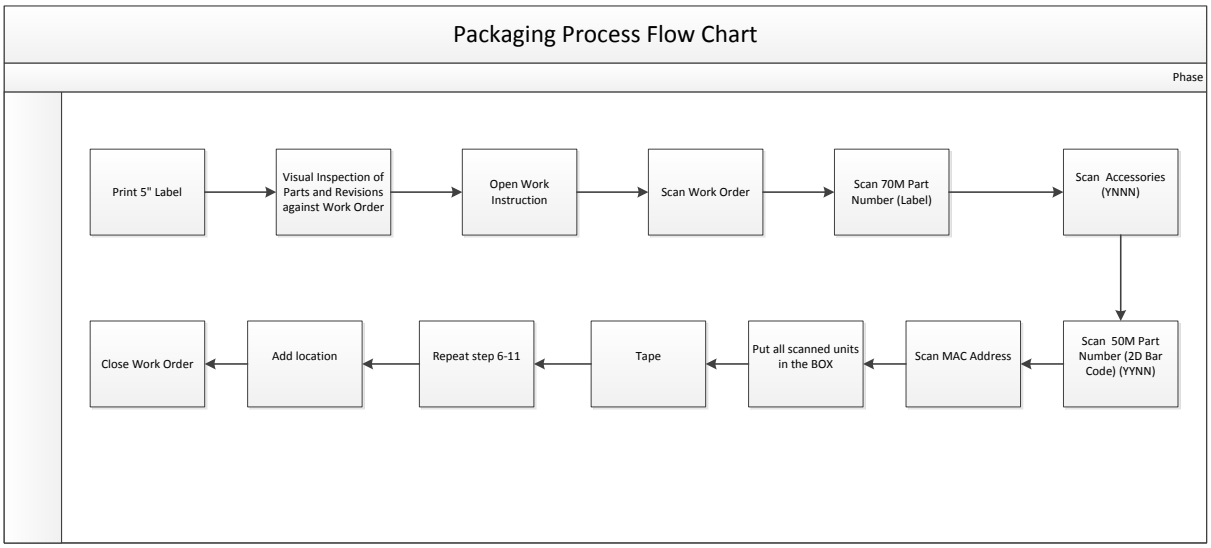


Figure 6: Packaging Process Map

The packaging process is then analyzed for risk using FMEA methodology. Detail of the Packaging PFMEA is shown in Appendix F.

Table 6: Packaging PFMEA

Process / Product Failure Modes and Effects Analysis (FMEA)

Process or Product Name:	Packaging		Page ____ of
Faciliator/Responsible:	Saif Ullah	PACK MFG QUALITY	1

Process Step	Key Process Input	Potential Failure Mode	Potential Failure Effects	SEV	Potential Causes	OCC	DET	RPN	Actions Recommended	Resp.	Actions Taken	SEV	OCC	DET	RPN
What is the process step ?	What is the Key Process Input?	In what ways does the Key Input go wrong?	What is the impact on the Key Output Variables (Customer Requirements) or	How Severe is the effect	What causes the Key Input to go wrong?	How often does the cause occur?	How well can you detect the cause?	Risk Priority Number	What are the actions for reducing the occurrance of the Cause, or	Whose Responsible for the recommended action?	What are the completed actions taken with the recalculated	How Severe is the effect			
Printing 5" Label	Work Order 95M Part Number	Incorrect setup	Wrong Label Printed	6	Operator keying in wrong part number and revision	4	6	144	System enhancement and no operator key in and	Label Manager and IT	Action scheduled to be completed by December	6	3	1	#
		Wrong Rev of 95M	Wrong Label Printed	6	Missing current rev in the system	7	6	252	Train Label Operator to verify rev in work order	MFG Engineer1 and Label Manager	Trained Label Operator to verify rev in	6	4	2	#
		Incorrect Text	Wrong Label Printed	6	Missing current rev in the system	4	10	240	Train Label Opeart to verify rev in wo	MFG Engineer1 and Label Manager	Trained Label Operator to verify rev in	6	4	2	#
	50 M Serial Number	Does not scan	Wrong 50M Label because of using cheat sheet	8	Process to do it too slow/ Scannability	8	6	384	Eliminate Cheat Sheet	Quality Engineer1 and MFG Engineer2	Implemented bar code and eliminated the use of cheat sheet on 9/5/2015	8	3	1	#
Inspection of parts and revisions agaist work	Part and accessories	Wrong Part Number Pulled	Customer receives wrong part	8	Not following SOP	2	6	96	Scan Audit	MFG Engineers	Implemented scan audit in the ERP on	8	3	1	#
			Unable to detect it out of many parts that are pulled only one	8	Sampling plan	2	6	96	Scan Audit	MFG Engineers	Implemented scan audit in the ERP on 9/5/2015	8	2	1	#
			Wrong REV pulled	8	Improper Disposition	3	6	144	Scan Audit	Planner and MFG Engineer	Implemented scan audit in the ERP on	8	3	1	#
	Label and 50M Part Numbers	Wrong order	Wrong 50M in the 70M SKU	6	Mix work orders	7	6	252	Scan Audit	MFG Engineers	Implemented scan audit in the ERP on 9/5/2015	6	3	1	#
Open Instruction	96M Work Instruction	Not do it	Dissatisfied customer	7	Operator error	7	10	490	Training/Maintain Training Record/ Audit	MFG Engineers	Operators are trained for following Work	7	3	3	#
		Not following it accordingly	Dissatisfied customer	7	Operator error	4	10	280	Training/Maintain Training Record/ Audit	MFG Engineers	Operators are trained for following Work	7	3	3	#
		Link refers to wrong revision	Dissatisfied customer	7	MFG Engineer Error	3	6	126	Self audit of WI rev	MFG Engineers	Operators are trained for auditing each others work on 8/30/2015	7	3	3	#
	SCAN Work Order	Open Bridge Logic	Forget to log out	No traceability	5	Operator error	2	10	100	Train and Time out on Bridgelogi	MFG Engineers	Implemented time out on bridgelogic	5	2	1	#
	Scan Accessories	Label	Wrong label	Dissatisfied customer	7	Upstream Operator error	3	6	126	Train operators and implement scan audit	MFG Engineers	Trained operators and implement	7	2	1	#
Put all scanned items in the box	All items to be packaged	Mix item / Miss item	Dissatisfied customer	7	Operator error	5	6	210	Follow one piece flow	MFG Engineers	Trained Operators on one piece flow,	7	3	3	#
	Accessories	Forget to put inside	Dissatisfied customer	7	Operator error	2	6	84	Follow one piece flow	MFG Engineers	Trained Operators on one piece flow,	7	3	1	#
Tape	Package	Logo vs Non Logo	ssatisfied custom	7	Operator error	2	6	84	Training	MFG Engineers	Trained operators for following WI and	7	1	1	7
Close Work Order	Bridgelogic	Forget to log out	No traceability	5	Operator error	2	10	100	Train and Time out on Bridgelogi	MFG Engineers	Implemented time out on bridgelogic and trained operators on 8/30/2015	5	1	1	5

Data Analysis

It can be seen from the process flow map, that the packaging process consists of fourteen process steps. Once the process map is developed, each of the process steps are analyzed for risk using FMEA methodology.

There has been a series of meetings to get the packaging process analyzed for risks:

Followings are accomplished in these meetings:

1. Each of the process steps is analyzed for key process inputs. In doing so each of the process step is first analyzed by the subject matter expert (i.e., the packaging supervisor). The process is then walked through by the team for farther analysis.
2. From the process map, the process inputs for each of the process steps are found. Failure modes for each of the process inputs are analyzed. Data from the history (i.e., non-conformance record), expert opinion and brain storming of the group is used to generate failure modes for each of the key process inputs.
3. Effect of failure is the failure mode's impact on the key output variable (i.e., most importantly customer requirement). Information sources include clinical reports, customer complaints, field service and reliability data. Each of the failure mode is analyzed for its potential failure impacts. In cases where there is no source of potential failure impact, potential effects of failure are generated using brainstorm technique.
4. Each of the failure effects is ranked for its severity. This is done using corporate guideline for severity. (Refer to Appendix C: severity matrix.)
5. Each of the failure is analyzed for potential failures. Different root cause analysis techniques (cause and effect matrix, brainstorming, fault tree

analysis (FTA)), are used to identify causes and contributing factors for each of the failure.

6. Each of the causes is then ranked for its occurrences. Record of customer complaints, non-conformances are used for ranking occurrences. Occurrences are ranked using the corporate guideline. (Refer to Appendix D: occurrence matrix.)
7. Current Control & Detection Methods for detecting and controlling each of the failure mode is generated by identifying existing mitigation techniques in place to control risk.
8. Each of the current control is then ranked for its detection using the corporate guidelines. (Refer to Appendix E: detection matrix.)
9. Initial risk priority number (RPN) for each of the failure mode is then calculated with the multiplication of severity, occurrences, detection ranking of each.
10. Any failure modes of RPN greater than or equal to 70 must be mitigated with recommended action plan. This requires identifying the needed resources, including responsible person, and due date for each activity.
11. Confirmation of the activities completed and the controls actually implemented.

Summary

Chapter IV presents data with detail analysis. Chapter V will focus on the results, conclusion and recommendations.

Chapter V: Results, Conclusion, and Recommendations

Introduction

In Chapter V the results of risk analysis for packaging process is discussed. In doing so, all different project questions are answered. This chapter ends with conclusion and future recommendation for packaging process and FMEA for packaging process.

Results

Packaging process is observed and a packaging process map is developed. The process map is the basis of for risk analysis using FMEA methodology. For each of the process step, failure modes are identified. Identification of failure mode is followed with the identification if the failure effects, cause, and current control for failure mode. Each of the failure mode is then ranked for its severity, occurrences, and delectability using the corporate guideline described in appendices C, D, and E. RPN for each of the failure mode is calculated. Failure modes with intolerable risk (i.e., RPN value of equal or greater than 70) are then mitigated with recommended action plan. Action plans are then implemented. Upon the implementation of action plan severity, occurrence, and detectability for each of the failure mode are revised. This is followed by a revised RPN for the mitigated failure effects.

Answers to the project question provides us with the result of the risk analysis activity using FMEA:

1. What are the different process steps for packaging process?

There are 13 different process steps for packaging process. These process steps can be seen in the process flow map in Appendix B.

2. What are the process inputs for of each of the process step?

   There is at least one process input for each of the process steps. Some process steps have multiple process inputs. These process inputs are identified with the thorough analysis of each of the process inputs. In total there are 19 key process inputs. Detail of the process inputs and process outputs can be found in column A and column B of Packaging FMEA in Appendix F.

3. What are the failure modes of each of the process step?

   Data from the history (i.e., non-conformance record), expert opinion and brain storming of the group is used to generate failure modes for each of the key process inputs. Each key process input has at least one failure mode. There are in total 38 failure modes. Detail of the failure modes can be found in Column C of packaging FMEA in Appendix F.

4. What is the effect of each of the failure modes?

   Effect of failure is the failure mode's impact on the key output variable (i.e., most importantly customer requirement). It is the consequence of the failure on the product safety, design, performance, compliance with regulations, customer satisfaction, etc. Information sources include but not limited to clinical reports, customer complaints, device experience databases (e.g., FDA’s MAUDE), field service and reliability data. Each of

the failure mode is analyzed for its potential failure impacts. In cases where there is no source of potential failure impact, potential effects of failure can also be generated using brainstorm technique. In some failure modes have more than one effect. The failure effects range from delay in operation to customer dissatisfaction. Some of the failure effects are repeated for different failure modes. Thirty-eight failure modes are found to have a total of 42 potential failure effects. This can be located in Column D of the packaging FMEA in Appendix F.

5. What is the severity for each of the failure effects?

   It is qualitative or quantitative ranking of the seriousness of the failure effect. In this case, worst case effect is considered. However, all effects are then considered individually as well. Each of the potential failure effects is analyzed for its severity (i.e., effect to customer). They are ranked between 1 to 10, with 1 representing no severe effect to customer and 10 representing high severity. In doing so severity matrix presented in Appendix C is used for reference.

   Severity rankings for all different failure modes for packaging range between 2 to 8. Severity for all different failure modes are listed in column E of packaging FMEA in Appendix F. The table below shows the number of failure effects for each of the severity ranking for different failure effects:

Table 7: Severity Ranking and Number of Failure Effects

Severity	Number of failure Effects
2	1
3	13
5	2
6	4
7	18
8	4

6. What are the different causes of the failure modes?

   Different root cause analysis techniques (cause and effect matrix, brainstorming, fault tree analysis (FTA)), are used to identify causes and contributing factors for each of the failure. In this case each effect has one cause. These causes range from operator error to manufacturing engineer error, from system error to the use of sampling plan. Details of different causes for the failure modes can be found in Column F of packaging FMEA in Appendix F.

7. What are the occurrences?

   Each of the potential cause for failure effects is analyzed for its occurrences (i.e., frequency of failure modes). They are ranked between 1 to 10, with 1 representing remote occurrence and 10 representing very high occurrence. In doing so occurrence matrix presented in Appendix D is

used for reference. Occurrences for all different failure modes for packaging ranged between 1-8, which are listed in column G of packaging FMEA in Appendix F.

The table below shows number of potential causes for each of the occurrence ranking in the FMEA:

Table 8: Occurrence Ranking and Number of Potential Causes

Occurrence Ranking	Number of Potential Causes
1	2
2	13
3	10
4	5
5	5
7	4
8	3

8. What are current controls for failure modes?

Methods for detecting and controlling each of the failure mode is generated by identifying existing mitigation techniques in place to control risk. The current control range from manual inspection to automated scanner audit. The list of current controls for each of the failure mode can be located in Column H of FMEA.

9. What are the detectability for each of the current controls?

Each of the current controls for failure effects is analyzed for its detectability. They are ranked between 1 to 10, with 1 representing easily detectable and 10 representing very hardly detectable. In doing so detectability matrix presented in Appendix E is used for reference. Detectability for all different failure modes for packaging range between 1-10, which are listed in column I of packaging FMEA in Appendix F.

The table below shows number of current controls for each of the detection ranking in the FMEA:

Table 9: Detection Ranking and Number of Current Controls

Detection Ranking	Number of current controls
1	21
2	2
6	14
10	5

10. What is the risk (i.e Risk Priority Number) for each of the failure mode?

Risk priority number (RPN) of each of the failure mode is calculated with the multiplication of severity, occurrences, and detectability. RPN for different failure modes range from 1-490.

The failure modes, for which risk need to be mitigated are then identified. According to corporate risk management policy, any failure

mode with RPN equal to or greater than 70 are intolerable, hence risk for these failure modes are in need of mitigation. There are 17 failure modes with RPN>=70.

RPN for each of the failure mode can be found in column J of packaging FMEA in Appendix F. RPN>=70 are indicated with bold red font.

The table below shows number of failure effects for each of the RPN ranking in the FMEA:

Table 10: RPN Ranking and Number of Failure Effects

RPN Ranking	Number of Failure Effects
3	1
4	1
6	4
9	2
14	2
15	2
21	5
24	2
35	2
42	1
54	1

56	2
84	2
96	2
100	2
126	2
144	2
210	1
240	1
252	2
280	1
384	1
490	1

11. What are the mitigation and/or control plan for each of the failure mode needing mitigation?

    There are 17 failure effects for which the RPN is greater than 70. Risk for each of the 17 RPN therefore needs mitigation. Action plan for mitigating each of the risk is then brainstormed and finalized. These mitigation plans are listed in column K of packaging FMEA in Appendix F.

    Given below is a list of these mitigation plans:

Table 11: Risk Mitigation Action Plan for RPN>=70

RPN	Actions Recommended	Resp.	Actions Taken
144	System enhancement and no operator key in and should be scanning barcode for 95M	Label Manager and IT	Action scheduled to be completed by December 2015
252	Train Label Operator to verify rev in work order	MFG Engineer1 and Label Manager	Trained Label Operator to verify rev in work order 8/30/2015
240	Train Label Opeart to verify rev in wo	MFG Engineer1 and Label Manager	Trained Label Operator to verify rev in work order 8/30/2015
384	Eliminate Cheat Sheet	Quality Engineer1 and MFG Engineer2	Implemented bar code and eliminated the use of cheat sheet on 9/5/2015
96	Scan Audit	MFG Engineers	Implemented scan audit in the ERP on 9/5/2015
96	Scan Audit	MFG Engineers	Implemented scan audit in the ERP on 9/5/2015
144	Scan Audit	Planner and MFG Engineer	Implemented scan audit in the ERP on 9/5/2015
252	Scan Audit	MFG Engineers	Implemented scan audit in the ERP on 9/5/2015
490	Training/Maintain Training Record/ Audit	MFG Engineers	Operators are trained for following Work Instruction / Work Order and auditing each others work on 8/30/2015

280	Training/Maintain Training Record/ Audit	MFG Engineers	Operators are trained for following Work Instruction / Work Order and auditing each others work on 8/30/2015
126	Self audit of WI rev	MFG Engineers	Operators are trained for auditing each others work on 8/30/2015
100	Train and Time out on Bridgelogi	MFG Engineers	Implemented time out on bridgelogic and trained operators on 8/30/2015
126	Train operators and implement scan audit	MFG Engineers	Trained operators and implement scan audit on 8/30/2015
210	Follow one piece flow	MFG Engineers	Trained Operators on one piece flow, implemented audit for one piece flow
84	Follow one piece flow	MFG Engineers	Trained Operators on one piece flow, implemented audit for one piece flow
84	Training	MFG Engineers	Trained operators for following WI and implemented Audit
100	Train and Time out on Bridgelogic	MFG Engineers	Implemented time out on bridgelogic and trained operators on 8/30/2015

12. What is the new estimated severity upon mitigation action?

    Design change is very costly. Change in design of the process is beyond the scope of the project. None of the mitigation plan recommends any design change. Therefore severity would remain same after mitigation.

13. What is the new estimated new occurrence(s) upon mitigation action?

    Mitigation plan has reduced the estimated new occurrences. New estimated occurrence upon implementation each of the mitigation plan are listed in column O of packaging FMEA in Appendix F.

14. What is the new estimated detection(s) upon mitigation action?

    Mitigation plan has reduced the estimated new detection ranking. New estimated detection ranking upon implementation each of the mitigation plan are listed in column P of packaging FMEA in Appendix F.

15. What is the new RPN upon mitigation action?

    Since with the implementation of mitigation plan, occurrences and detection ranking is reduced, keeping the severity unchanged, RPN of each of the failure effects has also been reduced. The mitigation plan has reduced RPN for each of the failure effects below 70 resulting in all risks to an acceptable risk. New estimated RPN upon implementation each of the mitigation plan are listed in column Q of packaging FMEA in Appendix F.

    The table below shows the effect of mitigation plan on the occurrence, detection and the RPN:

Table 12: Effect of Risk Mitigation Plan with New RPN

OCC	DET	RPN	Actions Recommended	Resp.	Actions Taken	SEV	New OCC	New DET	New RPN
4	6	144	System enhancement and no operator key in and should be scanning barcode for 95M	Label Manager and IT	Action scheduled to be completed by December 2015	6	3	1	18
7	6	252	Train Label Operator to verify rev in work order	MFG Engineer1 and Label Manager	Trained Label Operator to verify rev in work order 8/30/2015	6	4	2	48
4	10	240	Train Label Opeart to verify rev in wo	MFG Engineer1 and Label Manager	Trained Label Operator to verify rev in work order 8/30/2015	6	4	2	48
8	6	384	Eliminate Cheat Sheet	Quality Engineer1 and MFG Engineer2	Implemented bar code and eliminated the use of cheat sheet on 9/5/2015	8	3	1	24
2	6	96	Scan Audit	MFG Engineers	Implemented scan audit in the ERP on 9/5/2015	8	3	1	24
2	6	96	Scan Audit	MFG Engineers	Implemented scan audit in the ERP on 9/5/2015	8	2	1	16
3	6	144	Scan Audit	Planner and MFG Engineer	Implemented scan audit in the ERP on 9/5/2015	8	3	1	24

7	6	252	Scan Audit	MFG Engineers	Implemented scan audit in the ERP on 9/5/2015	6	3	1	18
7	10	490	Training/Maintain Training Record/ Audit	MFG Engineers	Operators are trained for following Work Instruction / Work Order and auditing each others work on 8/30/2015	7	3	3	63
4	10	280	Training/Maintain Training Record/ Audit	MFG Engineers	Operators are trained for following Work Instruction / Work Order and auditing each others work on 8/30/2015	7	3	3	63
3	6	126	Self audit of WI rev	MFG Engineers	Operators are trained for auditing each others work on 8/30/2015	7	3	3	63
2	10	100	Train and Time out on Bridgelogi	MFG Engineers	Implemented time out on bridgelogic and trained operators on 8/30/2015	5	2	1	10
3	6	126	Train operators and implement scan audit	MFG Engineers	Trained operators and implement scan audit on 8/30/2015	7	2	1	14
5	6	210	Follow one piece flow	MFG Engineers	Trained Operators on one piece flow, implemented audit for one piece flow	7	3	3	63

2	**6**	**84**	**Follow one piece flow**	**MFG Engineers**	**Trained Operators on one piece flow, implemented audit for one piece flow**	**7**	**3**	**1**	21
2	**6**	**84**	**Training**	**MFG Engineers**	**Trained operators for following WI and implemented Audit**	**7**	**1**	**1**	7
2	**10**	**100**	**Train and Time out on Bridgelogi**	**MFG Engineers**	**Implemented time out on bridgelogic and trained operators on 8/30/2015**	**5**	**1**	**1**	5

Conclusion

Using FMEA methodology, the risk for packaging process could be calculated. This provided a baseline for calculating and mitigating risk for packaging process, thereby building quality into the process. Packaging is now managed for risk as a part of fulfillment of organizations certification for ISO 13485 and ISO 14971.

A risk benefit analysis is not required in this exercise of FMEA, since all risks with RPN>=70, is mitigated. Verification of RPN for each risk control identified as part of the risk mitigation is beyond the scope of this project. This will need to be conducted within the next 6 months. FMEA is a living document. This FMEA would need to be reviewed periodically as any new risk is identified.

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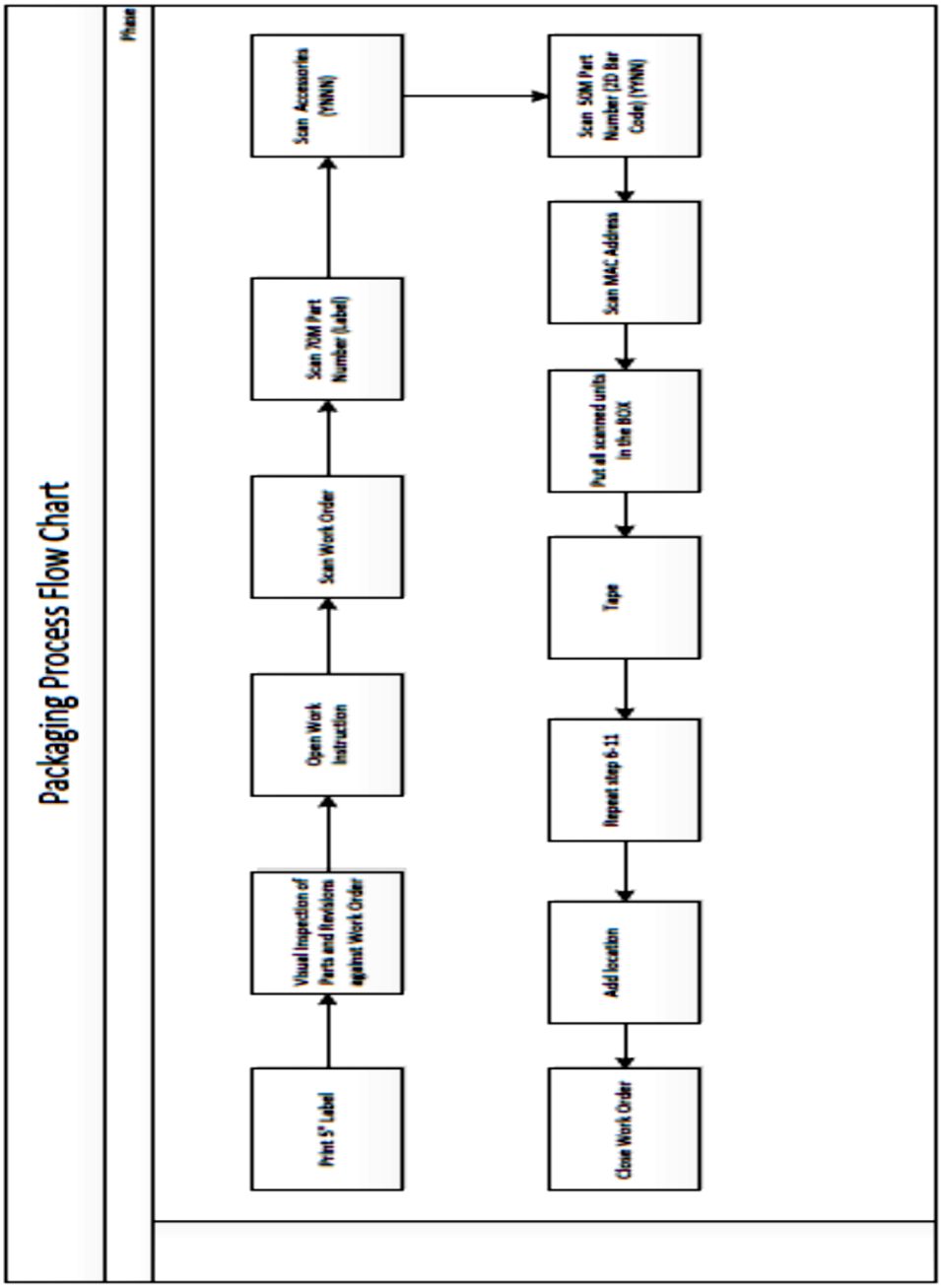
Appendix A: Package Process Flow Chart



Appendix B: FMEA Training Presentation

PFMEA Kick Off Meeting

Saif Ullah

7/20/2015

Agenda

- Purpose of the meeting
- PFMEA as a risk Management Tool
- Deliverables
- Schedule

Purpose of the meeting

- ISO 13485
- ISO 14971
- Building Quality to Product

What is FMEA

- FMEA
  - Risk Management Tool
- What is Risk
  - A situation involving exposure to danger
  - The possibility of loss or injury
  - Something involving uncertain danger
  - The possibility that something unpleasant or dangerous might happen
  - ISO 14971 Definition:
    - Combination of the probability of occurrence of harm and the severity of that harm

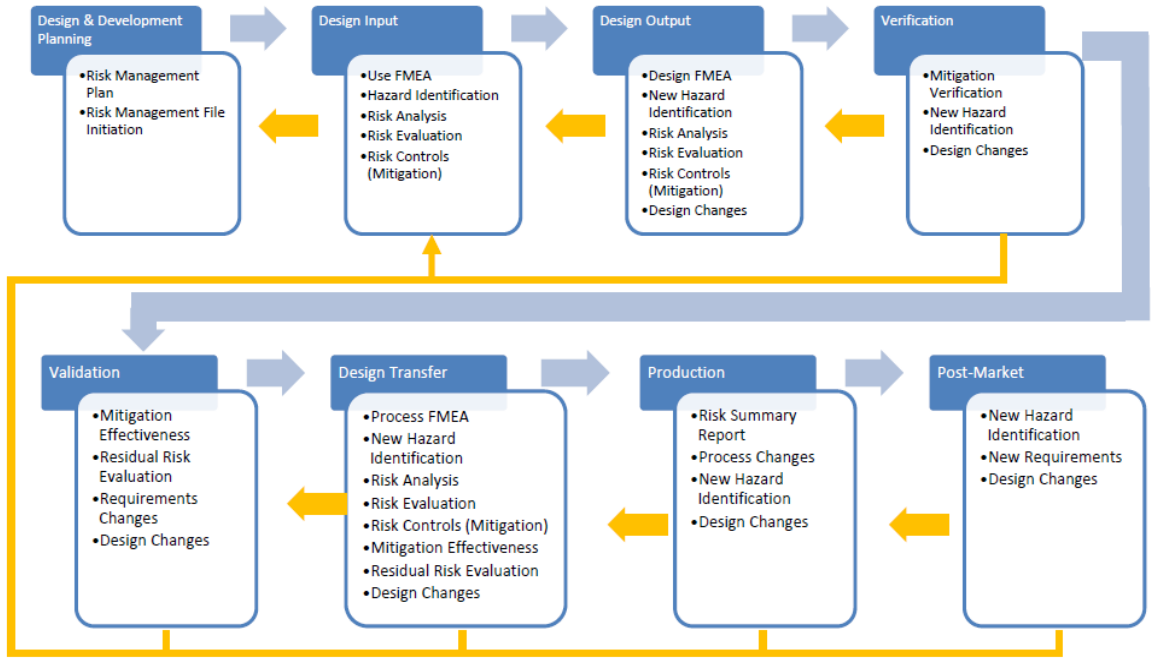
What is FMEA (Some Key Terms)

- **Hazard** = potential source of harm
  - Hazard evaluation is often a separate process integrated with Complaint Handling; i.e. – evaluation of harm that may have already occurred
  - Example = Electricity
- **Harm** = physical injury or damage to the health of people, or damage to property or the environment
  - Includes operator, not just the patient
  - Example = Electrocution or burns
- **Mitigation** = reduction of risk levels to "as low as reasonably practicable" (ALARP)
- **Residual Risk** = risk remaining after mitigations have been applied
- **Safety** = freedom from "unacceptable" risk

Source of Risk

- Device Use
  - Inherent Risk
  - **Human Factors**
  - Intended Use
  - Misuse
  - Off-Label Use
  - Disposal
  - Maintenance
  - Packaging & Labeling
  - Instructions for Use
  - Training
  - Combination Devices (Device + Pharmaceutical)
  - Integration/Interaction with other Devices
- Device Design
  - Requirements Management
  - Materials/Biocompatibility
  - Technology
  - Complexity
  - Software/Firmware
  - Environment
  - Shelf-Life
  - Integrations/ Interfaces
- Processes
  - Manufacturing
  - Inspection
  - Cleaning/Sterilization
  - Delivery
  - Storage
  - Maintenance/Servicing
  - Change Management
  - Purchasing/Outsourcing

Risk Management Throughout Device Lifecycle



[Type] FMEA Matrix

Product / Process / Service: Date:				Team: [names, titles]					Revision Level: Rev of FMEA Reason for Change:					
[Type] Function	Potential Failure Mode	Potential Effect of Failure	Severity (S)	Potential Causes of Failure	Occurrence (O)	Current Controls & Detection Methods	Detection (D)	Initial RPN	Recommended Action Plan	Action Implemented	New Sev. (S)	New Occ. (O)	New Det. (D)	New RPN
Design														
Process														
Use														

FMEA Matrix Inputs

- **Index:** Line item numbering for easy reference. Optional but suggested. (Not shown in matrix.)
- **[Type] Function:** Intended purpose or objective of a specific design, process or service as it relates to a customer need or expectation, regulatory requirement , safety or performance specification. State the function as an action verb. Examples: provide vibration damping , bond Part A to Part B, store ECG waveform data, sharpen instrument cutting edge, etc.
- **Potential Failure Mode:** A specific failure, defect concern, or loss of design or operating function. E.g. corrosion, cannot control speed, lack of pressure, lack of biocompatibility, etc.
- **Potential Effect of Failure:** Consequence of the failure on the product safety, design, performance, compliance with regulations, customer satisfaction, etc. Information sources include clinical reports, customer complaints, device experience databases (e.g. FDA's MAUDE), field service and reliability data.
- **Severity (S) of Effect:** Qualitative or quantitative ranking of the seriousness of the failure. A scale of 1 – 5 might be used for less complex or critical devices; 1 – 10 for more complex or life-sustaining devices. Always consider the worst case effect but consider all effects individually.

  Note: Generally, the severity level can only be reduced through inherent safety by design so address high-severity hazards early in the design. Late design changes are very costly, especially time to market.

FMEA Matrix Inputs

- **Potential Cause(s) of Failure:** Employ root cause analysis techniques, especially fault tree analysis (FTA), to identify causes and contributing factors. There might be more than one cause of a failure, i.e. design and manufacturing concerns.
- **Occurrence (O):** Qualitative or quantitative ranking of the likelihood that the failure or hazardous situation will occur. A scale of 1 – 5 might be used for less complex or critical devices; 1 – 10 for more complex or life-sustaining devices.
- **Current Control & Detection Methods:** Identify existing mitigation techniques in place to control the risk, i.e. safety by design, protective measures (design / manufacturing), and safety information. Detection methods might include design / process engineering analysis, simulation or modeling, testing, inspection, design review, etc. Cite supporting technical documentation in the FMEA matrix or attach an index.
- **Detection (D):** Qualitative or quantitative ranking of the reliability of detecting a failure or hazardous situation before causing harm. A scale of 1 – 5 might be used for less complex or critical devices; 1 – 10 for more complex or life-sustaining devices. Do not rely on the customer or user to detect the failure or hazardous situation, e.g. the surgical prep / setup team.
- **Initial RPN:** The risk priority number is a quantified risk level calculated as S x O x D. It is compared to the risk acceptance criteria as stated in the risk management plan or by organization policy.

FMEA Matrix Inputs

- **Recommended Action Plan:** The activity(ies) needed to further control risks by reducing the severity, occurrence and/or detection level. This requires identifying the needed resources, including responsible person, and due date for each activity.
- **Action Implemented:** Confirmation of the activities completed and the controls actually implemented.
- **New Severity (S):** The estimated severity level following implementation of remedial action.
- **New Occurrence (O):** The estimated occurrence level following implementation of remedial action.
- **New Detection (D):** The estimated detection level following implementation of remedial action.
- **New RPN:** The risk priority number resulting from the new product of S x O x D. This value is then again compared to the risk acceptance criteria.

PFMEA

- Process MAP
- Process Input – Function
- Process Output – Possible Failure Mode

PFMEA Deliverables

- Process Map
- Packaging PFMEA
- Digi PFMEA Template
- Digi Guidelines for
  - Severity
  - Occurrence
  - Delectability
- Check for new risk due to mitigation
- Update FMEA
- FMEA is a living document

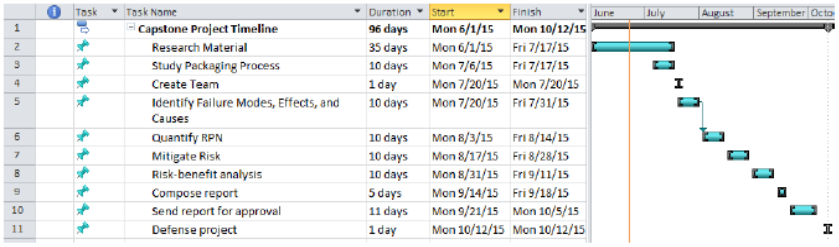
FMEA Deliverables

- Digi PFMEA Template
- Digi Guidelines for
  - Severity
  - Occurrence
  - Delectability
- Check for new risk due to mitigation
- Update FMEA
- FMEA is a living document

FMEA Team

- Manufacturing Engineer
- Quality Engineer
- Packaging Supervisor
- Packaging Operator
- Labeling Manager

FMEA SCHEDULE



	Task	Task Name	Duration	Start	Finish
1		**Capstone Project Timeline**	**96 days**	**Mon 6/1/15**	**Mon 10/12/15**
2		Research Material	35 days	Mon 6/1/15	Fri 7/17/15
3		Study Packaging Process	10 days	Mon 7/6/15	Fri 7/17/15
4		Create Team	1 day	Mon 7/20/15	Mon 7/20/15
5		Identify Failure Modes, Effects, and Causes	10 days	Mon 7/20/15	Fri 7/31/15
6		Quantify RPN	10 days	Mon 8/3/15	Fri 8/14/15
7		Mitigate Risk	10 days	Mon 8/17/15	Fri 8/28/15
8		Risk-benefit analysis	10 days	Mon 8/31/15	Fri 9/11/15
9		Compose report	5 days	Mon 9/14/15	Fri 9/18/15
10		Send report for approval	11 days	Mon 9/21/15	Mon 10/5/15
11		Defense project	1 day	Mon 10/12/15	Mon 10/12/15

Appendix C: Severity Matrix

Effect	Criteria: Severity of Effect Defined	Ranking
Hazardous: Without Warning	May endanger operator. Failure mode affects safe vehicle operation and / or involves noncompliance with government regulation. Failure will occur **WITHOUT** warning.	10
Hazardous: With Warning	May endanger operator. Failure mode affects safe vehicle operation and / or involves noncompliance with government regulation. Failure will occur **WITH** warning.	9
Very High	Major disruption to production line. 100% of product may have to be scrapped. Vehicle / item inoperable, loss of primary function. Customer very dissatisfied.	8
High	Minor disruption to production line. Product may have to be sorted and a portion (less than 100%) scrapped. Vehicle operable, but at a reduced level of performance. Customer dissatisfied.	7
Moderate	Minor disruption to production line. A portion (less than 100%) may have to be scrapped (no sorting). Vehicle / item operable, but some comfort / convenience item(s) inoperable. Customers experience discomfort.	6
Low	Minor disruption to production line. 100% of product may have to be reworked. Vehicle / item operable, but some comfort / convenience item(s) operable at reduced level of performance. Customer experiences some dissatisfaction.	5
Very Low	Minor disruption to production line. The product may have to be sorted and a portion (less than 100%) reworked. Fit / finish / squeak / rattle item does not conform. Defect noticed by most customers.	4
Minor	Minor disruption to production line. A portion (less than 100%) of the product may have to be reworked on-line but out-of-station. Fit / finish / squeak / rattle item does not conform. Defect noticed by average customers.	3
Very Minor	Minor disruption to production line. A portion (less than 100%) of the product may have to be reworked on-line but in-station. Fit / finish / squeak / rattle item does not conform. Defect noticed by discriminating customers.	2
None	No effect.	1

Appendix D: Occurrence Matrix

Probability of Failure	Possible Failure Rates	Cpk	Ranking
Very High: Failure is almost inevitable	≥ 1 in 2	< 0.33	10
	1 in 3	≥ 0.33	9
High: Generally associated with processes similar to previous processes that have often failed	1 in 8	≥ 0.51	8
	1 in 20	≥ 0.67	7
Moderate: Generally associated with processes similar to previous which have experienced occasional failures, but not in major proportions.	1 in 80	≥ 0.83	6
	1 in 400	≥ 1.00	5
	1 in 2,000	≥ 1.17	4
Low: Isolated failures associated with similar processes	1 in 15,000	≥ 1.33	3
Very Low: Only isolated failures associated with almost identical processes	1 in 150,000	≥ 1.5	2
Remote: Failure is unlikely. No failures ever associated with almost identical processes	≤ 1 in 1,500,000	≥ 1.67	1

Appendix E: Detection Matrix

Detection	**Criteria**: Likelihood the existence of a defect will be detected by test content before product advances to next or subsequent process	**Ranking**
Almost Impossible	Test content detects < 80 % of failures	10
Very Remote	Test content must detect 80 % of failures	9
Remote	Test content must detect 82.5 % of failures	8
Very Low	Test content must detect 85 % of failures	7
Low	Test content must detect 87.5 % of failures	6
Moderate	Test content must detect 90 % of failures	5
Moderately High	Test content must detect 92.5 % of failures	4
High	Test content must detect 95 % of failures	3
Very High	Test content must detect 97.5 % of failures	2
Almost Certain	Test content must detect 99.5 % of failures	1

Appendix F: Packaging PFMEA

Process / Product
Failure Modes and Effects Analysis
(FMEA)

Process or Product Name:	Packaging		Prepared by: MFG/PACK/QLTY	Page ____ of ____
Facilitor/Responsible:	Saif Ullah	PACK MFG QLTY	FMEA Date (Orig) 20 JULY 2015 - 10 OCT 2015 (Rev) A _____ 1	

Process Step	Key Process Input	Potential Failure Mode	Potential Failure Effects	SEV	Potential Causes	OCC	Current Controls	DET	RPN	Actions Recommended	Resp.	Actions Taken	SEV	OCC	DET	RPN
What is the process step ?	What is the Key Process Input?	In what ways does the Key Input go wrong?	What is the impact on the Key Output Variables (Customer Requirements) or internal requirements?	How Severe is the effect to the customer?	What causes the Key Input to go wrong?	How often does cause occur?	What are the existing controls and procedures (inspection and test) that prevent with the cause or the Failure Mode? Should include an SOP number.	How well can you detect cause or FM?	Risk Priority Number	What are the actions for reducing the occurrence of the Cause, or improving detection? Should have actions only on high RPN's or easy fixes.	Whose Responsible for the recommended action?	What are the completed actions taken with the recalculated RPN? Be sure to include completion month/year	How Severe is the effect to the customer?			
Printing 6" Label	Work Order 9GM Part Number	Unable to find part number in the system	Delay	3	Not entered in the system	8	Label operator coming to Label Manager	1	24				3			0
		Incorrect setup	Wrong Label Printed	6	Operator keying in wrong part number and revision	4	Manual Inspection	6	144	System enhancement and no operator key in and should be soanning barcode for 9GM	Label Manager and IT	Action scheduled to be completed by December 2016	6	3	1	18
		Wrong Rev of 9GM	Wrong Label Printed	6	Missing current rev in the system	7	Manual Inspection	6	252	Train Label Operator to verify rev in work order	MFG Engineer1 and Label Manager	Trained Label Operator to verify rev in work order 8/30/2016	6	4	2	48
		Incorrect location	Delay	3	Where use not updated	8	Label Manager and System	1	24				3			0
		Incorrect Text	Wrong Label Printed	6	Missing current rev in the system	4	Label Manager and System	10	240	Train Label Opeart to verify rev in wo	MFG Engineer1 and Label Manager	Trained Label Operator to verify rev in work order 8/30/2016	6	4	2	48
	Label Stock	Unable to find	Delay	3	Not in correct location	2	5S and Kanban	1	6				3			0
		No Part Number	Label format not acoording to customer expectation	2	Not changing the label stock	2	Easy label detection	1	4				2			0
	6D M Serial Number	Does not scan	Delay	3	BadScanner/ Using wrong scanner/ Bad print of bar code	2	Part would not scan	1	6	Train 6DM Operator	MFG Engineer1	Trained upstream Operator to verify part number in work order 8/30/2016	3			0
			Wrong 6DM Label because of using cheat sheet	8	Process to do it too slow/ Scannability	8	Manual Inspection	6	384	Eliminate Cheat Sheet	Quality Engineer1 and MFG Engineer2	Implemented bar code and eliminated the use of cheat sheet on 9/6/2016	8	3	1	24
		Bad Bar Code	Delay	3	BadScanner/ Using wrong scanner/ Bad print of bar code		Part would not scan		0	Train 6DM Operator	MFG Engineer1	Trained upstream Operator to verify part number in work order 8/30/2016	3			0
Visual inspection of parts and revisions agaist work order	Part and accessories	Wrong Part Number Pulled	Customer receives wrong part	8	Not following SOP	2	Manual Inspection	6	96	Scan Audit	MFG Engineers	Implemented scan audit in the ERP on 9/6/2016	8	3	1	24
			Unable to detect it out of many parts that are pulled only one of each is checked	8	Sampling plan	2	Manual Inspection	6	96	Scan Audit	MFG Engineers	Implemented scan audit in the ERP on 9/6/2016	8	2	1	16
			Wrong REV pulled	8	Improper Disposition	3	Manual Inspection	6	144	Scan Audit	Planner and MFG Engineer	Implemented scan audit in the ERP on 9/6/2016	8	3	1	24
		Wrong order	Delay	3	Mix work orders	6	Scan audit	1	15				3			0

	Label and 60M Part Numbers		Wrong 60M in the 70M BKU	6	Mix work orders	7	Manual Inspection	6	252	Soan Audit	MFG Engineers	Implemented soan audit in the ERP on 9/6/2016	6	
		Missing label	Delay	3	Upstream operation	3	Soan audit	1	9				3	
	Quantity Check	Miscount	Customer receives order with missing equipment	7	Operator error	3	Soan audit	1	21				7	
		Inaccurate quantity	Customer receives order with missing equipment	7	Operator error	3	Soan audit	1	21				7	
Open Instruction	90M Work Instruction	Not do it	Dissatisfied customer	7	Operator error	7	None	10	490	Training/Maintain Training Record/ Audit	MFG Engineers	Operators are trained for following Work Instruction / Work Order and auditing each others work on 8/30/2016	7	
		Incomplete WI	Dissatisfied customer	7	MFG Engineer Error	4	Operator communicate with MFG Engineer	2	56	Bucket List			7	
		Inaccurate Instruction	Dissatisfied customer	7	MFG Engineer Error	4	Operator communicate with MFG Engineer	2	56				7	
		Not following it accordingly	Dissatisfied customer	7	Operator error	4	None	10	280	Training/Maintain Training Record/ Audit	MFG Engineers	Operators are trained for following Work Instruction / Work Order and auditing each others work on 8/30/2016	7	
		Link does not work	Delay	3	MFG Engineer Error	3	Link (Operator communicate with MFG Engineer	1	9				3	
		Link refers to wrong revision	Dissatisfied customer	7	MFG Engineer Error	3	Manual Inspection	8	126	Self audit of WI rev	MFG Engineers	Operators are trained for auditing each others work on 8/30/2016	7	
SCAN Work Order	Open Bridge Logic	Unavailable log in	Dissatisfied customer	7	Non registration of operator	2	No operation	1	14				7	
		Forget to log out	No traceability	6	Operator error	3	None	10	180	Train and Time out on Bridgelogi	MFG Engineers	Implemented time out on bridgelogic and trained operators on 8/30/2016	6	
Soan 70M Part Number (Label)	Work Order	Wrong Serial Tracker (YYXX)	Dissatisfied customer	7	Operator error	3	Soan audit	1	35				7	
		Wrong Work Order	Dissatisfied customer	7	Operator error	3	Soan audit	1	21				7	
Soan Accessories	Accessories	Item not setup	Delay	3	MFG Engineer Error	7	Soan audit	1	21				3	
		Soaning wrong number	Dissatisfied customer	7	Operator error	3	Soan audit	1	35				7	
	Label	Wrong label	Dissatisfied customer	7	Upstream Operator error	3	Manual Inspection	6	126	Train operators and implement soan audit	MFG Engineers	Trained operators and implement soan audit on 8/30/2016	7	
Soan 60M Part Number	Check 70M label against 60M label for (IMEI, MEID, MAC, SN, Standard)	Not do it	Dissatisfied customer	7	Operator error	3	Soan audit	1	21				7	
		Misreading it	Dissatisfied customer	7	Operator error	2	Soan audit	1	14				7	
	60M Part Number	Wrong barcode on the right item	Delay	3	MFG Engineer Error	2	Soan audit	1	6				3	
		Wrong Bar Code	Delay	3	Labeling Error by Upstream Operator	2	Soan audit	1	6				3	
Soan MAC Address	MAC Address Label	Unscannable barcode	Delay	3	Labeling Error by Upstream Operator	3	Soan audit	1	15	Maintain Printer	Label Manager and MFG Engineer1		3	
Put all soanned items in the box	All items to be packaged	Mix item / Miss item	Dissatisfied customer	7	Operator error	3	Manual Inspection	6	210	Follow one piece flow	MFG Engineers	Trained Operators on one piece flow, implemented audit for one piece flow	7	
	Accessories	Forget to put inside	Dissatisfied customer	7	Operator error	2	Manual Inspection	6	84	Follow one piece flow	MFG Engineers	Trained Operators on one piece flow, implemented audit for one piece flow	7	
Tape	Package	Logo vs Non Logo	Dissatisfied customer	7	Operator error	2	Manual Inspection	6	84	Training	MFG Engineers	Trained operators for following WI and implemented Audit	7	
		Putting tape in wrong location	Dissatisfied customer	7	Operator error	1	Manual Inspection	6	42				7	
Add location	Package	Put in physical wrong location	Delay	3	Operator error	3	Manual Inspection	6	54				3	
Close Work Order	Bridgelogic	Forget to log out	No traceability	6	Operator error	3	None	10	180	Train and Time out on Bridgelogi	MFG Engineers	Implemented time out on bridgelogic and trained operators on 8/30/2016	6	