

## How To Do A Process FMEA (Failure Modes & Effects Analysis) for Medical Devices.

If you read the ATL White Paper for ISO-14971 Risk Analysis, what comes next?

For ISO-14971:2012 and/ or MDD 93/42/EEC Medical Devices, it is highly recommended that you provide a process for documenting the steps involved in the development of new products, or improvement to existing products/ processes. Using a process FMEA (Failure Modes & Effects Analysis) you can establish phases and timelines for new product development. You also can assign responsibilities for the tasks involved.

Below is a sample ATL FMEA form. We have detailed, line by line, ATL's (Process) "FMEA Form". If ATL Form #191 is used for risk assessment per the requirements of ISO-14971 or MDD/93/42/EEC, the medical device control feature is always indicated with a double asterisk (\*\*), and so noted in the header of the FMEA form.

Form 191, Rev 0, 05-21-15		AD TAPE & LABEL COMPANY - POTENTIAL FAILURE MODE AND EFFECTS ANALYSIS (PROCESS FMEA)						PAGE 1										
ITEM NAME: 4.2		PART / ASSEMBLY NAME: 4.3		FMEA NUMBER: 4.1		CORE TEAM 4.8												
PROCESS. RESF.: 4.3		PREPARED BY: 4.4		CUSTOMER NAME:		QUALITY: D. DOBERT												
OTHERS INVOLVED:		SUPPLIERS AFFECTED: 4.5		PROCESS FMEA DATE: START - 4.7		SALES:												
* = CTQ (CLASS CONTROL FEATURE "CRITICAL TO QUAL		MODEL YEAR: 4.5		PROCESS FMEA REV.: REVISION UU		REVISION: 00												
KEY DATE: 4.6																		
PROCESS FUNCTION 4.9	POTENTIAL FAILURE MODE 4.10	POTENTIAL EFFECTS OF FAILURE 4.11	S L E A V S	POTENTIAL CAUSES OF FAILURE 4.14	D C C	EXISTING CONDITIONS			RECOMMENDED ACTIONS 4.19	RESPONSIBLE FOR ACTION/ TARGET DATE 4.20	ACTION RESULTS							
						CURRENT CONTROL 4.16	D E T	RPN 4.18			ACTIONS TAKEN 4.21	S E V	O C V	D E T	RPN 4.22			
				←-- 4.13														
				4.15 →														
								4.17										
<b>SAMPLE</b>																		

### Step by step instructions for you:

The process FMEA should begin with some sort of risk assessment of the general process.

An ATL FMEA form is included as an exhibit with this white paper.

Correct application of this form begins with paragraph 4.1 below. Paragraph numbers are indicated as "numbered points" on the "Sample FMEA Form".

- 4.1 FMEA Number: Enter the FMEA document number which may be used for tracking.
- 4.2 Item: Enter the name of the drawing, system, subsystem, etc. for which the process is being analyzed.
- 4.3 Process Responsibility: Enter the person responsible for the process development.
- 4.4 Prepared By: Enter the name or the person responsible for preparing the FMEA.
- 4.5 Model Year(s): If applicable, enter the intended model year(s) and product line(s) that will utilize and/or be affected by the design/process being analyzed (if known). This step may not be applicable.
- 4.6 Key Date: Enter the initial FMEA meeting date.
- 4.7 FMEA Date: Enter the date the original FMEA was compiled, and the latest revision date.
- 4.8 Core Team: List the names of the responsible individuals and departments which have the authority to identify and/or perform tasks.
- 4.9 Process Function/Requirements: Enter a simple description of the process or operation being analyzed (e.g., print, die cut). Indicate as concisely as possible the purpose of the process or operation being analyzed. Where the process involves numerous operations (e.g. assembling) with different potential modes of failure, it may be desirable to list the operations as separate processes.
- 4.10 Potential Failure Mode: Potential Failure Mode is defined as the manner in which the process could potentially fail to meet the process requirements and/or design intent. It is a description of the non-conformance at that specific operation. It can be a cause associated with a potential failure mode in a subsequent (downstream) operation or an effect associated with a potential failure in a previous (upstream) operation. However, in preparation of the FMEA, the assumption should be made that the incoming part(s)/material(s) are correct.

List each potential failure mode for the particular operation in terms of a component, subsystem, system or process characteristic. The assumption is made that the failure could occur, but may not necessarily occur. The process engineer/team should be able to pose and answer the following questions:

- “How can the process/part fail to meet specifications?”
- “Regardless of engineering specifications, what would a customer (end user, subsequent operations, or service) consider objectionable?” What might be a hazard?

4.11 Potential Effect(s) of Failure: Potential Effects of Failure are defined as the effects of the failure mode on the customer(s). The customer(s) in this context could be

the next operation, subsequent operations or locations. Each must be considered when assessing the potential effect of a failure.

4.12 Severity (S): Severity is an assessment of the seriousness of the effect (listed in the previous column) of the potential failure mode to the customer. Severity applies to the effect only. Severity should be estimated on a “1” to “10” scale, with 10 the most severe.

4.13 Classification: This column may be used to classify any special process characteristics (e.g., critical, key, major, significant) for components, subsystems, or systems that may require additional process controls.

4.14 Potential Cause(s)/Mechanism(s) of Failure: Potential Cause of Failure is defined as how the failure could occur, described in terms of something that can be corrected or can be controlled.

List, to the extent possible, every conceivable failure cause assignable to each potential failure mode. If a cause is exclusive to the failure mode, i.e., if correcting the cause has a direct impact on the failure mode, then this portion of the FMEA thought process is completed. Many causes however are not mutually exclusive, and to correct or control the cause, a design of experiments, for example, may be considered to determine which root causes are the major contributors and which can be most easily controlled. The causes should be described so that remedial efforts can be aimed at those causes which are pertinent. Only specific errors or malfunctions (e.g., operator fails to install seal) should be listed; ambiguous phrases (e.g., operator error, machine malfunction) should not be used.

4.15 Occurrence (O): Occurrence is how frequently the specific failure cause/mechanism is projected to occur (listed in the previous column). The occurrence ranking number has a meaning rather than a value.

Estimate the likelihood of the occurrence on a “1” to “10” scale. Only occurrences resulting in the failure mode should be considered for this ranking; failure detecting measures are not considered here.

4.16 Current Process Controls: Current Process Controls are descriptions of the controls that either prevent to the extent possible the failure mode from occurring or detect the failure mode should it occur. These controls can be process controls such as fixture error-proofing or Statistical Process Control (SPC), or can be post-process evaluation. The evaluation may occur at the subject operation or at subsequent operations. There are three types of Process Controls/features to consider; those that:

- (1) prevent the cause/mechanism or failure mode/effect
- (2) detect the cause/mechanism and lead to corrective actions, and
- (3) detect the failure mode.

The preferred approach is to first use type (1) controls if possible; second, use the type (2) controls; and third, use the type (3) controls. The initial occurrence rankings will be affected by the type (1) controls provided they are integrated as part of the design intent. The initial detection rankings will be based on the type (2) or type (3) current controls, provided the process being used is representative of process intent.

4.17 Detection (D): Detection is an assessment of the probability that the proposed type (2) current process controls, listed in column 16, will detect a potential cause/mechanism (process weakness), or the probability that the proposed type (3) process controls will detect the subsequent failure mode, before the part or component leaves the manufacturing operations or assembly location. A "1" to "10" scale is used. Assume the failure has occurred and then assess the capabilities of all "Current Process Controls" to prevent shipment of the part having this failure mode or defect. Do not automatically presume that the detection ranking is low because the occurrence is low (e.g., when Control Charts are used), but do assess the ability of the process controls to detect low frequency failure modes or prevent them from going further in the process. Random quality checks are unlikely to detect the existence of an isolated defect and should not influence the detection ranking. Sampling done on a statistical basis is a valid detection control.

4.18 Risk Priority Number (RPN): The Risk Priority Number is the product of Severity (S), Occurrence (O), and Detection (D) rankings.

$RPN = (S) \times (O) \times (D)$  (also equals the hazard number for end user)

This value should be used to rank order the concerns in the process (e.g., in Pareto fashion). The RPN will be between "1" and "1,000". For higher RPN's the team must undertake efforts to reduce this calculated risk through corrective action(s). In general practice, regardless of the resultant RPN, special attention should be given when severity is high.

4.19 Recommended Action(s): When the failure modes have been rank ordered by RPN, corrective action should be first directed at the highest ranked concerns and critical items. If for example, the causes are not fully understood, a recommended action might be determined by a statistical designed experiment (DOE). The intent of any recommended action is to reduce the severity, occurrence, and/or detection rankings. If no actions are recommended for a specific cause, then indicate this by entering a "NONE" in this column.

In all cases where the effect of an identified potential failure mode could be a hazard to manufacturing/assembly personnel, corrective actions should be taken to prevent the failure mode by eliminating or controlling the cause(s), or appropriate operator protection should be specified.

The need for taking specific, positive corrective actions with quantifiable benefits, recommending actions to other activities and following-up all recommendations cannot be overemphasized. A thoroughly thought out and well developed Process FMEA will be of limited value without positive and effective corrective actions. It is the responsibility of all affected activities to implement effective follow-up programs to address all recommendations.

Actions such as the following should be considered:

- To reduce the probability of occurrence, process and/or design revisions are required. An action-oriented study of the process using statistical methods could be implemented with an ongoing feedback of information to the appropriate operations for continuous improvement and defect prevention.
- Only a design and/or process revision can bring about a reduction in the severity ranking.
- To increase the probability of detection, process and/or design revisions are required. Generally, improving detection controls is costly and ineffective for quality improvements. Increasing quality controls inspection frequency is not positive corrective action and should only be utilized as a temporary measure, permanent corrective action is required. In some cases, a design change to a specific part may be required to assist in the detection. Changes to the current control system may be implemented to increase this probability. Emphasis must, however, be placed on preventing defects (i.e., reducing the occurrence) rather than detecting them. An example would be the use of Statistical Process Control and process improvement rather than random quality checks or associated inspection.

4.20 Responsibility (for the Recommended Action): Enter the Organization and individual responsible for the recommended action, and the target completion date.

4.21 Actions Taken: After an action has been implemented, enter a brief description of the action and effective date.

4.22 Resulting RPN: After corrective actions have been identified, estimate and record the resulting occurrence, severity, and detection rankings. Calculate and record the resulting RPN. If no actions are taken, leave the "Resulting RPN" and related ranking columns blank.

Follow Up: The process responsible engineer is responsible for assuring that all actions recommended have been implemented or adequately addressed. The FMEA is a living document and should always reflect the latest design level, as well as the latest relevant actions, including those occurring after the start of production.

It is also advisable to take your RPN's (Risk Priority Numbers" and make a Pareto Chart. This chart will tell you which problems you need to address and those problems that are not significant. A sample FMEA Pareto Chart is given on the next page:

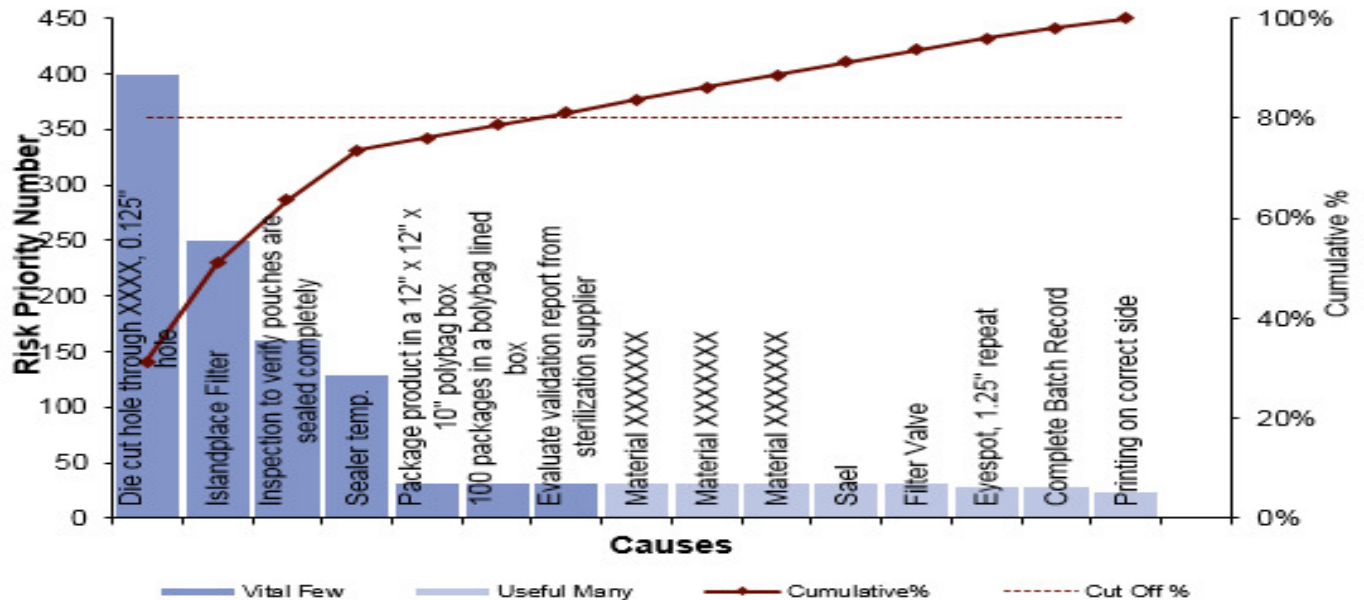
# Pareto Analysis For RPN's

## ATL Pharamceutical / Medical

XXXXXXXXXX, LLC, P/N XXXXXXXX May 21, 2015

Prepared by Carolin Duncan, ATL Senior Quality Engin *carol duncan*

### FMEA Rankings For Control Plan P/N XXXXXX



The first 7 Causes cover 81.16% of the Total R P N's

		Cumulative Percentage Cutoff: 80%	
#	Causes	R P N's	Cumulative%
1	Die cut hole through XXXX, 0.125" hole	400	31.4%
2	Islandplace Filter	250	51.0%
3	Inspection to verify pouches are sealed comple	160	63.6%
4	Sealer temp.	128	73.6%
5	Package product in a 12" x 12" x 10" polybag bo:	32	76.1%
6	100 packages in a bolybag lined box	32	78.6%
7	Evaluate validation report from sterilization sup	32	81.2%
8	Material XXXXXXXX	32	83.7%
9	Material XXXXXXXX	32	86.2%
10	Material XXXXXXXX	32	88.7%
11	Sael	32	91.2%
12	Filter Valve	32	93.7%
13	Eyespot, 1.25" repeat	28	95.9%
14	Complete Batch Record	28	98.1%
15	Printing on correct side	24	100.0%

In the Pareto Chart above we would concentrate most improvement efforts on the first seven items listed. These demonstrate the highest risk (81.2% of the potential failures).

We hope this white paper has helped you to understand ISO-14971 risk analysis and the disciplines of FMEA. If you have any questions please contact ATL. Donald Dobert (President) and Carolin Duncan (Senior Quality Engineer) put this white paper together, and we would be more than happy to answer your questions. ATL Pharmaceutical / Medical: Phone (262) 255-6150, (800) 444-5144, or our website: [www.atlco.com](http://www.atlco.com)