Quality Tools

Failure Mode and Effects Analysis

Description

This template is for use by Product Resources to record the Process Failure Mode and Effects Analysis (DFMEA) for medical and other devices. FMEA is also referred to as Failure Modes, Effects, and Criticality Analysis (FMECA).

Process FMEA

Instructions

- Please see the guidance in 90-2000-7.1 regarding FMEA process before beginning an FMEA
- Initiate action to reduce the RPN
- Re-evaluate the RPN value after completion of the recommended actions

PRODUCT RESOURCES
DESIGN – BUILD – SERVICE

	Value
	200
	8

Process FAILURE MODE AND EFFECTS ANALYSIS (DFMEA)

Item:	8000001				Responsibility:		Calogero Ramirez								
Description	ATP Inserter, 25 deg				Prepared by:		Calogero Ramirez								
Core Team:										Rev:	0				
										Rev:	0				
Process	Potential Failure Mode	Potential Effect(s) of Failure	Sev	Class	Potential Cause(s)/ Mechanism(s) of Failure	Occur	Current Process Controls	Detec	RPN	Sev	Occ	Det		RPN
Raw Material	pick the wrong material	material scrap	9	1	human	9	DOC-201	5	405	6	4	3		72
Raw Material	don't check the cert	material scrap	9	1	human	9	DOC-202	5	405	6	4	3		72
Saw	cut off too much (under dim)	material scrap	9	2	human	9	DOC-203	5	405	6	4	3		72
Machine	cut off too much (under dim)	material scrap	9	1	human	9	DOC-204	5	405	6	4	3		72
Ship	wrong label	material scrap	9	1	human	9	DOC-205	5	405	6	4	3		72
stock	bad stocking	material scrap	9	1	human	9	DOC-206	5	405	6	4	3		72
									0					0
									0					0
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Assumptions for this PFMEA:

Misc. Assumptions: (itemize and describe below)
1. All provisions of Product Resources' ISO 9001 QMS apply and are implemented.
2.
3.
4.
5.

Severity (Sev): (alter if needed to be appropriate for this PFMEA)	Sev
the lowest severity	1
	2
	3
	4
moderate severity	5
	6
	7
high severity / trigger level for mitigation action required	8
	9
the highest severity	10

Occurrence (Occur): (alter if needed to be appropriate for this PFMEA)	Occur
the lowest likelihood of occurrence	1
	2
	3
	4
moderately likely to occur	5
	6
	7
	8
	9
the highest likelihood of occurrence	10

Detection (Detec): (alter if needed to be appropriate for this PFMEA)	Det
the highest ability to detect	1
	2
	3
	4
moderate ability to detect	5
	6

	7
	8
	9
the lowest ability to detect	10

Examples:

User is unlikely to notice and/or a cosmetic item
Customer is inconvenienced and/or annoyed

Potential to cause operator anxiety or uncertainty
Not performed the intended test, may require some later action

Bodily harm caused to operator
Test will be performed with a potentially inaccurate/incorrect result
Severe bodily harm caused to operator

nearly 0% / very improbable
1 in 100 chance
1 in 10 chance

1 in 3 chance

1 in 2 chance

nearly 100% / very probable

nearly 100% / very probable

1 in 2 chance

1 in 3 chance

1 in 10 chance
1 in 100 chance
nearly 0% / very improbable