

FMEA

Process/Product Name _____
Responsible _____

Prepared By _____
FMEA Date (Orig.) _____ (Rev.) _____

Process Step/Step	Potential Failure Mode	Potential Failure Effects	Severity (1-10)	Potential Cause	Occurrence (1-10)	Current Controls	Detectability (1-10)	Actions Recommended	Owner	Action Status	Severity (1-10)	Occurrence (1-10)	Detectability (1-10)	Score
What is the process step, change or failure under investigation?	Is what might could be the step, change or failure go wrong?	What's the impact on the customer if the failure is not prevented or corrected?		What causes the step, change or failure to go wrong? (How could it occur?)		What controls exist that either prevent or detect the failure?		What are the recommended actions for reducing the occurrence of the cause or improving detection?	Who is responsible for making specific actions be completed?	What actions are completed (and when) with respect to the failure?				
Example: Administering medication through the device	Device dispenses incorrect dosage of medication	If dose expression differs with effects of medication treatment or condition, performance without injury or death	8	Calibration error, contamination of device, user error	5	Regular calibration and maintenance of device, use of double technology during medication administration	5 (6)	Implement additional user training on proper medication administration	Training Manager	All operators on the medication device reviewed and added to a user profile which includes training session	8	5	5	(6)
							5	Package device to include additional safeguards against calibration errors and contamination	Technical Department	Package device safeguards to highlight calibration events	8	5	5	(6)
							5	Consider adding a sensor to alert users to potential dosage errors	Technical Department	Add sensor that highlights user and presents user of device if incorrect dosage error is detected	8	5	5	(6)
							5							5
							5							5
							5							5

FMEA TEMPLATE

Failure Modes And Effects Analysis Fmea Tool

Peipei Pang



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