

Workshop A: RISK ANALYSIS using FMEA Failure Modes and Effects Analysis -

Assembly Set-Up & Picking

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Process Steps	Failure Mode: What could go wrong?	Failure causes: Why would the failure happen?	Failure effects: What would be the consequences of failure?	S <small>Severity</small>	O <small>Occurrence</small>	D <small>Detection</small>	RPN <small>Risk Priority No. S x O x D</small>	Action to Reduce Risk
Worksheet preparation	Data Entry Calculation Wrong work/s selection Version control	Lack of doc control Human error Incorrect info on master Comp. validation	Wrong product Instability Pt. harm Wrong Pt.	4 4 4	2 2	1 1	8 8	Validated computerised system 2 nd person checks Dose banding SOP's
Picking <ul style="list-style-type: none"> ○ drugs & ingredients ○ components ○ secondary materials (e.g. swabs & sprays) 	Wrong drug Strength Preparation Components	Storage Training Knowledge	Pt harm Delays Wrong end product and presentation	4	3	2	24	Training App checking App. Storage App. Design of unit
Tray Assembly	ditto	Contamination Not signing docs	Wrong end product Contaminated end product	4				
Assembly checks	Concentration Workload pressure							Suitable facility