

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

Transfer Process

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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
Transfer into clean room hatch	Not cleaned properly Wrong items put through Contact times Mix up	Lack of attention Training Labelling errors Work load Staffing System inefficiencies	Death Infection	4	1	2	8	Staff training
				3	1	3	9	Check list
				3	2	2	12	Timed hatches
								Check list
Transfer to clean room bench	Drop items Misplace	Clumsy Lack of attention Distraction	Exposure of operators	2	2	1	4	Dedicated trays/areas designed correctly
Transfer into Isolator hatch	Loading things too close together Breach of integrity Mix up	Improper training, lack of attention/ignorance Insufficient checks	Occluded surfaces Contamination transfer/product Death Infection	4	2	3	24	1 in 1 out system
				3	2	3	18	Load patterns Check list
				3	1	2	6	Training Segregation
Transfer to work surface								