

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	Inadequate decontamination	Poor training	Contamination	2	3	3	18	Ensure training Segregation, training and validation
		Poor technique		2	3	3	18	
	Batch cross contamination	Time pressure	Product error	4	3	1	12	
Transfer to clean room bench Prep 2	Inadequate decontamination Batch cross contamination	Poor training Poor technique Time pressure		4	2	2	16	
Transfer into Isolator hatch	Inadequate decontamination	Poor training Poor technique Time pressure	Contamination	3	2	3	18	
Transfer to work surface Critical zone	Inadequate decontamination	Poor training Poor technique	Contamination	4	2	3	24	Training SOP's Segregation validation