

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

Transfer Process

2

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 Severity	O Occurrence	D Detection	RPN Risk Priority No. S x O x D	Action to Reduce Risk
Transfer into clean room hatch	Ingredients not properly decontaminated	Inadequate procedure	Contamination of end product	3	3	4	36	Train/ validate/ monitor
	Muddle of 2 different batches	Human error Inadequate batch separation	Incorrect dose/drug/diluent	4	1	1	4	Update sop Final check Check in progress
Transfer to clean room bench	Contamination to bench	Not following procedure	Contamination of product/cleanroom	3	3	4	36	As above
	Incorrect item			4	1	4	16	
Transfer into Isolator hatch	Contamination carried into isolator	ditto	Contamination of products and isolator	4	2	4	32	As above
	Incorrect item			4	1	1	4	
Transfer to work surface	Contamination of isolator	ditto	ditto	4	2	4	32	As above
	Incorrect item			4	1	1	4	