Workshop A: RISK ANALYSIS using FMEA

Checking / Inspection / Release **4**

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
Correct labelling	Data input Software failure Power failure	Software operator	Incorrect info. Eg expiry Wrong patient	4 4	4 1	1 4	16 16	Process check Operator check Validate software
Label orientation / obscuring	Size/shape of container obscuring product	Poor operator technique	Patient might get faulty product	4	1	1	4	Perm labels Flag labels Training
Visual checks e.g. colour / particles /air seal / leaks / cap fluid	Undetected particles Damaged containers	Poor storage Operator technique	Contamination hazardous to staff/pts	4	1	1	4	SOP's Supervision Observation
Label reconciliation								
Product yield / Ingredient reconciliation								
Final release process								