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
Correcta e ing (L)	Wrong name on label Wrong sex on label	Human error Poor writing Distraction Similar name Input error	Death Negligible effect	4 1	2 3	2 3	16 9	Use of addressograph Remove distractions (Mr/Mrs off label
b e orient tion o scuring								
W Visa chec s e.g. co our a rtic esa ir sa a s a p f uid	Don't notice particle Fluid in syringe past seal	Distraction Poor attention to detail Forgot glasses	Pain on injection Blocked line embolism Risk of contamination	3 2	2 3	3 2	18 12	Remove distractions Improve lighting Staff eye checks Look at storage
b e reconci tion								
Product yie d ngredient reconci tion								
Fi re a se process								