Workshop A: RISK ANALYSIS using FMEA Failure Modes and Effects Analysis – Aseptic Processing 3

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
Item selection and preparation (e.g. swab vial cap)	Wrong item	Looks similar Colour coding Similar name	Death	3	3	2	18	Separate storage barcodes
Assembly of needles/syringes /components	Wrong size syringe	Staff error Dose wrong	Therapy compromised	2	1	2	4	
Withdraw right dose(s) / volumes	Wrong volume	Calculation error Operator error Syringe size	Death	3	3	3 2	27 18	Volume checks
Correct technique Filtration								
Correct order of addition								
Appropriate mixing								
Capping								
Product identity prior to labelling								