

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

## Aseptic Processing

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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 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)								
Assembly of needles/syringes /components								
Withdraw right dose(s) / volumes	Wrong dose withdrawn	Checking failure	Pnt needs not met	4	1	3	12	Improve in-process checking Send vials with product
Correct technique Filtration								
Correct order of addition	Wrong picker	Failure to follow SOP	Phlebitis drug unstable	3	2	4 adult	24	Training stability data
Appropriate mixing								
Capping								
Product identity prior to labelling	paperwork		Pnt gets wrong drug and dose	4	2-3	3	24-36	Tray system Vials with product space Mark products