Workshop A: RISK ANALYSIS using FMEA Failure Modes and Effects Analysis – Assembly Set-Up & Picking 1

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
Worksheet preparation	Label errors Worksheet selection Calculations Expiry dates	Units (conc) Distractions (radio) Human error 2nd check Inexperience	Wrong dose Death Pt	3 4	3 3	2 2	18 24	Independent checking PC In process checks Training Final product testing
Picking o drugs & ingredients o components o secondary materials (e.g. swabs & sprays)	Wrong drug Wrong diluent Out of date Wrong strength Wrong quantity	Storage Packing similar Inexperience Unfamiliar Similar drug name Stock rotation	Wrong drug Wrong dose Death pt Stability	4	3	2	24	Checking process Stock storage Change brand Training Awareness of errors (learn from experience)
Tray Assembly	As above	Segregation Storage (fridge items) Consumables	Delays in production Missing consumables	2	3	1	6	Consumables listed on worksheet Training Assembly check
Assembly checks								