

WORKSHOP ON OUTSOURCING

Exercise 2 - Risk assessment

ITEM	VARIABLE	QA IMPACTED	POTENTIAL CRITICALITY	RISK PRIORITY NUMBER EVALUATION				MITIGATION PLAN
				SEVERITY	OCCURANCE	DETECTION	RPN	
Process	Filtration	Density	Incompability between filter and solution can modify the system's chemical profile					
		Bioburden	Holding time of before filtration can increase the bioburden of the compound solution					
	Crimping	Cosmetic appearance	Incorrect sealing of the vials can result in cosmetic defects					
		Sterility	Incorrect sealing of the vials can result in non-closure of vials					
Primary packing	Stoppers	Impurity	An impurity from the stopper can modify the solutions chemical profile					
		Appearance	Substances released from the stopper can modify the appearance of the solution					
	Vials	Impurity	Leachables, extractables and ions from the glass can modify the profile of the solution					
		Endotoxins	An incorrect depyrogenation cycle can impact the endotoxin level of the final product					
	Plastic disposable bag for solution preparation	Impurity	Leachables and extractables from the product contact layer can modify the chemical profile of the solution					
API attributes	API particle matter	Particle maqgter	Insoluble matter in the drug substance can impact product quality					