

WORKED EXAMPLE

Risk Assessment Form - Example only - Not all-inclusive

Project Title / Risk Assessment Overview Fixemol Facility EDMS					Project Number FXM-123				
Assessment Scope / Assumptions Made See relevant CS Validation Plan.									
Function	Sub-function	Assessment of Risk							Measures
		Relevance (GxP / Business)	Risk Scenarios	Probability	Severity	Class	Detect.	Priority	
Document Approval	Display document to approve	GxP	Wrong document displayed	M	H	One	M	H	Specific testing. User SOP
		GxP	Corrupted document	L	H	Three	H	L	Acceptable
	Apply electronic signature to approve	GxP	Incorrect version displayed	M	H	One	L	H	Testing. User SOP
		GxP	Approver not authorized, but accepted: <ul style="list-style-type: none"> • system bug • wrongly configured • fraud 	L	H	Three	L	M	System test
				M	H	One	L	H	Config test. Config SOP including verification
				L	H	Three	L	M	Training and security policy
		GxP	Approver authorized, but not accepted <ul style="list-style-type: none"> • bug • configuration 	L	L	Three	H	L	Acceptable
				M	L	Three	H	L	Acceptable
		GxP	Operation seems successful but approval applied to incorrect document <ul style="list-style-type: none"> • incorrect document • incorrect version 	L	H	Three	L	M	Design review of logic. System test
				L	H	Three	L	M	Design review of logic. System test
Risk Assessment Approved by:									

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	Apply electronic signature to approve	GxP	Incorrect approver details recorded						
	Reject document if approved	GxP	Incorrect signature meaning recorded						
		GxP	Time/date details incorrect						
		GxP	Rejected document is flagged as approved						

Risk Assessment Approved by:			
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