Logo

<insert company name>

Risk Assessment and Traceability matrix

Project name	
Project number	

Name	Function	Signature
	Qualification coordinator (author)	
	Engineering	
	HSE	
	User Lead	

Document History

Version	Date	Author	Changes
1.0.0	25.05.2016	John Doe	First version

Risk description				Evaluation						Traceability Matrix		
# ID	Potential failure (risk description)	Potential cause for the failure	Effects of failure	HSE / Busine	erity (S)	urre nce	ction (D)	level (S*O*	Proposed actions	Affected URS	Installation verification (IQ test)	Functional verification (OQ test)
1	**General risks**											
1.1	GMP Design / Construction	Use of wrong materials	Insufficient cleanability	GxP					Checking the material certificates in the scope of the IQ			
1.2												
2	**Production and handling**											
2.1	Improper feeding of products to system	Input container runs empty Malfunction of level sensor	Machine stops Filling system over-filled. Possible overspill of products.	GxP					Checking the sensors in the scope of the IQ			
2.2	Production reproducibility	Missing scales, inaccurate scales, inappropriate settings by operator	Impact to product quality	GxP					Checking the scales in the scope of the IQ Operator training			
2.3	Unsafe machine for the operator	Malfunction of safety sensors so operator can reach moving parts, while machine is operational	Possible injury	HSE					Checking the fail-safe design of sensors in the scope of the IQ			
3	**Cleaning**											
3.1	Cleaning of parts in contact with product	Inappropriate cleaning procedure Inappropriate materials Improper execution of the construction Surface roughness does not comply with the specification Surface shows scratches and damages	Cross contamination Product contamination	GxP					Use of FDA compliant materials Disassembly and cleanability of individual components Use of recommended washing liquids Checking the cleaning instruction in the scope of the IQ Checking the training documentation in the scope of the IQ Training of operating personnel. Determine limits for cleaning validation.			
5	**Hardware and maintenance**											
5.1	Safety devices malfunction	Improper installation of PE (earth potential). Maschine running with open safetyguards. Defective safety devices	Operator safety endangered	HSE					Checking acc. to technical documentation in scope of the IQ. Checking PE (earth potential)			
6	**Software and 21 CFR Part 11**											
6.1	Production reports are not generated correctly	Software error	Data in the batch report is incorrect or missing	GxP					Checking report generation during the OQ			

Risk description				Evaluation						Traceability Matrix		
# ID	Potential failure (risk description)	Potential cause for the failure	Effects of failure	HSE / Busine	erity (S)	urre nce	ction (D)	level (S*O*	Proposed actions	Affected URS	Installation verification (IQ test)	Functional verification (OQ test)
6.2	Incorrect or no data records are saved or incompletely saved or loaded	Data record is corrupted Data record is falsified Saving of data fails Operating system crashes	Incorrect documentation of the batch data Clear and continuous traceability of the product inspection not guaranteed Data loss	GxP					Data management system checks integrity of all data records and notifies user if integrity of data is compromised.			
6.3	Audit Trail does not function according to specifications	Software error	Incomplete batch report, Incomplete traceability of activities	GxP					Checking of Audit Trail reports during the OQ			

Risk evaluation
- Severity (S) : 1-10
- Occurrence (O): 1-10
- Detection (D): 1-10

Risk level = S*O*D
Risk threshold for actions >= 80-100