## Impact Assessment Template for Equipment, Utility and Computer (Ref.VAL-005)

1	Current Status	
1.1	Identify Equipment/System Status (tick one box):	
	New Equipment / System	Go to Step 1.3
		Record change control no.:
	Existing Equipment / System . with change	& Go to Step 1.2
		Go to Step 1.2
		- Co to Glop 1.2
	Existing Equipment / System . no change	
1.2	Identify Validation Status: Is existing equipment /	Yes Record IQ Ref:
	System qualified?	Record OQ Ref:
		Record PQ Ref:
		Go to Step 1.3
		No Go to Step 1.3
1.3	Has equipment / system been impact assessed?	Yes Record IA Ref:
		& Go to Step 1.4 No Go to Step 2
1.4	Is IA affected by current change/ or needs	Yes Update existing IA by re-assessing using
1.4	updating?	the current form. Use same IA #.
	apadang.	Increment version #.
		Go to Step 4
		_
		No Attach existing IA to this form, complete
	Our town Invest Access to the	No Attach existing IA to this form, complete 2.1, then proceed to Step 4
2	System Impact Assessment  Define Equipment/ System Boundary (describe in	2.1, then proceed to Step 4
2 2.1	System Impact Assessment  Define Equipment/ System Boundary: (describe in	2.1, then proceed to Step 4
		2.1, then proceed to Step 4
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		2.1, then proceed to Step 4
2.1	Define Equipment/ System Boundary: (describe in	2.1, then proceed to Step 4
		2.1, then proceed to Step 4
2.1	Determine System Impact – Refer to table 2.2  1. Does the system come in direct contact with the page 2.2.	2.1, then proceed to Step 4  words and attach P&ID or schematic)  product?
2.1	Determine System Impact – Refer to table 2.2  1. Does the system come in direct contact with the part 2. Does the system provide an excipient or produce	2.1, then proceed to Step 4  words and attach P&ID or schematic)  product?
2.1	Define Equipment/ System Boundary: (describe in Determine System Impact – Refer to table 2.2  1. Does the system come in direct contact with the part 2. Does the system provide an excipient or produce 3. Is the system used in cleaning/sterilizing?	2.1, then proceed to Step 4  words and attach P&ID or schematic)  product?
2.1	Determine System Impact – Refer to table 2.2  1. Does the system come in direct contact with the part 2. Does the system provide an excipient or produce 3. Is the system used in cleaning/sterilizing? 4. Does the system preserve product status?	2.1, then proceed to Step 4  words and attach P&ID or schematic)  product? an ingredient or solvent?
2.1	Determine System Impact – Refer to table 2.2  1. Does the system come in direct contact with the part 2. Does the system provide an excipient or produce 3. Is the system used in cleaning/sterilizing? 4. Does the system produce data used to accept or	2.1, then proceed to Step 4  words and attach P&ID or schematic)  product? an ingredient or solvent?  reject product?
2.1	Determine System Impact – Refer to table 2.2  1. Does the system come in direct contact with the part 2. Does the system provide an excipient or produce 3. Is the system used in cleaning/sterilizing? 4. Does the system produce data used to accept or	2.1, then proceed to Step 4  words and attach P&ID or schematic)  product? an ingredient or solvent?  reject product? control or manipulate the process in such a way to

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## **Table 3 Determine Component Impact**

Plant No. / FRS No.	System Name or Description / FRS	Basis used for Component Assessment							Commission	IQ	OQ	PQ
		1	2	3	4	5	6	7				
		1	2	3	4	5	6	7				
		1	2	3	4	5	6	7				
		1	2	3	4	5	6	7				
		1	2	3	4	5	6	7				
		1	2	3	4	5	6	7				
		1	2	3	4	5	6	7				
		1	2	3	4	5	6	7				
		1	2	3	4	5	6	7				
		1	2	3	4	5	6	7				
		1	2	3	4	5	6	7				

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