



IMPACT ASSESSMENT FORM - Computerised System Item

(Ref SOP VAL 045)

Description of the Inventory Item being assessed:	Equipment No:
Description of Master Item in the Computerised System to which this Item belongs:	Equipment No:

Not Programmed !	Programmed/Configured by	Programmed/Configured by: Ext. Contractor
Name of External Contractor (if applicable):		

Functions within the Inventory Item: <i>(Including Security Attributes and Data Management)</i>	GxP Direct Impact <i>(Incl. Quality risks)</i>	GxP Indirect Impact <i>(Incl. Quality risks)</i>	No GxP Impact & rationale
<p><i>Consider (Blue text to be removed):</i></p> <p><i>Discrete actions undertaken,</i></p> <p><i>What process information is sent to/from other items in the group,</i></p> <p><i>What machine control information is sent/received (e.g. healthy signals, alarms)</i></p> <p><i>How information is tracked (e.g. shift register),</i></p> <p><i>What records are generated (e.g. autoclave cycle records),</i></p> <p><i>What files are used (e.g. vision system models),</i></p> <p><i>How machine control parameters are altered (e.g. Operator Panels)</i></p> <p><i>Processing of inputs from sensors,</i></p> <p><i>Interactions with other systems (use of network drives, SCADA etc);</i></p> <p><i>Presence of control procedures (SOP's etc);</i></p> <p><i>Primary record (e.g. signed paper v. electronic record);</i></p> <p><i>Access control to and changeability of data and user-configured files;</i></p> <p><i>Back-up & recovery procedures.</i></p>	<p><i>Consider</i></p> <p><i>role/effect on:</i></p> <p><i>Identity, Safety, Efficacy, Purity and Evidence (GxP records).</i></p>		

Address of URS:

GAMP Category of this Inventory Item:	GAMPx	Rationale:
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Criticality Assessment of assessed Item per SOP VAL 045 (Combining GAMP Category and GxP Impact).	GAMPx-Cy
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Related Computerised Equipment in the group, if the Inventory Item being assessed is the Master Item.

Equipment No	Description	Criticality Assessment

! Guide to Validation requirements for Inventory Item (highest rated Function) per SOP VAL 045 and justification of any variations.

	C-1. Record Version, (with Commissioning & GEP Functional)
	C-2. Record Configuration & Version (with GEP Functional)
	C-3. Minimal Functional
	C-4. Some Functional, Min. Structural
	C-5. Extensive Functional, Extensive Structural

Variations:

Prepared by		Date:
Checked by	Electrical Services Manager, or Senior Electrical Engineer, or Comp. Systems Validation Mgr.	Date:

Assessment Version	Reason (with reference to Validation Plan/Change Requests)
	New