**IMPACT ASSESSMENT FORM - Computerised System Item**

*(Ref SOP VAL 045)*

<table>
<thead>
<tr>
<th>Description of the Inventory Item being assessed:</th>
<th>Equipment No:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Description of Master Item in the Computerised System to which this Item belongs:</th>
<th>Equipment No:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Not Programmed</th>
<th>Programmed/Configured by Programmed/Configured by: Ext. Contractor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of External Contractor (if applicable):</td>
<td></td>
</tr>
</tbody>
</table>

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

Address of URS:  
GAMP Category of this Inventory Item: *GAMP*  
Rationale:  
Criticality Assessment of assessed Item per SOP VAL 045 *(Combining GAMP Category and GxP Impact).*  
Relate Computerised Equipment in the group, if the Inventory Item being assessed is the Master Item.  
Equipment No Description Criticality Assessment:  

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

<table>
<thead>
<tr>
<th>Variations:</th>
</tr>
</thead>
</table>
| 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 Date:  

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