**Process Development plan**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Q-Pulse Reference | <Provided On Submission to QA> | | | | | | | |
| Process Development Plan Author |  | | | | | | | |
| Title |  | | | | | | | |
| New or Updated Process |  | | | | | | | |
| Submission Date of Plan |  | | | | | | | |
| Target End Date |  | | | | | | | |
| Scope of Trial (Limited or Full) |  | | | | | | | |
| Type | SOP |  | Form |  | GUI |  | Other |  |

**Summary**

*<Summary of the process and changes>*

**Stakeholders**

<Please describe who will be involved in the trial of the new process>

**Current Process**

*<Description of the current process (if applicable) including compliance with SOPs and regulations. Description of reason for amendment to current process*

*If no current process state None.>*

**New process**

*<Description of the new process including how this will comply with current SOPs and regulations or what SOP amendments will be required>*

**Validation**

*<Description of how the process will be validated, what measures will be in place and which stakeholders other than those listed above who will be involved in Independent Stakeholder Assessment.>*

**Deviation**

*<Please state if the new process will deviate from any existing SOPs>*