SOLABS QM VALIDATION DOCUMENTATION INDEX



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| **CONTROL NUMBER:**  INDEX-SOL-001  **DOCUMENT VERSION:** 1.0  **DOCUMENT OWNER (Company):** Client  **DOCUMENT AUTHOR(S):**  [Author] |

Document Approval

*We, the underneath signers, acknowledge to have thoroughly read, understood and agree with the content of the present document.*

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| **Document Approvers** | **Date (DD-MMM-YYYY)** |
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Document History

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| **Version** | **Date** | **Author** | **Changes** |
| 1.0 | Refer to cover page |  |  |

| **DOCUMENT NAME** | **SOLABS DOCUMENT #** | **Client DOCUMENT #** | **SOLABS**  **Approval** | **Client**  **Approval** |
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| **CORE Software** | | | | |
| Validation Plan | VP-SOL-001 | CVP-SOL-001 | N/A | X |
| Core Software Functional Specifications | FS-SOL-001 | N/A | X | N/A |
| Core Software Configuration and Design Specifications | CDS-SOL-001 | N/A | N/A | N/A |
| Client Environment Compatibility Assessment | CEA-SOL-001\* | CCEA-SOL-001 | N/A  (X if hosted) | X  (N/A if Hosted) |
| Client Software Configuration | CSC- SOL-001\* | CSC-SOL-001 | N/A  (X if hosted) | X  (N/A if Hosted) |
| Core Software Installation Qualification | IQ-SOL-001\* | CIQ-SOL-001 | N/A | X |
| Core Software Installation Qualification Summary Report | IQR-SOL-001\* | CIQR-SOL-001 | N/A | X |
| Core Software Operational Qualification Protocol (Release 10.1.1) | OQ-SOL-001\* | COQ-SOL-001 | N/A | X |
| Core Software Operational Qualification Protocol (Release 10.2.5) | OQP-SOL-002\* | COQ-SOL-001 | N/A | N/A |
| Core Software Operational Qualification Protocol (Release 10.3.1) | OQP-SOL-003\* | COQ-SOL-001 | N/A | N/A |
| Core Software Operational Qualification Protocol (Release 10.4 (first issue)) | OQP-SOL-004\* | COQ-SOL-001 | N/A | N/A |
| Core Software Operational Qualification Protocol (Release 10.4 (second issue)) | OQP-SOL-005\* | COQ-SOL-001 | N/A | N/A |
| Core Software Operational Qualification Protocol (Release 10.4 (third issue)) | OQP-SOL-006\* | COQ-SOL-001 | N/A | N/A |
| Core Software Operational Qualification Protocol (Release 10.4 (fourth issue)) | OQP-SOL-007\* | COQ-SOL-001 | N/A | N/A |
| Core Software Operational Qualification Protocol (Release 10.4 (fifth issue)) | OQP-SOL-008\* | COQ-SOL-001 | N/A | N/A |
| Core Software Operational Qualification Protocol (Release 10.4 (sixth issue)) | OQP-SOL-009\* | COQ-SOL-001 | N/A | N/A |
| Core Software Operational Qualification Protocol (Release 10.5.0) | OQP-SOL-010\* | COQ-SOL-001 | N/A | N/A |
| Core Software Operational Qualification Protocol (Release 10.5.1) | OQP-SOL-011\* | COQ-SOL-001 | N/A | N/A |
| Core Software Operational Qualification Protocol (Release 10.5.2) | OQP-SOL-012\* | COQ-SOL-001 | N/A | N/A |
| Core Software Operational Qualification Protocol (Release 10.5.3) | OQP-SOL-013\* | COQ-SOL-001 | N/A | N/A |
| Core Software Operational Qualification Protocol (Release 10.5.4) | OQP-SOL-014\* | COQ-SOL-001 | N/A | N/A |
| Core Software Operational Qualification Protocol (Release 10.6.0) | OQP-SOL-015\* | COQ-SOL-001 | N/A | N/A |
| Core Software Operational Qualification Protocol (Release 10.6.1) | OQP-SOL-016\* | COQ-SOL-001 | N/A | N/A |
| Core Software Operational Qualification Protocol (Release 10.7.0) | OQP-SOL-017\* | COQ-SOL-001 | N/A | N/A |
| Core Software Operational Qualification Protocol (Release 10.8.0) | OQP-SOL-018\* | COQ-SOL-001 | N/A | N/A |
| Core Software Operational Qualification Summary Report (Release 10.1.1) | OQR-SOL-001\* | COQR-SOL-001 | N/A | X |
| Core Software Operational Qualification Summary Report (Release 10.2.5) | OQR-SOL-002\* | COQR-SOL-001 | N/A | N/A |
| Core Software Operational Qualification Summary Report (Release 10.3.1) | OQR-SOL-003\* | COQR-SOL-001 | N/A | N/A |
| Core Software Operational Qualification Summary Report (Release 10.4.2) | OQR-SOL-004\* | COQR-SOL-001 | N/A | N/A |
| Core Software Operational Qualification Summary Report (Release 10.4.3) | OQR-SOL-005\* | COQR-SOL-001 | N/A | N/A |
| Core Software Operational Qualification Summary Report (Release 10.4.4) | OQR-SOL-006\* | COQR-SOL-001 | N/A | N/A |
| Core Software Operational Qualification Summary Report (Release 10.4.5) | OQR-SOL-007\* | COQR-SOL-001 | N/A | N/A |
| Core Software Operational Qualification Summary Report (Release 10.4.6) | OQR-SOL-008\* | COQR-SOL-001 | N/A | N/A |
| Core Software Operational Qualification Summary Report (Release 10.4.7) | OQR-SOL-009\* | COQR-SOL-001 | N/A | N/A |
| Core Software Operational Qualification Summary Report (Release 10.5.0) | OQR-SOL-010\* | COQR-SOL-001 | N/A | N/A |
| Core Software Operational Qualification Summary Report (Release 10.5.1) | OQR-SOL-011\* | COQR-SOL-001 | N/A | N/A |
| Core Software Operational Qualification  Summary Report (Release 10.5.2) | OQR-SOL-012\* | COQR-SOL-001 | N/A | N/A |
| Core Software Operational Qualification  Summary Report (Release 10.5.3) | OQR-SOL-013\* | COQR-SOL-001 | N/A | N/A |
| Core Software Operational Qualification  Summary Report (Release 10.5.4) | OQR-SOL-014\* | COQR-SOL-001 | N/A | N/A |
| Core Software Operational Qualification  Summary Report (Release 10.6.0) | OQR-SOL-015\* | COQR-SOL-001 | N/A | N/A |
| Core Software Operational Qualification  Summary Report (Release 10.6.1) | OQR-SOL-016\* | COQR-SOL-001 | N/A | N/A |
| Core Software Operational Qualification  Summary Report (Release 10.7.0) | OQR-SOL-017\* | COQR-SOL-001 | N/A | N/A |
| Core Software Operational Qualification  Summary Report (Release 10.8.0) | OQR-SOL-018\* | COQR-SOL-001 | N/A | N/A |
| Core Software Traceability Matrix | TRM-SOL-001 | N/A | N/A | N/A |
| Core Software Performance Qualification | N/A | CPQ-SOL-001 | N/A | X |
| Core Software Performance Qualification Summary Report | N/A | CPQR-SOL-001 | NA | X |
| 21 CFR Part 11 Assessment | N/A | CCFR-SOL-001 | N/A | X |
| Environment Configurations for SOLABS QM10 | N/A | EC-SOL-001 | N/A | N/A |
| **Users and Roles Migration** | | |  |  |
| Users-Roles Migration Spreadsheet | N/A | UR-SOL-001 | N/A | N/A |
| Users-Roles Migration Qualification Protocol (and test scripts) | N/A | COQP-URMIG-SOL-001 | N/A | X |
| Users-Roles Migration Qualification Summary Report | N/A | COQR-URMIG-SOL-001 | N/A | X |
| **Processes** | | |  |  |
| **Document Control Process (P007)** | | |  |  |
| Document Control Process User Functional and Design Specifications | PUFDS-DOC-SOL-007 | N/A | N/A | N/A |
| Installation & Operational Qualification Protocol for the Document Control Process | PIOQ-DOC-SOL-007\*\* | CPIOQ-DOC-SOL-007 | N/A | X |
| Installation & Operational Qualification Protocol for the Document Control Process (Release 2.X) | PIOQ-DOC-SOL-007(2)\*\* | CPIOQ-DOC-SOL-007 | N/A | N/A |
| Installation & Operational Qualification Protocol for the Document Control Process (Release 2.4.2) | PIOQ-DOC-SOL-007 – 3\*\* | CPIOQ-DOC-SOL-007 | N/A | N/A |
| Installation & Operational Qualification Protocol for the Document Control Process (Release 2.5.0) | PIOQ-DOC-SOL-007 – 4\*\* | CPIOQ-DOC-SOL-007 | N/A | N/A |
| (Installation & Operational Qualification Protocol for the Document Control Process (Release 2.5.1) | PIOQ-DOC-SOL-007 – 5\*\* | CPIOQ-DOC-SOL-007 | N/A | N/A |
| (Installation & Operational Qualification Protocol for the Document Control Process (Release 3.0.0) | PIOQ-DOC-SOL-007 – 6\*\* | CPIOQ-DOC-SOL-007 | N/A | N/A |
| (Installation & Operational Qualification Protocol for the Document Control Process (Release 3.1.0) | PIOQ-DOC-SOL-0007 – 7\*\* | CPIOQ-DOC-SOL-0007 | N/A | N/A |
| Installation & Operational Qualification Summary Report for the Document Control Process | PIOQR-DOC-007\*\* | CPIOQR-DOC-SOL-007 | N/A | X |
| Installation & Operational Qualification Summary Report for the Document Control Process (Release 2.2) | PIOQR-DOC-SOL-007(2)\*\* | CPIOQR-DOC-SOL-007 | N/A | N/A |
| Installation & Operational Qualification Summary Report for the Document Control Process (Release 2.4.2) | PIOQR-DOC-SOL-007 – 3\*\* | CPIOQR-DOC-SOL-007 | N/A | N/A |
| Installation & Operational Qualification Summary Report for the Document Control Process (Release 2.5.0) | PIOQR-DOC-SOL-007 – 4\*\* | CPIOQR-DOC-SOL-007 | N/A | N/A |
| Installation & Operational Qualification Summary Report for the Document Control Process (Release 2.5.1) | PIOQR-DOC-SOL-007 – 5\*\* | CPIOQR-DOC-SOL-007 | N/A | N/A |
| Installation & Operational Qualification Summary Report for the Document Control Process (Release 3.0.0) | PIOQR-DOC-SOL-007 – 6\*\* | CPIOQR-DOC-SOL-007 | N/A | N/A |
| Installation & Operational Qualification Summary Report for the Document Control Process (Release 3.1.0) | PIOQR-DOC-SOL-0007 – 7\*\* | CPIOQR-DOC-SOL-0007 | N/A | N/A |
| Document Control Process Traceability Matrix | PTRM-DOC-SOL-0007 | N/A | N/A | N/A |
| **Data Migration** | | |  |  |
| Migration User Requirement Specification | N/A | CURS-MIG-SOL-001 | N/A | X |
| Migration Operational Qualification Protocol (and test scripts) | N/A | OQP-MIG-SOL-001 | N/A | X |
| Migration Operational Qualification Summary Report | N/A | OQR-MIG-SOL-001 | N/A | X |
| **QM Apps** | | | | |
| **OTS Process Name** |  |  |  |  |
| Process User Functional and Design Specifications | TBD | N/A |  |  |
| Process Traceability Matrix | TBD | N/A |  |  |
| Process Installation & Operational Qualification Protocol | TBD | N/A |  |  |
| Process Installation & Operational Qualification Summary Report | TBD | N/A |  |  |
| Client Process Installation & Operational Qualification Protocol | TBD | TBD |  |  |
| Client Process Installation & Operational Qualification Summary Report | TBD | TBD |  |  |
| **MEMO** | | | | |
| Handover Assessment Memo | N/A | N/A | X | X |

Notes:

* The letter “C” at the beginning is used to identify a client document and the letter “R” added to a document number is used to identify a summary report.
* Documents identified with a \* sign are referenced in the client Core Software Operational Qualification document (COQ-SOL-001).
* Documents identified with a \*\* sign are referenced in the client Document Control Process Installation & Operational Qualification document (CPIOQ-DOC-SOL-007).
* “TBD” indicates document number is not known at the time this document was issued.