

Validation Packet

Provide Your Organization With the Resources to Optimize Validation of Your Advarra EDC Instance

Advarra EDC

Streamline your data collection and management while ensuring the security and integrity to fully support validation and compliance with 21 CFR Part 11.

Advarra has compiled validation documents to reduce your testing burden when validating the Advarra EDC system for your use. All organizations receive site specific Installation Qualification documentation. A User Requirements Specification (URS) which outlines user requirements for the Advarra EDC system, is available on the Advarra EDC Learning Portal.

For further resources to assist in your validation, your organization can purchase an annual subscription of validation materials. This subscription provides additional documentation that can be incorporated into your validation process to reduce the testing and documentation burden for your team.

Validation Packet Materials

Validation plan

Describes the activities, deliverables and resources necessary to execute test suites for the Advarra EDC system. Covers installation and operation qualification on a customer simulated implementation.

Traceability matrix and test suite approvals

Links each test suite to the requirements to ensure full coverage of testing.

Installation qualification report

Documents the instructions followed and objective evidence that the installation and configuration of the Advarra EDC validation instance was successful.

Executed test suites

Complete Test Suites with objective evidence filled in and a minimum of one screenshot per test suite.

Validation summary report

Describes the activities, deliverables and resources used to qualify the EDC system, in addition to outlining the validation acceptance criteria and a results summary.