21 CFR PART 11 COMPLIANCE FACT SHEET

As part of Innovit's Master Data Management and UDI Multi-Connector solution, medical device data will be reported to the FDA. This requires compliance with 21 CFR Part 11 regulations.

21 CFR PART 11

Title 21 of the Code of Federal Regulations establishes the United States FDA's regulation on electronic records and electronic signatures (ERES). Part 11 sets out how a company operating in the US can use electronic quality records and digital signatures in place of paper-based documentation and 'wet signatures' in such a way that complies with FDA regulations.

Compliance is essential for those FDA regulated companies that wish to use electronic quality records and electronic signatures to comply with FDA regulations faster and more efficiently (in lieu of their paper-based and ink-based counterparts).

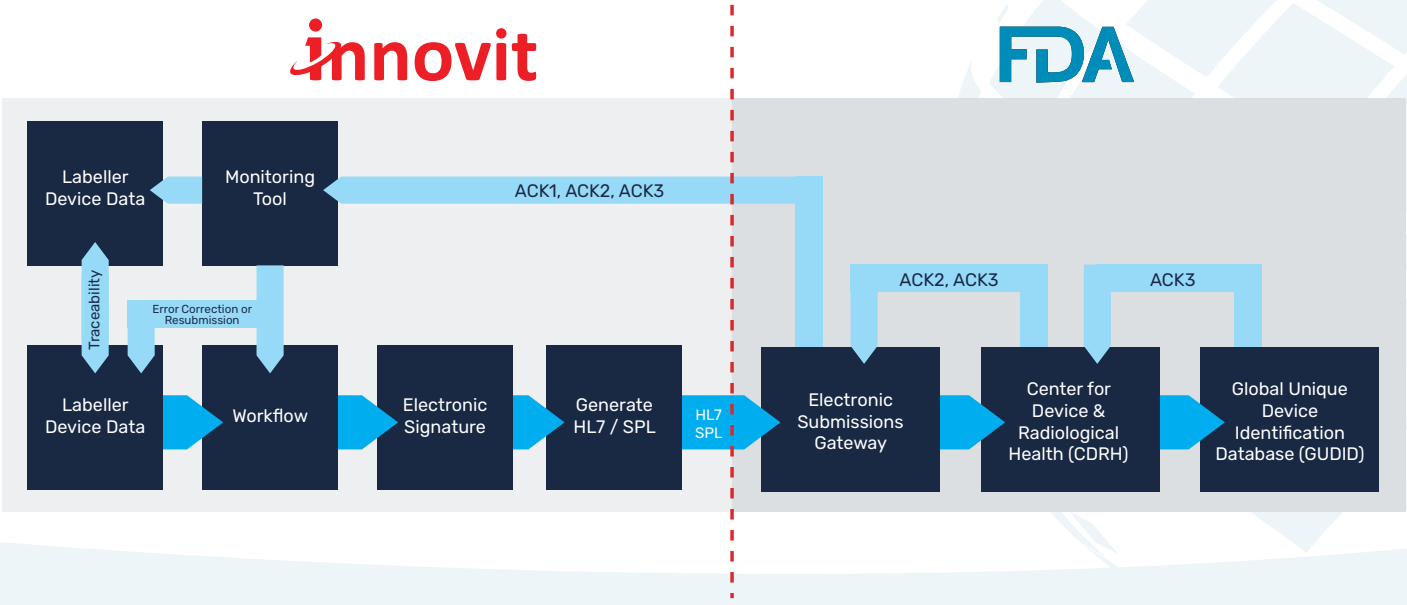
Innovit's MDM and UDI solution is an open computer system, which means the system access may not be controlled by individuals who are responsible for the content of electronic records on the system. Per 21 CFR Part 11, open computer systems must include controls to ensure that all records are authentic, secure, incorruptible and (where applicable) confidential.

HOW DOES INNOVIT SUPPORT 21 CFR PART 11?

- Versioning and change history are stored for all device records to enable full audit trail
- E-signature is enforced for final submission to the GUDID capturing the printed name of the signer, date/time the signature was applied and the meaning of the electronic signature; E-signatures are unique to a person and cannot be re-used
- Confidential information is masked from users who do not need the information to perform their jobs
- Procedural and automated controls exist to ensure that:
  - No two individuals have the same user ID and password
  - Passwords are periodically checked and expire
  - Loss management procedures exists to deauthorize lost, stolen or missing passwords

TRACEABILITY AND DATA RETENTION

To ensure and verify compliance Innovit provides the ability to track UDI Submissions throughout the lifecycle of the device. It provides visibility to all 3 levels of acknowledgement (ACKs) which ensure successful submission to the GUDID.



- ACK1, ACK2, ACK3
  - ACK1 message from the Electronic Submissions Gateway (ESG) - the system will confirm the success or failure of the UDI data message to the ESG; if the initial communication fails, the system will notify the user
  - ACK2 message from the Center for Device and Radiological Health (CDRH) - the system will record the success or failure of the UDI record routing to the CDRH
  - ACK3 message from the Global Unique Device Identifier Database (GUDID) - the system will record the success or failure of the UDI record routing to the GUDID
- The transaction logs in Innovit's UDI solution contain important identifiers to help track device submissions:
  - SetID - Global Unique Identifier which is a unique identifier for the device that remains constant through all versions/revisions of the device record
  - CoreID - A unique identifier which the FDA Electronic Secure Gateway (ESG) assigns to every submission; this core ID should be used to refer to a Gateway SPL submission
- Compliance with 21 CFR Part 11 record retention requirements are supported by Innovit's UDI Device Submission Record including:
  - Complete set of GUDID data attributes at the time of submission
  - UDI Device Submission Record is designed to be stored in perpetuity
  - Capability to view and/or print an UDI Device Submission Record

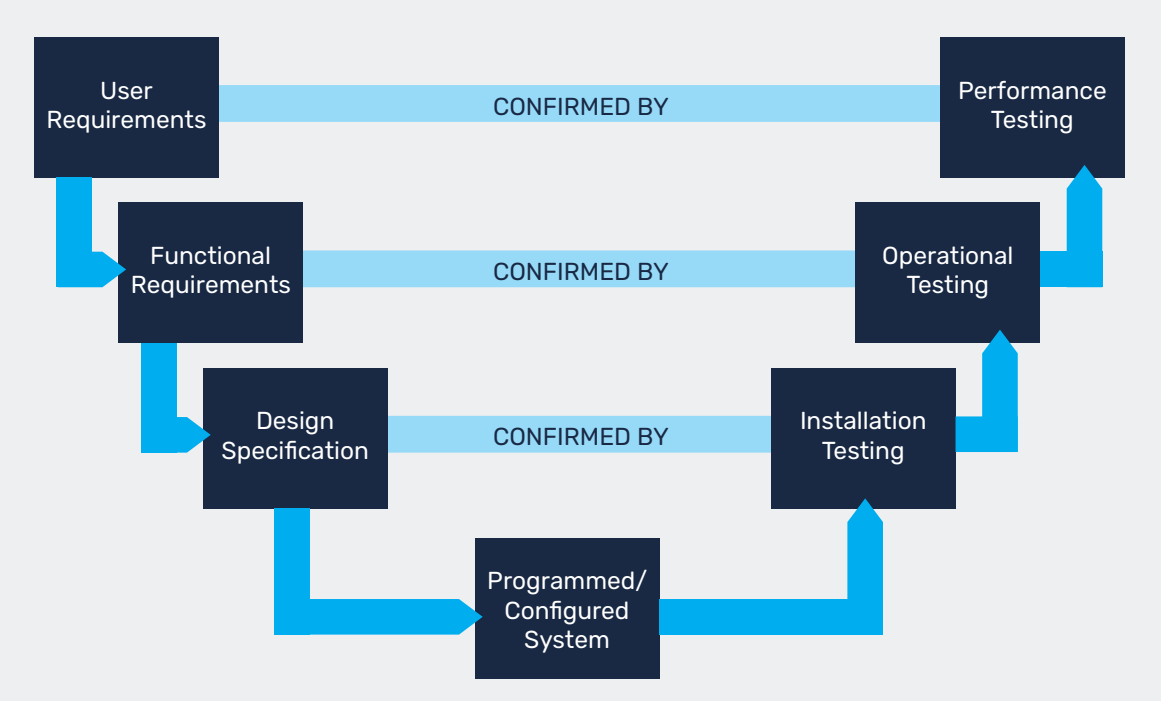
innovit

Tel: +1 512 730 3800
Fax: +1 888 478 4438

www.innovit.com
400 Concar Drive
San Mateo
CA 94402 USA

COMPUTER SYSTEM VALIDATION

Validation is a systematic documentation of system requirements, combined with documented testing, demonstrating that the computer system meets the documented requirements. Computer System Validation (CSV) is often portrayed in terms of the "V Model" below.



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HOW DOES INNOVIT SUPPORT COMPUTER SYSTEM VALIDATION?

Innovit's MDM and UDI Multi-Connector system is highly configurable and falls under GAMP 5, Category 4 Configurable Software for Validation purposes.

Innovit can work with your IT and Quality Assurance organization to streamline your Computer System Validation process and minimize these costs. Documentation in support of the following can be provided to augment your Innovit MDM and UDI Multi-Connector Validation Plan.

- Architecture Diagram
- System Requirements Specification
- User Requirements Specification
- Requirements Traceability Matrix
- Standard Operating Procedures (SOPs) for software development, QA, implementation and support
- Installation Qualification (IQ) where Innovit is hosting the system (for client-hosted deployments, we offer consulting services to help with preparing IQ documentation)
- Operational Qualification (OQ)
- Performance Qualification (PQ)