

Tricentis Vera and qTest: Compliance in Agile testing

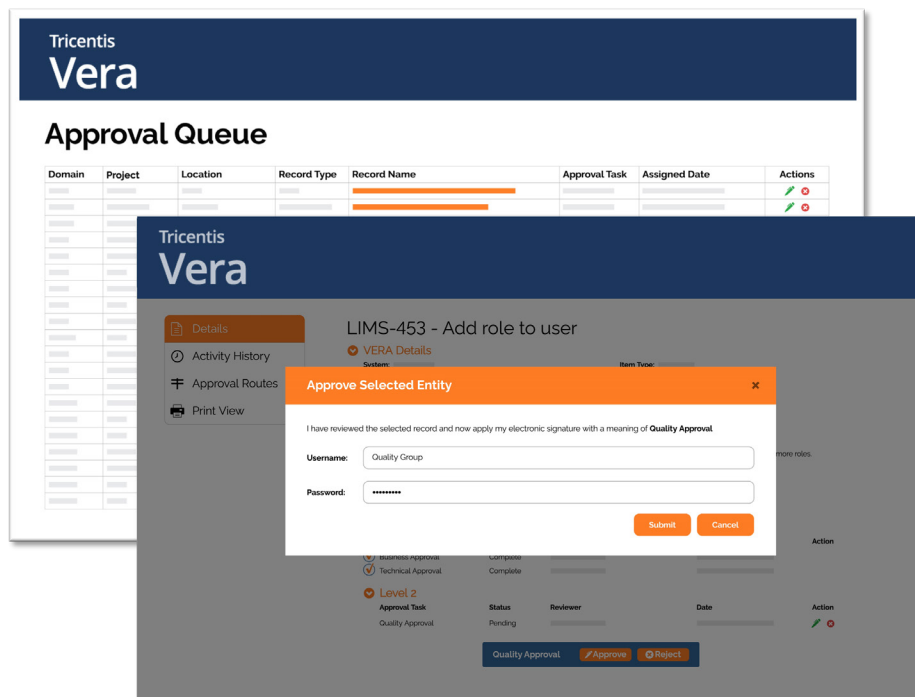
Agile testing challenges in computer systems validation

Increased demands around agile and digital transformation initiatives continue to complicate an already complex regulatory compliance landscape. With the Business demanding higher quality builds at faster speeds than ever before, traditional validation and documentation frameworks are struggling to support the needs of those objectives. IT needs modern tools and methodologies to meet the demands of the Business, but QA and Regulatory teams need to ensure compliance is met, leaving many organizations struggling to find a viable solution.

Leading technology to enable compliance in agile frameworks

The Composition of Compliant, Agile Test Management

As a leading Digital Validation solution, Tricentis Vera was designed to simplify computer systems validation and address the needs of modern testing teams. The tight integration with qTest provides the features and technical controls to enable 21 CFR Part 11 and FDA compliance throughout the testing lifecycle and can be extended even further to support qTest's Jira integration. This allows Vera to control Jira and qTest data while standardizing and centralizing review/approvals across tools and teams - all without restricting core functionality or requiring customization.



The image displays two overlapping screenshots of the Tricentis Vera application interface. The background screenshot shows the 'Approval Queue' page with a table listing various records. The foreground screenshot shows a detailed view of a record titled 'LIMS-453 - Add role to user'. This view includes a sidebar with navigation options like 'Details', 'Activity History', 'Approval Routes', and 'Print View'. A modal window titled 'Approve Selected Entity' is open, containing a confirmation message and input fields for 'Username' (set to 'Quality Group') and 'Password'. Below the modal, there is a table showing the approval process for 'Level 2' with columns for 'Approval Task', 'Status', 'Reviewer', and 'Date'. At the bottom, there are 'Approve' and 'Reject' buttons.

Domain	Project	Location	Record Type	Record Name	Approval Task	Assigned Date	Actions

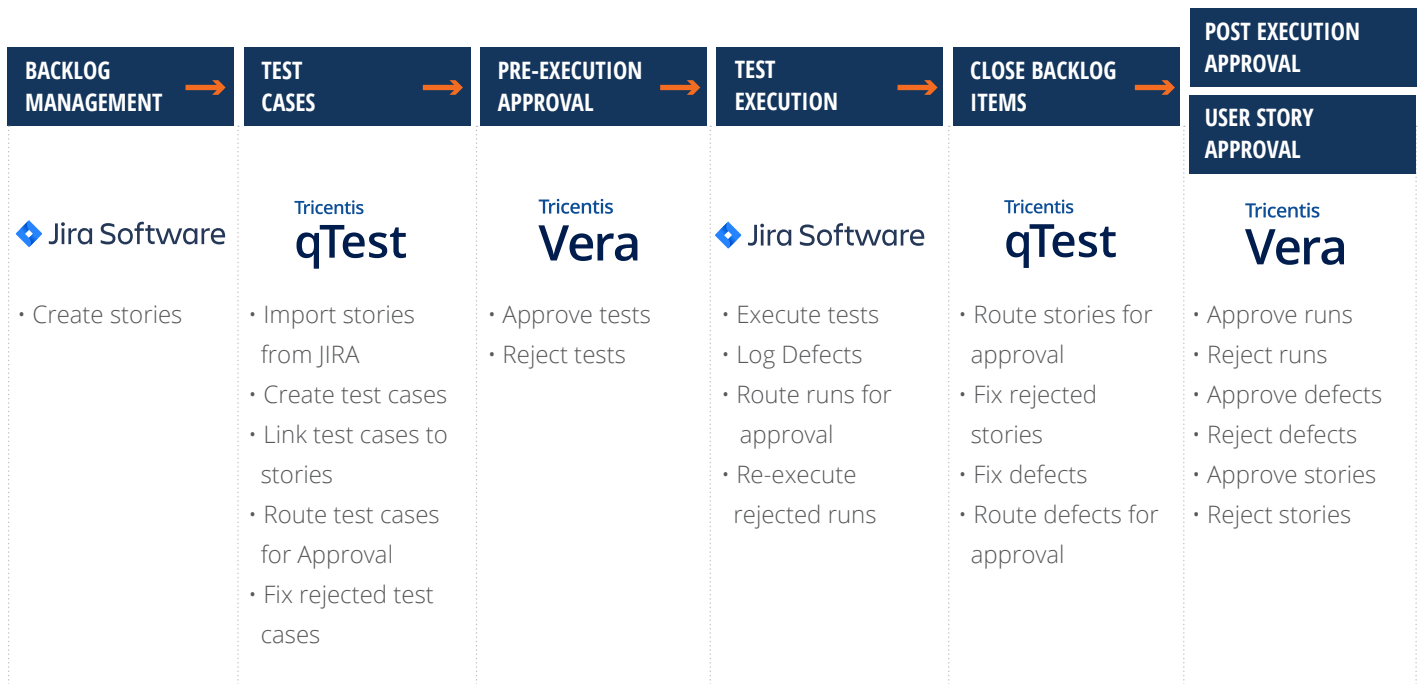
More than just electronic signatures

With Tricentis Vera, Digital Validation means more than just applying electronic signatures to digitize document-based validation. Review/approval tasks, electronic signatures, and technical controls are tightly integrated into qTest and Jira work-streams at the data level to accelerate project delivery while drastically reducing the risk of human error across the CSV lifecycle. By seamlessly inserting validation features and automating the capturing of associated data, Vera allows teams to shed cumbersome, extraneous documentation practices and instead achieve compliance as a byproduct of good software quality practices with supporting electronic records.

Solution benefits include:

- 21 CFR Part 11 Compliance
- Replace the use of traditional documents with electronic records
- SDLC record traceability
- Single UI to manage review and approval tasks across teams and tools
- Automate regulatory compliance tasks
- Lock records in qTest and Jira
- Seamlessly embed and capture compliance deliverables
- Controls to ensure adherence to defined processes
- Configurable approval routes
- Approve or reject records on the fly
- Seamless record revision process
- Vera acts as the single system of record

Tricentis Vera: Common workflow scenario



DISCLAIMER: Note, the information provided in this statement should not be considered as legal advice. Readers are cautioned not to place undue reliance on these statements, and they should not be relied upon in making purchasing decisions or for achieving compliance to legal regulations.