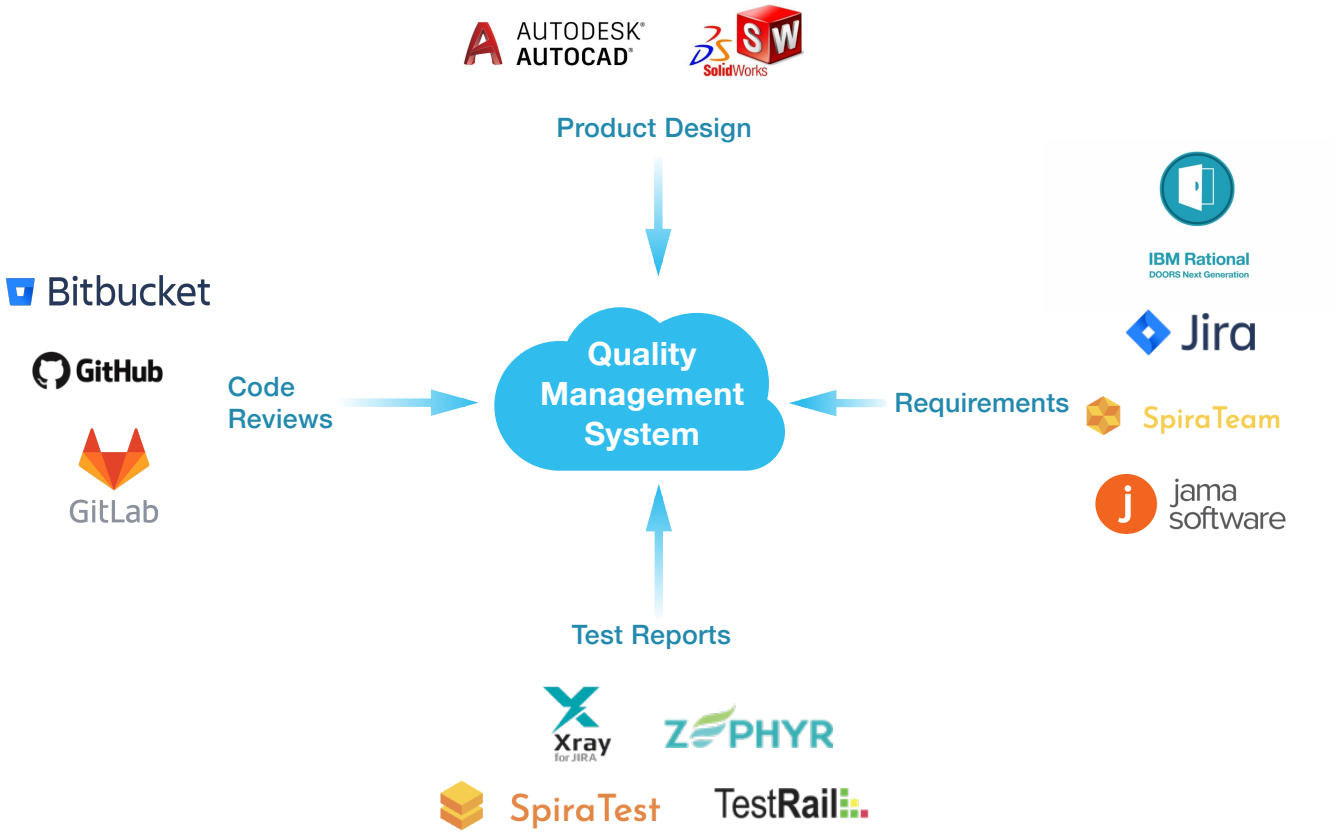
SierraLabs

Quality Management System

QMS with 21 CFR Part 11 compliance and application development integration

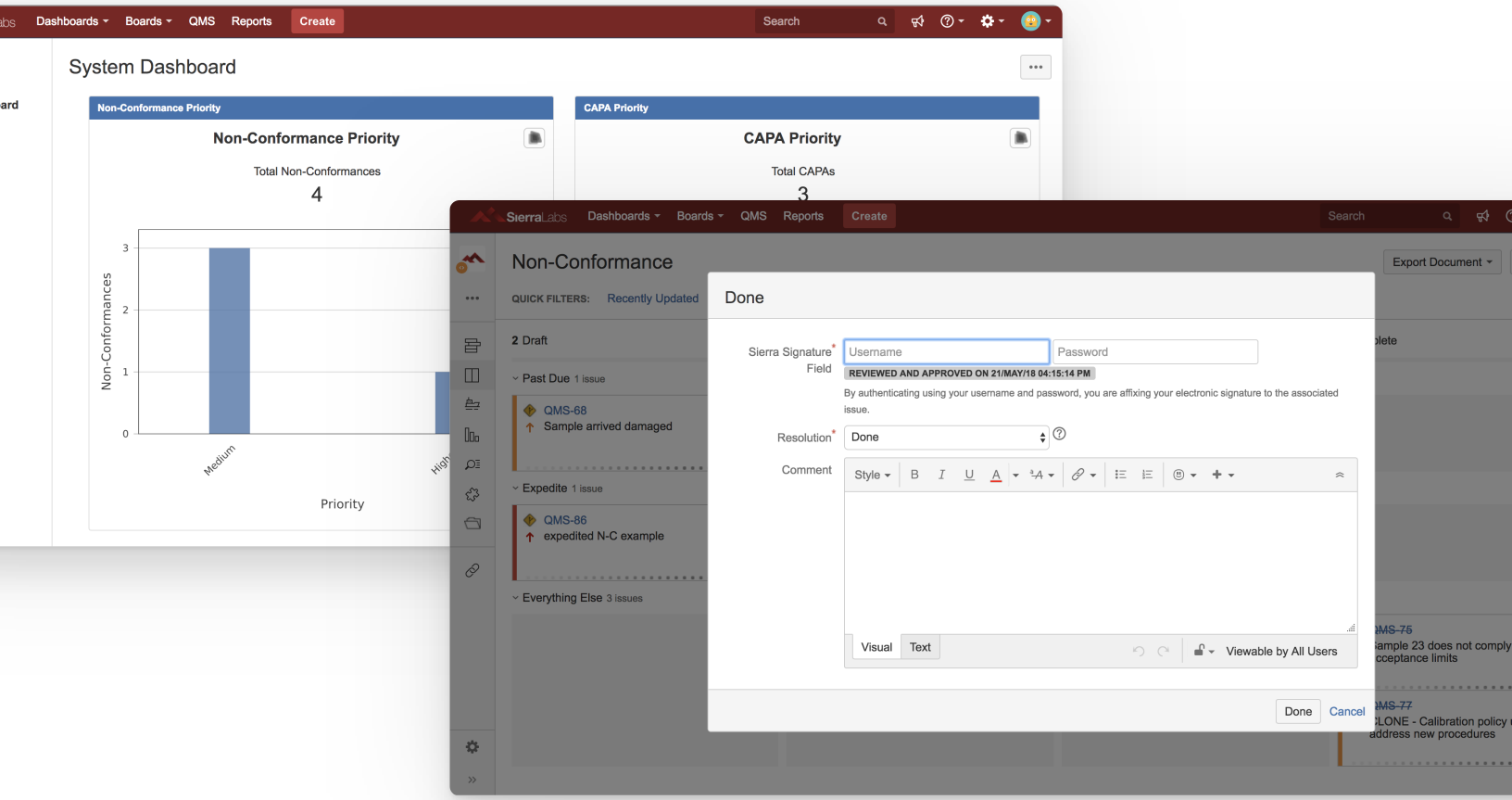
Solution Overview

The Sierra Labs Quality Management System (QMS) application is designed to support management of documents, trainings, non-conformances, CAPAs, and audit events to show compliance with GxP validation and verification processes and 21 CFR Part 11 requirements. The QMS also automates the publishing of validation artifacts (such as user requirements, functional specifications, code review reports, etc.) from other applications. The following diagram illustrates example integrations with the QMS from different areas of product and application development:



Compliance Procedures

Configure your teams workflows for managing CAPAs, non-conformances, and document trainings. Electronic signatures can be applied to all items for recording approvals directly in the system. Dashboards and notifications are configurable to make sure your team can quickly access the information they need to stay compliant.

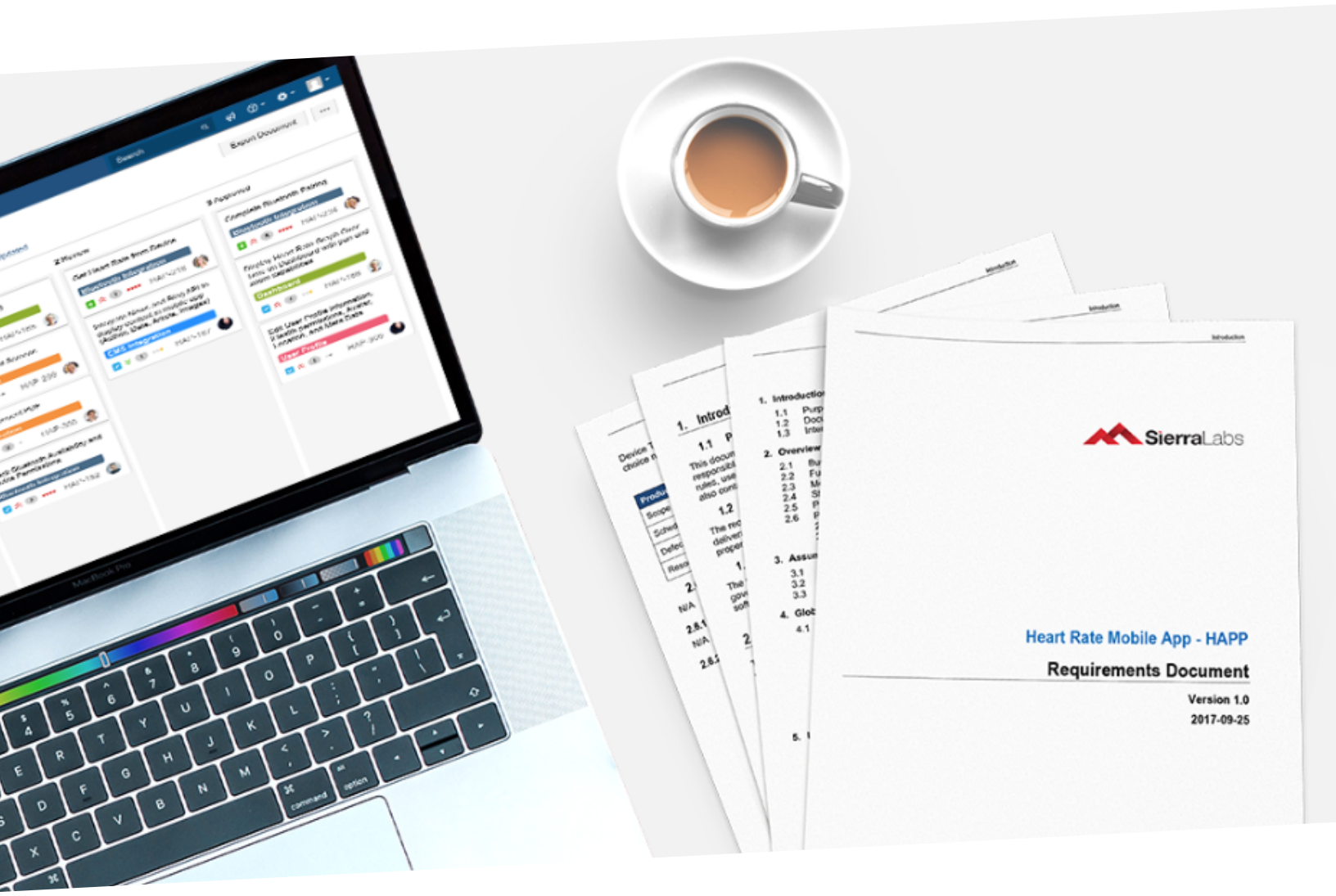


- Create and track non-conformance and CAPAs with deep linking to related policies, audit events, trainings, and other related items. Dashboard to quickly monitor non-conformance and CAPA status.
- Apply a 21 CFR Part 11 compliant electronic signature to all approved items and view associated audit trail.

Automated Publishing

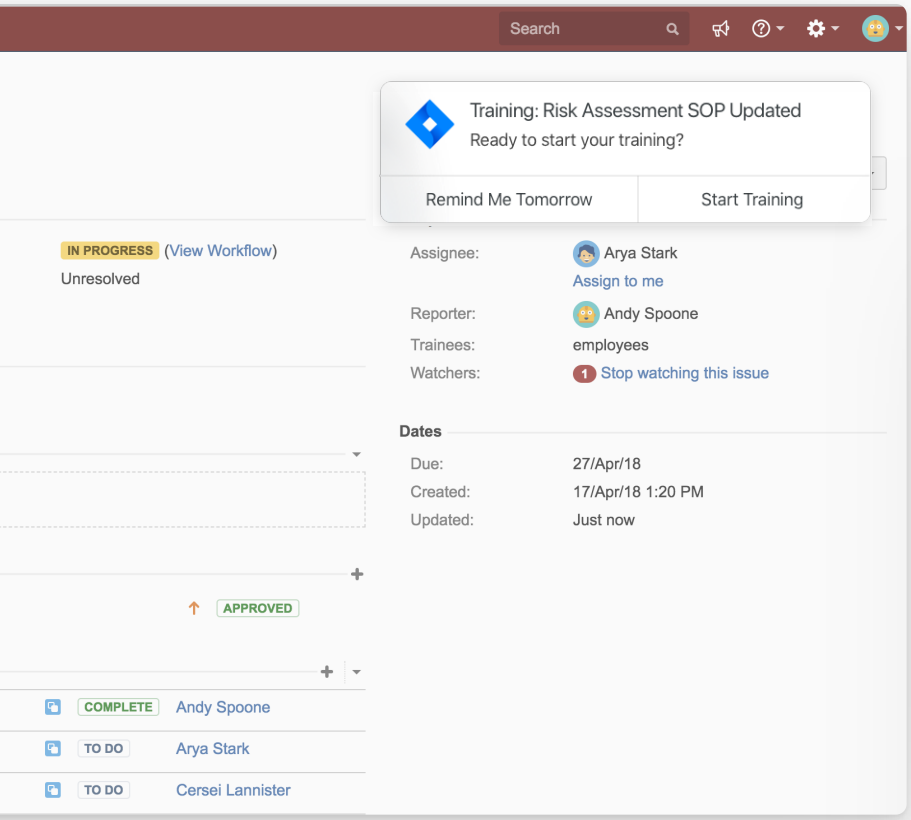
Generate validation artifacts directly from source data in application lifecycle projects in Jira. The published documents can be transitioned through approval workflows using the QMS and exported to PDF format for presenting or sharing with auditors.

- Automate the publishing of user requirements, functional specification, code review reports, and other validation artifacts during release cycles.

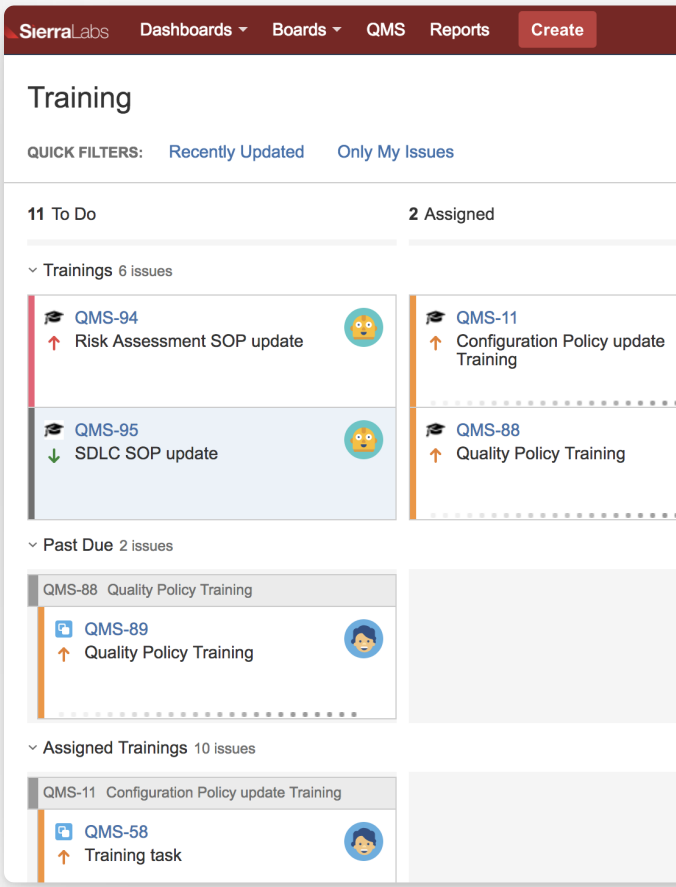


Automated Training

Automate the assigning and notifications of required document trainings when new users are onboarded or when procedures and policies are revised. Users can quickly locate their assigned trainings and move them through simple workflows with electronic signatures to confirm their reading and understanding of policies.



- Auto assign training tasks to users and monitor training status with custom notifications and reports.



- Quickly view trainings based on due date, priority, and status.
- Access controls restrict visibility and available actions to the assigned user.

About Us

Sierra Labs is focused on aligning engineering/IT teams with quality and compliance teams in FDA regulated environments. Our QMS, cloud validation, and automation products are designed to be easily adaptable in pre-existing workflows and assist teams in producing validation and verification artifacts needed in high quality environments.

For more information, visit sierralabs.com.

Set up a demo with us.

Connect with us! We're compliance experts who can help you.

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