AODocs for Life Sciences: Continuous Validation

The framework for ensuring your quality management solution can accelerate the delivery of business solutions in highly regulated environments

Transforming Compliance

How does AODocs ensure "Continuous Validation" for registered AODocs libraries and applications?
The underlying Google Cloud / G-Suite Infrastructure is constantly changing, in fact, the AODocs platform has major releases scheduled 3-4 times a year, with supporting patches and minor improvements deployed periodically between those scheduled releases. This would make traditional "regulatory validation" processes difficult to maintain. Thus AODocs leverages a "Continuous Validation" framework to mitigate these risks and ensure that AODocs libraries and applications are maintained in a validated state.

Platform

Automated Qualification processes supports 3-4 major releases a year and every feature and service patch for the AODocs Platform

Solutions

Customer libraries and applications registered for "Continuous Validation" are provided and processed during the delayed release cycle afforded those domains, typically 30 days.

Innovate

New features and functions can be leveraged quickly to improve business processes and adoption.

The framework is supported by the AODocs QMS system. Based on industry standards as well as applicable GxPs. This framework is based on ISO 9001:2015, GAMP5, and ASTM E2500 as well as FDA 21 CFR Part 11, EudraLex Annex 11. AODocs QMS enables us to deliver our managed services that not only meets, but exceeds the expectations of regulatory agencies in the USA, Europe, and Japan.

Build your Quality Program with Confidence Using AODocs for Life Sciences

Framework Features

This framework contains all the key artifacts for each installation of the AODocs platform on the customer's domain and those registered applications or libraries needing to have a validated state maintained.

AODocs Platform

- Risk Assessment
- Specification Definition
- Traceability Matrix
- Test Model Validation
- Automated Test Execution
- Validation Reporting

AODocs Applications & Libraries registered for continuous validation

- Intended Use Definition
- Test Automation Scripts
- Automated Test Execution
- Audit Trail/Reporting
- Validation Reporting Portal

FDA 21 CFR Part 11 for Electronic Records

- Single Sign On (SSO) Authentication
- Permissions Integration
- Immutable Audit Log
- Electronic Signatures 3rd party authentication challenge

AODocs for Life Sciences

A modern quality management solution designed to accelerate the delivery of business solutions in FDA-regulated companies

Learn More

AODocs is the only document management and business process platform fully integrated with G Suite, allowing organizations in all industries to easily control their documents, scale their business-critical processes, and meet compliance requirements — all while enhancing user experience.

Replacing legacy ECM platforms with a cloud-based, collaborative platform, AODocs dramatically reduces the time and money spent maintaining IT systems. AODocs' patented business process platform is used by Google and recommended for G Suite.

Headquarters
149 East 36th Street
New York, NY 10016

info@aodocs.com
www.aodocs.com