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.

How does AODocs provide for 21 CFR Part 11, Electronic Records; Electronic Signatures?

The AODocs Platform in conjunction with AODocs libraries and applications registered for Continuous Validation can fulfill all the provisions in CPG 7153.17: Enforcement Policy: 21 CFR Part 11; Electronic Signatures;

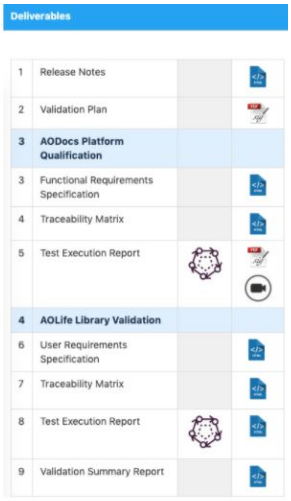
- Validation
- Time Stamps
- Maintenance
- Copies

We do this through a combination of our platform security and permissions integration with Google Authentication and immutable AODocs Audit Log to establish authorizations and controls of those closed applications. Also to fulfill those requirements used to document the fact that certain events or actions occurred in accordance with the predicated rule e.g. Electronic Signatures, AODocs supports 3rd party authentication challenge via mobile or external apps, with DUO and Okta our most common customer choices.

These combined, provide closed systems with the assurance needed to assert full control and authenticity of their processes and documents.

Validation Health Portal

- Artifacts updated at each release through change control
- Standard Platform Qualification
- Validation of Customer's Library
- GxP Compliant Validation Reports



Modules Available

- Document Control
- Change Management Training & Acknowledgement Records
- Corrective Action, Preventative Actions (CAPA)
- Audits
- Quality Events
- Customer Complaints, Non-Conformity
- Post market activity