

ARCC Infrastructure for Documentum

Audit Ready Compliant Cloud for Life Science Applications

ARCC for DOCUMENTUM HIGHLIGHTS

ARCC is an Audit Ready Compliant Cloud Infrastructure for the Life Science Industry that enables Documentum Users to take Complexity, Cost and Risk out of obtaining, deploying and managing a qualified and validated cloud solution to support life sciences workloads and regulations.

ARCC enables Documentum users to host and have managed Electronic Document Management System (EDMS), electronic Common Technical Documents (eCTD) software and FDA gateway applications in a single regulated environment.

ARCC's FDA 21 CFR Part 11 Qualified Infrastructure provides clients and their software partners' immediate time to market advantage combined with data integrity, privacy, security and regulatory compliance.

ARCC supports our clients' test, development and live production environments.

ARCC has predefined IQs for both Documentum and software built on Documentum.

ARCC brings together Documentum, Captiva and EMC Document Sciences xPression together with other applications that need to reside in a qualified environment.

ARCC enables Life Science Clients to host multiple applications in the qualified environment.

Life Science Challenges and Regulation:

- ❖ It is currently a confusing and exhaustive process for Life Sciences companies to obtain FDA and EU approval
- ❖ Regulatory requirements are now forcing Life Science companies to be highly automated.
- ❖ 2017 is the deadline for meeting the electronic storage regulatory requirements (PDUFA)
- ❖ Building, maintaining, and managing FDA 21 CFR Part 11 qualified environments is a significant challenge for Life Science Companies.
- ❖ Rapid scale and expansion support is necessary to insure faster time to value by accelerating the product development lifecycle.



Good System Practice for Documentum

Safe and Secure – Messages, documents and intellectual properties are stored in a safe and secure environment. (SSAE16 collocation facility)

Back Up and Restore – Files, documents, and messages are backed up daily.

Scalable – We grow with your company.

Regulatory Compliant Qualified Infrastructure – Meets regulatory requirements for qualification while providing a scalable platform to host multiple applications for **FDA 21 CFR Part 11** compliance validation.

Flexible – Ability to host multiple applications in the same environment.

Security Policy and Procedure Samples

- ❖ CS-POL-020 Master Security Plan
- ❖ SE-POL-001 Network Logging
- ❖ SE-POL-002 Intrusion Detection
- ❖ SE-POL-003 Web Services Security
- ❖ SE-POL-004 Security Risk Acceptance
- ❖ SE-POL-005 Network Log Review
- ❖ SE-POL-007 Privileged Accounts
- ❖ SE-POL-008 Cisco Network Device Compliance Policy
- ❖ SE-POL-011 Firewall Security Policy
- ❖ SE-SOP-014 Network Intrusion Detection System (IDS)
- ❖ SE-SOP-015 Microsoft Server Vulnerability Assessment
- ❖ SE-WRK-001 Password Audit
- ❖ SE-FRM-009 Security Risk Acceptance

ARCC's Datacenter for Documentum

Customers have uninterrupted access to the information systems they need in order to do business.

PHYSICAL FEATURES

- 62,000 Sq/Ft, total building size
- 27,000 Sq/Ft of raised floor across 3 floors
- One (1) individual room or command center

POWER MANAGEMENT

- Supported by UPS and diesel generation
- Four (4) 750KW Diesel Generator (1000 KVA)
- Automatic Transfer Switch
- Liebert SitesScan monitoring system

ENVIRONMENTAL CONTROLS

- Protected by a pre-action sprinkler system

PHYSICAL SECURITY

- Integrated card reader security system
- Closed circuit TV throughout the facility

CONNECTIVITY

- Network connectivity with other SunGard facilities provides maximum flexibility
- 100+ miles of CAT-5 data cable
- 2 hour fire wall surrounds entire data center
- SunGard Global Network Access
- Net ReDirect – On Demand DS1 & DS3
- Web ReDirect – Up to two (2) 100 Mbps

- Platforms supported: Remote testing command center
- 5,000 Sq/Ft of AdvancedRecoverySM space
- 10,000 gallon fuel tank good for 72 hours at the current load
- Siemens switches
- Six (6) (3 A side and 3 B side) Liebert 500 KVA UPS
- 560-ton of Liebert cooling total on the raised floors
- Exterior security cameras
- 24/7 Security Service
- AT&T Frame DRO
- Verizon Business Frame Relay PVC ReDirect
- Verizon
- Verosity
- LightTower – Dark fiber – multi points of entry
- ISDN BRI & PRI

ARCC is an Audit Ready qualified and compliant cloud Infrastructure designed specifically for the Life Sciences Industry. The solution is based on Court Square Group's 30 years of Good Systems Practice (GSPSM) and Regulatory Reference Architecture for maintaining an FDA 21 CFR Part 11 qualified environment for the Life Science industry.