



**Addendum A: ENSURCloud
Service Level Agreement (SLA)**



ENSURCloud Service Level Agreement

TABLE OF CONTENTS

1. OVERVIEW 3

 1.1 Definitions and Abbreviations 3

2 DUTIES AND RESPONSIBILITIES 4

 2.1 Scope and Segregation of Services 4

 2.2 Roles and Responsibilities 5

3 SUPPORT..... 6

 3.1 Scope 6

 3.2 Priorities 6

 3.3 Availability..... 6

 3.4 Service Methods 7

 3.5 Response Times 7

4 CHANGE MANAGEMENT 8

5 MAINTENANCE..... 8

 5.1 Application Installation 8

 5.2 Application Updates..... 8

 5.3 Platform Software Updates..... 9

 5.4 Emergency Maintenance..... 9

 5.5 Timeframes..... 9

 5.6 Logging..... 10

6 BACKUP AND DISASTER RECOVERY 10

 6.1 Backups 10

 6.2 Disaster Recovery 10

 6.3 Timeframes..... 11

7 MONITORING..... 11

 7.1 Trigger-Based Alarms 11

8 IaaS AVAILABILITY..... 12

9 ACCEPTABLE USE..... 12

10 ADDITIONAL SERVICES 12

 10.1 Validation Services 13

 10.2 User Training..... 13

 10.3 Environment Duplication 13

 10.4 Custom Development..... 13



ENSURCloud Service Level Agreement

1. OVERVIEW

This Service Level Agreement (“SLA”) describes the commitments by DocXellent to Client for providing services as they relate to the application and hosting infrastructure collectively referred to as the “**ENSURCloud** Solution”.

This SLA specifies the services, service levels, conditions and responsibilities that are required to establish and maintain a suitable operational state of the **ENSURCloud** Solution for Client. Further, this SLA is subject to the terms and conditions of the License and Support Agreement between DocXellent and Client.

DocXellent reserves the right to change the terms of this SLA as deemed appropriate by company governance in order to provide the highest appropriate level of product operational excellence and Client satisfaction.

1.1 Definitions and Abbreviations

Term/Abbreviation	Definition
A/I	Anti-Intrusion software, typically installed on the server
A/V	Anti-virus software, typically installed on the server
AWS	Amazon Web Services – an industry leading IaaS hosted infrastructure provider.
Backup	Copying data and files to protect against loss of integrity or availability of the original.
Change Request (CR)	Request from Client or datacenter for changes to documents, application, environments or security
Client	The entity requesting products and services from DocXellent.
DBMS	Database Management Systems such as MS SQL Server
Disaster	A significant negative event that has rendered the system unusable, inclusive of software or hardware failures caused by unforeseen circumstances.
Emergency Maintenance	Maintenance that DocXellent determines, in its sole discretion, must be performed immediately to respond to an emergency situation.
ENSURCloud Solution	The collection of application software, programs and IaaS components used to make the ENSUR software solution available to Client via Internet access.
Hosted Infrastructure	The collection of networks, systems, servers, services, security appliances and software provided by a hosting company for the purposes of making a software application available on the Internet.
IaaS	Infrastructure as a Service – the Hosted Infrastructure provided by 3 rd party agency such as Amazon Web Services (AWS).
Incident	A problem report or support request from Client to DocXellent pertaining to the provisions of this service level agreement.
Maintenance	The execution of all activities required to keep the ENSURCloud Solution functioning at the highest appropriate level of operational readiness.



ENSURCloud Service Level Agreement

Term/Abbreviation	Definition
Monitoring	Continuous manual or automated observation of the ENSURCloud Solution operational readiness.
MUSA	Validated Cloud – a leading IaaS hosting provider that specializes in FDA 21 CFR Part 11 compliance hosting solutions.
N/A	Not Applicable
OS	Operating System, typically referring to one that is installed on a hosted server.
Outage	The ENSURCloud solution is unexpectedly offline or otherwise not available to normal business usage.
Planned Maintenance	A planned period of time in which preventive maintenance is performed such as application or OS updates (Client may experience a limitation of services during this timeframe).
Recovery	The restoring of data and files back to an original state after a “disaster” event occurrence or client request.
Response time	Measure of time to start the diagnosis.
SLA	Service Level Agreement – this document.
SOP	Standard Operating Procedure

2 DUTIES AND RESPONSIBILITIES

2.1 Scope and Segregation of Services

The ENSURCloud Solution is comprised of the **ENSUR** Document Control and Quality Management System installed atop a premier Internet facing hosted infrastructure, referred to as Infrastructure as a Service (IaaS).

DocXellent, makers of the **ENSUR** system, provides a full complement of professional services pertaining to the application layer of the **ENSURCloud** Solution. These services include, but are not limited to, the application installation, updates, backup, recovery, monitoring and user training for the **ENSUR** application. DocXellent is also the single point of contact for the coordination of applicable services required of the chosen IaaS hosted infrastructure provider.

Through a comprehensive vetting process of IaaS providers, DocXellent has chosen the following 2 leading providers of hosted infrastructure:

Non-Validated **ENSURCloud** Solution = **Amazon Web Services (AWS)**

AWS is a pioneering trailblazer and highly regarded “gold standard” provider in cloud hosted infrastructure services. AWS has the resources, reputability, scalability and market presence needed to achieve excellence in the Cloud.

For more information about AWS: <http://aws.amazon.com/>

Validated **ENSURCloud** Solution = **MUSA Validated Cloud**



ENSURCloud Service Level Agreement

MUSA is a highly experienced leading provider in 21 CFR Part 11 compliant hosted cloud solutions, capable of matching the AWS service standards combined with an ironclad audit-ready set of validation products, processes and services.

For more information about Validated Cloud: <http://www.validatedcloud.com/>

All services as they pertain to the infrastructure layer of the **ENSURCloud** Solutions are the responsibility of the respective hosting provider.

Successful implementation of the ENSUR system requires Client to identify an ENSUR System Administrator (and designated backup administrators). These individuals will be trained by DocXellent on ENSUR system configuration and related administration consoles. It is the responsibility of Client System Administrator to maintain all ENSUR configuration settings as they relate to Client business process need.

The following section delineates the segmentation of these services and identifies responsible parties thereof.

2.2 Roles and Responsibilities

Service	DocX	IaaS Host	Client
Delivery of the infrastructure		X	
Infrastructure Availability and Response Time		X	
Change Management of the infrastructure		X	
Support and Maintenance of the infrastructure		X	
Backup and restore of the infrastructure		X	
Delivery of the application	X		
Support and Maintenance of the application	X		
Maintenance of the OS	X		
Change Management of the application and OS	X		
Server Maintenance logs	X		
Backup and restore of the application	X		
Monitoring of the application availability	X		
A/V and A/I installation and maintenance	X		
DBMS maintenance	X		
DocXellent VPN Access to Server	X	X	
Client VPN access to server (if required)		X	X
ENSUR user account creation and permissions settings			X
ENSUR Administrative configuration / maintenance			X
Microsoft Active Directory Administration			X
SSL Certificate Administration	X		X
DNS URL Administration	X		X



ENSURCloud Service Level Agreement

3 SUPPORT

3.1 Scope

DocXellent has support staff available 24x7x365 to deliver the highest reasonable level of product operational readiness and Client satisfaction. Our support staff will respond to any and all requests for support per the availability and response times of this SLA. This is inclusive of, but not limited to, system outages or responsiveness issues, application functionality issues, problem reports, application usage questions, administrative configuration assistance, training requests and software or services improvement suggestions.

3.2 Priorities

Priority	Description
1	Production outage – System unavailable
2	Operational readiness issues with production causing degraded availability and/or connectivity and prohibiting critical business functions.
3	Operational Issues with production inhibiting non-critical business functions.
4	Usage questions or user training issues/requests
5	Other non-critical support request

3.3 Availability

Service Window	Delivery Hours	Priorities Serviced
Office Hours	Monday-Thursday: 8:00 AM to 5:30 PM Eastern Time* Friday: 8:00 AM to 3:00 PM Eastern Time* Saturday-Sunday: Closed *Excludes certain US holidays	1, 2, 3, 4, 5
After Hours	Monday-Thursday: 5:30 PM – 8:00AM Eastern Time Friday: 3:00 PM – 8:00AM Eastern Time Saturday-Sunday: All Day US Holidays: All Day	1, 2



ENSURCloud Service Level Agreement

3.4 Service Methods

Service Window	Service Request Method	Priorities Serviced
Office Hours	Phone – 860-887-2900: Immediate Answer Email – support@docxellent.com : ASAP reply	1, 2, 3, 4, 5
After Hours	Phone – 860-887-2900: Answering Service Call back for priority 1 and 2 incidents Email – support@docxellent.com : Monitored from 5:30 PM EST – 10:00 PM EST ASAP responses for priority 1 and 2 issues	1, 2 1, 2, 3, 4

3.5 Response Times

Priority	Method	Response Time
1	Phone Email	≤ 1 hour ≤ 8 hours
2	Phone Email	≤ 4 hour ≤ 8 hours
3	Any	≤ 8 hours
4	Any	≤ 8 hours
5	Any	≤ 24 hours



ENSURCloud Service Level Agreement

4 CHANGE MANAGEMENT

All application change requests can be submitted by Client to DocXellent via phone or email. This will invoke the DocXellent Change Control Procedure (SOP.0035). Requests will be evaluated for issue type (bug or enhancement) and urgency. Non-urgent requests will proceed through the DocXellent approval and prioritization process. Approved requests shall be scheduled for inclusion into the standard **ENSUR** software development lifecycle so that the change may be included in a future version (Major, Minor or Service Pack release). Urgent issues that present an immediate and significant consequence to Client business-critical operations may, at the sole discretion of DocXellent, result in a "Hot Fix" release of **ENSUR** to correct the immediate problem. Hot Fix changes are visually verified for proper function by the DocXellent quality team before being released. All changes released in a Hot Fix are subsequently included in the formal system testing process of the very next scheduled product release.

All application or platform software changes will be deployed to the server in accordance with the "Maintenance" below in this SLA.

5 MAINTENANCE

There are 2 classifications of system maintenance, specifically Planned Maintenance and Emergency Maintenance. Planned Maintenance includes, application installation, application updates and platform software update as described in the sections below. Emergency Maintenance would only occur as a reactionary measure to a significant negative event or threat of an impending negative event.

5.1 Application Installation

DocXellent shall perform the following activities to establish each **ENSURCloud** application instance:

- Contract with the IaaS hosting provider to establish the needed cloud servers
- Procure and install an SSL certificate for HTTPS communications
- Procure a DNS URL for site access and provide DNS configuration assistance
- Install Anti-Virus/Intrusion software on all cloud servers
- Establish Data Volume encryption
- Install the **ENSUR** application (execute IQ as needed for validated clients)
- Configure backup snapshot schedule per this SLA
- Establish monitoring alarms per this SLA

5.2 Application Updates

DocXellent shall provide resources to fully manage the deployment of all new **ENSUR** application updates. As new versions of the **ENSUR** application are released, DocXellent shall perform the following activities:

- Send to Client a Release Notice email announcing the new version and providing release notes that detail changes and enhancements.
- Initiate an application update process with Client per the change management requirements of this SLA.
- Schedule environment update dates and times with Client.
- Send update reminders to Client on the day of the installation of updates.
- Install application update and verify proper operational readiness.
- For validated clients, provide any needed OQ and/or PQ documents.



ENSURCloud Service Level Agreement

- Notify Client that the update has been completed.

5.3 Platform Software Updates

DocXellent shall provide resources to fully manage the deployment of all supporting software on the **ENSURCloud** servers. This shall include updates/patches to the Operating System, SQL Server Database, Anti-Virus/Intrusion tools and the MS Office suite. When it has been determined that updates need to be applied, DocXellent shall perform the following activities:

- Notify Client of the schedule update window
- Send update reminders to Client on the day of the deployment of updates.
- Apply pending updates and verify proper success
- Verify proper **ENSUR** application operational readiness

5.4 Emergency Maintenance

DocXellent reserves the right to perform Emergency Maintenance to an **ENSURCloud** server if it has been determined that, in DocXellent's sole discretion, either 1) an adverse event has resulted or will imminently result in significantly degraded performance or complete application outage or 2) a security threat poses an immediate risk to the hosted environment and requires urgent mitigation. In extreme cases, Emergency Maintenance services may include a disaster recovery process as defined by this SLA. While emergency maintenance is extremely rare, DocXellent will notify Client of the emergency event and the corrective actions being taken. However, Client response is not specifically required before corrective actions are implemented to resolve the emergency situation.

5.5 Timeframes

Maintenance Type	Timeframe
New Installations	New installations are performed as needed based upon either a new instance of an ENSURCloud system or the migration of an existing ENSURCloud system as required by Client. New installations require a 5 business day lead time and generally required 4 hours to complete.
Application Updates	Application updates are performed as needed, pursuant to the ENSUR development release schedule. Application updates require an outage and are conducted in a mutually agreed upon maintenance window. These updates typically take 90 minutes or less to install per each ENSURCloud instance (i.e. Test, Validation and Production)
Platform Updates	Platform updates are performed monthly as needed for each platform software package per the recommendations of the software vendor. Platform updates are typically deployed in either the early morning or late day hours (Eastern Time) to minimize potential disruptions to end-users of the system.
Emergency Maintenance	Emergency maintenance, if ever required, can be performed at any time.



ENSURCloud Service Level Agreement

5.6 Logging

All maintenance activities to each **ENSURCloud** environment shall be logged by DocXellent.

Logs shall contain the following information:

- Date/Time of the maintenance activity
- Who performed the activity
- What maintenance tasks were performed

Maintenance logs shall be stored in DocXellent's internal **ENSUR** Document Control System and can be provided to Client upon request.

6 BACKUP AND DISASTER RECOVERY

6.1 Backups

All **ENSURCloud** server instances shall be configured to perform twice daily VM snapshots of each server environment. VM backups shall encompass both the "Product Disk Volume" (i.e., OS and **ENSUR** application) as well as the "Data Volume" containing Client's database and content files. The backup jobs shall be scheduled in accordance with the client's time zone such that there is 1 "mid-day" backup and 1 "end of day" backup performed.

In addition to VM backups, each **ENSURCloud** system shall additionally be configured to perform hourly incremental SQL Server database backups throughout the client's standard working hours to provide fine-grained hourly rollback capabilities.

6.2 Disaster Recovery

In the event of a disaster, DocXellent shall provide rollback assistance in accordance with the service definitions and timing of this SLA.

If the adverse event necessitating recovery was a major functional "mistake" made by Client within the **ENSUR** system that has caused the controlled data to no longer meet business needs (for example, an unintended global cascade of folder permissions changes by an administrator), Client may request that DocXellent perform an incremental database rollback. Once DocXellent has confirmed stakeholder approval to perform this action, the current database will be archived and the most recent appropriate hourly backup will be restored.

If a significant negative event that has rendered the system unusable, DocXellent shall provide services to restore the full system to a working state from the most recent appropriate VM snapshot. This will result in a loss of data from the time of the most recent VM backup to the time of the disaster event. For this reason, twice daily system snapshots are taken so that the maximum amount of potential data loss is ½ of the client's business day.

Once a restore process has been completed, it shall be the responsibility of Client to properly test and, if needed, qualify the business purpose validity of the restored environment.



ENSURCloud Service Level Agreement

6.3 Timeframes

Any form of system recovery shall be performed in 2 hours or less as measure from the recovery "Start Time" to the recovery "End Time". "Start Time" is defined as the DocXellent acknowledgement that the recovery process has begun and "End Time" is defined as a notification to Client that the system is back online and available for regular business operations. The invocation and execution of a recovery process shall be classified as "Emergency Maintenance" in the context of this SLA.

7 MONITORING

The **ENSURCloud** system shall be monitored by DocXellent both with automated trigger-based alarms as well as manual periodic inspection and reviews. Manual inspection may include, but are not limited to: server resource availability, cloud security assessments, concurrent memory load, disk consumption, and bandwidth traffic.

Monitor services are "server-side" activities aimed at ensuring optimal system security and performance. DocXellent does not presently provide Client with usage monitoring reports or statistics. User access attempts (who, when, results) are logged by the **ENSUR** application and can be queried by Client as needed.

7.1 Trigger-Based Alarms

DocXellent shall configure the following trigger-based alarms. If an alarm event occurs, DocXellent support personnel shall be notified of the alarm event so that a proper corrective action may be taken. If the alarm is the result of a disruption in service, Client shall be notified of the alarm and the corrective action taken.

Alarm Type	Trigger Description
Server Outage	<p>The server shall be automatically monitored to verify that it is online. If the server does not respond to the health ping, DocXellent support staff shall be notified of the server outage.</p> <p>For Production servers, a "Server Outage" alarm shall be handled as a "Priority 1 Email" Support incident in accordance with the terms of this SLA.</p> <p>For Test servers, a "Server Outage" alarm shall be handled as a "Priority 3 Email" Support incident in accordance with the terms of this SLA.</p>
Server CPU Usage	<p>The server shall be automatically monitored for server CPU usage. If CPU usage peaks at 100%, this alarm shall alert the DocXellent support staff of this event. CPU Usage alarms shall be handled as a "Priority 2 Email" Support incident in accordance with the terms of this SLA.</p>



ENSURCloud Service Level Agreement

8 IaaS AVAILABILITY

The IaaS platform shall be operational 99.95% of the time in any given month during the term of the Agreement, meaning that the Outage Percentage (as defined below) shall not be more than 0.05%. An Outage means that the **ENSURCloud** system is not online and available for regular business usage. Outages do not include Planned Maintenance activities as defined by this agreement. If one or more Outages occur in a given month, the total duration of such Outages during such month, expressed as a percentage of the total time during such month, shall be the outage percentage (the "Outage Percentage").

9 ACCEPTABLE USE

The IaaS hosting providers contracted by DocXellent institute policies for acceptable use of their equipment and services. Clients must agree to the terms of the Acceptable Use Policy for the agency providing their **ENSURCloud** IaaS hosting services. DocXellent will make available the corresponding policy to Client for review and agreement.

10 ADDITIONAL SERVICES

The following professional services are not included in the scope of this SLA. Upon Customer's request, DocXellent shall render professional services pursuant to an executed statement of work and Purchase Order governed by the terms of this SLA and the executed ENSURCloud HOSTING LICENSE and SUPPORT AGREEMENT. Professional services requested by Customer outside of the normal business hours of the professional services team (9:00 am – 5:00 pm EST Monday through Friday excluding local holidays) may be subject to additional charges. The rates for professional services is based on DocXellent's then-standard time and materials rates.

The following are examples of professional services that may be requested by Customer. Note, this list is not exhaustive but is provided as examples of tasks for which DocXellent charges an hourly or fixed-price service fee:

- Training beyond initial 6 hours provided during Implementation phase
 - New Editor/Admin training; (where the former Admin has been removed from ENSUR responsibilities or separated from the company)
 - Refresher Training
 - Training on new versions of ENSUR (Note: documentation and training videos are provided as part of Maintenance & Support and posted to the Customer Portal)
- Workflow (e.g. my goal is X, how do I use the software to accomplish this goal?)
- Consulting (e.g. I need a field/form/report that does Y, how should I set it up?)
- Design and Setup of customer Forms, Overlays, Reports.
- Error reconciliation (e.g. I did A which causes result B and now need to fix it)
- Infrastructure growth, workload balancing, etc.
- Custom Reports, SQL Queries, etc.
- Assistance with Auditor requests/questions
- Server migrations where ENSUR installation is to be moved to a different physical or virtual server
- Legacy data migrations



ENSURCloud Service Level Agreement

- Integration with other internal systems such as ERP, SAP, or LMS
- Environment duplication; Database copying to replicate one instance to another (e.g. copy Production to TEST to have configured templates, content types, and document samples available in TEST).

Detailed descriptions of common professional service requests are noted in the following sections.

10.1 Validation Services

For clients required to comply with FDA 21CFR Part 11, DocXellent provides services to establish proper requirements, installation and functionality qualification documentation and evidence inclusive of a User Requirements Specification, Traceability Matrix, Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ) as well as Deviation and Validation Summary Reports. For Cloud clients, these services are included in Cloud pricing. Additional Client initiated validation services that not part of the standard DocXellent provided services can be considered on an as-needed basis and may be subject to further quotation.

10.2 User Training

All new Clients will receive DocXellent "train-the-trainer" services as an integral element of the new system rollout process. If preferred, our training can be focused on priority document type/samples using Customer content. Upon request, DocXellent will also provide supplemental user training services for all types of users of the system. This includes advanced training for additional System Administrators as well as comprehensive training for Editors, Approvers and Viewers. Training is commonly delivered through web meetings between DocXellent staff and Client **ENSUR** users. DocXellent can also provide in-person training either at our facility or on-site at Client's facility as needed. Additional costs apply for supplemental training.

10.3 Environment Duplication

DocXellent understands that clients sometimes need to have a "testing" environment that is a recent copy of their production system. Common drivers for this need are to verify new business process before implementing configuration changes in production or conducting end-user training in a sandbox having recent and representative production data. DocXellent has resources available to duplicate environments as needed, a process sometime referred to as "refreshing the test environment from production". Given that the frequency of request to perform this activity are beyond our control, additional costs may apply for DocXellent resources to perform this work.

10.4 Custom Development

Any and all requests for custom development shall be individually assessed, approved, prioritized and quoted on an as-needed basis.