opentext™

OpenText™ Documentum™ for Life Science CE 23.4

Release Notes

1 Introduction

These Release Notes provide an overview of Documentum™ for Life Science 23.4, including new features, delivery information, and supported platforms.

OpenText recommends that you read these Release Notes in conjunction with the documentation included with the software package. If any conflicts exist, the Release Notes supersede the other documentation.

We also recommend that you check OpenText My Support for any patches or documentation updates that may have been posted after the initial release of this product.

1.1 Release Notes revision history

Revision date	Sections revised	Description of revisions
8-Dec-2023	1.0	Initial release.
12-Sept-2024	4.2	Added a Documentation errata section.
10-Oct-2024	5.2.1	Corrected the supported version for Documentum xPlore.
16-Dec-2024	4.2	Updated the Documentation errata section.

2 About Documentum[™] for Life Science 23.4

This section provides an overview of Documentum™ for Life Science 23.4.

The OpenText Documentum for Life Sciences solution suite (Life Sciences solution suite) helps organizations meet compliance requirements, increase productivity, and securely collaborate across the extended enterprise. The Life Sciences solution suite includes:

- Documentum for eTMF (LSTMF)
- Documentum for Quality and Manufacturing (LSQM)
- Documentum for Research and Development (LSRD)
- Documentum Submission Store and View (LSSSV)

The Life Sciences solutions are built on the Documentum D2 web application and Documentum platform.

Documentum D2 is a web-based application that enables users to store, retrieve, and manage documents in a Documentum repository. It is highly customizable through a configuration application that does not require programming knowledge.

The Documentum for eTMF solution helps Life Sciences organizations manage clinical trial documentation and establish consistent records management practices across the entire virtual research organization. This single source, enterprise-class solution ensures that clinical trial teams can easily and effectively track progress in trial documentation, control and synchronize study artifacts, and ensure fast, secure access both during and after the trial.

The Documentum for Quality and Manufacturing solution enables Life Sciences organizations to control quality and manufacturing documents, automate workflows across the extended enterprise, and ensure compliance with GMP (Good Manufacturing Practices) standards.

The Documentum for Research and Development solution enables Life Sciences organizations to manage research and development documents in preparation for regulatory submissions. It helps ensure compliance with regulatory agency standards and provides visibility to track progress on the documents.

The Documentum Submission Store and View enables Life Sciences users to archive the submissions, store the submitted content in Documentum, and manage the lifecycle of their regulatory content.

2.1 New features

Documentum™ for Life Science 23.4 includes the following new features.

2.1.1 eTMF Reports

Introduced in this release the support for below iHub Reports:

2.1.1.1 Trial Overview

The Trial Overview report provides a status overview of all trials for a selected product and the percentage completion status for its countries and sites.

2.1.1.2 Trial QC Metrics

The Trial QC Metrics report shows the QC pass or fail status of artifacts at the trial, country, and site levels for a selected trial. This report can help a trial manager understand the extent of document rework required due to issues with content quality, image quality, indexing errors, and metadata errors. The report can help them address source reasons of rework and improve the QC process and timeliness of documents becoming final.

2.1.1.3 Global QC Trends

The Global QC Trends report shows the overall pass and fail QC trend over time for all Clinical trials.

2.1.1.4 QC Fail by Reason

The QC Fail by Reason report shows the percentage of QC failures grouped by reason code.

2.1.1.5 Trials by Status

The Trials by Status report provides a status summary of all trials for a selected Product by Status.

2.1.1.6 Missing Documents

The Missing Documents report shows the number of missing documents (placeholders) at the trial, country, and site levels for a selected trial.

2.1.1.7 Received Documents

The Received Documents reports displays the number of documents received at the trial, country, and site levels for a selected trial by status. The status includes Draft, Final, Index, Quality Check, and Reviewed.

2.1.1.8 Full Inventory

The Full Inventory report provides an overall view of the placeholders along with the current status of the required artifacts at the site, country, and trial levels for a selected trial.

2.1.2 LMS Integration

- Introduced in this release, the LMS Integration Framework enables/empowers a System Administrator to configure an integration between Quality and Manufacturing and a 3rd party Learning Management System (LMS) (i.e., UL Compliance Wire).
- With the LMS Integration Framework, a System Administrator can make a configurable integration with a 3rd party LMS without having to create a custom code; refer to the OpenText Documentum for Quality and Manufacturing Installation Guide, Section 4.11 Configuring external LMS integration, to learn more.

2.1.3 Technical File Creation for Medical Devices

- Introduced in this release, a technical writer, can create Technical File artifacts for EU MDR.
- With the new Technical Files artifacts, the technical writer can create and manage the associated artifacts. To learn more, refer to OpenText Documentum for Quality and Manufacturing Configuration Requirements Section 1: Document Inventory.
- Introduced in this release is the extension of Virtual Document Creation and Virtual Document Template management via the Virtual Document Template Spreadsheet (VDTS) into the Quality and Manufacturing module, with this a template author in the GMP and Med Device domain can create and modify their own VDTS Templates.
- The Technical File Virtual Document Assembly can be managed with a VDTS, that can be created and modified by a template author to fit the business use case(s) without requiring system configuration or impact to system validation; refer to the User Guide
- Validation GMP Doc Assembly can be used to manage VDoc creation, assembly with VDTS templates in the Validation Group to help organize and manage all documents associated with a Validation Package.

2.1.4 Submission Assembler Creation

- Introduced in this release, a submission Manager can create a Submission Assembler with the required artifacts for submission.
- Introduced virtual document submission assembler can be create and managed with the relevant submission documents in one place per submission registration form.
- With the new submission assembler, submission manager can reuse the M2-M5 modules in various submission.
- With the new submission assembler, submission manager can create and manage M1 module in various country specific submissions.
- Introduced virtual document submission assembler can be transferred to the publishing tool for down streaming process.

2.1.5 vDoc supporting Regional support

• Introduced in this release the support for module 1 in a virtual document.

- With this new feature customer could create and manage Module 1 in a virtual document with regional artifacts.
- Introduced in this release customer could create and manage a virtual document with regional in the virtual document templates.

2.1.6 Lifecycle Transaction Stability

• In the Life Sciences Solutions (LSS), certain operations are implemented through multi-step D2 lifecycle actions – some involving 20 steps or more. To achieve transactional stability, the following features have been implemented:

2.1.6.1 Post-document-approval processing

The lifecycle transitions from pre-approved states to the **Effective / Approved / Final** state in LSS involve many steps, all of which must succeed in order to avoid potential data corruption and / or loss of functionality

2.1.6.2 Document initialization

When a new document is created or imported in LSS, D2 triggers the "(Init)" lifecycle transition after creating and initializing the object internally as a no-content object (the template content or imported file is applied after the initial lifecycle transition actions, as appropriate).

2.1.6.3 Superseding prior Approved / Effective / Final versions

This lifecycle transition is applied to the previous "Effective" version of a document (if there is one) as part of the post-approval transition for the next "Effective" version, described previously.

2.1.6.4 Reverting an Approved / Effective / Final document to Draft

The post-check-in transition from **Effective** back to **Draft** in LSQM

2.1.7 Intelligent upgrade

- Introduced in this release is the Upgrade Manager Framework designed to facilitate the upgrade process in a more efficient and reliable manner.
- The Upgrade Manager Framework provides a generic GUI that system administrators can use to
 perform an in-place upgrade of the Life Science solutions to the latest version in an automated
 way that is efficient and reliable with minimal manual interventions. The utility is restricted to
 Upgrade Managers users. Some of the key benefits of using the Upgrade Manager Framework
 are as follows:
 - Automates the D2 configuration upgrade and data migration from version-to- version that is handled by the D2ConfigDiffTracker and ApplyUpgradePlan utility scripts respectively in a seamless manner.
 - Enables the administrator to review the default upgrade plans and modify them as necessary or extend them with custom upgrade steps.
 - Outlines the lifecycle transitions with relevant security models and auditing during the upgrade process.

• Generates an upgrade output report after the completion of an upgrade run, which can help administrators determine whether the upgrade was successful or requires a rerun.

2.1.8 Technology Stack Upgrade

Backend upgrades for Spring and GWT technologies mandate Tomcat 10+ and Java 17+.
 Please refer to section: Supported environment and compatibility guide.

2.1.9 Content Connect Certification

- Introduced in this release, certification of Content Connect enables a contributor to import content directly from outlook to the Life Sciences Solution.
- With the new feature, certification of Content Connect an author can import from outlook:
 - o emails with attachments directly to Life Sciences solution
 - o emails with special characters in the subject:
 { ~ `!#\$@%^&*(){}[].,+";:\/_=|?}
 - o email and attachments as Single Attachment
 - o email and attachments as Multiple Attachments
 - o email and attachments as Multiple Attachments of 10MB
 - o email and attachments from a configured Folder/Subfolder
 - o email and attachments as image
 - o email and attachments as .msg
 - o email with attachments which has multiple emails with the same subject
 - o email and attachments with a combination of document, images, email

2.1.10 Public Containers

Content cloud for life science supports a set of pre-built Docker images that can be downloaded from the OpenText My Support download center along with Docker YAML files and Kubernetes Helm charts and scripts. These Docker images, scripts, yaml files and helm charts are supported for use in deploying life science solutions products as is or can be modified as needed and/or serve as the foundation for your own Docker and Kubernetes environment.

OpenText provides reference images (default docker containers) that support Kubernetes as the container orchestration platform for deploying these docker images. OpenText published Docker images/containers are built using Oracle Linux as server operating systems with support for PostgreSQL as database.

Customers can deploy the OpenText reference images or build their own images deploying in various scenarios including hybrid deployments. A combination of database and storage technologies can be used with supported services and infrastructure as described in the guide OpenText Documentum CE 23.4 Infrastructure Certification Guide.pdf.

2.2 Limitations and deprecated features

The following features have been Limitations in this release:

- Language Pack: Chinees language requires to install an additional Content server hotfix Out of the box, refer to known issues section (LSCI-52247).
- Controlled and issued printing of documents configured with dynamic eSignature pages is not supported. You can only print documents with fused eSignature pages

The following features have been deprecated in this release:

 Pdf box support in controlled and issued print is deprecated. Customers are encouraged to use output server for controlled and issued print.

3 Downloads

Downloads for Documentum™ for Life Science are available on My Support.

To search and download the list of software binaries on OpenText My Support, go to **Knowledge** and type #<ProductName><ReleaseVersion>SoftwareDownloads in the search box and click **Search**.

For example, to search the list of all software binaries for:

- Documentum Quality and Manufacturing, type
 #documentumqualityandmanufacturing23.4softwaredownloads
- Documentum Research and Development, type
 #documentumresearchanddevelopment23.4softwaredownloads
- Documentum Submission Store and View, type
 #documentumsubmissionstoreandview23.4softwaredownloads
- Documentum for eTMF, type #documentumetmf23.4softwaredownloads

4 Documentation

Documentation for Documentum™ for Life Science is available on My Support.

To search and download documentation on OpenText My Support, go to **Knowledge** and type #<ProductName><ReleaseVersion>documentation in the search box and click **Search**.

For example, to search the list of documents for:

- Documentum Quality and Manufacturing, type
 #documentumqualityandmanufacturing23.4documentation
- Documentum Research and Development, type

#documentumresearchanddevelopment23.4 documentation

Documentum Submission Store and View, type

#documentumsubmissionstoreandview23.4 documentation

Documentum for eTMF, type

#documentumetmf23.4documentation

4.1 Related documentation

For additional information about Documentum for Life Sciences, or for supplemental information about related products, for peer contacts, conversations with customers, partners, and certified professionals, and content on product support and solutions, visit https://forums.opentext.com/forums/categories/DocumentumLifeSciences.

4.2 Documentation errata

This section covers corrections to erroneous content in the guides and any new information not available in the guides.

4.2.1 Documentum for Life Sciences Administration Guide

4.2.1.1 Disabling Print Approval Required and Reconciliation Due Date in Issue Print

This section provides instructions to disable these fields, which are incorrect. The section has been updated as follows:

Setting Print Approval Required and Reconciliation Due Date as optional in Issued Print
If you do not want to specify the Print Approval Required and Reconciliation Due Date Required
values when issued printing a document, you can make these fields optional using the following
steps:

- 1. Log in to D2-Config.
- 2. In the filter on the main toolbar, select All elements.
- 3. Select Data > Dictionary.
- 4. In the **Dictionaries** area, select **GMP Groups**.
- 5. On the Alias tab, set the value in the Print Approval Required and Reconciliation Due Date Required columns to No or leave it blank for all the relevant groups.
- 6. Click Save.

4.2.2 Documentum for Quality and Manufacturing Installation Guide

4.2.2.1 Registering the d2ls web application DFC client as a privileged client

This section is missing in the "Installing BI & Reporting reports" section in the Documentum for Quality and Manufacturing Installation Guide.

The d2ls web application DFC client must be approved as privileged clients in each applicable repository. Failure to approve the d2ls DFC client as a privileged client will result in errors when that DFC client attempts to access the keystore in the global registry repository or attempts to execute code in privileged mode.

Approval is granted using Documentum Administrator (DA).

To register the d2ls web application DFC client as a privileged client:

- You can view the list of DFC clients for a given repository that can be approved as privileged clients in DA by navigating to Administration > Client Rights Management > Privileged Clients. See OpenText Documentum Content Management Server Administration and Configuration Guide (EDCCS-AGD) for more information.
- 2. If the clients that you want to approve as a privileged client do not appear in the list, click **Manage**Clients. A list of all registered DFC clients known to the repository is displayed.



Note

Note that a DFC client is registered the first time it connects to the Documentum Server. You might need to run the client once (for example, run the d2ls web application) in order to register it. To help you locate clients in the list of registered clients, you can filter the list by Client Name by entering a prefix in the text box with help text "Starts with" and clicking the arrow button to the right.

- 3. Select the d2ls web application client from the list on the left-hand side and insert it into the list on the right-hand side. Click **OK**.
- 4. Right-click the client and select Approve Privilege.

With default settings in dfc.properties, it can be difficult to identify the registered clients that you want to approve of as privileged clients. To help, you can associate a client name with each by adding a **dfc.name** property to the client's dfc.properties file. For example: **dfc.name=D2_10.141.58.212**

The Client Name is prefixed with this value when it appears in the list of Privileged Clients or list of registered clients in the **Manage Clients** dialog box. You can then filter by Client Name to find registered clients that have a given prefix in their name.

To confirm that the client you selected is the one that you want to approve as a privileged client, you might need to compare its Client ID value as displayed in DA with the client ID value stored in its dfc.keystore file.

To find the client ID, use the java keytool command-line utility as described in "Registering the XMLViewer web application DFC client as a privileged client" section in the installation guide.

5 Supported environments and compatibility

This section provides details about supported platforms, systems, and versions.



Note

- A product configuration running on a particular environment is supported
 as long as versions of the components in the environment (for example,
 operating system, database, web server, browser, SSO, Directory
 Servers, and so on) are in standard/primary support by their vendors.
- Software requirements are listed with release numbers. Software updates—including patches, Service Packs, and equivalent updates sometimes introduce unanticipated changes. Compatibility with software

- updates that are not listed here cannot be guaranteed.
- All certifications provided in this document are relevant to the current release. Certifications for patches are documented in the *Patch Notes* documents published for the patch releases.

5.1 Supported systems

The Documentum for Life Sciences solutions are certified on Documentum D2 23.4 and supports all platforms supported by the Documentum D2 23.4 product. Review the system requirements in this release notes and the *Documentum D2 23.4 Release Notes* to verify the product versions supported by the Documentum platform and Documentum D2. There may be new certifications added after this initial release. Check the <u>OpenText My Support</u> site for updates made to these documents between releases.



Note

Documentum for Life Sciences is supported on MacOS but not certified for this release.

5.2 OpenText product compatibility

This section provides details about which versions of other OpenText products are compatible with this release of Documentum™ for Life Science 23.4.



Note

For the latest compatibility information for OpenText products, refer to the Product Compatibility Matrix.

5.2.1 Product compatibility with Documentum Platform and other OpenText products

Product name	Version	Notes
Blazon	16.6.5	
Brava! Enterprise	16.6.8	Not required to install unless additionally licensed Brava! functionality is required. Brava CSR is included with D2.
Documentum Administrator	23.4	
Documentum Branch Office Caching Services (BOCS)	23.4	

Documentum Composer	23.4	
Documentum Content Transformation Services (CTS)	23.4	CTS stand alone can be used to generate PDF renditions. For ICH compliant renditions CTS must be used with Blazon.
Documentum Connector for Microsoft SharePoint	22.2	
Documentum D2	23.4	
Documentum D2 Advanced Publishing Services	23.4	
Documentum Foundation Classes (DFC)	23.4	
Documentum Foundation Services (DFS)	23.4	Required for the D2 installation and for using the Documentum for Life Sciences Software Development Kit (SDK).
Documentum Retention Policy Services (RPS)	23.4	
Documentum Server	23.4	
Documentum xPlore	22.1 P04	
Magellan BI & Reporting	23.2	Formerly known as Information Hub (iHub).
Output Server	22.2	
Process Engine	23.4	
Workflow Designer	23.4	

5.2.2 Product compatibility with third-party products

Product name	Version	Notes
Microsoft Office	2016, 365	
Oracle Database	19c, 21c	
PostgreSQL	12.x, 13.x, 14.x, 15.x	
Microsoft SQL Server	2017, 2019,2022	

5.3 Language support

Documentum™ for Life Science is currently localized in the following languages. Additional languages may be available in future releases.

UI = user interface only

B = both user interface and online help

Component	AR	DE	EN	ES	FR	IT	JA	ко	NL	PT	RU
Documentum for Quality and Manufacturing	UI										



Note

Localization is supported only for the Documentum Quality and Manufacturing solution. If users have installed LSQM along with the other solutions (LSTMF, LSRD, LSSSV) in their environment and a non-English language is selected for that user, then the text in the other solutions will NOT be translated, resulting in a partially translated UI. For consistency, it is recommended that in such an environment where multiple solutions are installed, you use English so that only one language is displayed.

5.3.1 Supported operating systems

The Localization Support Kit is certified on the following OS:

Windows Server 2016

5.4 Application server

As stated earlier, the Life Sciences solution is certified on Documentum D2 23.4 and supports all platforms supported by the Documentum D2 23.4 product.

For Apache Tomcat, the Controlled Print feature is supported on all versions that are supported by Documentum D2 23.4.

5.5 Browsers

As stated earlier, the Life Sciences solution is certified on Documentum D2 23.4 and supports all platforms supported by the Documentum D2 23.4 product.

The Life Sciences solution is not supported on the iPad. For more information on limitations related to the iPad, see *Documentum D2 23.4 Release Notes*.



Note

The Life Sciences solution supports the Apple Safari browser only on the Apple Mac OS.

5.6 Client applications

The screen resolution for users should be no less than 1280 pixels in width. To perform the bulk document loading feature, you need:

- Microsoft Excel 2010 or later
- File archiving utility that supports the ZIP extension, such as Winzip for the bulk loading process.

To edit Documentum for eTMF file plans, you need Microsoft Excel 2010 or later.

Collaborative editing in Microsoft SharePoint is supported only on the .docm/.docx Word format. It is not supported on the .doc format.

For document viewing, you need Adobe Acrobat Reader or Adobe Acrobat Professional.

The behavior of certain D2 functionality in the Life Science solutions may vary when using browsers with different modes such as Applet or Thin Client mode. To view how the D2 functionality behaves each mode, see the "Client Behavior" section in the *Documentum 23.4 Release Notes*.

To view media player documents in the Document Viewer widget in the Browse workspace of the D2 Client, you must install media player plugins such as VLC plugin.

6 Installation and upgrade notes

This section provides additional installation and upgrade information, including related or third-party product information and any required critical patches.

Before beginning installation, ensure that your system meets the requirements listed in Chapter 4, *Supported environments and compatibility*. After installation, be sure to update your software to the latest patched release, if any patches are available.

The *OpenText Documentum for eTMF Installation Guide* contains information on how to install Documentum eTMF.

The *OpenText Documentum for Quality and Manufacturing Installation Guide* contains information on how to install Documentum for Quality and Manufacturing.

The OpenText Documentum for Research and Development Installation Guide contains information on how to install Documentum for Research and Development.

The *OpenText Documentum Submission Store and View Installation Guide* contains information on how to install Documentum Submission Store and View.

7 Fixed issues

This section provides information about past issues that have been fixed in this release.

Table 1. Common Life Sciences solutions fixed issues.

Issue number	Issue description
LSCI-40089	Widgets do not auto refresh after opening the Magellan BI & Reporting reports.
LSCI-23104	In the SharePoint Collaborative workflow, consolidators can change the participants on the Workflow participants tab during the rejection or acceptance of the task, leaving required fields blank.
LSCI-14465/ DTWO-35689	In the Collaborative Editing workflow, selecting the Review and Edit Consolidated Copy option does not open the Microsoft Word document with the merged changes if Word is already open.
	Workaround : This is a D2-dependent issue. As a workaround, you can try the following steps:
	Log out and log in to the D2 Client and try to perform the action.
	Log out of the D2 Client, clear the cache, restart the browser, log in to the D2 Client, and try to perform the action.
	3. Change the browser and try to perform the action.
	4. Uninstall and reinstall the browser plugin/addon.
	Additionally, in the case of Internet Explorer:
	Ensure that the Java addon is enabled in the browser.
	Disable the Enable Protected Mode option on the Internet Options > Security tab.
LSCI-10794/ DTWO-25851	When adding custom attributes in Doc List columns that do not belong to dm_sysobject such as In Workflow column, results in extra request time for loading the documents in the Doc List.
LSCI-45708	LC transition to draft is made after a document reached x.0 Final, so it ends up in x.0 draft, which shouldn't be happening

Issue number	Issue description
LSCI-44315	Collaborator of SharePoint Collaboration WF getting removed from SharePoint site if also the SharePoint Supervisor and "Update performers" replaces SharePoint Supervisor
LSCI-45611	Clicking OK on the Update Performers screen of a SharePoint Collaboration 2 Step workflow and "Consolidator" field is blank - results in "Failure" message
LSCI-44687	SharePoint workflows are getting stuck, and workflow related attributes are not getting cleared properly when aborting SharePoint workflows.
LSCI-45611	Users are unable to complete the SharePoint collaboration, and any documents in SharePoint cannot be checked back into the Documentum repository. This results in documents getting stuck in a workflow that can no longer end as well as the potential to lose changes that were collaborated on in SharePoint.
LSCI-45959	Zip function is not sending email to "Users to Notify" - regardless of Success or Failure from the Zip action.

Table 2. Electronic Trial Master File (LSTMF) fixed issues

Issue number	Issue description
LSCI-32349	While running the TMFAdmin tool with repair command, there is a possibility of infinite loop if repairDynamicRoleGroups fails to repair the role group without throwing any exception. The UpdateContributorGroupsMethod.validateDynamicRoleGroup method will fail and re-enter the repair cycle in infinite loop. The existing fail safe mechanism is not enough to avoid infinite loop.
LSCI-26547	The Finalize Indexing and Quality Check widgets does not work properly if the Authors column is added to these widgets.
LSCI-45276	Unable to create TMF dynamic roles
LSCI-45800	DIA Ref Model defaults to "DIA TMF 3.0" when user tries to create a document by selecting the Country or Site registration form that belongs to DIA Ref Model 3.1.0 or 3.2.0 Workaround: It is recommended to avoid setting the dia_tmf_ref_model_verion in the TMF Document Default Values, to ensure that clinical trial countries and
	site reflect the employed DIA TMF Reference Model of the associated clinical trial.
LSCI-26547	The Finalize Indexing and Quality Check widgets does not work properly if the Authors column is added to these widgets.

Issue number	Issue description
LSCI-45179	Clinical inspector workspace is having performance issues to Load.

Table 3. Research and Development (LSRD) fixed issues

Issue number	Issue description
LSCI-45012	Virtual Document creation failed if name of "No-Content PlaceHolder" in Chinese
LSCI-47724	When a user creates a document, a rendition request is sent prior to the creation process being completed. This results in multiple PDF renditions where the primary PDF rendition is not correct.
LSCI-48495	When a user sends a Virtual Document to a For Edit workflow the status of the children (and descendants) in "Draft" state are not transitioned to "For Edit".

Table 4. Submission Store and View (LSSSV) fixed issues

None

Table 5. Quality and Manufacturing (LSQM) fixed issues

Issue name	Issue description
LSCI-43537	Print functionality fails with database error during a transaction condition. To mitigate this failure, the system provides a query form titled Find Issued Print Requests that have failed to print and require approval that lists any issued prints that did not require approval but failed to print due to the error above. If the user receives an error indicating another user is printing the document, this does not apply. If the error is a printer error and not a transaction error message, this is also not the case as both the Issued Print request and Issued Print objects were created but the printer failed. At that point, the print would need to be reconciled as a failure to print.
LSCI-45596	Asterisk symbol is not seen in any of the required attributes in the affected documents section for CR property page
LSCI-44681	Document Training job did not capture full log in PrintWriter log file to log information in PrintWriter object
LSCI-39811	When Documentum training job fails with any of the document, it doesn't skip the failed document, instead, it doesn't process any document in the queue
LSCI-39811	Document training job stops when an error is encountered.
LSCI-44681	Users are not receiving Training tasks and the full Job log is missing information to help troubleshoot any errors.

Issue name	Issue description
LSCI-46032	Asterisk symbol is missing in some of the required attributes in the affected documents section for CR property page
LSCI-47730	When checking in a Change Request that contains a checked out child, the checked out child is getting removed from the Change Request.
LSCI-48467	When a user imports a document as Release Pending, reverts it to Draft, and makes the document Effective, the signature page will not be present.
LSCI-48983	Users are unable to see the site folder created if the generated group name based on site name exceeds 48 characters.
LSCI-50057	Users are unable to Reinstate previous Suspended versions.
LSCI-50077	Change Request virtual documents lose more than the selected child when it is not the last child, and it is removed and the Change Request contains more than one child.
LSCI-50916	Issued print reporting for type "Prints Pending Reconciliation" is not loading
LSCI-50053	Site name does not display in drop down in Controlled print widget if the site name has an "&" value
LSCI-49096	D2JobLifecycleBatch job is not moving documents from Release Pending to Effective

Language pack-related fixed issues

Issue number	Issue description
LSCI-34375	The OK button is not translated in the Russian and Korean languages.
LSCI-33709/ DCSPO-5112	The SharePoint Collaboration workflow does not work in any localized environment other than the English locale. This is a Documentum for Microsoft SharePoint Connector-related issue that occurs when the localized login names contain unique non-English characters. Contact OpenText My Support for the resolution.
LSCI-30613	The Restricted Edit dialog box header text should only display Restricted Edit ; however, the header also includes the translated Change state text.
LSCI-31123	The GMP Applicable Sites dictionary is not translated and must use the English site names in all languages for LSQM functionalities to work properly.

8 Known issues

The following known issues exist in this release.

8.1 Life Sciences Solutions

The Life Sciences solutions known issues in the following table pertain to Documentum for eTMF, Documentum for Quality and Manufacturing, Documentum for Research and Development, and Documentum Submission Store and View.

Issue number	Issue description
LSCI-42900	When D2 is deployed in the WebLogic server, downloading a document fails.
LSCI-41684	In Advance Search, if the definition in search configuration is not defined, the value is treated as a free text field.
LSCI-51979	Handling special charters in the user name / user Display name we need to set the requestParameterEncryptEnabled parameter to false in <tomcat>\webapps\D2\WEB-INF\classes\settings.properties on the Application Server. This is applicable for</tomcat>
	This is applicable to
LSCI-52087	There is an Error thrown when applying Retention to a document .
	Workaround:
	1 - Downloads a zip file from https://download.com/cache_jars/jakarta.xml.ws-api/4.0.0/jar_files.zip. 2 - Extract and copy only jakarta.xml.ws-api-4.0.0.jar 3 - Placed at JMS %DM_JMS_HOME%\webapps\DmMethods\WEB-INF\lib and JMS %DM_JMS_HOME%\webapps\Dm\WEB-INF\lib folder location. 4 - Update the dfc.properties in JMS %Documentum\config by adding dfc.session.allow_trusted_login=true">dfc.session.allow_trusted_login=true at the end. 5 - Restart the JMS service.
LSCI-37017	There is a compatibility issue between Brava CSR and Brava Enterprise. Markups added in Brava CSR cannot be retrieved in Brava Enterprise and vice versa. Therefore, when upgrading or switching between these two viewers, ensure to complete any open workflows or tasks.
LSCI-33024	Variable Part of Name is not added to the object name if it contains single quotes or apostrophes.
LSCI-35555	Some Search Endpoint parameters in the Swagger UI have a different name that causes them to be neglected in the request sent.
LSCI-28105	Withdrawing the current version of a document does not withdraw the Approved versions.

Issue number	Issue description
LSCI-26998	After you create a distribution list and then create a document and associate it with the distribution list, if you change the domain of the distribution list or any other property in the distribution list, the changes are not cascaded to the associated document.
LSCI-22676	When the Inherit rule to copy the VDoc structure is configured and during the creation process of the document, if the user selects a template, the final document creates all the child documents of both the template and inherited document.
LSCI- 25576/DTWO-	Multiple copies of the same document are displayed in the Doc List widget. This is a D2-dependent issue.
52702	Workaround : If the D2 installer modifies the 'return_top_results_row_based' flag in the server.ini file, then you must restart the repository for the changes to take effect.
LSCI- 19208/DTWO-	Users cannot perform the "Reselect Performers and Resend" action and assign Approvers on a document in a workflow when it is checked out.
35674	The following D2-Config workflow configuration for correcting the invalid Approver task must be applied:
	1. The Check lifecycle consistency on task end check box is not selected—If the task owner checks out a document that is in a workflow but does not check it in prior to completing the task, they will lose their work. To avoid this, ensure that this check box is selected to ensure no data loss occurs if a user forgets to check in the document. However, it can have an impact on the system.
	2. The Check lifecycle consistency on task end check box is selected— If the user receives a sole Approver task (they assigned the Approval task to themselves), the user will need to use the Update Performers option in the Workflow Overview widget to first select a new Approver and then complete their task. They will no longer be able to select new Approvers from the Complete Workflow Task dialog box with this check box selected.
LSCI-16828	Renditions are not created for the documents imported by Consumers. This is because Consumers do not have access to Draft documents, so the renditions will not be generated. The rendition will only be generated when a Contributor accesses the document. This is a Life Sciences limitation.

Issue number	Issue description
LSCI-16443/ DTWO-3628	Unable to hide or disable the default Brava! menu options such as Signature and Redaction and the dialog box options like the Save with All Versions and Save Private Markup checkboxes in the Life Sciences solution. This is because menu customization is not supported in Brava! for D2.
	It is recommended that you not use the Signature and Redaction options when annotating a document or the Save with All Versions and Save Private Markup options when saving the markup as these options are not relevant to the Life Sciences use-cases.
LSCI-15131	The Magellan BI & Reporting My Workflows report does not show the Content Template and Controlled Print workflows in the list of workflows.
LSCI- 13265/DTWO-	D2 dictionary with more number of rows fails to show in D2-Config. The dictionary cannot be deleted from D2-Config. This is a limitation.
30488	Workaround: The Administrator must export the entire dictionary, make necessary changes, and then import it back into D2-Config.
LSCI- 11281/DTWO- 26811	Documents in the "Effective" or "Final" state are listed under the Approved facet.
LSCI- 10722/DTWO- 26095	In the Review/Approve workflow for any document, if you try to attach a document to the workflow through the Workflow Task List widget > Manage workflow attachments , the attachment does not appear in the Task Attachment widget.
LSCI- 10621/DTWO- 26218	When using O2 Configuration to populate values in the document content and when those values are updated through properties Save, the document native content updates but the PDF rendition still shows the old values.
	Workaround : It is not possible to control the triggering of PDF rendition request automatically for each property save. If any properties of the document updated through O2, which internally changes the document content, then you must manually trigger a PDF rendition.
LSCI- 9620/DTWO- 25169	In multi-view workspaces that contain multiple Doc List widgets, whenever you switch between views, the Doc List widget shows the wrong document highlighted even though the Properties widget shows the correct properties of the currently-selected document.

Issue number	Issue description
LSCI- 8015/DTWO- 22625	Tasks do not auto-refresh in the Tasks widget during an active session. Workaround: This is a D2-dependent issue where the refreshing of tasks is not handled intuitively by D2 when the user switches views from a workspace view to the Welcome page. To resolve this issue, you need to manually refresh the widget whenever you switch views.
LSCI-51510	When a submission assembly is created, Placeholders are not hidden in the vDoc structure for the virtual documents.

8.2 Documentum for eTMF

Issue number	Issue description
LSCI-41315	UpdateContributorGroupsMethod does not behave well under multi thread/process access due to concurrent access to groups from more than one thread/process. This is due to multiple groups being attached to the same parent, coming from different threads/processes.
LSCI-42897	As part of the IDMP implementation, the Update Trial Info menu has been removed and there is no UI option to update the trial registration form.
LSCI-42880	On document creation, when Enable Content is selected, attributes get updated. However, after check-in, the PDF generated does not contain the values.
	Workaround: When you "Enable Content," select all the content of the checked out Word document and click F9. Save it. Then check in the document.
LSCI-40625	When a repeating property on the Parent document used in creating the VDoc structure from a VDTS template contains an apostrophe in one of the values, then all the child documents will have that repeating value concatenated with a comma of all the repeating values following that value. Additionally, this concatenated string will then be assigned to the position in the repeating attribute with the entire concatenated string instead of the individual repeating attributes.
LSCI-33060	Variable Part of Name is not added to the object name if it contains single quotes or apostrophes
LSCI-23068	Additional attributes configured in the TMF reference model for a document do not get applied on the document that is imported through Bulk Import-Export.

Issue number	Issue description
LSCI-16652	When using the "(Reject QC)" action from the context menu, the "(Index via Effective)" transition is called through the CDFApplyD2ConfigurationsMethod, which uses the system security context for its actions. As a result, when the "(Index via Effective)" adds the current user, the system user, to the authors attribute. This is generally not an interactive user and has supervisory access to the system. As such, this is not a security concern, however, be aware that the document could have the system login name value in its Authors attribute.

8.3 Documentum for Quality and Manufacturing



Note

Note that language pack-related issues that can be resolved through manual configurations are documented in the *Preparing the Life Sciences Solution for Localization* section in the *OpenText Documentum for Quality and Manufacturing Installation Guide*. Known limitations are also documented in the *Language Pack Overview* section in the *OpenText Documentum for Quality and Manufacturing Installation Guide*.

Issue number	Issue description
LSCI- 49859	Site wise folder permission requires the keywords attributes to be populated correctly. Keywords attribute is of length 64 characters, if the site names are more 64 characters increase the length of the keywords attribute by using the below query:
	EXECUTE ALLOW_BASE_TYPE_CHANGES WITH ALLOW_CHANGE_FLAG=1 GO alter type "dm_sysobject" MODIFY ("keywords" char(255) REPEATING) PUBLISH GO EXECUTE ALLOW_BASE_TYPE_CHANGES WITH ALLOW_CHANGE_FLAG=0 GO
LSCI- 52247	All Workflow participants does not get tasks when Chinese Language pack is enabled in the system. Workaround: please apply the Content server Hotfix as applicable: For Windows SQL: KB0804038 https://support.opentext.com/csm?id=kb_article_view&sysparm_article=KB0804040 Por Linux Oracle: KB0804040 https://support.opentext.com/csm?id=kb_article_view&sysparm_article=KB0804040

1.00:	
LSCI- 52230 / LSCI- 52178	Arabic Language pack Is supported with below workarounds :
	Increase the workflow name attribute length.
	Document following dql query to be executed:
	EXECUTE ALLOW_BASE_TYPE_CHANGES WITH ALLOW_CHANGE_FLAG=1
	alter type "dm_workflow" MODIFY ("object_name" char(255))
	EXECUTE ALLOW_BASE_TYPE_CHANGES WITH ALLOW_CHANGE_FLAG=0
	Execute iapi command to run dd publish job post above changes:
	<pre>publish_dd,c,,dm_workflow,,T</pre>
	 Need to set the requestParameterEncryptEnabled parameter to false in <tomcat>\webapps\D2\WEB-INF\classes\settings.properties on the Application Server.</tomcat>
LSCI-	Print functionality fails when print profiles are deleted.
43542	Workaround : In case LS Print profiles are deleted, the print profile can be re-created or re-installed and unchecked in the matrix. This allows existing prints to find the profile for display purposes but does not allow printers to select it for new prints.
LSCI- 43196	Controlled Print widget loads slowly for first-time user logged into the system.
LSCI- 27223	When you import a Category 3 VDoc with the Import State selected as Approved, the document created in the system shows the state as Draft instead of Approved.
LSCI- 13785	The controlled printing of multiple documents is not supported.
LSCI- 13372	To streamline Tech Transfer notifications, state change notifications should be sent only when a new version of the document is approved or if it is withdrawn. The notification list users should not receive interim work-in-progress state change notifications.
LSCI- 11749	When sending a document for controlled printing, the Print dialog box is populated with information that is shown on PDF rendition. The Location of print-out field does not have any restriction on the number of characters that can be added and therefore does not limit the number of characters displayed on the PDF rendition.
LSCI- 17095	System allows download a PDF through the Doc Preview widgets
	Current Behavior:
	Edge does not provide option to download while Chrome allows.
	With Chrome browser settings, there are two behaviors how to work with PDF. Either view it within browser or download.
	Workaround:

	System can be Configured to use "For Doc Preview & Annotations" Widget then download option is not available. This a Brava CSR which can be configured to prevent download
LSCI- 37347	Controlled print will not work when language pack is installed on PostgreSQL.
LSCI- 33821	The Find My Documents search does not work properly in the localized environment. When a user runs the search using keywords, only some or none of the documents having the keywords are returned. This is also the case when no keywords are entered.
LSCI- 33161/ DTWO- 67126	Some D2 property page strings are not translated in Portuguese. This is a D2-dependent issue.
LSCI- 33082	GMP Applicable Sites must use the English site name in all languages.
LSCI- 33080	Print Report exports do not support localized text.
LSCI- 32768	OK button is not translated in Chinese.
LSCI- 32763	Radial buttons in the Document Training creation profile (Group and User) are not translated in Chinese.
LSCI- 32384	If multiple languages are installed, the subject and message body of an email notification will show the translated text for all the installed languages, resulting in longer emails. This is a D2 limitation. However, if you want to improve shorten the email and improve readability, in D2-Config, go to Mailing list and add the text for only one language in the Email subject and Email message fields.
LSCI- 32383	The list of workflow names in the Find Documents in a specific workflow query form search results are not translated.
LSCI- 32078	The workflows in the Workflow Name list in the Find Documents in a specific workflow search query is not translated.
	Workaround : You can convert this from a query to a dictionary. This would be a standard D2 dictionary, in which the keys are the workflow process template names and the labels in English are the same as the keys. The dictionary can then be localized. This would also enable the workflows shown in the query form to be restricted to relevant ones. However, this workaround results in the maintaining of a duplicate list.

LSCI- 31007	The Change Type values in the properties page of a Change Request is not translated.
LSCI- 31005/ DTWO- 63712	Relation names are not being translated in the UI. This is a D2-dependent issue.
LSCI- 30609	The errors messages that appear on the System Messages tab for Change Requests are not translated.

8.4 Documentum for Research and Development

Issue number	Issue description
LSCI-42967	VDoc creation stuck at Constructing state. Workaround: In RD-SSV Cat 2 Controlled Document Lifecycle, "(Generate VDoc)" LC state, the max_threads parameter must be passed as 1 always in order to avoid session failures with VDoc structure construction.
LSCI-51138	Creation of vDoc Submission Assembly creation, user's might abserve a error message like "Required property psmf_component_type is undefined". Vdoc Assembler's reporting of missing required properties, as it does not support "conditionally-required" properties. For example, the eudact_number property is required only for clinical documents in the subgroup "CTA Document" in the Clinical Properties Non-Study-Specific property page. You can safely ignore these Error messages.
LSCI-51515	Harvested Clinical, Non-Clinical artifacts in the virtual document assembly are not visible to regulatory managers
LSCI-51202	Creation of quality artifacts in the vDoc Submission Assembly may lead to "Undefined" folder due to country_code in the Auto linking.
LSCI-38946	Medical devices specific artifact dictionaries are not set by default and needed to be defined by implementation team during the Project Implementation
LSCI-35802	Users in the cd_regulatory_template_authors group may observe an error in the Authors list under the Process Info tab during the creation of a Regulatory Labeling Content Template.
	Workaround: Users intending to create both Regulatory Admin Content Template and Regulatory Labeling Content Template must be added to both cd_regulatory_template_authors AND cd_labeling_template_authors groups.
LSCI-33107	VDocs for Submission Assembly/Submission Subassembly/Submission Component are created as normal documents.

Issue number	Issue description
LSCI-42967	VDoc creation stuck at Constructing state.
	Workaround : In RD-SSV Cat 2 Controlled Document Lifecycle, "(Generate VDoc)" LC state, the max_threads parameter must be passed as 1 always in order to avoid session failures with VDoc structure construction.
LSCI-51138	Creation of vDoc Submission Assembly creation , user's might abserve a error message like "Required property psmf_component_type is undefined".
	Vdoc Assembler's reporting of missing required properties, as it does not support "conditionally-required" properties. For example, the eudact_number property is required only for clinical documents in the subgroup "CTA Document" in the Clinical Properties Non-Study-Specific property page.
	You can safely ignore these Error messages.
LSCI-51515	Harvested Clinical, Non-Clinical artifacts in the virtual document assembly are not visible to regulatory managers
LSCI-51202	Creation of quality artifacts in the vDoc Submission Assembly may lead to "Undefined" folder due to country_code in the Auto linking.
LSCI-38946	Medical devices specific artifact dictionaries are not set by default and needed to be defined by implementation team during the Project Implementation
LSCI-27723	If a document is selected/highlighted prior to initiating the creation of a Non- clinical Module 4 virtual document, the appropriate document templates will not be displayed.
	Workaround: To resolve this issue, follow these steps:
	Log into D2-Config as Administrator.
	2. In the filter on the main toolbar, select All elements .
	3. Select Creation > Creation profile.
	4. Under Profiles , select Non-Clinical Virtual Documents .
	5. Under Default options , clear the Properties inheritance check box.
	6. Click Save .
LSCI-24395	The name of the Change Security Model dialog box is not correctly displayed.
LSCI-22620	Template selection is executed and ignored when copy VDoc structure is selected in the document creation dialog box.
LSCI-14258	Incorrect inheritance attribute mapping causes all the properties from the selected document to be copied to the target document (newly created document) regardless of whether these properties are applicable to a target document or not.

Issue number	Issue description
LSCI-42967	VDoc creation stuck at Constructing state.
	Workaround: In RD-SSV Cat 2 Controlled Document Lifecycle, "(Generate VDoc)" LC state, the max_threads parameter must be passed as 1 always in order to avoid session failures with VDoc structure construction.
LSCI-51138	Creation of vDoc Submission Assembly creation , user's might abserve a error message like "Required property psmf_component_type is undefined".
	Vdoc Assembler's reporting of missing required properties, as it does not support "conditionally-required" properties. For example, the eudact_number property is required only for clinical documents in the subgroup "CTA Document" in the Clinical Properties Non-Study-Specific property page.
	You can safely ignore these Error messages.
LSCI-51515	Harvested Clinical, Non-Clinical artifacts in the virtual document assembly are not visible to regulatory managers
LSCI-51202	Creation of quality artifacts in the vDoc Submission Assembly may lead to "Undefined" folder due to country_code in the Auto linking.
LSCI-38946	Medical devices specific artifact dictionaries are not set by default and needed to be defined by implementation team during the Project Implementation
LSCI-13932	Duplicate rows in the grid on the property page of the Related Applications/Submissions lifecycle action on a Regulatory Activity Package are not automatically deleted.
LSCI-13553	The "Regulatory-Admin Classification by EU Region" taxonomy in D2-Config has multiple entries for the EMA for certain EU countries when there should only be one entry.
LSCI-13372	To streamline Tech Transfer notifications, state change notifications should be sent only when a new version of the document is approved or if it is withdrawn. The notification list users should not receive interim work-in-progress state change notifications.
LSCI-10786	There is no uniqueness check for the device code field in the Medical Device Registration Form creation being case sensitive. You can create a Medical Device Registration Form with an existing device code but with a different case.
LSCI- 4884/DTWO- 18867	When approving a virtual document structure that is in a workflow, such as for Submit for Review / Approval, the virtual document structure is validated to ensure that its component documents are in an appropriate state, that is, Draft or Approved. Individual component documents and sub-sections of the virtual document can be pre-approved if necessary. "Withdrawn" documents are disregarded. If the virtual document contains documents in other lifecycle states

Issue number	Issue description
LSCI-42967	VDoc creation stuck at Constructing state. Workaround: In RD-SSV Cat 2 Controlled Document Lifecycle, "(Generate VDoc)" LC state, the max_threads parameter must be passed as 1 always in order to avoid session failures with VDoc structure construction.
LSCI-51138	Creation of vDoc Submission Assembly creation, user's might abserve a error message like "Required property psmf_component_type is undefined". Vdoc Assembler's reporting of missing required properties, as it does not support "conditionally-required" properties. For example, the eudact_number property is required only for clinical documents in the subgroup "CTA Document" in the Clinical Properties Non-Study-Specific property page. You can safely ignore these Error messages.
LSCI-51515	Harvested Clinical, Non-Clinical artifacts in the virtual document assembly are not visible to regulatory managers
LSCI-51202	Creation of quality artifacts in the vDoc Submission Assembly may lead to "Undefined" folder due to country_code in the Auto linking.
LSCI-38946	Medical devices specific artifact dictionaries are not set by default and needed to be defined by implementation team during the Project Implementation such as "For Review" or "For Approval", or checked-out documents, or documents involved in other workflows, the operation is reported as invalid. The relevant documents must be checked-in, approved as and where necessary, and any workflows they are involved in completed, prior to sending the virtual document itself for review / approval and / or self-approving it. However, because of a D2 limitation which prevents validation error messages from being sent to the client, the invalid documents are not reported.

8.5 Documentum Submission Store and View

Issue number	Issue description
LSCI-43489	The Magellan BI & Reporting Submission Dashboard report does not work as designed.
LSCI-35967	The Magellan BI & Reporting report, My Workflows, does not work for the Content Template Approval workflow.
LSCI-18378	The Submission Viewer shows names of hidden submission documents. LSSSV does not support the "a_is_hidden" flag on Submission documents and does not set it when importing them. Therefore, NeeS files marked as hidden in the operating system will not be imported as hidden in the Submission Viewer. In

Issue number	Issue description
	eCTD submissions, hidden files are not included in the backbone XML files and therefore, they do not appear in the Submission Viewer. This is a limitation.
LSCI-13932	Duplicate rows in the grid on the property page of the Related Applications/Submissions lifecycle action on a Regulatory Activity Package are not automatically deleted.
LSCI-13553	The "Regulatory-Admin Classification by EU Region" taxonomy in D2-Config has multiple entries for the EMA for certain EU countries when there should only be one entry.
LSCI-7448	Audited attributes are empty in the Audit Trail entries of Submission subfolders.
LSCI-6777	Unable to preview SPL documents, PDFs with hyperlinks, regional XML files, and STF documents in the Document Viewer widget in the Browse workspace. This is a limitation.
	Workaround: You can preview all these documents in the Submission Viewer. Right-click the SPL or other documents and select Show in Submission viewer. The selected object is displayed in the Submission Viewer in View Submission workspace. The XMLViewer sends a request to the document viewer and the Submission Document Viewer widget renders the object as expected.
LSCI- 4955/DTWO- 18930	A user can access hyperlinks present in a Regulatory Submission document without entering any credentials using the same browser that was left open by another user who had accessed those hyperlinks.
LSCI-3213	Clicking the inter-document hyperlinks in a PDF in the Submission Document Viewer in Google Chrome on Windows and in Safari on Macintosh opens the corresponding PDF in the whole window instead of opening it inside the Submission Document Viewer.
	Workaround: To resolve this issue, for Chrome on Windows, hold down the CTRL key and click the hyperlink to open the PDF in a new window. For Safari on Macintosh, hold down the COMMAND key and click the hyperlink to open the PDF in a new window.

9 Contact information

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