

OmniVIEW Next Generation

How-To Guide

Revision Sheet

Revision	Revised on Date	Content Updates
Rev-1	01/04/2019	Sprint 1 Topics: Introduction to OmniVIEW, First time login, Forgot password, and Accessing Application
Rev - 2	01/28/2019	Validate Submission

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WHAT IS OMNIVIEW?

OmniVIEW is an application that allows you to view and validate the submissions in Electronic Common Technical Document (eCTD) format with XML support. The electronic common technical document (eCTD) is an interface and international specification between the pharmaceutical industries and agencies for the regulatory information. Using OmniVIEW, you can view the submissions in lifecycle view and validate at any stage of the drug development.

The eCTD has 5 modules and these modules are divided into two categories as follows:

- **Regional module:** eCTD maintains a different module (m1) for each country.
 - **M1:** This module has administrative and prescribing information.
- **Common modules:** eCTD maintains common modules (m2–m5) for all the countries.
 - **M2:** This module has information about Common technical document summaries.
 - **M3:** This module deals with information about quality.
 - **M4:** This module has information about nonclinical study reports.
 - **M5:** This module has information about clinical study reports.

The content for the modules are defined by the following:

- For common modules, CTD defines the content.
- For regional module, ICH regions such as USA, CA, Europe, and Japan define the content.

The eCTD is a message specification that allows the submitter to transfer the files and metadata to a receiver. eCTD contains the following primary components:

- A high-level folder structure.
- An XML file that provides metadata about content files and lifecycle instructions for the receiving system.
- An optional lower level folder structure.
- Associated document type definitions (DTDs) and stylesheets.

Each submission message consists of a sequence. A collection of eCTD files consists of one or more sequences. You can view a single sequence in a web browser. However, to view the collection of sequences, you can use OmniVIEW.

Following is a sample directory structure:

- ctd-123456/0000/index.xml
- ctd-123456/0000/index-md5.txt
- ctd-123456/0000/m1
- ctd-123456/0000/m2
- ctd-123456/0000/m3

- ctd-123456/0000/m4
- ctd-123456/0000/m5
- ctd-123456/0000/util

The string ctd-123456/0000 is an example.

About Index File

Index.xml file is the backbone of the submission sequence number folder. For example,

ctd-123456/0000/index.xml

The index.xml file has two purposes as follows:

- Manage meta-data for the entire submission
- Constitute a comprehensive table of contents and provide corresponding navigation aid.

WHAT ARE THE SUPPORTED ACRONYMS AND ABBREVIATIONS?

eCTD	Electronic Common Technical Document
MVP	Minimum Viable Product
OAdmin	Omnicia Admin
OP	Omnicia Publisher
OA	Omnicia Author
CAdmin	Customer Admin
CP	Customer Publisher
CA	Customer Author
DTDs	Document Type Definitions

WHAT ARE THE SUPPORTED BROWSERS AND DEVICES?

Following are the supported browsers and devices.

Browsers	Versions
Google Chrome	67.0.3396 and above
Safari	11 and above
Mozilla Firefox	
Devices	Size
iPad/Tablet	Screen size 9.7 and above

WHAT ARE THE AVAILABLE USER ROLES?

OmniVIEW supports the following user roles:

- **Omnicia Users**
 - **Omnicia Administrators (OAdmin):** An Omnicia Administrator can create new customers (that is the pharmaceutical organizations). An OAdmin can restrict the customer to access limited features out of all the features available in OmniVIEW such as follows:
 - Ability to view and validate eCTD submissions.
 - Ability to access only specific sequence folders.
 - Ability to access only specific eCTD folders.
 - Ability to access only specific files or folders.

An OAdmin can create Omnicia Administrators(OAdmin), Omnicia Publishers(OP), and Omnicia Authors(OA).
 - **Omnicia Publishers (OP):** An Omnicia Publisher can access submissions of all the customers of Omnicia.
 - **Omnicia Authors (OA):** An Omnicia Author can access a sequence, folder, study file and so forth of the customers that are assigned by an Omnicia Administrator or Omnicia Publisher.
- **Customer Users**
 - **Customer Admin (CAdmin):** A Customer Administrator is usually the owner of an organization. A CAdmin is responsible to maintain Customer Publishers (CP) and Customer Authors (CA) of an organization. A CAdmin can access all the submissions of an organization.
 - **Customer Publisher (CP):** A Customer Publisher can access all submissions, create new submissions (via OmniFile), or upload new submissions of their company. A CP can share part of the submissions with Customer Authors within the same company.

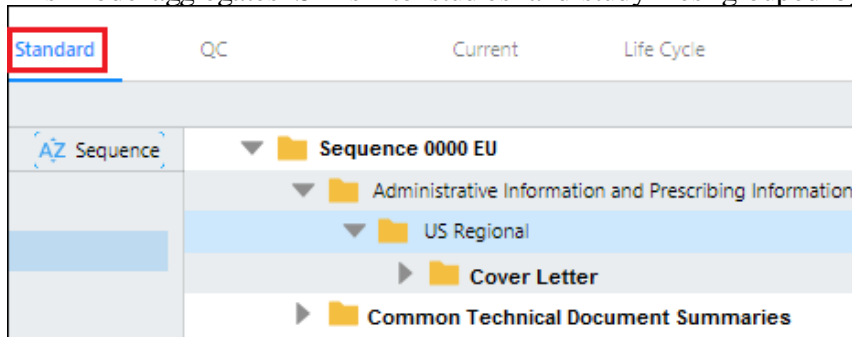
- **Customer Author (CA):** A Customer Author can perform the following:
 - Create documents for eCTD.
 - Review eCTD output produced by an eCTD publisher.

CA can access only that portion of submission which was shared to them by a CP.

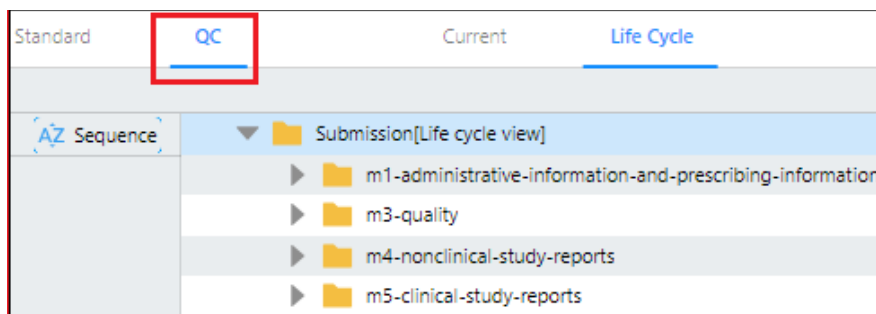
WHAT ARE THE DIFFERENT MODES AVAILABLE IN OMNIVIEW?

Following are the different modes available in OmniVIEW:

- **Standard Mode:** In this mode, you can view the node names as readable titles. For example, the XML heading '*m4-nonclinical-study-reports*' is displayed as '*Nonclinical Study Report*'. By default, the sequence of an application opens in the Standard Mode. This mode aggregates STF's into studies and study files grouped by file tag.



- **QC Mode:** In this mode, you can view:
 - The submissions based on the pure or true format of each XML backbone file.
 - The XML heading elements with their XML element names (as per the ICH DTD).
 - The STF's in non-aggregation format.
 - The study files in flat structure.



WHAT ARE THE DIFFERENT DISPLAY OPTIONS AVAILABLE IN OMNIVIEW?

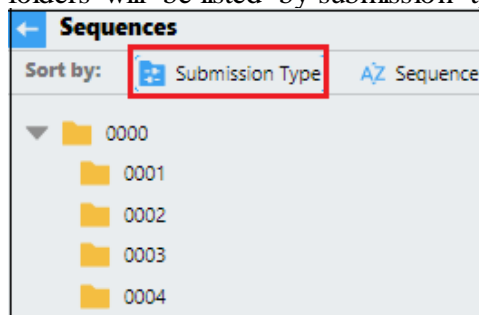
OmniVIEW supports two display options for both Standard and QC mode:

- **Current View:** This view displays only the current version of the file and you can perform all the following amendments:
 - Adding new file or node
 - Replacing and existing file or node
 - Appending information to an existing file
 - Deleting a file or node
- **Life Cycle View:** In this view, you can view the list of amendments performed on a node or a file. You can view the revision of a file distributed across multiple submissions under the appropriate module folder. The status of each leaf element will be displayed as a different color for each operation type.

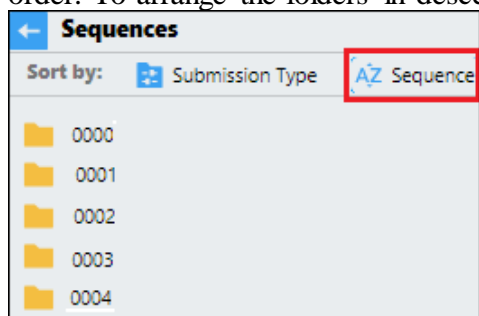
WHAT ARE THE AVAILABLE SORTING OPTIONS?

Following are the available sorting options:

- **List by Submission Type:** The Submission Type view displays the relationship between submissions as parent-child based on <submission-type> and <related-sequence> attribute values assigned to each us-regional.xml file. By default, the eCTD sequence folders will be listed by submission type.



- **List by Sequence:** The Sequence Type view displays folders in ascending numerical order. To arrange the folders in descending order, click Sequence again.



HOW TO LOGIN FOR THE FIRST TIME

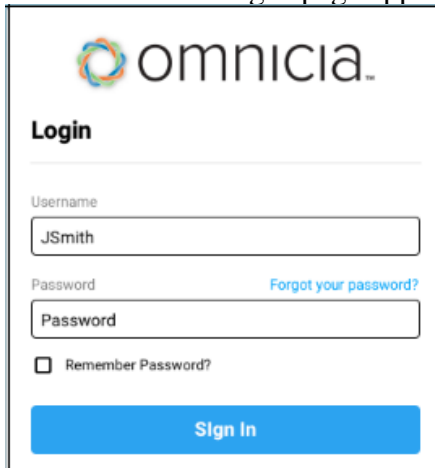
You can login to OmniVIEW with the User ID and Password created by your administrator. After your administrator creates your profile, an email is sent to you with the login credentials. You can login to OmniVIEW using those credentials.

Note:

- If you do not have login credentials, please contact your company's administrator.
- You can create your new profile only when you are logging in for the first time.

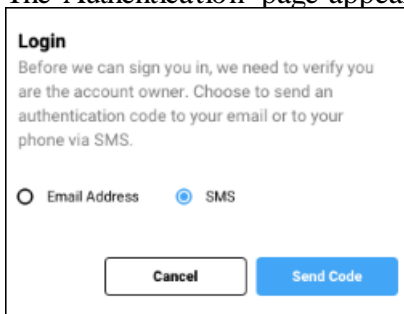
To login for the first time:

1. Open the email you have received from your administrator and click the link. The OmniVIEW login page appears.



The screenshot shows the OmniVIEW login page. At the top is the 'omnicia' logo. Below it is the heading 'Login'. There are two input fields: 'Username' with the text 'JSmith' and 'Password' with the text 'Password'. A link 'Forgot your password?' is next to the password field. Below the fields is a checkbox labeled 'Remember Password?'. At the bottom is a blue button labeled 'Sign In'.

2. In the Login page, enter the **Username** and **Password** that you have received in the email.
3. Click **Sign In**.
The Authentication page appears.



The screenshot shows the Authentication page. It has the heading 'Login' and a message: 'Before we can sign you in, we need to verify you are the account owner. Choose to send an authentication code to your email or to your phone via SMS.' There are two radio buttons: 'Email Address' and 'SMS', with 'SMS' selected. At the bottom are two buttons: 'Cancel' and 'Send Code'.

4. In the Authentication page, select either **Email Address** or **SMS** to receive the authentication code.
5. Click **Send Code**.
6. In the Authentication Code text box, enter the code that you have received.
7. Click **Login**.
The Create Your Profile page appears.

Create Your Profile

Complete the form below to create a profile. Fields with an * are mandatory.

Username and Password

Create a unique username and password. Passwords must be (password requirements go here)

Username*

Password*

Password Again*


User Details

First Name*

Last Name*


Email Address*

Phone Number*

 (123) 456-7890

Profile Picture

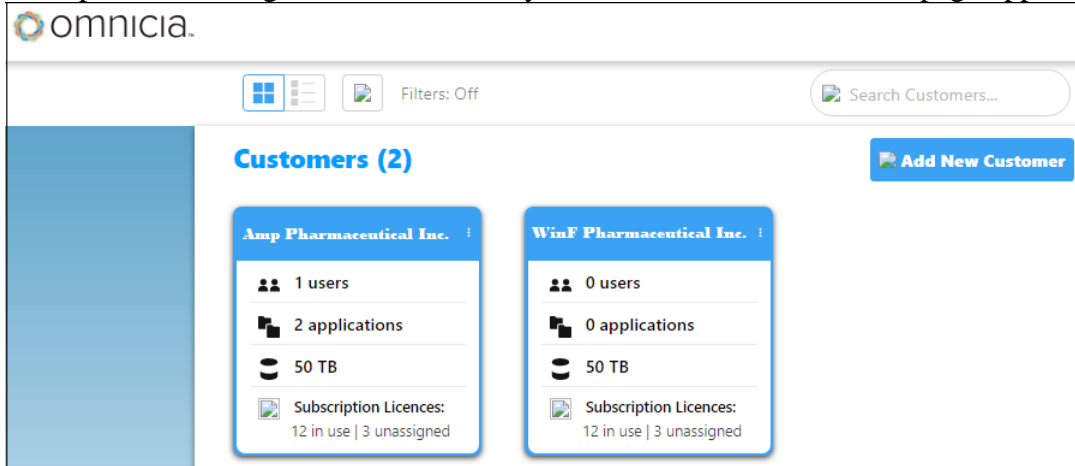
(Profile picture file size requirements go here)

 Drag & Drop or [Choose File](#)

8. In the Create Your Profile page, verify if the information such as **Username**, **First Name**, **Last Name**, and **Email Address** are correct.
9. In the Profile Picture, click **Choose File** to upload your profile picture.

10. Click **Save & Submit**.

Your profile details get saved successfully and OmniVIEW Dashboard page appears.



HOW TO LOGIN FOR THE SUBSEQUENT TIMES?

You can login to OmniVIEW with the User ID and Password created by your administrator.

Note: If you do not have login credentials, please contact your company's administrator.

1. Open the OmniVIEW login page.

The screenshot shows the OmniVIEW Login page. It features the OmniVIEW logo at the top, followed by the word 'Login'. Below this, there are input fields for 'Username' (containing 'JSmith') and 'Password' (containing 'Password'). A link 'Forgot your password?' is next to the password field. There is a checkbox for 'Remember Password?' and a blue 'Sign In' button at the bottom.

2. In the Login page, enter the **Username** and **Password**.

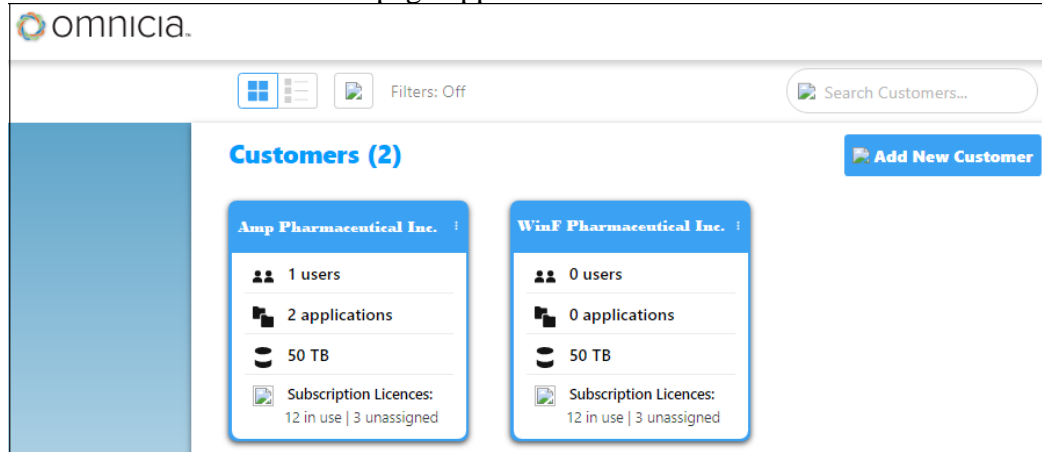
3. Click **Sign In**.

The Authentication page appears.

The screenshot shows the OmniVIEW Authentication page. It has the title 'Login' and a message: 'Before we can sign you in, we need to verify you are the account owner. Choose to send an authentication code to your email or to your phone via SMS.' Below this, there are two radio buttons: 'Email Address' and 'SMS' (which is selected). At the bottom, there are two buttons: 'Cancel' and 'Send Code'.

4. In the Authentication page, select either **Email Address** or **SMS** to receive the authentication code.
5. Click **Send Code**.
6. In the **Authentication Code** text box, enter the code that you have received.
7. Click **Login**.

The OmniVIEW Dashboard page appears.



HOW TO ACCESS APPLICATIONS?

You can access all the applications related to a customer and perform tasks such as follows:

- Open sequences
- View amendment list
- Expand all the nodes at once
- Validate sequences and so forth

You can view the structure of a sequence in the following modes:

- **Standard Mode:** In this mode, you can view the node names as readable titles. For example, the XML heading '*m4-nonclinical-study-reports*' is displayed as '*Nonclinical Study Report*'. By default, the sequence of an application opens in the Standard Mode. This mode aggregates STFs into studies and study files grouped by file tag
- **QC Mode:** In this mode, you can view:
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 - The STFs in non-aggregation format.
 - The study files in flat structure.

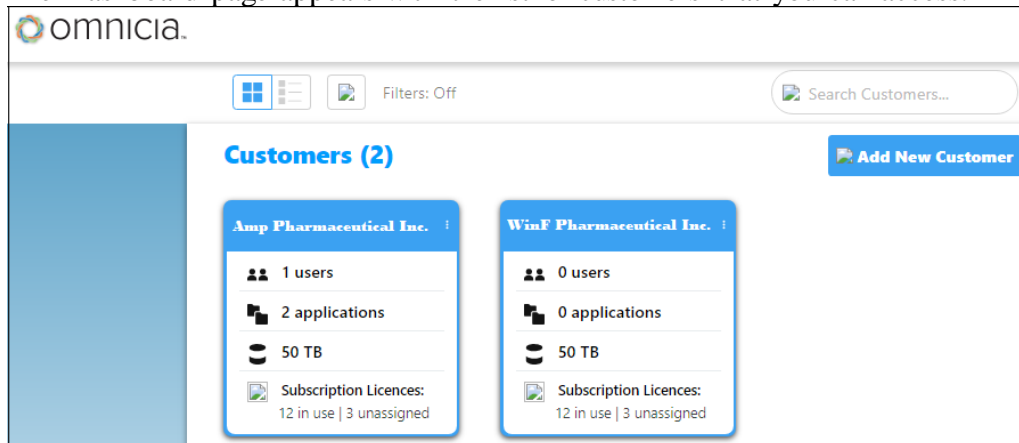
In both Standard and QC mode, OmniVIEW has two display options as follows:

- **Current View:** This view displays only the current version of the file and you can perform all the following amendments:
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 - Appending information to an existing file
 - Deleting a file or node
- **Life Cycle View:** In this view, you can view the list of amendments performed on a node or a file. You can view the revision of a file distributed across multiple submissions under the appropriate module folder. The status of each leaf element will be displayed as a different color for each operation type.

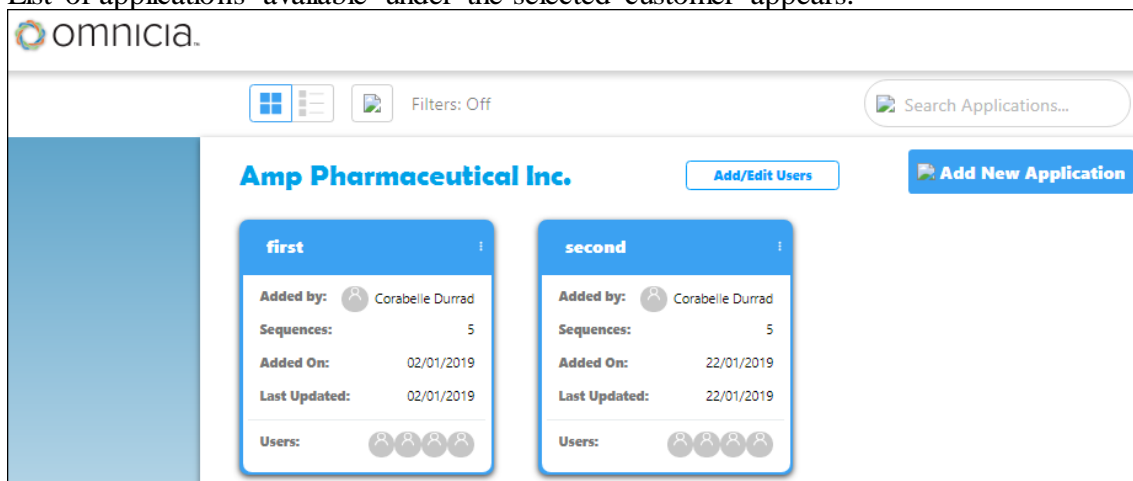
To access an application:

1. Log in to OmniVIEW.

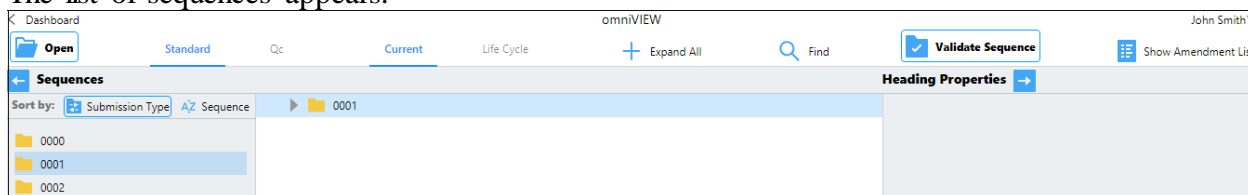
The Dashboard page appears with the list of customers that you can access.



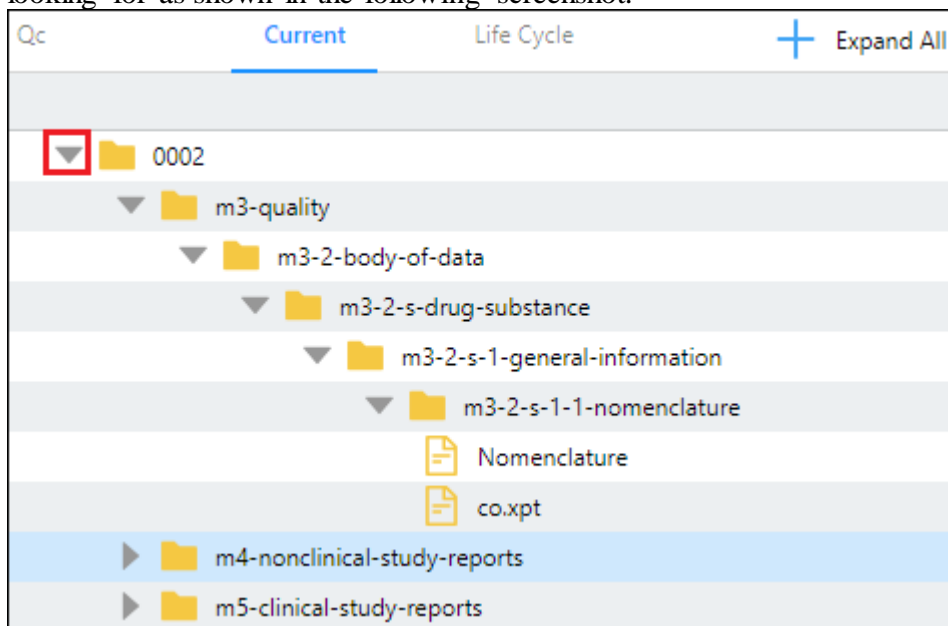
2. In the Dashboard page, click the customer for which you want to view the applications. List of applications available under the selected customer appears.



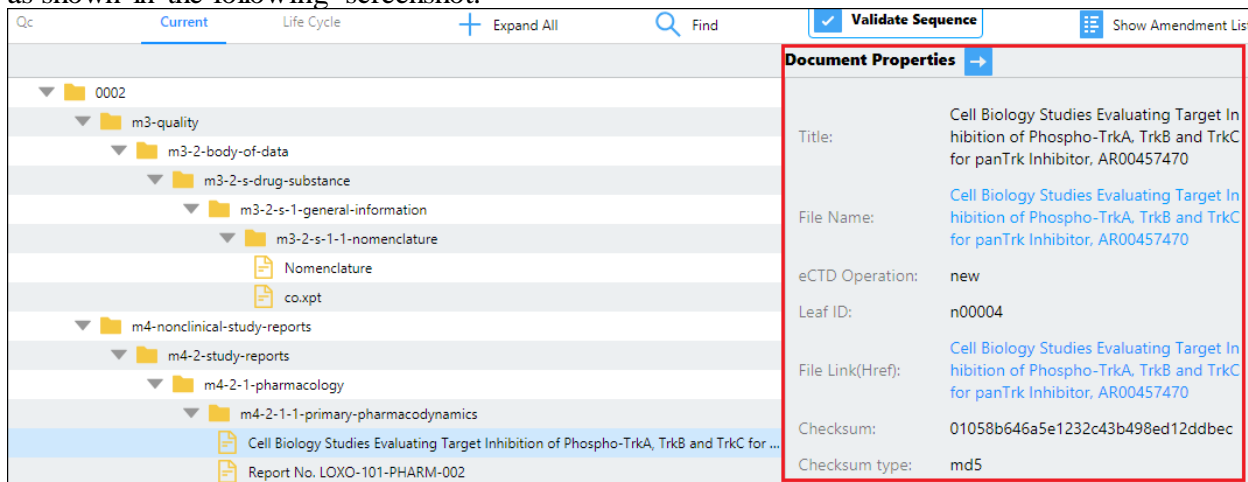
- Click the application for which you want to view the list of sequences.
The list of sequences appears.



- In the Sequences pane, click arrow for the required node till you reach the file you are looking for as shown in the following screenshot.



- Click a node or a file to view the properties in the **Heading** or **Document Properties** pane as shown in the following screenshot:



In addition to the current view, you can view the application in life cycle view.

The screenshot shows the OmniVIEW application in the 'Life Cycle' view. The left pane shows a tree structure of folders and files. The main pane displays a list of documents, with one document selected and its properties shown on the right. The properties include Title, File Name, eCTD Operation, Leaf ID, File Link(Href), Checksum, Checksum type, and Xlink Type. A 'Document Life Cycle' table is also visible at the bottom right.

Leaf ID	Operation	Modified File	File Name	Title
n00006	new		stf-loxo-101-dmpk-001.xml	stf-loxo-101-dmpk-001.xml
n02005	append		stf-loxo-101-dmpk-001.xml	stf-loxo-101-dmpk-001.xml

In the current view, you can perform all the amendments such as

- Add a node or file
- Replace a node or file
- Append a node or file
- Delete a node or file

In the Lifecycle view, for a file or a node, you can view the list the amendments performed for a file or a node.

HOW TO VALIDATE A SEQUENCE?

You can scan and validate a sequence according to your regional (CA, EU, and the US) validation criteria.

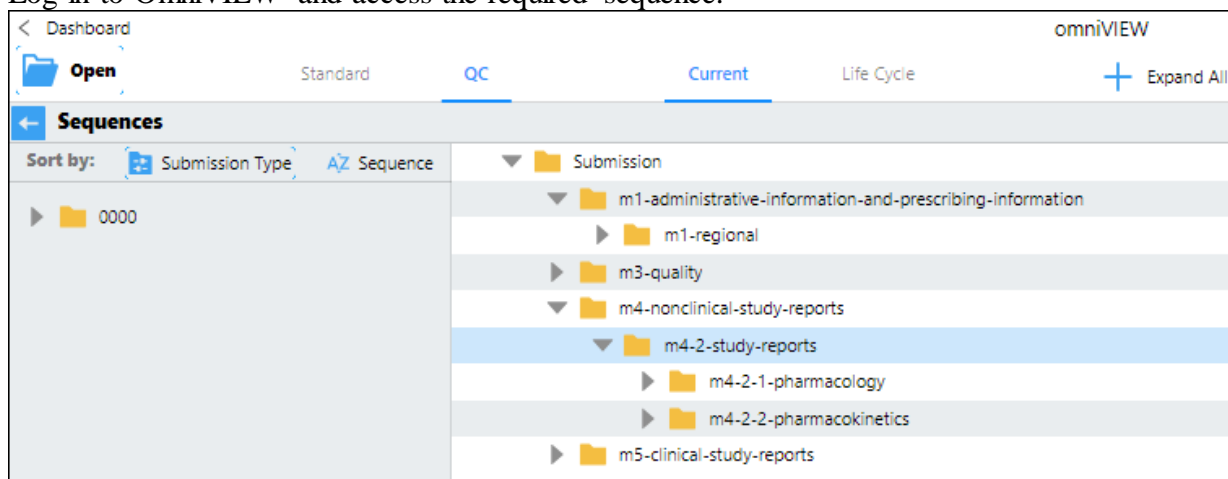
For each validation, details such as error number, description, and the following severity levels are displayed:

- **High:** This is a serious technical error which prevents the processing of the submission and requires a resubmission.
- **Medium:** This error might impact the reviewability of the submission which can be determined by further inspection.
- **Low:** This is a technical error which might or might not impact the reviewability or the integrity of the submission.

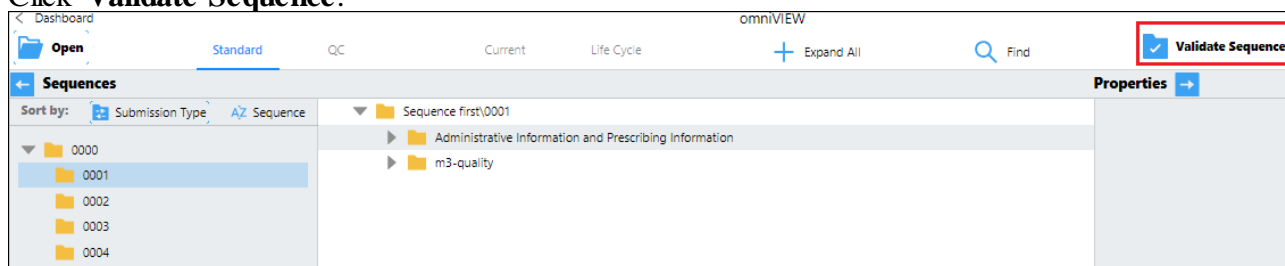
Note: For the latest version of the eCTD validation guidance documents, visit appropriate website.

To validate a sequence:

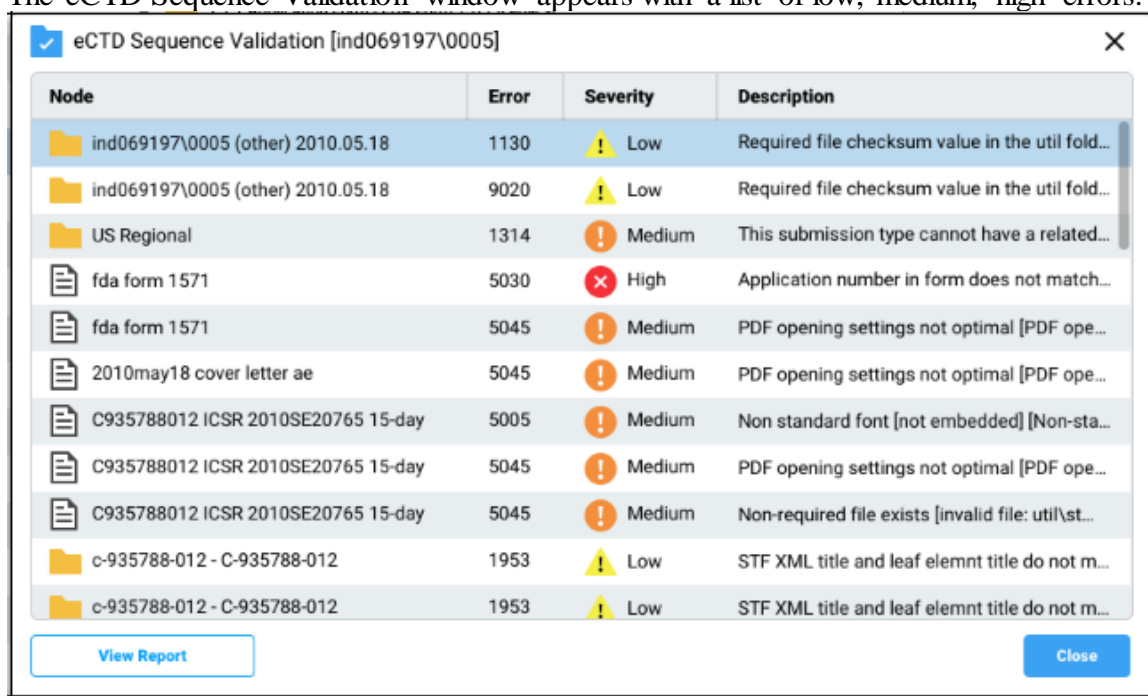
1. Log in to OmniVIEW and access the required sequence.



2. Click **Validate Sequence**.



The eCTD Sequence Validation window appears with a list of low, medium, high errors.



Node	Error	Severity	Description
ind069197\0005 (other) 2010.05.18	1130	Low	Required file checksum value in the util fold...
ind069197\0005 (other) 2010.05.18	9020	Low	Required file checksum value in the util fold...
US Regional	1314	Medium	This submission type cannot have a related...
fda form 1571	5030	High	Application number in form does not match...
fda form 1571	5045	Medium	PDF opening settings not optimal [PDF ope...
2010may18 cover letter ae	5045	Medium	PDF opening settings not optimal [PDF ope...
C935788012 ICSR 2010SE20765 15-day	5005	Medium	Non standard font [not embedded] [Non-sta...
C935788012 ICSR 2010SE20765 15-day	5045	Medium	PDF opening settings not optimal [PDF ope...
C935788012 ICSR 2010SE20765 15-day	5045	Medium	Non-required file exists [invalid file: util\st...
c-935788-012 - C-935788-012	1953	Low	STF XML title and leaf elemnt title do not m...
c-935788-012 - C-935788-012	1953	Low	STF XML title and leaf elemnt title do not m...

Note: The high and medium severity errors must be fixed to submit the sequences without any issues.

Click on the file or node to go to the location where the file or node folder is available. Ensure that you address each error by going back to the submission project structure in OmniFILE.

- (Optional) To save the validation report, click **View Report**.
OmniVIEW displays the validation report in Microsoft Word document (in .htm format).