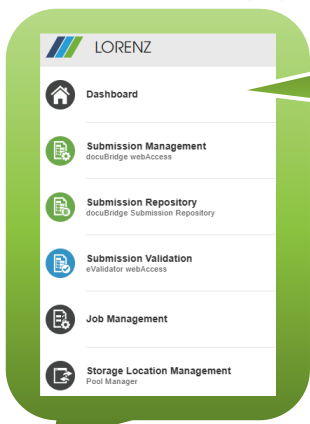




Quick Reference Guide



March 2024



Main menu: Find your Dashboard, Submission Management and Validator here.

Ribbon: Create New, Open, Custom Procedures, Check In, Check Out. Context Sensitive.

Filter: Refine your search by filtering for specific criteria. Multiple filters can be active simultaneously.

Change Layout

Profile

The screenshot shows the docuBridge Explorer interface. On the left is the 'Navigation Section' with a tree view of searches and reports. The center is the 'List Section' displaying a table of search results. On the right is the 'Properties Section' showing details for a selected application. A callout points to the 'My Workspace (Clinical)' section in the list, stating: 'My Workspace. All the submissions and sequences that need to be worked on by you, will appear here.'

Navigating docuBridge® Explorer Finding Submissions & Documents

At the bottom of the properties section, there are two important reports for the initial screening of the sequence.

Detailed hyperlink report for sequence

- Validation Report
<https://db-vec002//api/job-mngt/reports/f01309bbcb364a3a83239c28f37dae5/eVReport.html>
- Sequence Statistics
<https://db-vec002//api/job-mngt/reports/557c3d7f9dfa4f82a5df3d772017d8bd/eVReport.html>

Once a submission is open the screen shown below is displayed.

Sequences Pane

Delta Slider

Ribbons: Colours for Annotations, Highlights & Hyperlinks are selected under the Annotations Menu

Interact Mode
Select Mode

Create Annotations, Highlights & Hyperlinks

Useful panes during the evaluation process: Search Pane & Nodes Content Pane

View Controls: Page Transition, Page Orientation, Page Layout

Zoom, use Drop-Down for more options

Node Filter: Can be set based for Unit, or Review Status

Application View: All Sequences
Nodes: 24 Documents: 5 Pages: 15

docuBridge® Submission Workbench Viewing & Evaluating Submissions

Show content changes in following sequences

Node Content

Show subsequent content operations

0000	Sequence Letter of Application
	Description:
	Version Number:
	Pages: 3
	Format Version: 1.4
	File Size: 70 KB
	Protected or XFA: <input checked="" type="checkbox"/>
	Fast Webview: <input checked="" type="checkbox"/>

Node Content History: This useful panel displays the history of documents. If a document has been replaced, you will find all versions of the document here.

- A document taking the place of a previous document
- A document added to an application for the first time
- A document has been withdrawn from the Submission

Search

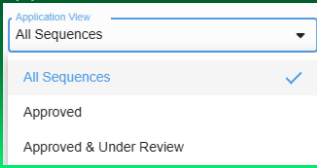
Nodes Annotations Hyperlinks

Please enter the search phrase...

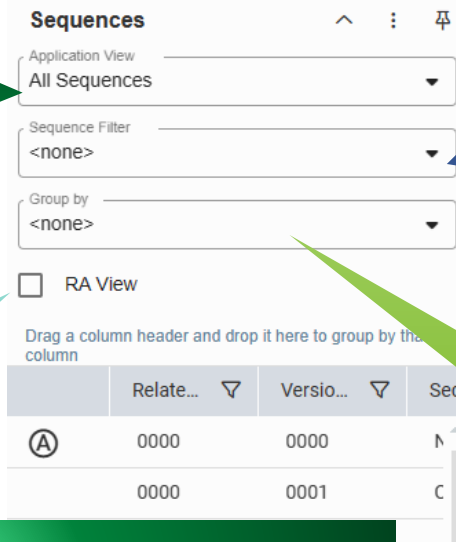
Search only in: 0000 - New Generic (Multi-source) - 0000 (New Application) **Find**

Use the search pane, to search Annotations, Nodes and Hyperlinks. Search Criteria available for each search.

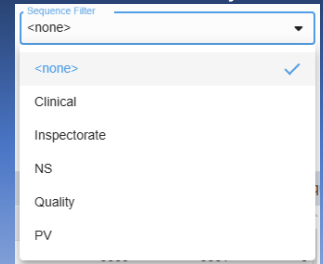
Filter Applications based on their status



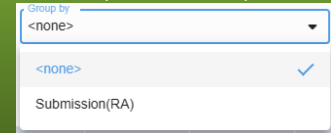
View only content that is related to the Submission (Regulatory Activity)



Filter sequences based on UNIT activity



Group sequences by Regulatory Activity (Submission)



Sequences Pane Group & Filter

Key Definitions

Application:

The term Application is used for SAHPRA's medicine registration process and is the top group of a series of sequences for the same product (e.g. active ingredient). One Application is usually defined for the complete life cycle of the specific product.



Submission/Regulatory Activity:

The term Submission or Regulatory Activity is a subgroup of an Application which can be a group or series of related sequences for one approval process (e.g. one variation). These sequences do not have to be sequential. One Regulatory Activity is usually defined for the lifecycle of the specific approval process.

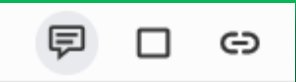


Sequence:

A sequence is a package of information bundled together in an electronic structure providing information to the agency. The contents of a sequence will depend on the regulatory activity type and whether it is the initial sequence of the regulatory activity or a follow-up providing additional data or changes.

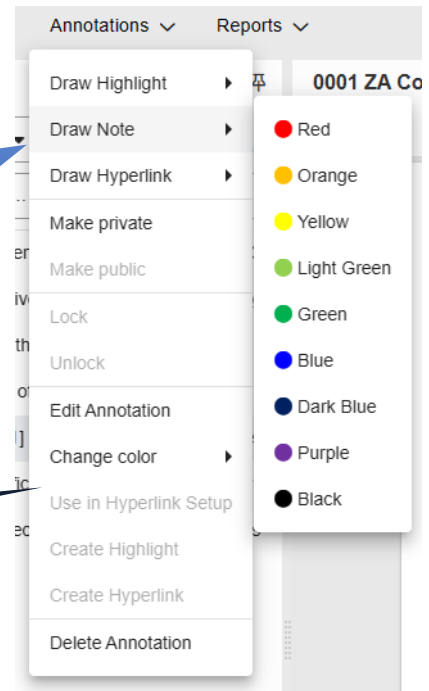
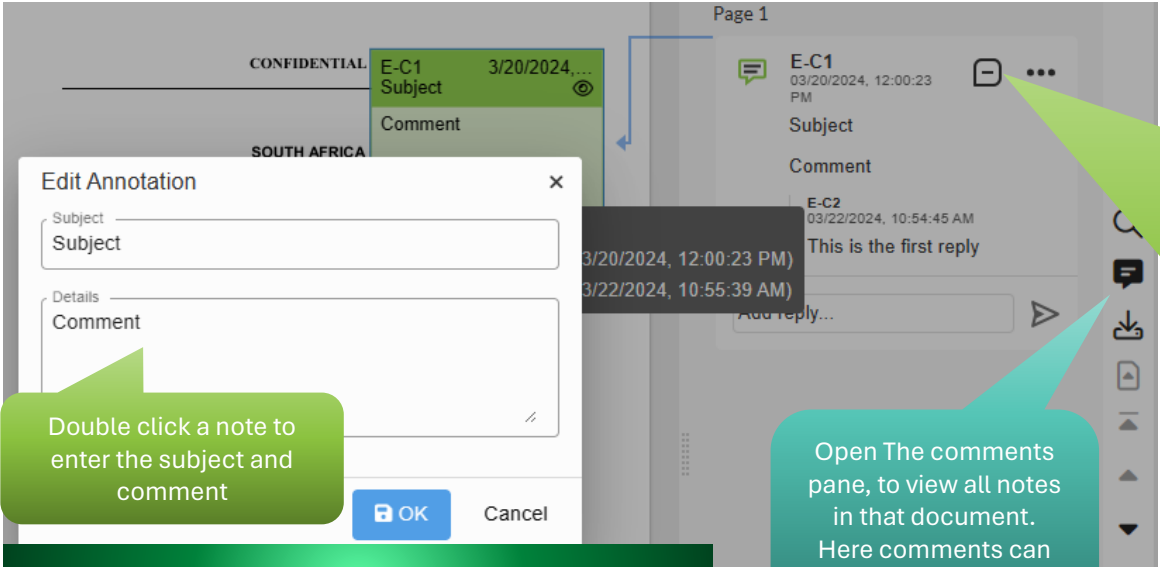
Using Annotations Highlights & Notes

Select colour for Highlights & Notes here. Mouse pointer will become a crosshair. Click, draw the annotation, and release.



Annotations can also be made using these buttons. The previously selected colour will be defaulted.

To change the colour, edit, or delete an annotation, select it and open the annotations drop down. The same options are available when right clicking the annotation.

Edit Annotation

Subject
Subject


Details
Comment

OK Cancel


Change Status here

- Accepted
- Rejected
- Cancelled
- Completed
- None

Comments Pane



Use these to interact and select annotations respectively.



Use this icon to show (make visible) or hide visible annotations.

Annotations can be searched based on author, type, text, and colours. Search results can be filtered by column for more precise results.

