

eCTD SmartViewer – Installation & User Guide

Currently, after downloading eCTD submissions, the files cannot be opened directly in standard web browsers such as Microsoft Edge or other commonly used browsers. Each time, users are required to manually configure a web page URL, and in addition, agency-specific stylesheets are not supported by most modern browsers.

To address this limitation, we have developed eCTD SmartViewer, a simple and effective solution that enables users to preview the final eCTD output seamlessly. This tool allows users to review the complete submission in a browser-friendly format before submitting it to the respective regulatory agency.

1) Introduction

eCTD SmartViewer is a lightweight utility designed to help users open and preview final eCTD submission XML files (US, Europe, Australia, Canada, Switzerland, Jordan, Gulf Cooperation Council (GCC), Thailand, WHO, South Africa, and all other regions) in compliance with backbone eCTD Viewer XMLs. This tool eliminates the need for manual browser configuration and unsupported agency stylesheets, enabling a smooth review experience before regulatory submission.

2) System Requirements & Pre-requisites

Before installing eCTD SmartViewer, please ensure the following requirements are met:

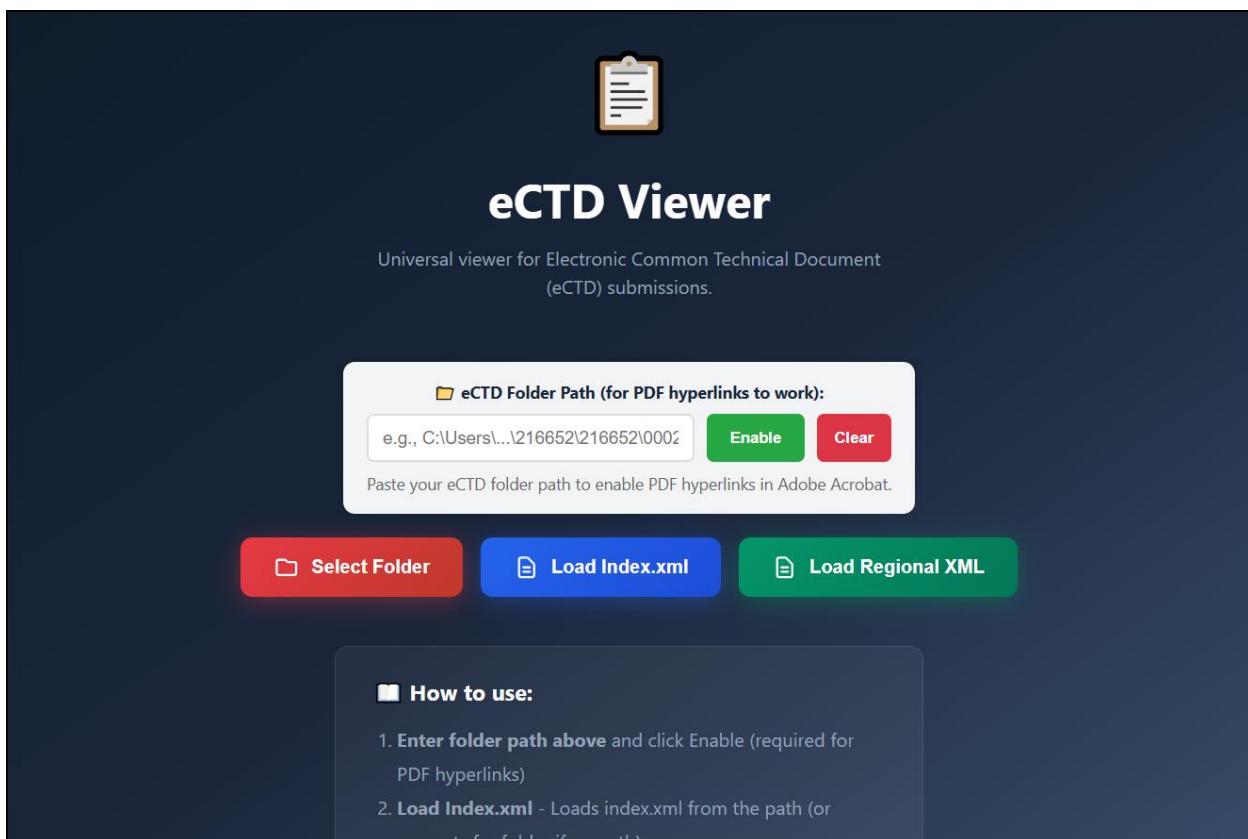
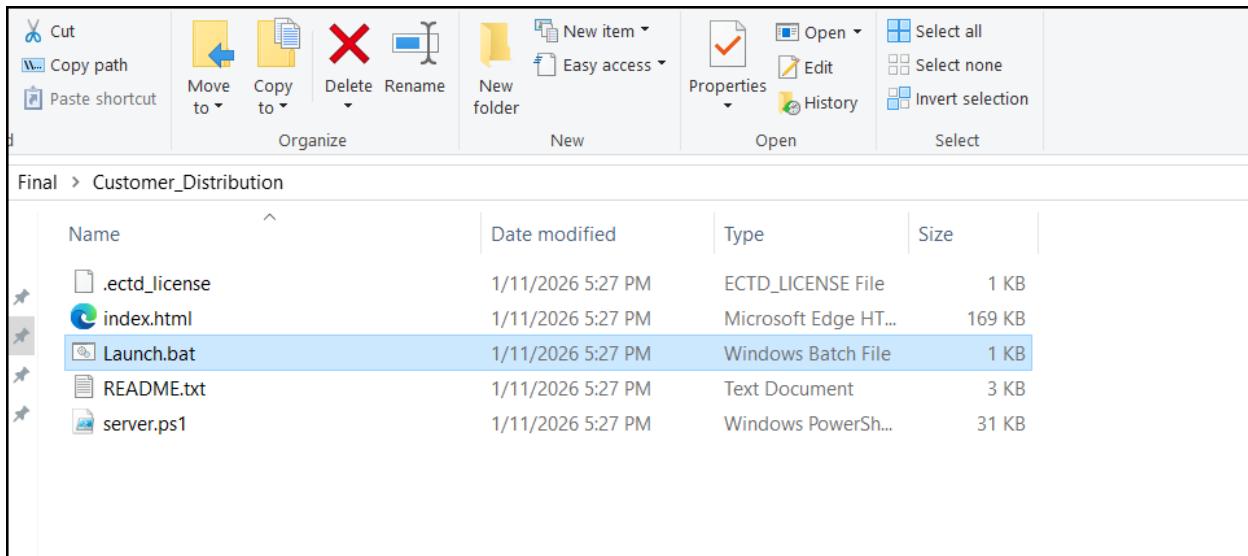
- Operating System: Windows (64-bit recommended)
- **Microsoft Edge** browser (required for viewing output)
- **PowerShell** setup file installed (mandatory prerequisite)

Note: No additional browsers or third-party viewers are required.

3) Download & Installation Steps

- Download the **eCTD SmartViewer** ZIP package from the provided link.
- Extract the downloaded ZIP folder to a desired location on your system.
- Open the extracted folder.

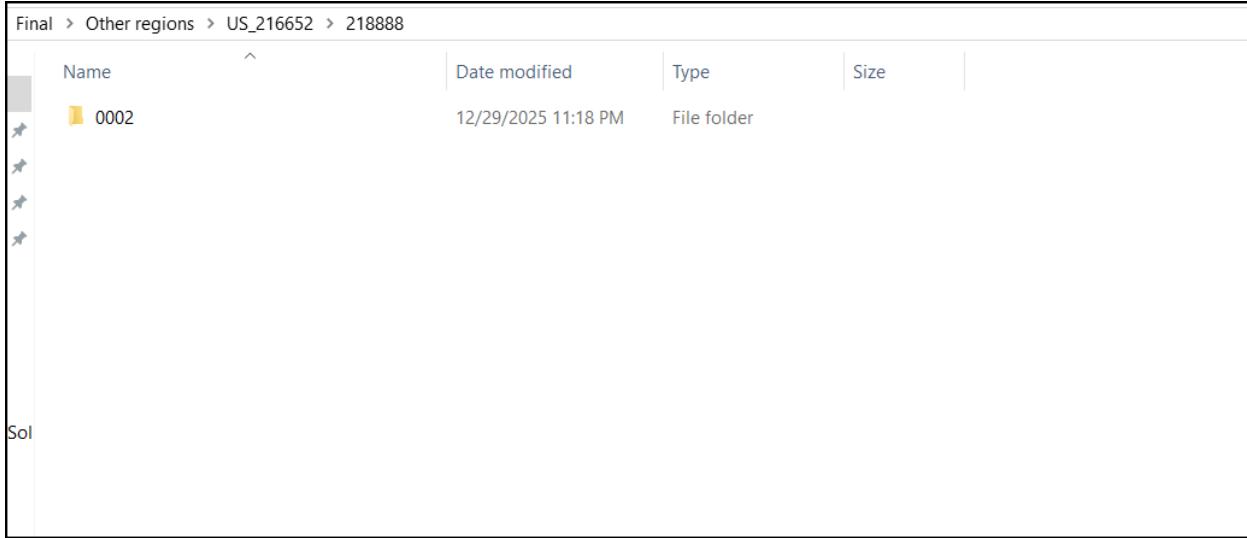
- Double-click on **Launch.bat** to start the application.
- Once launched successfully, the **eCTD SmartViewer** window will open.



4) Enabling PDF Hyperlinks (Important Step)

To ensure that PDF hyperlinks work correctly in Adobe Acrobat during review, please follow the steps below:

- Locate the folder path where your final eCTD submission is stored.
- Copy the complete folder path.

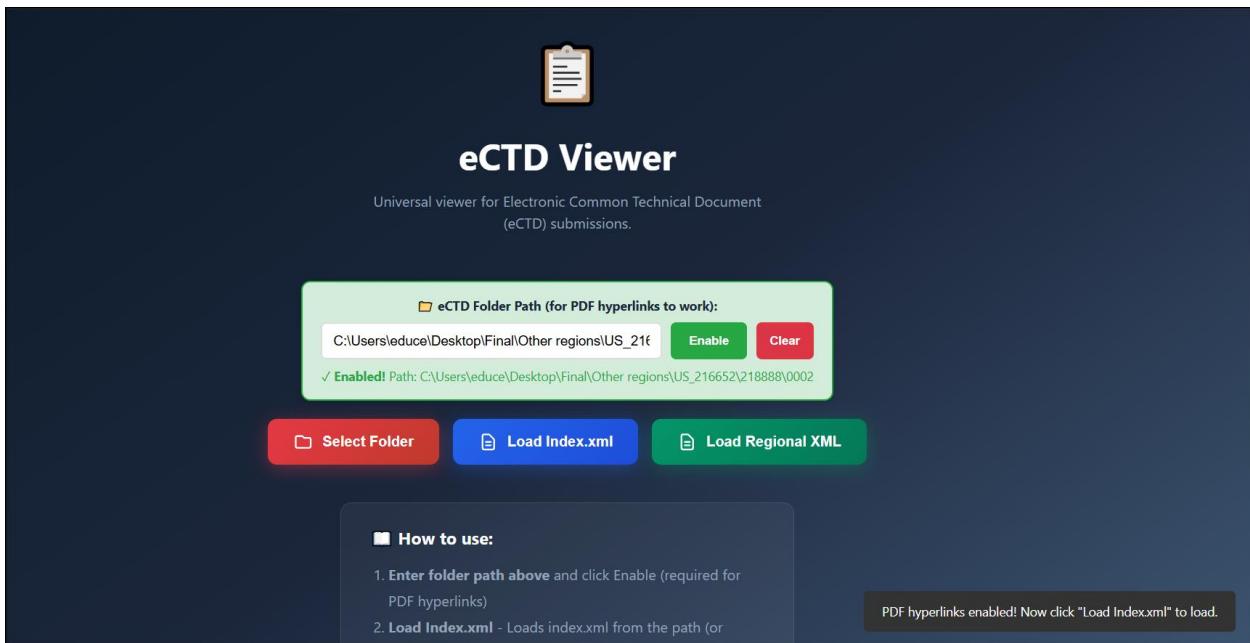
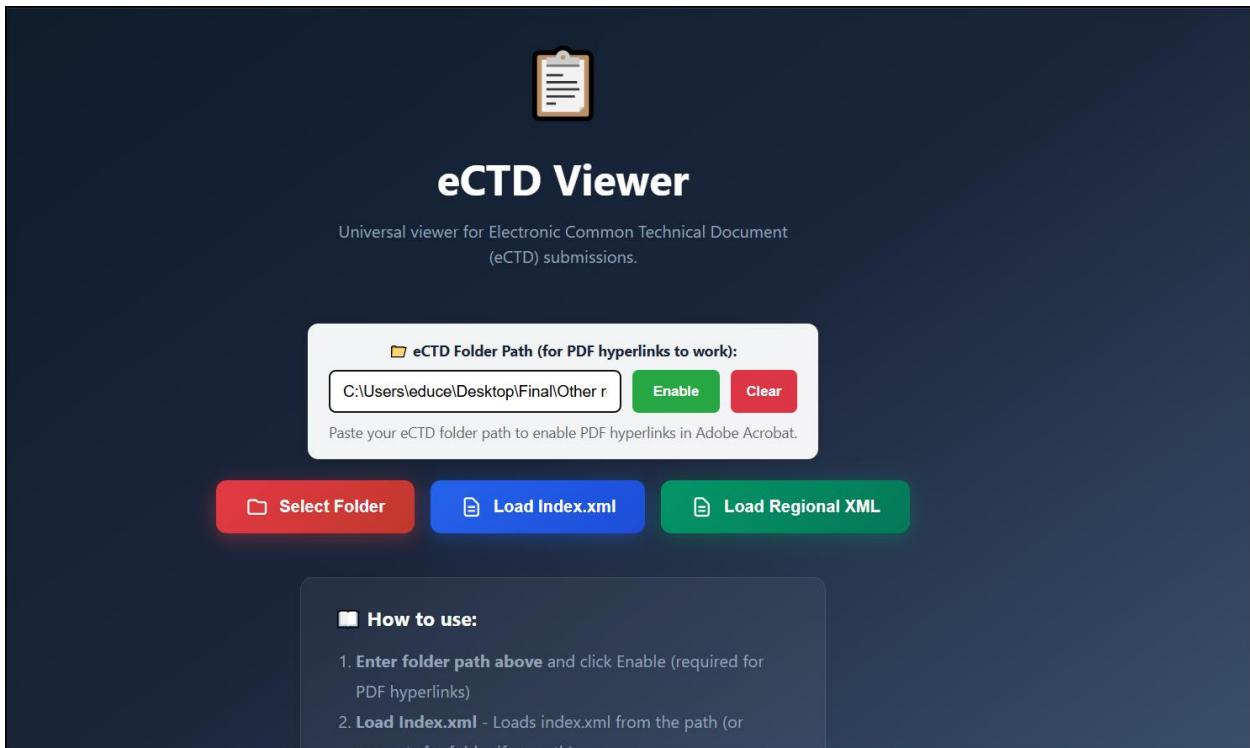


Example:

C:\Users\Desktop\218888\0002\

- Paste the copied path into the **Submission Path** field in the eCTD SmartViewer window.
- Click on the **Enable** button.

This step is required only once per submission location.



5) Loading the eCTD XML Files

After enabling the submission path:

- Click on **Load Index.xml** to view the main submission index, **OR**
- Click on **Load Regional.xml** to view the region-specific output

The selected XML file will be rendered automatically in the **Microsoft Edge** browser with proper styling and navigation.

eCTD DTD version 3.2

- m1-administrative-information-and-prescribing-information
 - [United States Index \[new\]](#)
- m2-common-technical-document-summaries
 - m2-3-quality-overall-summary
 - m2-3-s-drug-substance [manufacturer: Test Demo Limited] [substance: AP-QOS-Paracetamol]
 - [AP-manu1FDFD \[new\]](#)
 - [A-product \[new\]](#)
 - [Description-and-composition \[new\]](#)
 - [M-3-2-p-note-to-reviewer \[new\]](#)
 - [Qos-a \[new\]](#)
 - m2-3-s-drug-substance [manufacturer: Test Demo Limited] [substance: RP-QOS-Paracetamol]
 - [Qos-r \[new\]](#)
 - m2-3-r-regional-information
 - [abc \[new\]](#)

eCTD

Summary	Applicant Name: Test Solutions (Demo) Applicant Id: 999999999 Description: dummy new No. of Leaf Nodes: 4
Contact Information	Applicant Contact: Mr. Ganesh (Regulatory Contact) Contact Info: 8459323422 (Mobile Telephone Number) E-mail: temp99@gmail.com
Application Information	Application Containing Files: true Application Type: Drug Master File (DMF) Application Number: 787987 Submission Type: Original Application Submission Id: 0001 Submission Sub-Type: Application Sequence #: 0001

[Expand All](#) [Collapse All](#)

m1-1-forms
Form FDA 3938: Drug Master File
Form-3938 [new]

6) Key Benefits of eCTD SmartViewer

- No manual web URL configuration required
- Supports final eCTD output preview before submission
- Eliminates dependency on unsupported agency stylesheets
- Simple, lightweight, and user-friendly
- Suitable for US, EU, AU, CA, ZA, GCC, TH and all other regions

7) Purpose & Usage Note

Currently, downloaded eCTD submissions cannot be directly opened in standard browsers such as Microsoft Edge due to stylesheet limitations. **eCTD SmartViewer** addresses this limitation by providing a reliable and consistent preview mechanism, helping users review submissions confidently before final delivery to regulatory agencies.

8) Support

For any installation or usage-related queries, please contact your internal support team using the email ID or contact number provided below.