# Government of India Directorate General of Health Services Central Drugs Standard Control Organization

#### Notice

File No.: IT-13011(11)/1/2023-eoffice

Date: 01/01/2024

Subject - Launching of National Single Window System (NSWS) Portal- reg.

NSWS is established by the Central Government with the objective to build a genuine Single Window System which act as a one-stop shop for all the approvals required by the investor and facilitates ease of doing business. The scope of NSWS includes all the approvals/licenses/registrations/clearances as applicable.

In this regard, Invest India through TCS has developed NSWS portal has been developed for CDSCO, which will be independent from the existing SUGAM portal or cdscomdonline portal. Initially following three activities under the Medical Devices Rules, 2017 have been developed and will be made 'Live' on NSWS portal w.e.f. 01.01.2024:-

- 1. Application for grant of Certificate of Registration of a Notified Body-Form MD-01.
- Application for licence to manufacture medical device for purpose of clinical investigations, test, evaluation, examination, demonstration or training—Form MD-12.
- Application for Licence to Import Medical Devices for the Purposes of Clinical Investigations or Test or Evaluation or Demonstration or Training —Form MD-16.

In view of above, it is requested that all concerned stakeholders henceforth should submit application related to above said three activities through NSWS portal only and the existing cdscomdonline portal for the said activities will be disabled w.e.f. 15.01.2024.

The NSWS portal can be browsed through <a href="https://www.nsws.gov.in">https://www.nsws.gov.in</a> and a user guide is also attached herewith for guidance for ready reference.

This is for information of all concerned stakeholders.

Encl.: As above

(Dr. Rajeev Singh Raghuvanshi) Drugs Controller General (India)

To:

- 1. All the concerned stakeholders
- 2. CDSCO Website







User Guide:

How to apply for CDSCO Approval



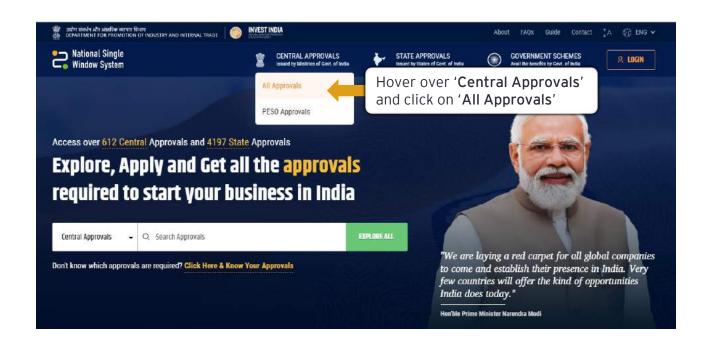
#### **Table of Contents**

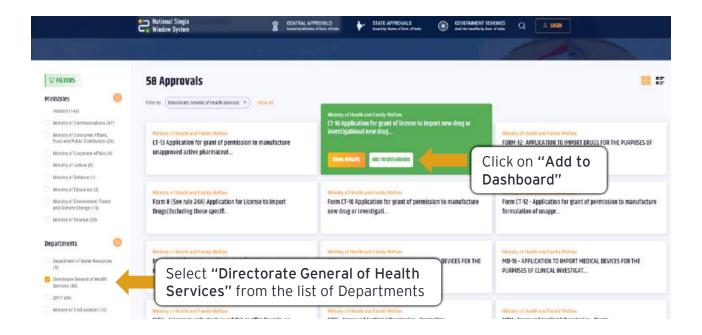
#	How to apply for Foreign Investment Approval	Reference slide
1	How to identify the approval	
1.1	How to view, add approval from 'All Approvals'	<u>1</u>
1.2	How to view, add approval through central KYA	<u>2</u>
1.3	How to add identified approval to the Dashboard	4
2	How to Apply for the Selected, identified Approval	
2.1	How to login and apply for approval (New User)	<u>5</u>
2.2	How to fill the application form	<u>6</u>
2.3	How to view the application form (Legal Form)	14
2.4	Checklist Activation	<u>15</u>
3	Technical Requirements and Contact Us	





## How to view, add approval from 'All Approvals'

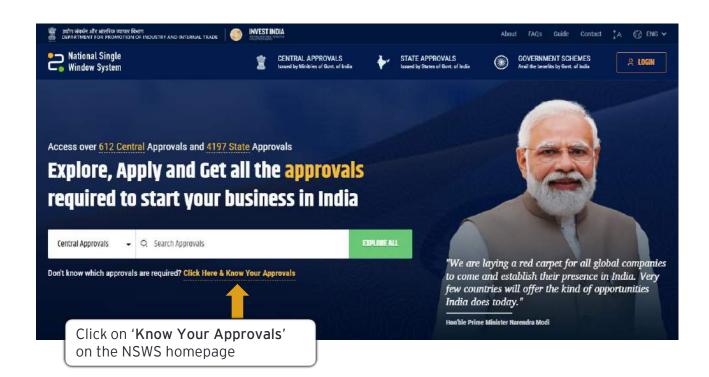


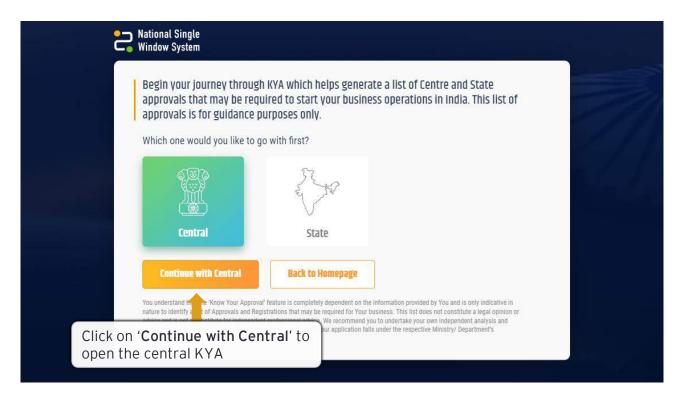






#### How to view, add approval through Central KYA

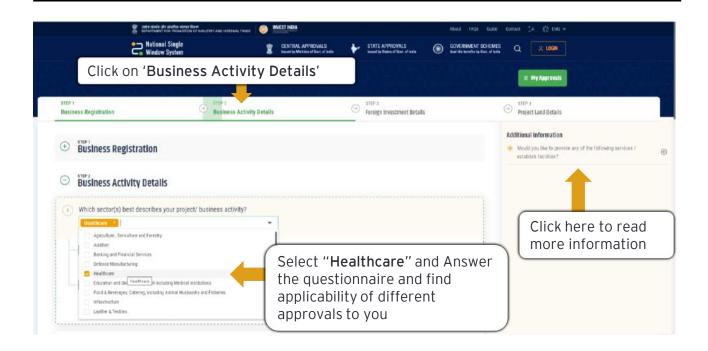


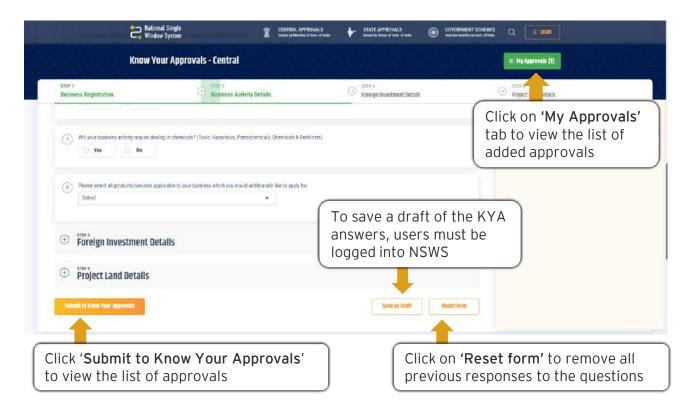






#### How to view, add approval through Central KYA

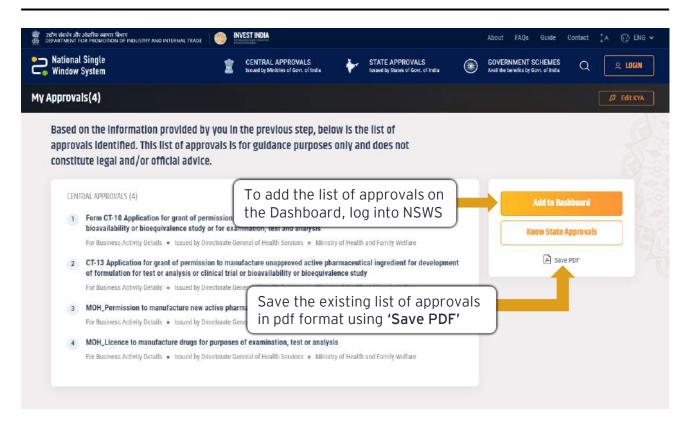








#### How to add identified approval to the Dashboard

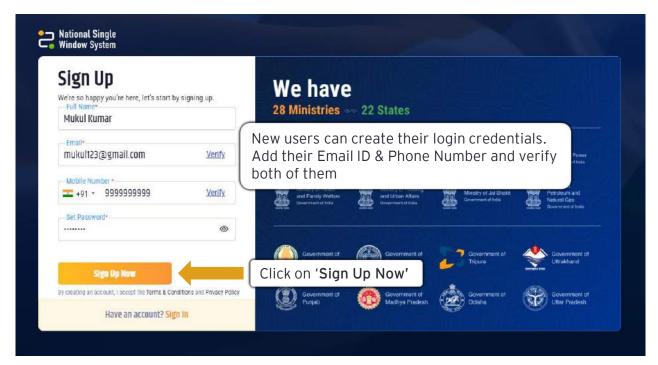


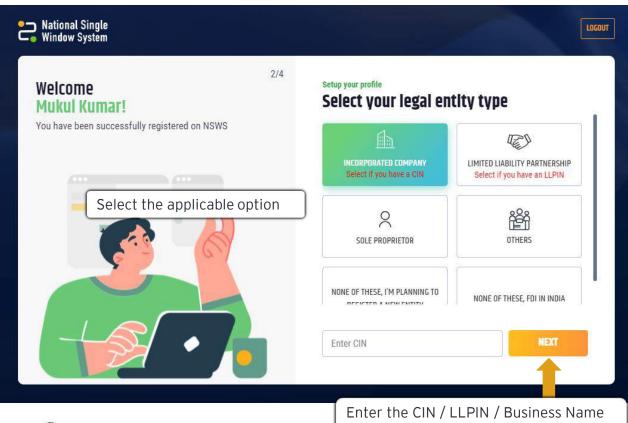






## How to login and apply for approval (New User)

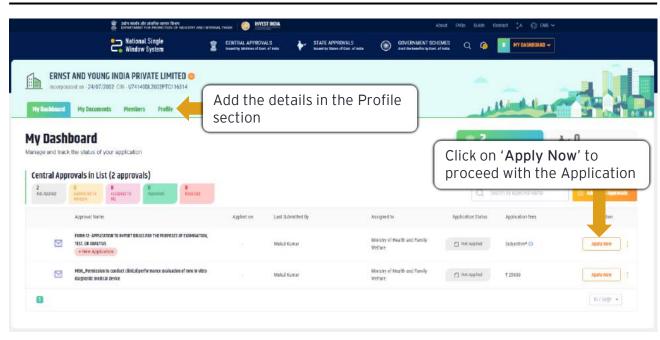


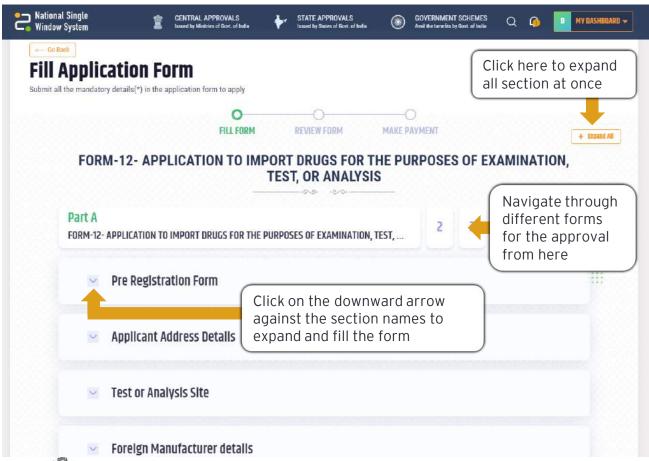




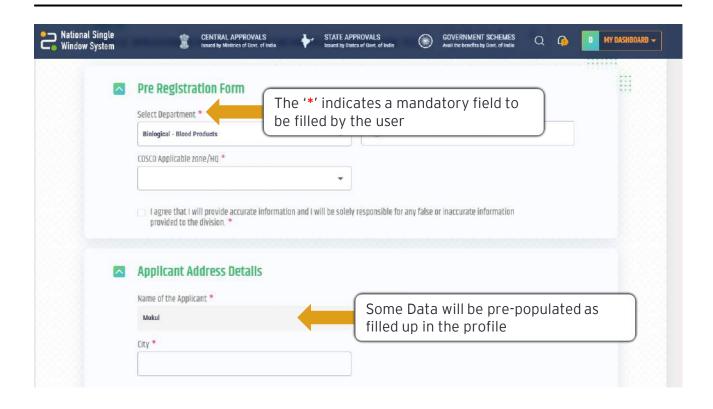


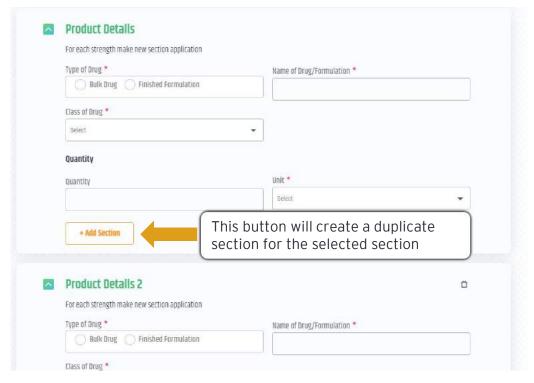
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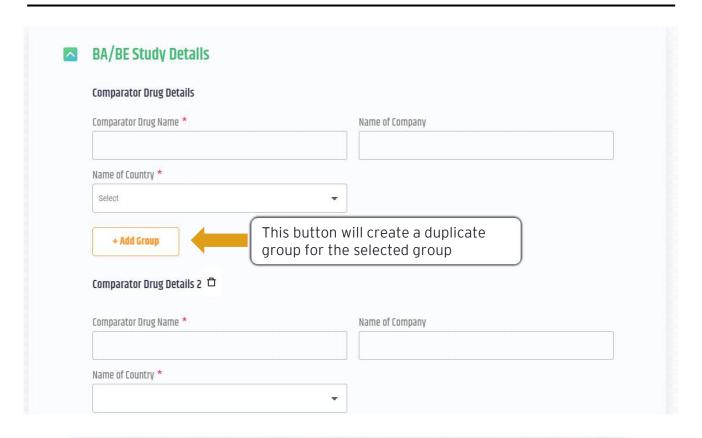


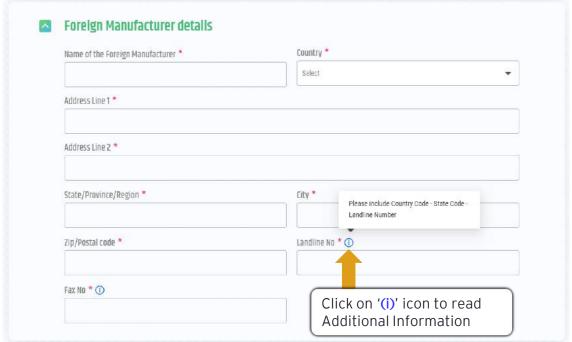












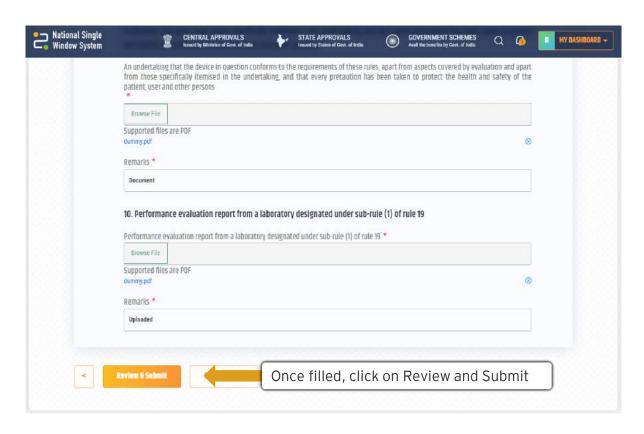


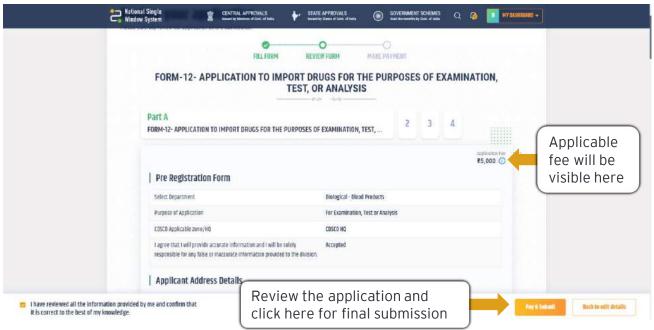


An explanation about whom to contact for trial rel	
Yes No	Yes No
Subject's responsibilities on participation in the tr	rial Statement that participation is voluntary, that the Subject can wif
○ Yes ○ No	Yes No
PI's undertaking	International prescribing information
Yes No	Yes No
Justification ①	
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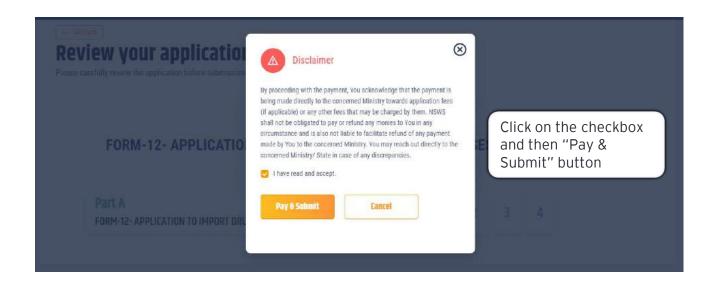


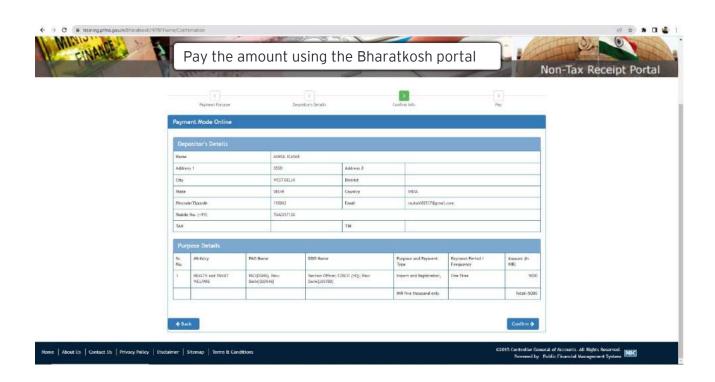






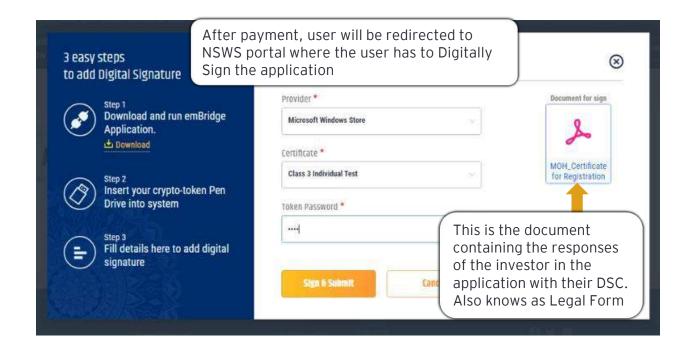


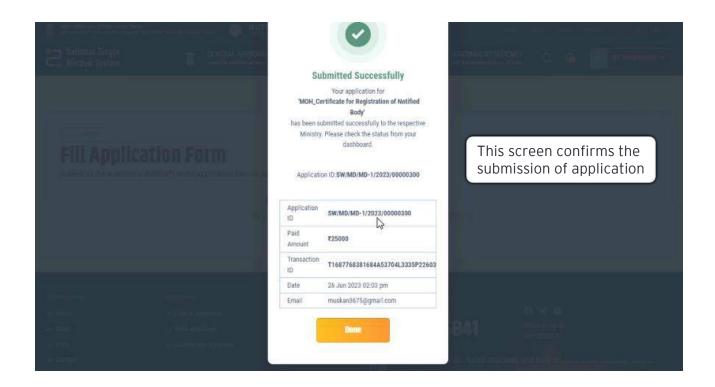






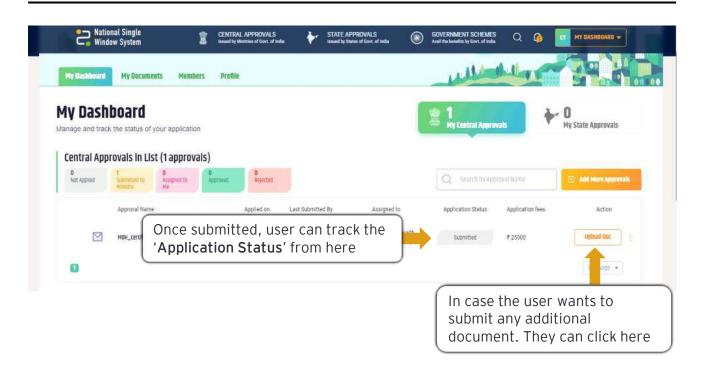


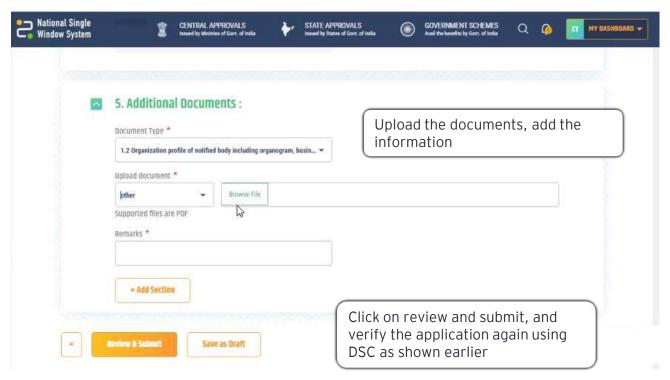








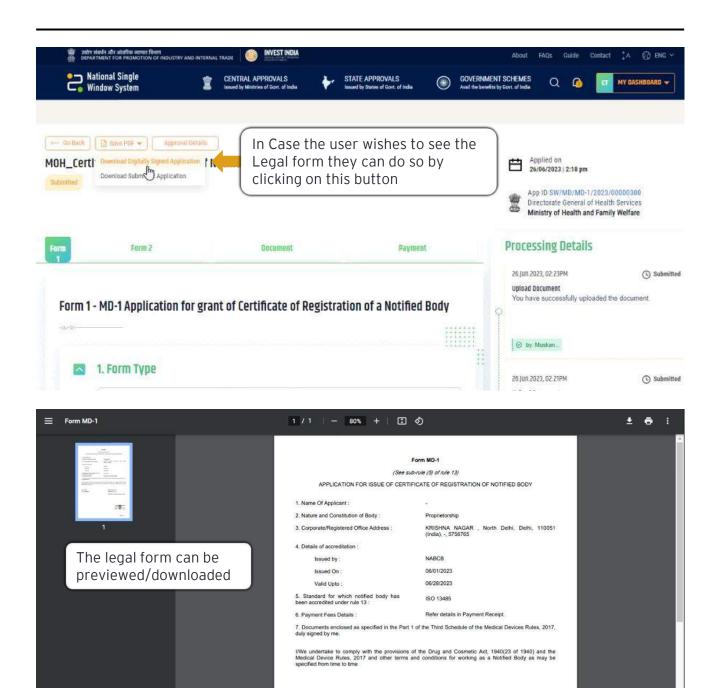








## How to view the application form (Legal Form)







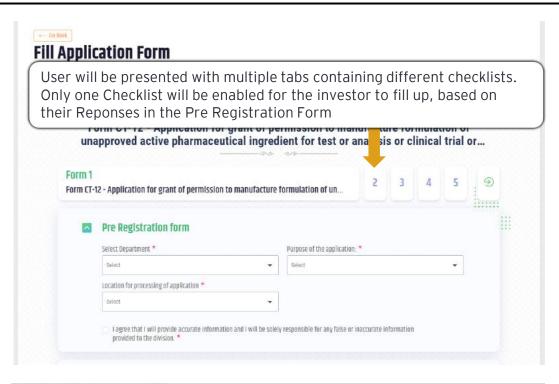
Name: Shaik Gajula

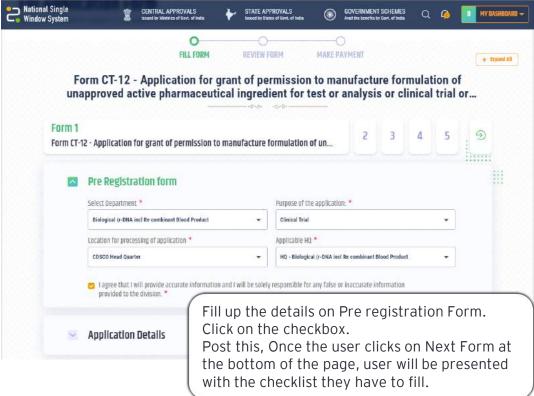
Designation: owner

Place : delih

Date: 26/06/2023

#### **Checklist Activation**

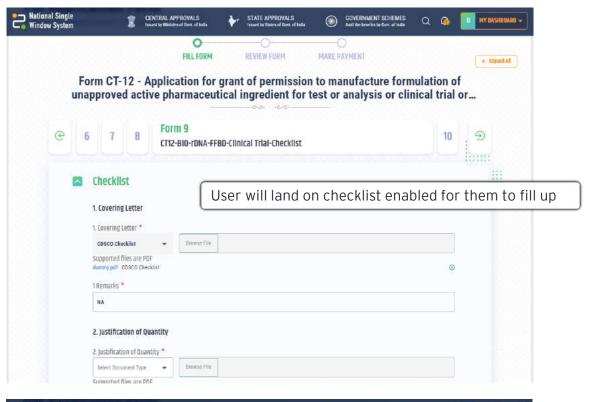


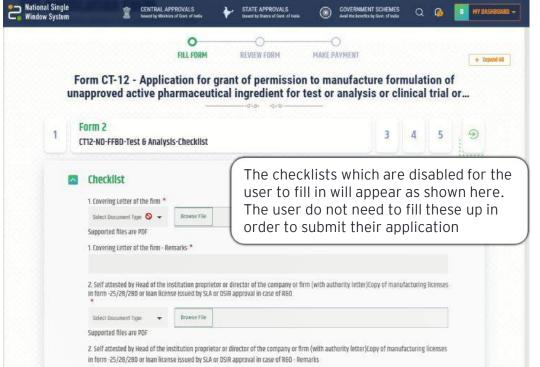






#### **Checklist Activation**













#### What are the technical Requirements for NSWS

#### System Requirements for National Single Window Portal

- Windows OS (XP or higher)
- MAC OS (X 10.9 or higher with latest updates)
- View/ Download Pdf: Download the pdf reader to view and download the pdf files from the link: https://get.adobe.com/reader/)
- Platform requires a minimum screen size of 976px wide, but using 1024px or higher is recommended
- Digital Signature Certificate (DSC): Latest version of emBridge software need to be installed in the system which acts a connecting link/driver between the NSWS and DSC

#### Web browsers best suited for National Single Window System

- Google Chrome
- Mozilla Firefox
- Apple Safari

#### Have any further questions?

Please submit your queries and feedback on:

https://www.nsws.gov.in/contact-us

Email: contactus-nsws@investindia.org.in

Ph: 1800 102 5841

(Monday - Saturday, 9am - 6pm)

Last Updated on 14 March 2023

