

Manufacturing Capacity Reference Guide



FDA CDER NextGen Portal

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Click [here](#) to access the CDER NextGen Portal.

Supported Browsers: Google Chrome and Mozilla Firefox

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Introduction

As part of ongoing efforts to support product development and availability in response to COVID-19, the Center for Drug Evaluation and Research (CDER) is collecting additional manufacturing capacity information from applicants for Investigational New Drugs (IND) that are safe to proceed for the intended use of COVID-19 treatment.

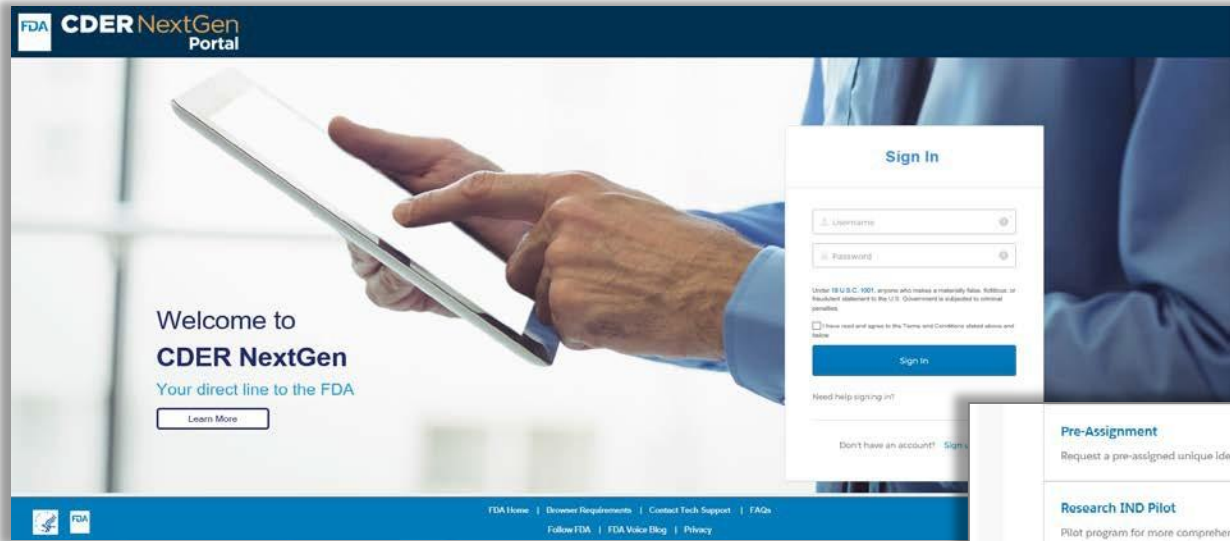
This solution provides a way for organizations to submit data related to manufacturing capacity to the FDA to analyze and support manufacturing efforts for potential vaccines and therapeutics such that there is a capability for mass production to meet the population need. The portal captures information about the specific IND information, manufacturer, production rates, treatment courses, and allocations.

Manufacturing Capacity submissions are voluntary, however, CDER strongly encourages sponsors and/or manufacturers to submit information in support of the COVID-19 response.

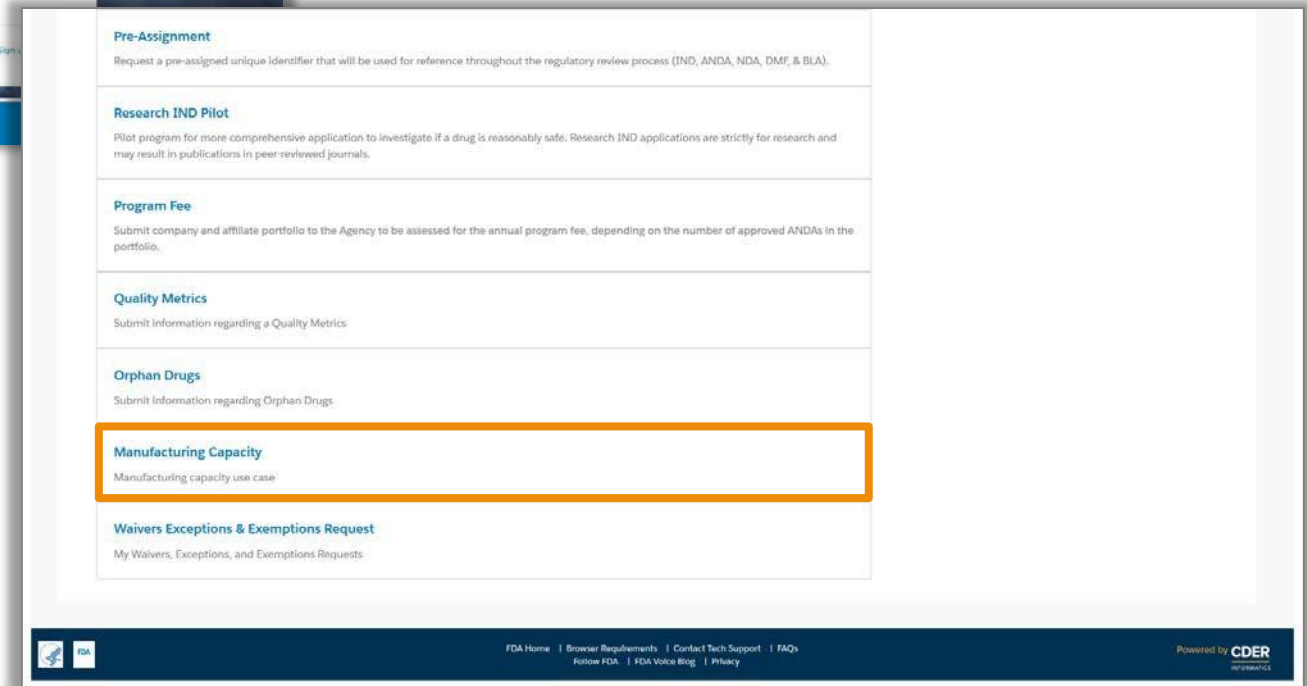
For technical assistance, please visit the [NextGen Portal Help Center](#).

For business assistance, contact the Regulatory Project Manager assigned to the IND associated with this submission.

CDER NextGen Portal Homepage



Step 1. Once you land on the CDER NextGen Portal homepage, Click **Manufacturing Capacity** to begin.



Submit a New Submission

Step 2. Select New Request.

Step 3. Review the “Getting Started” information for Manufacturing Capacity.

Step 4. Click Next.

Manufacturing Capacity

Sponsor Details

Step 5. Respond to the Sponsor Details question. If you are the Sponsor associated with the IND, the fields will pre-populate with your account credentials. If you are the US Agent associated with the IND, enter the required information for the Sponsor of the IND.

Step 6. Click **Next**.

The screenshot shows the 'Manufacturing Capacity' form. On the left is the 'APPLICATION BUILDER' menu with options: Sponsor Information, IND Information, Clinical Use, Drug Allocation Matrices, and Review & Submit. Below it is a 'Need Help?' section with a link to the Help Center. The main form area is titled 'Sponsor Information' and contains a 'Sponsor Details' section with a question: '* Are you the sponsor or the US Agent associated with this IND?'. Below the question are two radio buttons: 'Sponsor' and 'US Agent'. At the bottom right of the form are 'Save and Close' and 'Next' buttons.

i Additionally, notice the Application Builder and the Help Menu on the left. The Application Builder helps users navigate through the request section and view their status. Users can find FAQs, guides, and other helpful information in the Help Center.

The screenshot shows the 'Help Center' page. It has a blue header 'Manufacturing Capacity' and lists three sections: 'FAQs' (Common questions and answers about the Manufacturing Capacity), 'Getting Started' (Overview of the Manufacturing Capacity form and hyperlink to the published guidance), and 'Reference Guide' (Step-by-step guide for submitting a Manufacturing Capacity Request in the CDER NextGen Portal).

IND Information

Step 7. Complete the General Information questions.

Step 8. Enter a **Drug Substance/API**. Within this, enter the Substance Information. If a Drug Substance/API has multiple names, you can add more as needed.

Step 9. Continue by clicking **Next** or **Production Information** and enter the required information. If there are multiple facilities manufacturing the Drug Substance/API, you may add more as needed.

Step 10. Click **Save & Close**. Enter additional Drug Substance/API, as needed.

Manufacturing Capacity

IND Information

Step 11. Enter a **Drug Product Dosage Form**. Within this, enter the General Information and click **Next** or **Dosage Form Information**.

Step 12. Enter the required information. If there are multiple drug substances within a dosage form, you can add as needed. Click **Next** or **Production Information**.

Step 13. Click **Save & Close**. Enter additional Drug Product Dosage Forms, as needed.

Step 14. Click **Next**.

The screenshot displays the 'Manufacturing Capacity' application builder interface. On the left, the 'APPLICATION BUILDER' sidebar shows 'Sponsor Information' as completed and 'IND Information' as the current step. The main content area is titled 'IND Information' and contains sections for 'General Information', 'Drug Substance/API Information', and 'Drug Product Dosage Form Information'. A '+ Add Drug Product Dosage Form' button is visible at the bottom right of this section. Three overlapping modal windows are shown, each titled 'Add Drug Product Dosage Form'. The top modal is in the 'General Information' tab, with a 'Dosage Form Information' sub-section containing a text input field for the name. The middle modal is in the 'Dosage Form Information' tab, with a 'Production Information' sub-section containing a dropdown menu for dosage form selection and a volume input field. The bottom modal is in the 'Production Information' tab, with a 'Production Information' sub-section containing a dropdown for manufacturing facility, radio buttons for production change anticipation, and a percentage input field for US capacity. A callout box with an information icon points to the 'Drug Substance/API Information' section, stating that previously entered drug substances appear for selection in the 'Dosage Form Information' section.

i Drug Substances previously entered appear for selection in Dosage Form Information section.

Clinical Use

Step 15. Enter a **Treatment Course** and complete all required information.

Step 16. Click **Save**. Enter additional Treatment Courses, as needed.

Manufacturing Capacity

APPLICATION BUILDER

- Sponsor Information
- IND Information
- Clinical Use**
- Drug Allocation Matrices
- Review & Submit

Need Help?

The [Help Center](#) is available to answer all your Manufacturing Capacity related questions.

Clinical Use

Treatment Course Add Treatment Course

Clinical Trials

Add Treatment Course

* What is the name of this treatment course?

* What is the broader use of this treatment course?
Select an Option

* What is the Intended population for this treatment course?
Select an Option

Drug Product Dosage Form

* What drug product dosage form is associated with this treatment course?
Select an Option

* How many units of this drug product dosage form are needed for a treatment course?

* Is there another drug product dosage form associated with the treatment course?
 Yes
 No

* Is there a device necessary in addition to what is in the dosage form?
 Yes
 No

9



Drug Product Dosage Forms previously entered appear for selection in Treatment Courses and Clinical Trials.

Manufacturing Capacity

Clinical Use

Step 17. If there is a **Clinical Trial** associated with this IND, complete all required information. Clinical Trials are optional.

Step 18. Click **Save**. Enter additional Clinical Trials, as needed.

Step 19. Click **Next**.



Drug Product Dosage Forms previously entered appear for selection in Treatment Courses and Clinical Trials.

Manufacturing Capacity

Drug Allocation Matrices

Step 20. Enter the **Drug Product Dosage Forms per Kg Drug Substance Matrix** and complete all required information. Click **Save**.

Step 21. Similarly, enter the **Drug Substance Allocation Matrix** and **Treatment Course Allocation Matrix**, complete all required information, and click **Save**.

Step 22. Click **Next**.

i The fields within the matrices are dynamic based on the Drug Substance(s), Drug Product Dosage Form(s), and Treatment Course(s) previously entered.

Manufacturing Capacity

APPLICATION BUILDER

- Sponsor Information
- IND Information
- Clinical Use
- Drug Allocation Matrices**
- Review & Submit

Need Help?
The [Help Center](#) is available to answer all your Manufacturing Capacity related questions.

Drug Allocation Matrices

- Drug Product Dosage Form Per Kg Drug Substance Matrix Matrix Input
- Drug Substance Allocation Matrix Matrix Input
- Treatment Course Allocation Matrix Matrix Input

Drug Product Dosage Forms per Kg Drug Substance Matrix

For each Kg of Drug Substance, please enter how many units of each Drug Substance Dosage Form can be manufactured.

Kg Drug Substance 1 (name)

Units of Drug Product Dosage Form 1:

Units of Drug Product Dosage Form 2:

Units of Drug Product Dosage Form 3:

Kg Drug Substance 2 (name)

Units of Drug Product Dosage Form 1:

Units of Drug Product Dosage Form 2:

Units of Drug Product Dosage Form 3:

Manufacturing Capacity

Review and Submit

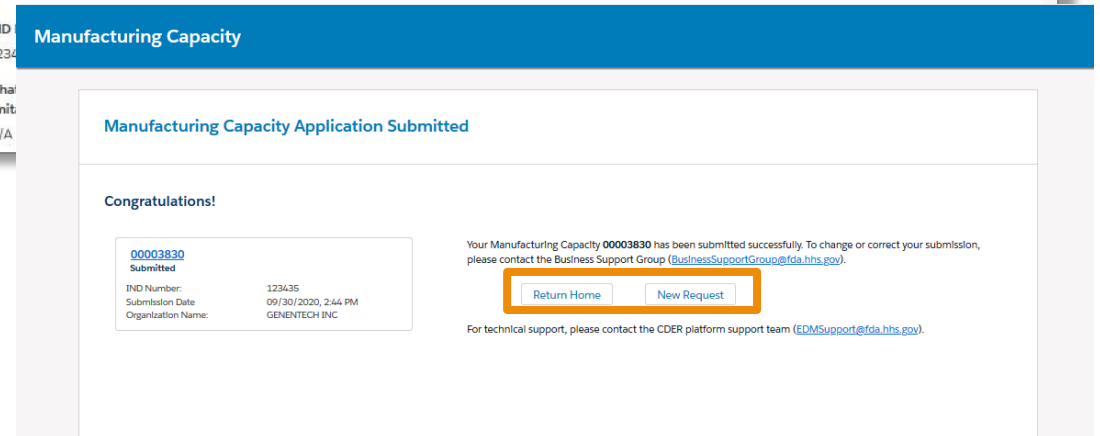
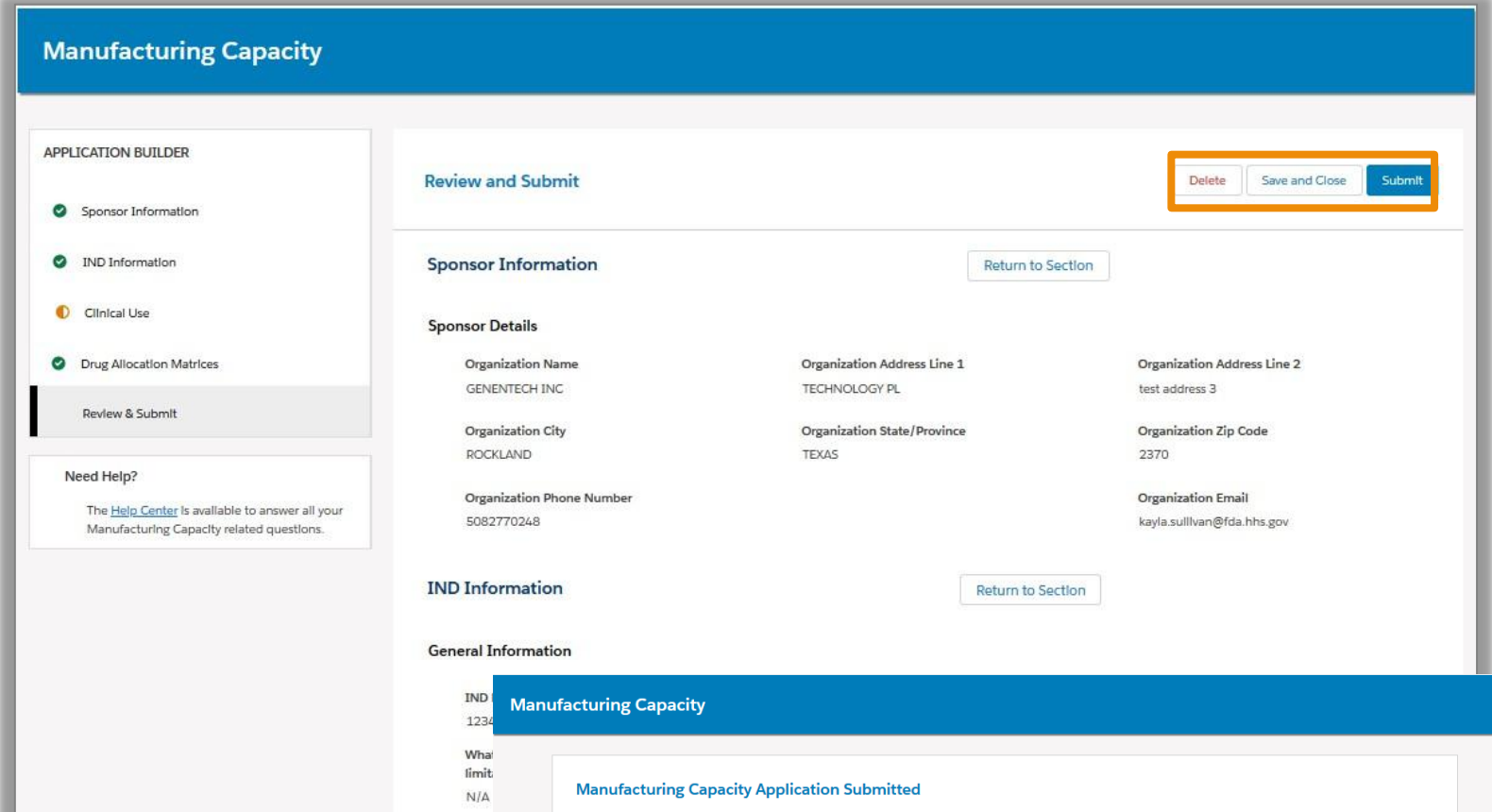
Step 23. Verify the information for the request and confirm all sections are complete.

Step 24. Click **Submit** to send your Manufacturing Capacity submission or **Save & Close** to keep your Manufacturing Capacity submission or **Delete** to remove your Manufacturing Capacity submission.

Note: Once you submit your entry, you will have the option to update any information by using the cloning capability. Reference the next few slides on how to use this functionality.

Receiving Notification(s) from FDA

You will view a confirmation screen to confirm your request was submitted to the FDA and receive an email confirming the submission of your Manufacturing Capacity submission. Please open the confirmation submission email: DoNotReply@fda.hhs.gov and Review the information submitted.



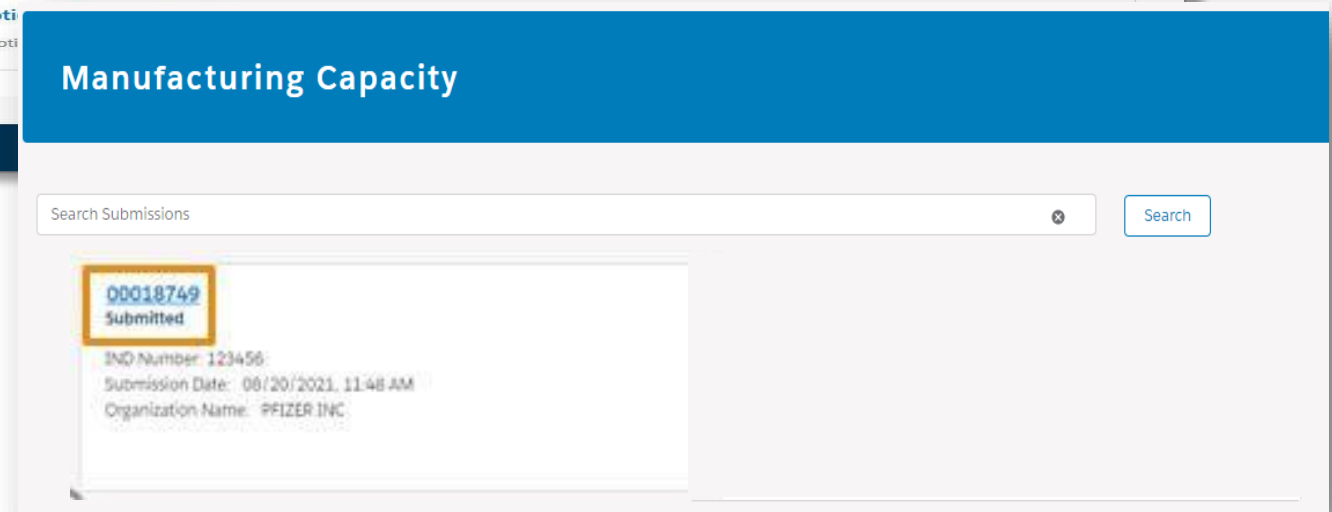
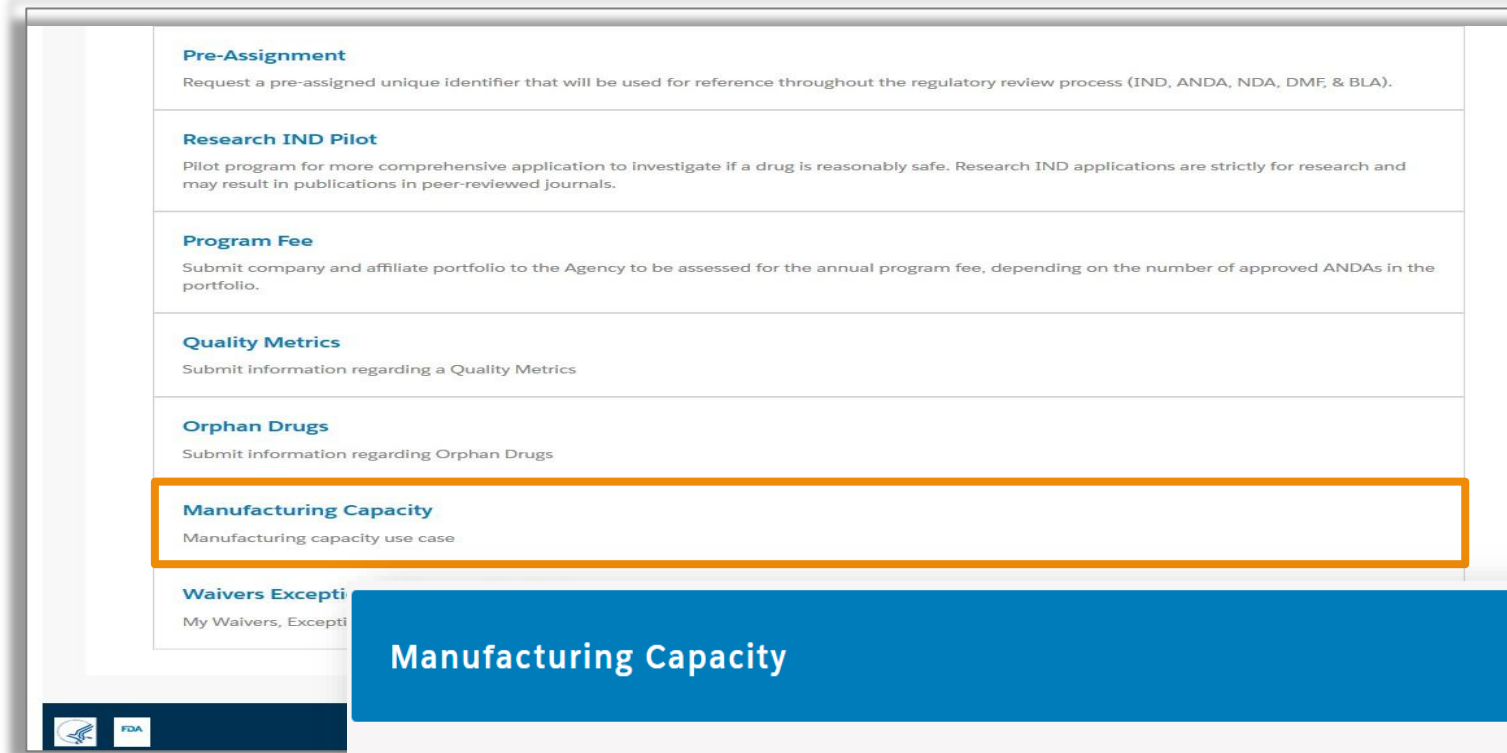
Cloning Capability

Cloning Capability

Step 1. Once you land on the CDER NextGen Portal homepage, Click **Manufacturing Capacity** to begin.

Step 2. From the landing page, **click** on a previously submitted application that you would like to clone.

Note: The Cloning Capability can be used to update information on an existing submission by keeping the IND number the same, OR to clone an existing submission with similar attributes but different IND.



Cloning Capability

Step 3. On the upper right-hand side of your screen, click **Clone**.

Step 4. Click **Continue**. You will then be directed to the Landing Page where you will be able to find the cloned record in Draft status.

The screenshot displays the 'Manufacturing Capacity' web application interface. At the top, there is a blue header with the text 'Manufacturing Capacity'. Below the header, on the right side, are two buttons: 'Review and Submit' and 'Clone'. The 'Clone' button is highlighted with an orange border. To the right of the 'Clone' button is a 'Return to Home' button. The main content area is titled 'Sponsor Information' and contains a 'Sponsor Details' section with the following fields:

Organization Name	Organization Address Line 1	Organization Address Line 2
PFIZER INC	235 E 42ND ST	
Organization City	Organization State/Province	Organization Zip Code
NEW YORK	NY	10017
Country	Organization Phone Number	Organization Email
US		
DUNS		
001326495		

Below the 'Sponsor Details' section is the 'IND Information' section, which is currently empty. A modal dialog box titled 'Clone Submission?' is overlaid on the bottom right of the page. The dialog contains the following text:

Clone Submission?

Select Continue to clone this record. You will be directed back to the Landing Page where you will see the cloned record in Draft status.

The new draft record may be utilized in one of two ways depending on your needs:

- 1) Update a submitted submission by keeping the IND Number the same
- 2) Create a new submission by updating the IND Number

Refer to the user guide for detailed information

At the bottom of the dialog are two buttons: 'Cancel' and 'Continue'. The 'Continue' button is highlighted with an orange border.

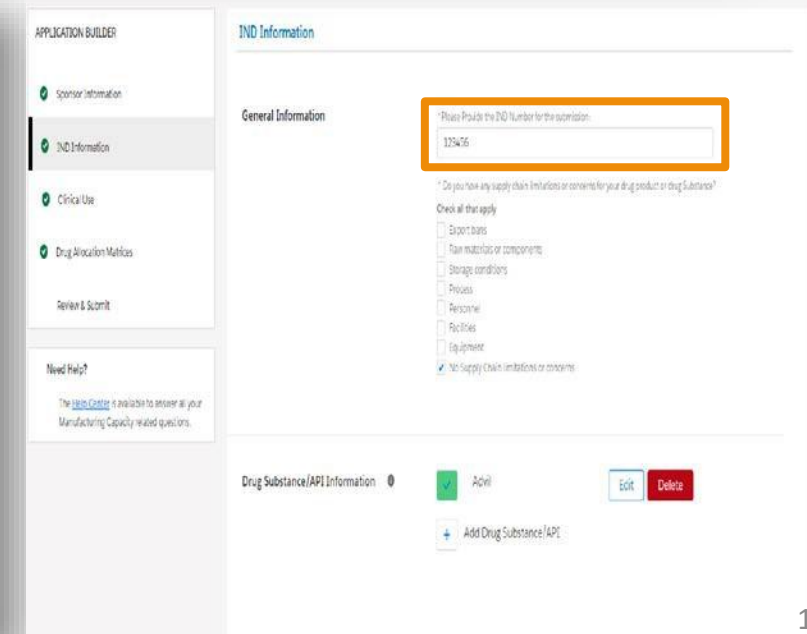
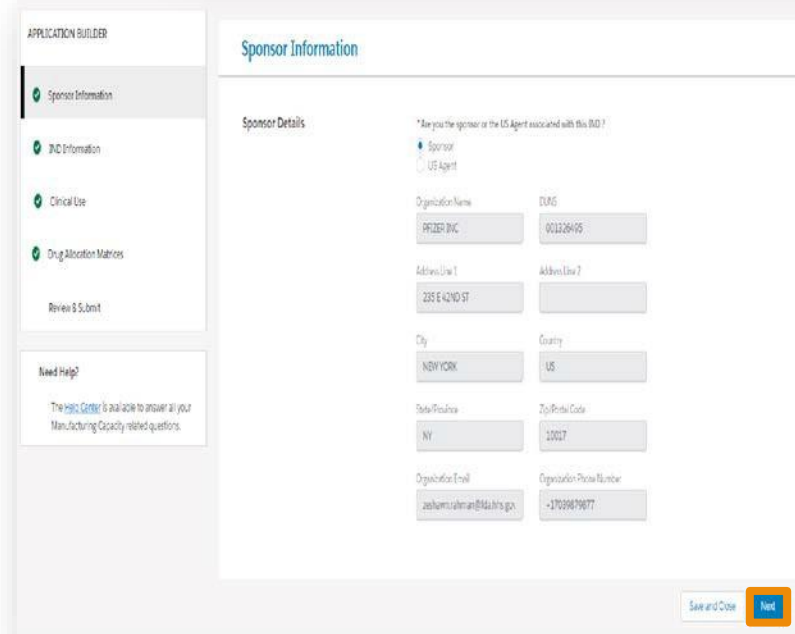
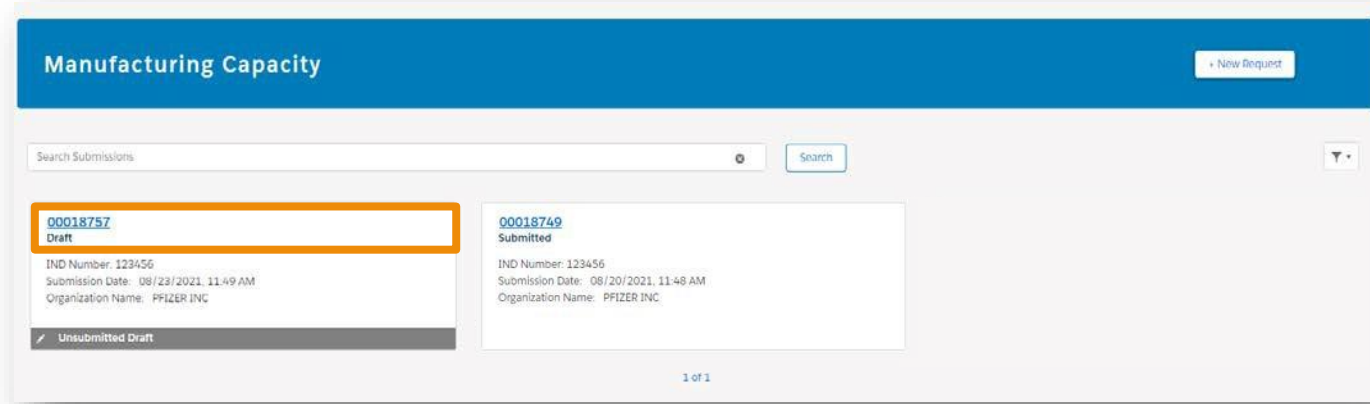
Manufacturing Capacity

Cloning Capability

Step 5. Click on the draft application that you would like to clone.

Step 6. Review/Edit the prepopulated information in the Sponsor Information Section, then click **Next**.

Step 7. Review/Edit the prepopulated information in the IND Information Section.



Manufacturing Capacity

Cloning Capability

Step 8. Review/Edit the information you provided for Clinical Use and then click **Next**.

Step 9. Review/Edit the prepopulated information in Drug Allocation Matrices and then click **Next**.

The screenshot displays the 'APPLICATION BUILDER' interface. On the left, a sidebar lists the application components: Sponsor Information, IND Information, Clinical Use, Drug Allocation Matrices, and Review & Submit. The 'Clinical Use' section is currently active, showing a 'Treatment Course' table with one entry, 'Course 1', which has 'Edit' and 'Delete' buttons. Below this is an 'Add Treatment Course' button. The 'Clinical Trials' section is also visible. A 'Previous' button is located at the bottom of the sidebar.

Overlaid on this is a second view of the 'APPLICATION BUILDER' interface, where the 'Drug Allocation Matrices' section is active. This view shows three matrices, each with a 'Matrix Input' button: 'Drug Product Dosage Form Per Kg Drug Substance Matrix', 'Drug Substance Allocation Matrix', and 'Treatment Course Allocation Matrix'. A 'Previous' button is at the bottom left, and a 'Save and Close' button with a '17' notification is at the bottom right. A blue 'Next' button is highlighted in the bottom right corner.

Cloning Capability

Step 10. Once you have reviewed the application, click **Submit** and then click **Continue**.

Step 11. Once **submitted** you will receive a confirmation message and a confirmation email.

Thank you for submitting your **Manufacturing Capacity Submission**. Your **Reference ID is 00018757** for identifying this request to the FDA. You can review your submission by returning to the [FDA CDER NextGen Portal](#)

Type of Request Summary: Manufacturing Capacity

Reference ID	IND Number	Sponsor Name
00018757	123456	PFIZER INC

There is no further action for you at this time. The FDA will review your request and follow up accordingly. If you need to update your request, contact the primary POC assigned to the IND associated with this submission.

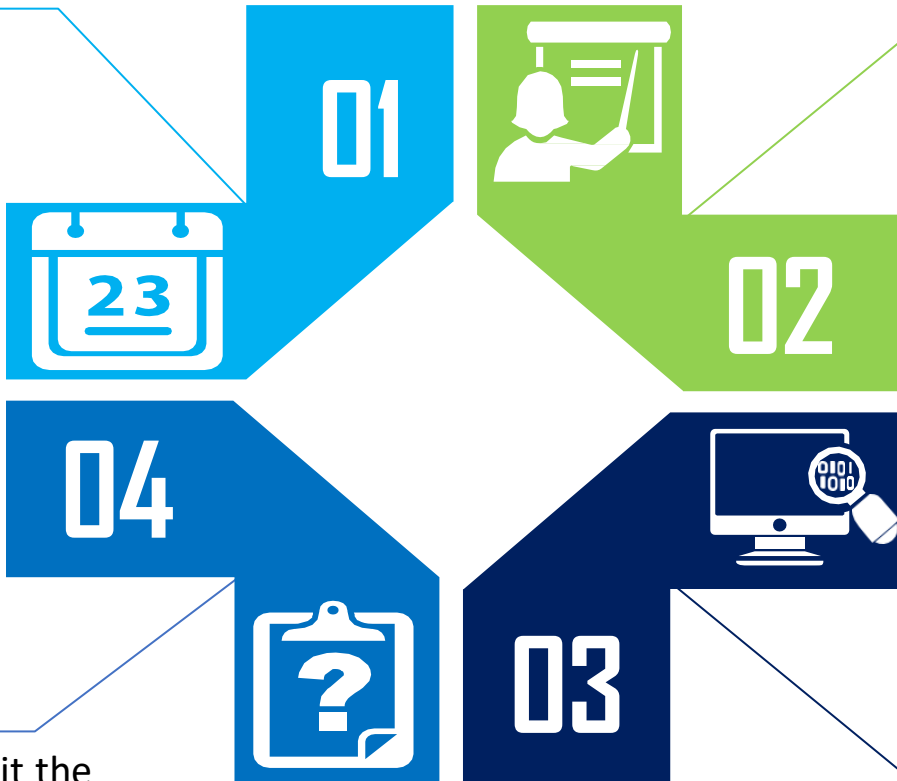
Technical Support and Resources

CDER NextGen Portal Support & Resources

The [CDER NextGen Portal](#) has many resources for support.

CDER NextGen Portal Announcements

Your Portal home page contains **portal announcements**, so users are always in the know.



Learn More Information

Everything related to the portal events can be found on the [NextGen Portal Help Center](#) that provides links to the Resource Center, which includes **Reference Guides and FAQs**.

Technical Support

For all technical support, contact visit the [NextGen Portal Help Center](#).

CDER NextGen Portal Video Tutorial

The “**Video Tutorial**” contains **1–4-minute video clips** on how to complete submissions for events on the portal.