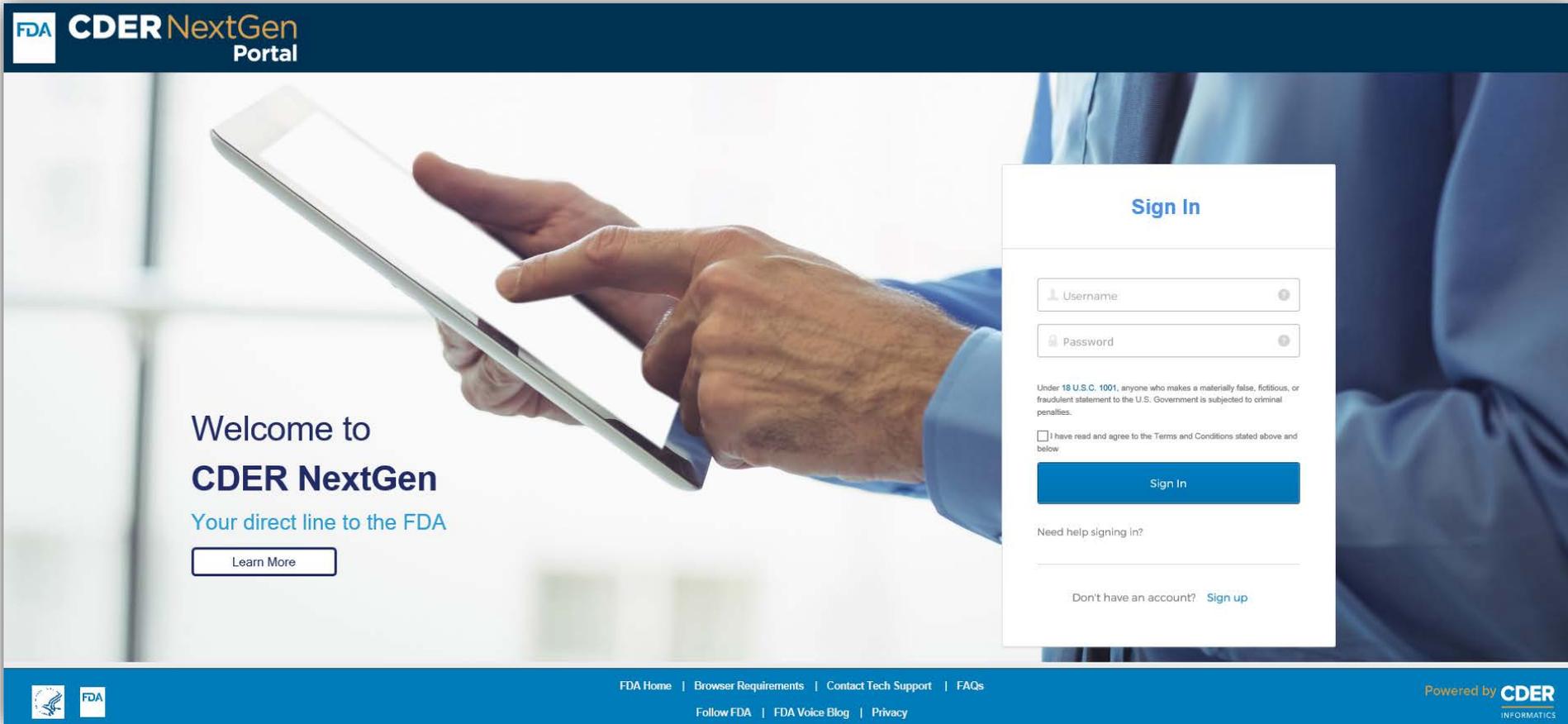


# Manufacturing Capacity Reference Guide



**FDA CDER NextGen Portal**

Welcome to  
**CDER NextGen**  
Your direct line to the FDA

[Learn More](#)

### Sign In

Username

Password

Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subjected to criminal penalties.

I have read and agree to the Terms and Conditions stated above and below.

[Sign In](#)

Need help signing in?

Don't have an account? [Sign up](#)

FDA Home | Browser Requirements | Contact Tech Support | FAQs

Follow FDA | FDA Voice Blog | Privacy

Powered by **CDER** INFORMATICS

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

Supported Browsers: Google Chrome and Mozilla Firefox

# Table of Contents

Introduction	<a href="#"><u>3</u></a>
CDER NextGen Portal Home Page	<a href="#"><u>4</u></a>
Submit a New Manufacturing Capacity	<a href="#"><u>5</u></a>
Sponsor Details	<a href="#"><u>6</u></a>
IND Information	<a href="#"><u>7</u></a>
Clinical Use	<a href="#"><u>9</u></a>
Drug Allocation Matrices	<a href="#"><u>11</u></a>
Review and Submit	<a href="#"><u>12</u></a>
Cloning Capability	<a href="#"><u>13</u></a>
CDER NextGen Portal Support & Resources	<a href="#"><u>19</u></a>

# Manufacturing Capacity

## 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.

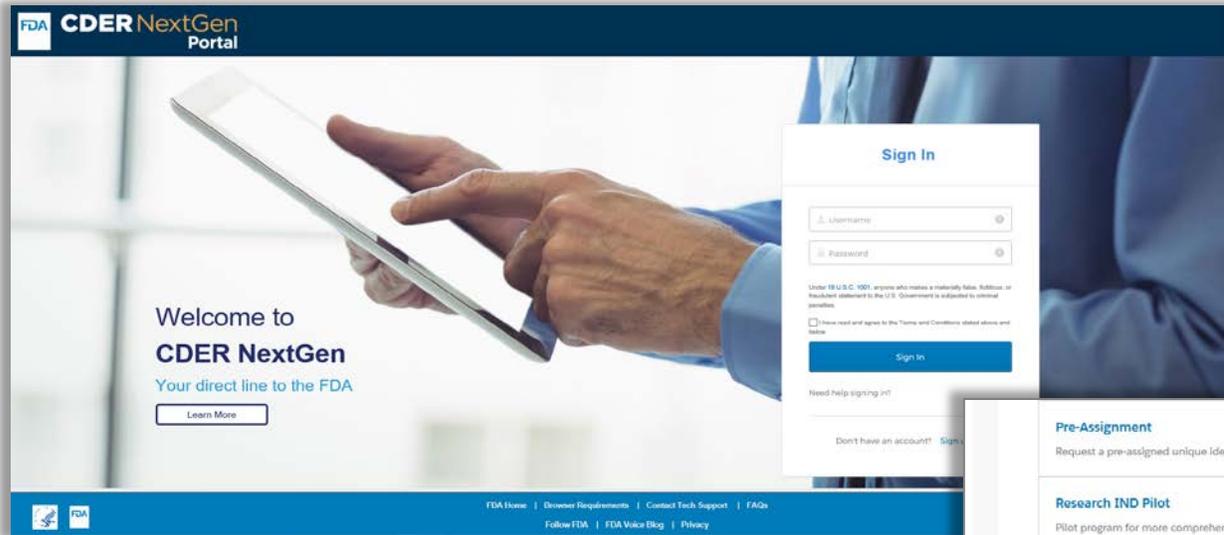
Manufacturing Capacity submissions are voluntary, however, CDER strongly encourages sponsors and/or manufacturers to submit information in support of the COVID-19 response.

For technical assistance, the FDA EDM Support Team ([EDMSupport@fda.hhs.gov](mailto:EDMSupport@fda.hhs.gov)) is available to help.

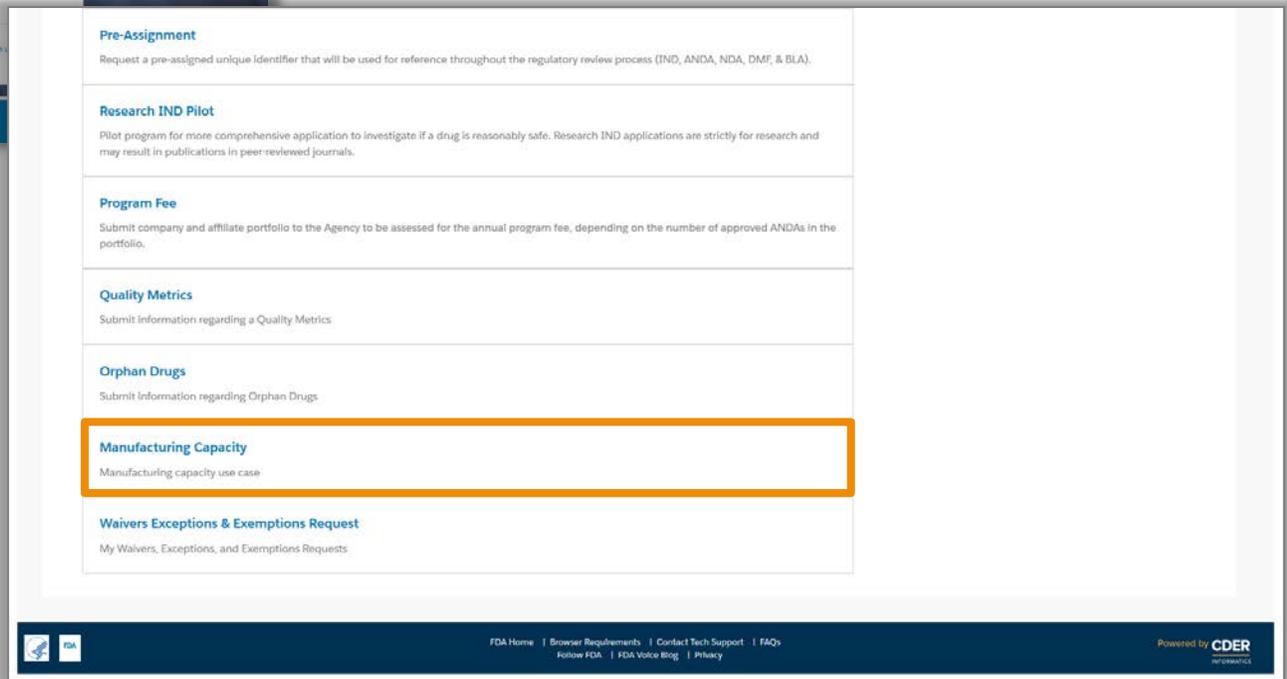
For business assistance, contact the Regulatory Project Manager assigned to the IND associated with this submission.

# Manufacturing Capacity

## CDER NextGen Portal Homepage



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



# Manufacturing Capacity

## Submit a New Submission

**Step 2. Select New Request.**

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

**Step 4. Click Next.**

CDER NextGen Portal

Manufacturing Capacity

+ New Request

Search Submissions Search

<p><a href="#">00003464</a> Submitted</p> <p>IND Number: 12345 Submission Date: 09/24/2020, 1:15 PM Organization Name: GENENTECH INC</p>	<p><a href="#">00003457</a> Submitted</p> <p>IND Number: 123333 Submission Date: 09/24/2020, 12:02 PM Organization Name: GENENTECH INC</p>	<p><a href="#">00003451</a> Draft</p> <p>IND Number: 345345 Submission Date: 09/24/2020, 11:28 AM Organization Name: GENENTECH INC</p> <p>Unsubmitted Draft</p>
<p><a href="#">00003445</a> Submitted</p> <p>IND Number: 123123 Submission Date: 09/24/2020, 10:34 AM Organization Name: GENENTECH INC</p>	<p><a href="#">00003441</a> Submitted</p> <p>IND Number: 454545 Submission Date: 09/24/2020, 9:50 AM Organization Name: GENENTECH INC</p>	<p><a href="#">00003213</a> Draft</p> <p>IND Number: Submission Date: 09/18/2020, 1:03 PM Organization Name: GENENTECH INC</p> <p>Unsubmitted Draft</p>
<p><a href="#">00003190</a> Draft</p> <p>IND Number: Submission Date: 09/18/2020, 11:29 AM Organization Name: GENENTECH INC</p> <p>Unsubmitted Draft</p>	<p><a href="#">00003154</a> Draft</p> <p>IND Number: Submission Date: 09/17/2020, 1:05 PM Organization Name: GENENTECH INC</p> <p>Unsubmitted Draft</p>	

1 of 3 > >>

Manufacturing Capacity

Introduction

Getting Started

Welcome to the Manufacturing Capacity Application Builder! Please complete the following sections in your preferred order. You can reference the [User Guide](#) as you complete your submission. When you are finished, please proceed to the Review and Submit section to formally send your submission to the FDA for review.

Manufacturing Capacity Assistant

Sponsor Information

Confirm the contact information for the organization completing the manufacturing capacity submission.

IND Information

Provide the IND information for the product, such as general information, as details pertaining to the drug substance(s)/API and the drug product dosage form(s), as well as the facilities in which production occurred.

Clinical Use

Provide information and data relating to the treatment course(s) and the clinical trial(s).

Drug Allocation

Confirm the allocation of the drug substances across 3 different matrices: Drug Product Dosage Forms per kg Drug Substance, Drug Substance Allocation Matrix, and Treatment Course Allocation Matrix.

Cancel 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 interface. On the left, the 'APPLICATION BUILDER' sidebar contains a list of steps: 'Sponsor Information' (highlighted with an orange box), 'IND Information', 'Clinical Use', 'Drug Allocation Matrices', and 'Review & Submit'. Below this is a 'Need Help?' section with a link to the 'Help Center'. On the right, the 'Sponsor Information' section contains a 'Sponsor Details' question: '\* Are you the sponsor or the US Agent associated with this IND?'. It has two radio button options: 'Sponsor' and 'US Agent'. At the bottom right, there are 'Save and Close' and 'Next' buttons, with the 'Next' button highlighted by an orange box.

**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 features a blue header for 'Manufacturing Capacity' and three main 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).

# Manufacturing Capacity

## 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.

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 three sections: 'General Information', 'Drug Substance/API Information', and 'Drug Product Dosage Form Information'. The 'General Information' section includes a text field for the IND number and a list of supply chain limitations. The 'Drug Substance/API Information' section features a '+ Add Drug Substance/API' button. The 'Drug Product Dosage Form Information' section features a '+ Add Drug Product Dosage Form' button. Two pop-up windows are overlaid: one for 'Add Drug Substance/API' with 'Substance Information' and 'Production Information' tabs, and another for 'Add Facility' with 'Drug Manufacturing Site Name' and 'Address' fields. A 'Save and Close' button is highlighted in the bottom right corner of the pop-up windows.

# 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 the progress: 'Sponsor Information' is complete, 'IND Information' is the current step, and 'Clinical Use' and 'Drug Allocation Matrices' are pending. Below this is a 'Need Help?' section with a link to the 'Help Center'. The main content area is divided into sections: 'IND Information' (with a 'General Information' sub-section), 'Drug Substance/API Information', and 'Drug Product Dosage Form Information'. Three overlapping 'Add Drug Product Dosage Form' dialog boxes are shown, each with a different tab selected: 'General Information', 'Dosage Form Information', and 'Production Information'. The 'General Information' tab asks for the drug product dosage form name. The 'Dosage Form Information' tab asks to select a dosage form and provides a fill volume field for liquids or lyophilized products. The 'Production Information' tab asks to identify the manufacturing facility, anticipate production changes, and estimate the percentage of capacity for the United States. A '+ Add Facility' button is present at the bottom of this dialog. At the bottom of the main application area, there is a '+ Add Drug Product Dosage Form' button and a 'Next' button.

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

# Manufacturing Capacity

## Clinical Use

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

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

The screenshot displays the 'Manufacturing Capacity' application builder interface. On the left, the 'APPLICATION BUILDER' sidebar shows progress: 'Sponsor Information' and 'IND Information' are complete (checked), 'Clinical Use' is the current step (highlighted), and 'Drug Allocation Matrices' and 'Review & Submit' are pending. A 'Need Help?' section provides a link to the 'Help Center'. The main content area is titled 'Clinical Use' and features a 'Treatment Course' section with an orange-bordered '+ Add Treatment Course' button. Below this is a 'Clinical Trials' section. An 'Add Treatment Course' modal form is open, containing the following fields:

- \* What is the name of this treatment course? (Text input)
- \* What is the broader use of this treatment course? (Dropdown menu: Select an Option)
- \* What is the Intended population for this treatment course? (Dropdown menu: Select an Option)
- Drug Product Dosage Form**
- \* What drug product dosage form is associated with this treatment course? (Dropdown menu: Select an Option)
- \* How many units of this drug product dosage form are needed for a treatment course? (Text input)
- \* Is there another drug product dosage form associated with the treatment course? (Radio buttons: Yes, No)
- \* Is there a device necessary in addition to what is in the dosage form? (Radio buttons: Yes, No)

At the bottom of the modal, there are 'Cancel' and 'Save' buttons, with the 'Save' button highlighted with an orange border.



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**.

The screenshot shows the 'Manufacturing Capacity' application interface. On the left, the 'APPLICATION BUILDER' sidebar has 'Clinical Use' selected. The main content area is titled 'Clinical Use' and shows a table with one entry: 'Treatment Course 1', which has 'Edit' and 'Delete' buttons. Below this is an 'Add Treatment Course' button. At the bottom right, there is a 'Save and Close' button and a 'Next' button. A modal window titled 'Add Clinical Trial' is overlaid on the screen, containing the following fields:

- \* What is the name of this Clinical Trial? (Text input)
- \* Is this clinical trial part of a master protocol? (Radio buttons: Yes, No)
- \* What is the Intended population for this clinical trial? (Dropdown menu)
- \* Is there another population in this clinical trial? (Radio buttons: Yes, No)
- Drug Product Dosage Form**
  - \* What drug product dosage form is associated with this treatment course? (Dropdown menu)
  - \* How many units of this drug product dosage form are needed for the entire clinical trial? (Text input)
  - \* Will these units be from the same capacity planned for broader use (Approval, EUA, Treatment IND) or from an alternative supply? (Radio buttons: Same as Broader Use, Alternative Supply)
  - \* Is there another drug product dosage form in this clinical trial? (Radio buttons: Yes, No)
- Clinical Trial Questions**
  - \* Duration of planned clinical trial? (Text input, dropdown menu)
  - \* Clinical Trial Phase (Radio buttons: 0, 1, 2, 3, 4)
- Please Provide National Clinical Trial (NCT) Number if possible: (Text input)
- \* Number of patients planned for enrollment (Text input)

Buttons for 'Cancel' and 'Save' are at the bottom of the modal.



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.

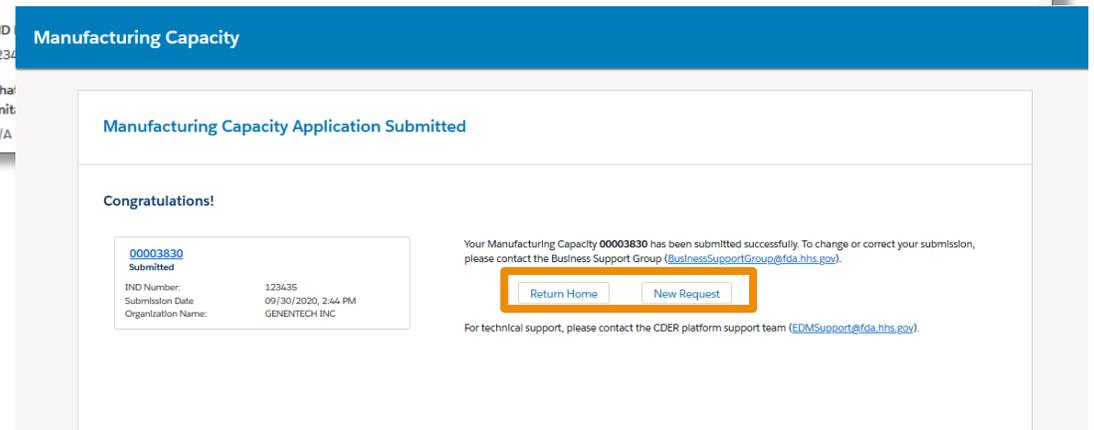
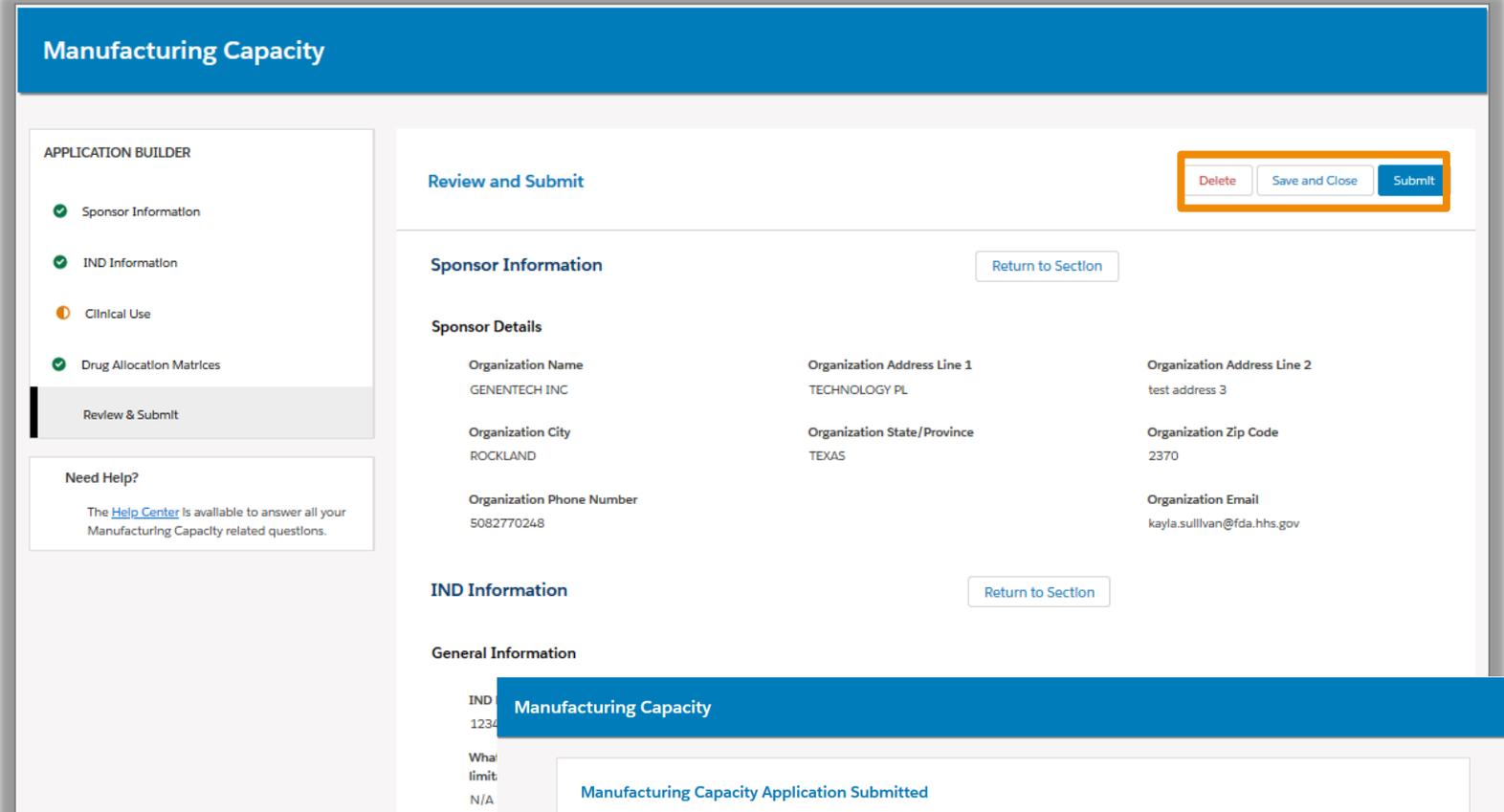
**Step 24.** Click **Submit** to send your Manufacturing Capacity submission or **Save & Close** to keep your Manufacturing Capacity submission or **Delete** to remove your Manufacturing Capacity submission.

**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](mailto:DoNotReply@fda.hhs.gov) and Review the information submitted.



## Cloning Capability

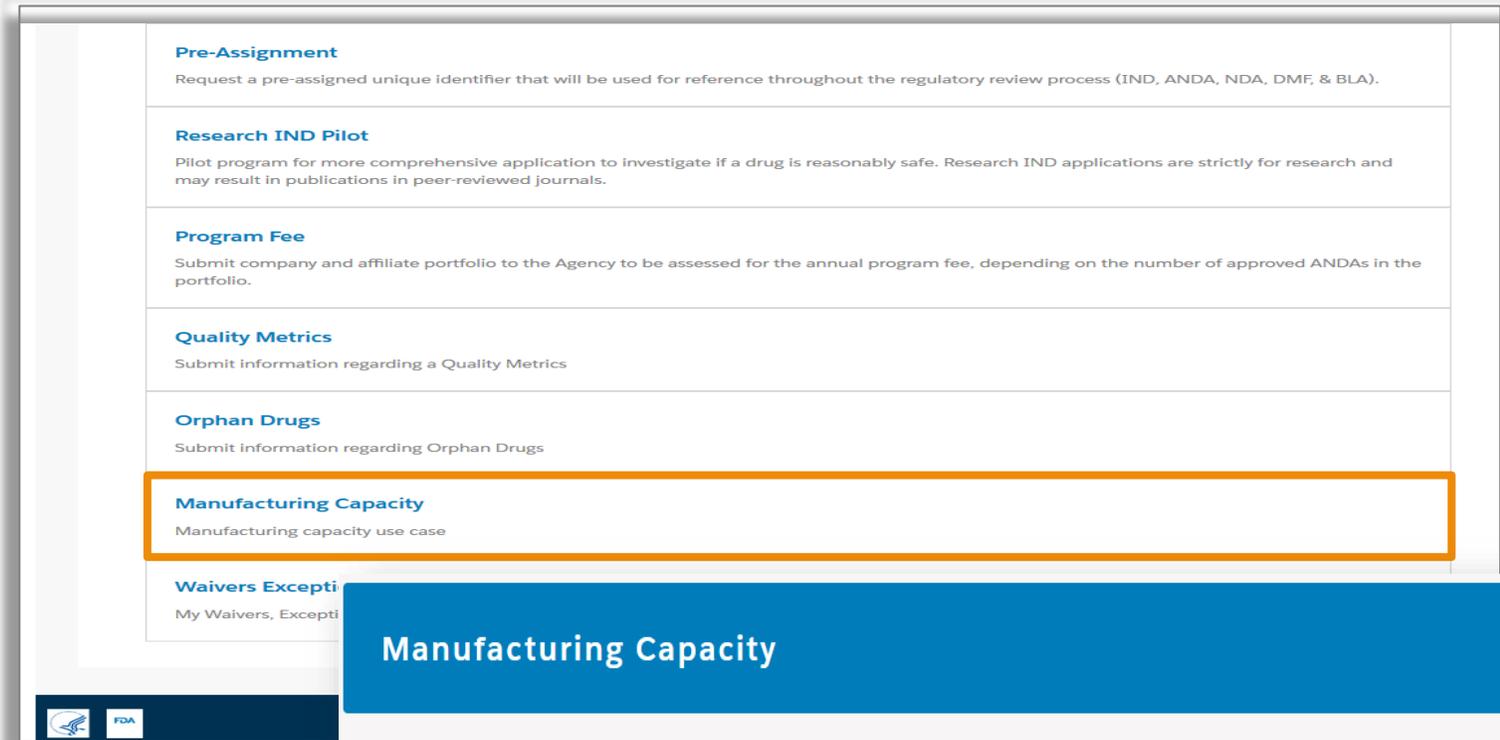
# Manufacturing Capacity

## 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.



# Manufacturing Capacity

## 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: 'Clone' (highlighted with an orange border) and 'Return to Home'. The main content area is divided into sections: 'Review and Submit' (with a link), 'Sponsor Information', and 'IND Information'. The 'Sponsor Information' section contains a table of 'Sponsor Details' with the following data:

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		

Overlaid on the bottom right of the form is a modal dialog box titled 'Clone Submission?'. The dialog contains the following text:

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' (highlighted with an orange border).

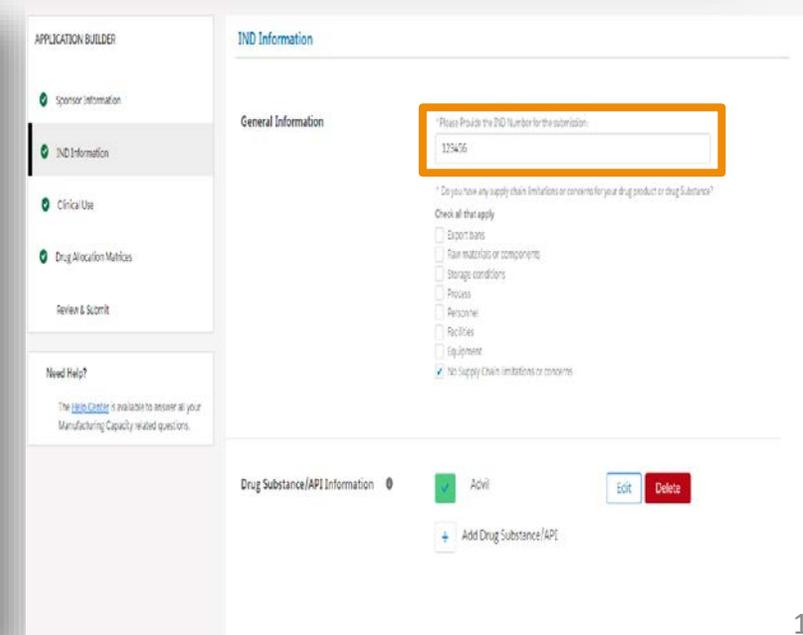
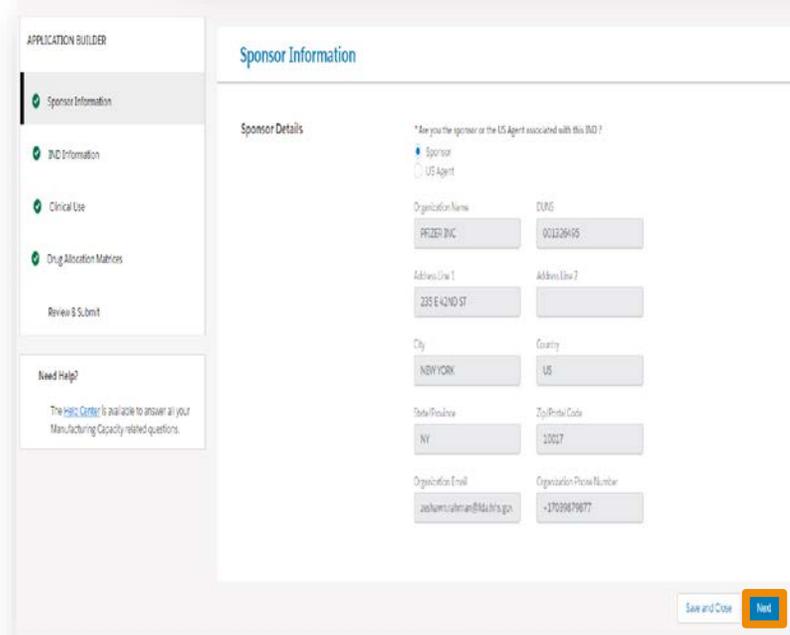
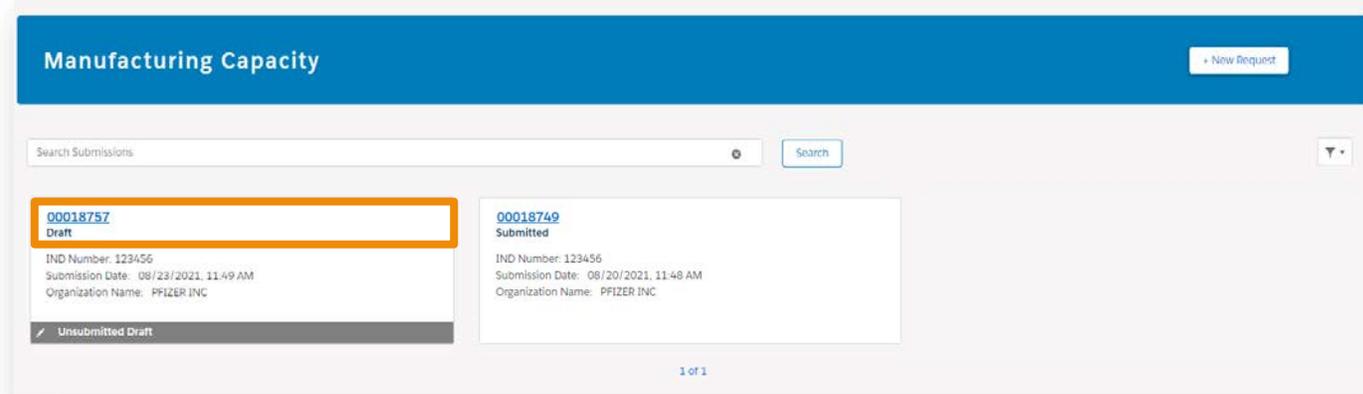
# Manufacturing Capacity

## 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 vertical 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 'Drug Allocation Matrices' section is also visible, showing three matrices: 'Drug Product Dosage Form Per Kg Drug Substance Matrix', 'Drug Substance Allocation Matrix', and 'Treatment Course Allocation Matrix', each with a 'Matrix Input' button. A 'Need Help?' section at the bottom provides a link to the 'Help Center'. Navigation buttons for 'Previous', 'Save and Close', and 'Next' are located at the bottom of the interface.

# Manufacturing Capacity

## 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 “**Learn More**” link. On the event home page, users can find the “Learn More” link to **Reference Guides and FAQs**.

## Technical Support

For all technical support, contact **CDER Platform Support Team** at [EDMSupport@fda.hhs.gov](mailto:EDMSupport@fda.hhs.gov).

## CDER NextGen Portal Video Tutorial

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