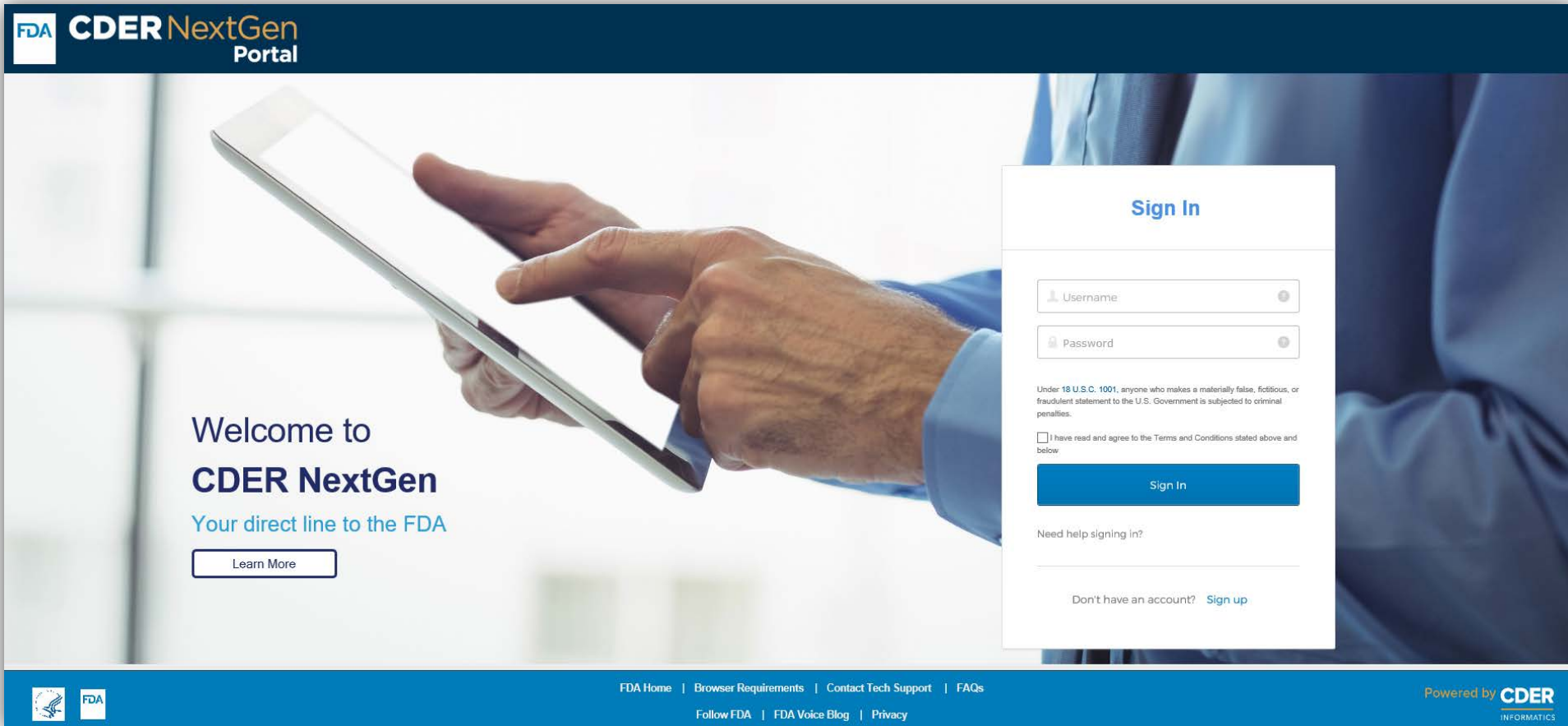


Manufacturing Capacity Reference Guide



The screenshot shows the CDER NextGen Portal sign-in interface. The header includes the FDA logo and 'CDER NextGen Portal'. The main content area features a background image of a person in a blue lab coat using a tablet. On the left, a welcome message reads 'Welcome to CDER NextGen Your direct line to the FDA' with a 'Learn More' button. On the right, a 'Sign In' form contains fields for 'Username' and 'Password', a checkbox for terms and conditions, a 'Sign In' button, and a 'Sign up' link. The footer contains navigation links for FDA Home, Browser Requirements, Contact Tech Support, and FAQs, along with social media links and a 'Powered by CDER INFORMATICS' logo.

Click [here](#) to access the portal.

Supported Browsers: Google Chrome and Mozilla Firefox

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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.

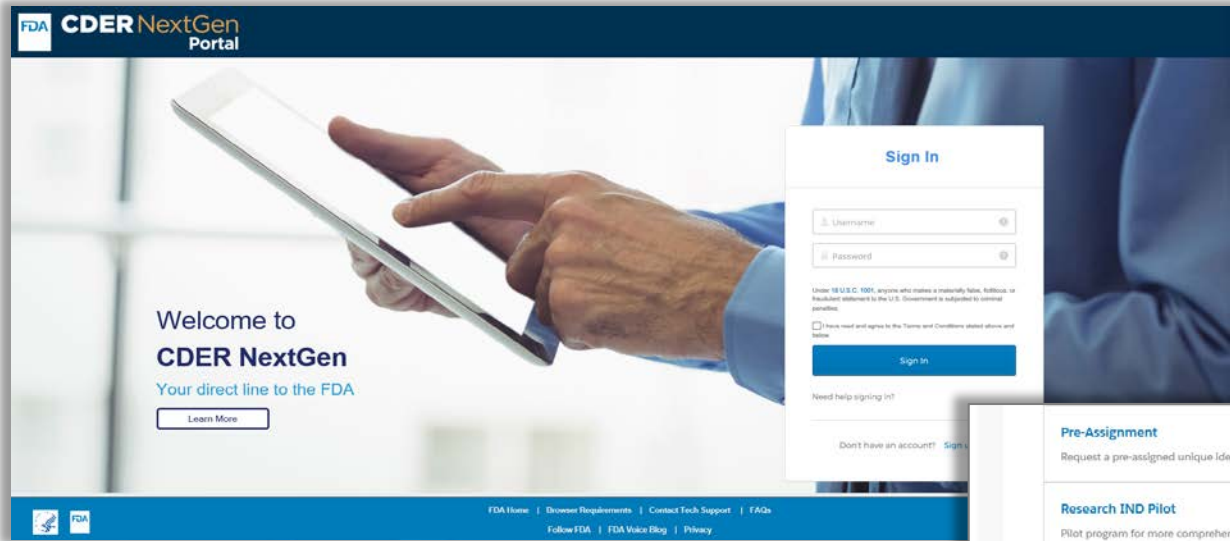
This solution provides a way for organizations to submit data related to manufacturing capacity to the FDA to analyze and support manufacturing efforts for potential vaccines and therapeutics such that there is a capability for mass production to meet the population need. The portal captures information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

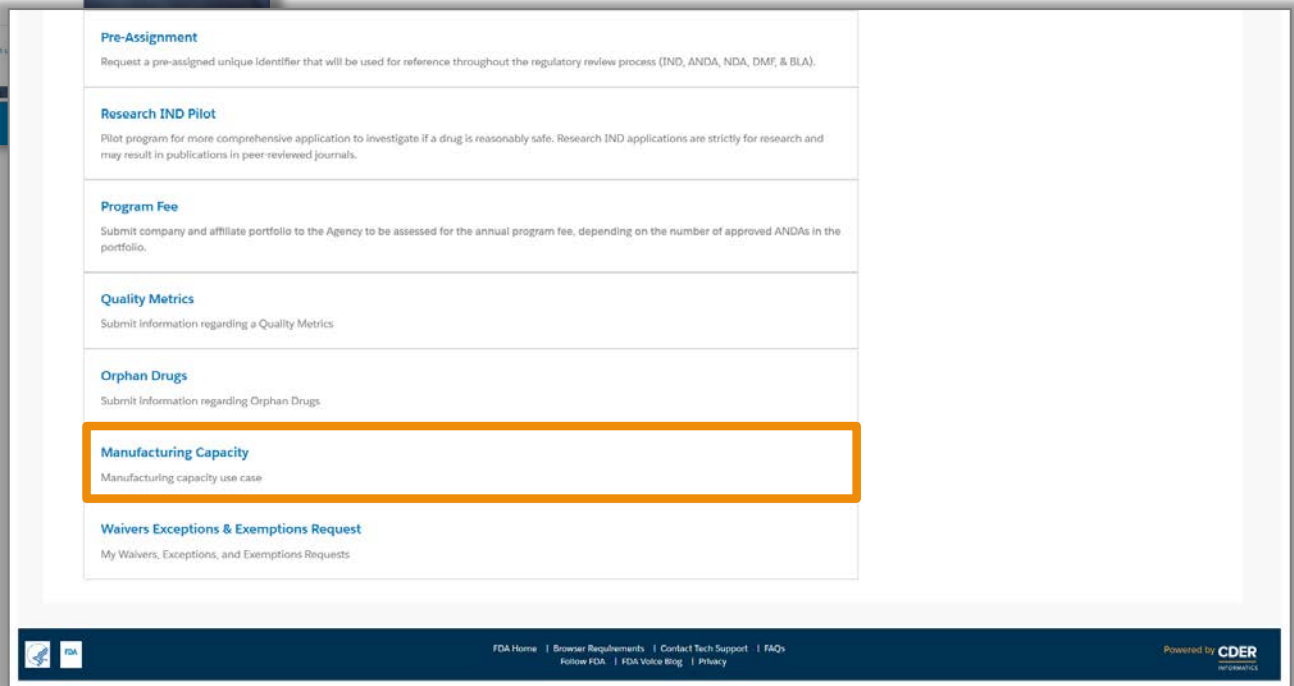
For technical assistance, the FDA EDM Support Team (EDMSupport@fda.hhs.gov) is available to help.

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

Portal Homepage



Step 1. Once you land on the 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.

The screenshot shows the CDER NextGen Portal interface for Manufacturing Capacity. At the top right, there are navigation icons for home, help, and a 'Log Out' button. Below the header, a blue banner contains the text 'Manufacturing Capacity' and a '+ New Request' button highlighted with an orange box. A search bar is located below the banner. The main content area displays a grid of submission cards. Each card shows an IND Number, submission date, and organization name. The status of each submission is indicated at the bottom of the card: 'Submitted' or 'Draft'. The cards are arranged in a 3x3 grid, with the bottom-right card partially obscured by a modal window.

The screenshot shows the 'Manufacturing Capacity Assistant' modal window. It has a blue header with the text 'Manufacturing Capacity'. Below the header, there are sections for 'Introduction', 'Getting Started', 'Manufacturing Capacity Assistant', 'Sponsor Information', 'IND Information', 'Clinical Use', and 'Drug Allocation'. Each section contains a brief description and a text input field. At the bottom of the modal, there are 'Cancel' and 'Next' buttons, with the 'Next' button highlighted in orange.

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**.

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.

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.

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. If there are multiple dosage forms within the drug product, 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**.

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

The screenshot displays the 'Manufacturing Capacity' application builder interface. On the left, the 'APPLICATION BUILDER' sidebar shows a progress indicator with 'Sponsor Information' completed and 'IND Information' selected. 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'. A modal window titled 'Add Drug Product Dosage Form' is open, showing a multi-step form. The 'General Information' step is highlighted, with a field for '*What Is the Drug Product Dosage Form name?'. A second modal window shows the 'Dosage Form Information' step, with a dropdown for '*Please select the dosage form:'. A third modal window shows the 'Production Information' step, with a dropdown for '*Please identify the manufacturing facility:' and a '+ Add Manually' button. A fourth modal window shows the 'Add Facility' step, with a question '* Do you anticipate a change in production at this facility?' and a percentage input field for '* Out of the total capacity, please estimate the percentage that will be provided for the United States.'. The interface includes 'Previous' and 'Next' buttons, and a 'Save and Close' button at the bottom right.

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 shows the 'Manufacturing Capacity' application builder interface. On the left, the 'APPLICATION BUILDER' sidebar has 'Clinical Use' selected. The main content area shows 'Clinical Use' and 'Clinical Trials' sections, each with an 'Add Treatment Course' button. A modal window titled 'Add Treatment Course' 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)
- * What is the Intended population for this treatment course? (Dropdown menu)
- 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 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)

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

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 builder interface. On the left, the 'APPLICATION BUILDER' sidebar has 'Clinical Use' selected. The main area shows the 'Clinical Use' section with a table containing one entry: 'Treatment Course 1'. Below the table is an 'Add Treatment Course' button. A modal window titled 'Add Clinical Trial' is open, displaying various form fields for entering trial information. A dashed box highlights the 'Drug Product Dosage Form' section of the modal, which includes a dropdown menu for selecting a dosage form. An information icon is positioned to the left of this dashed box.



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

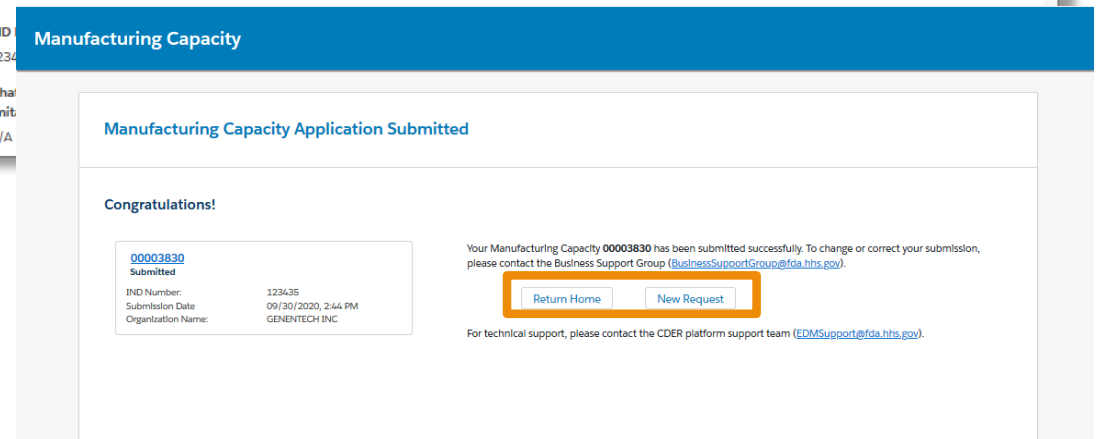
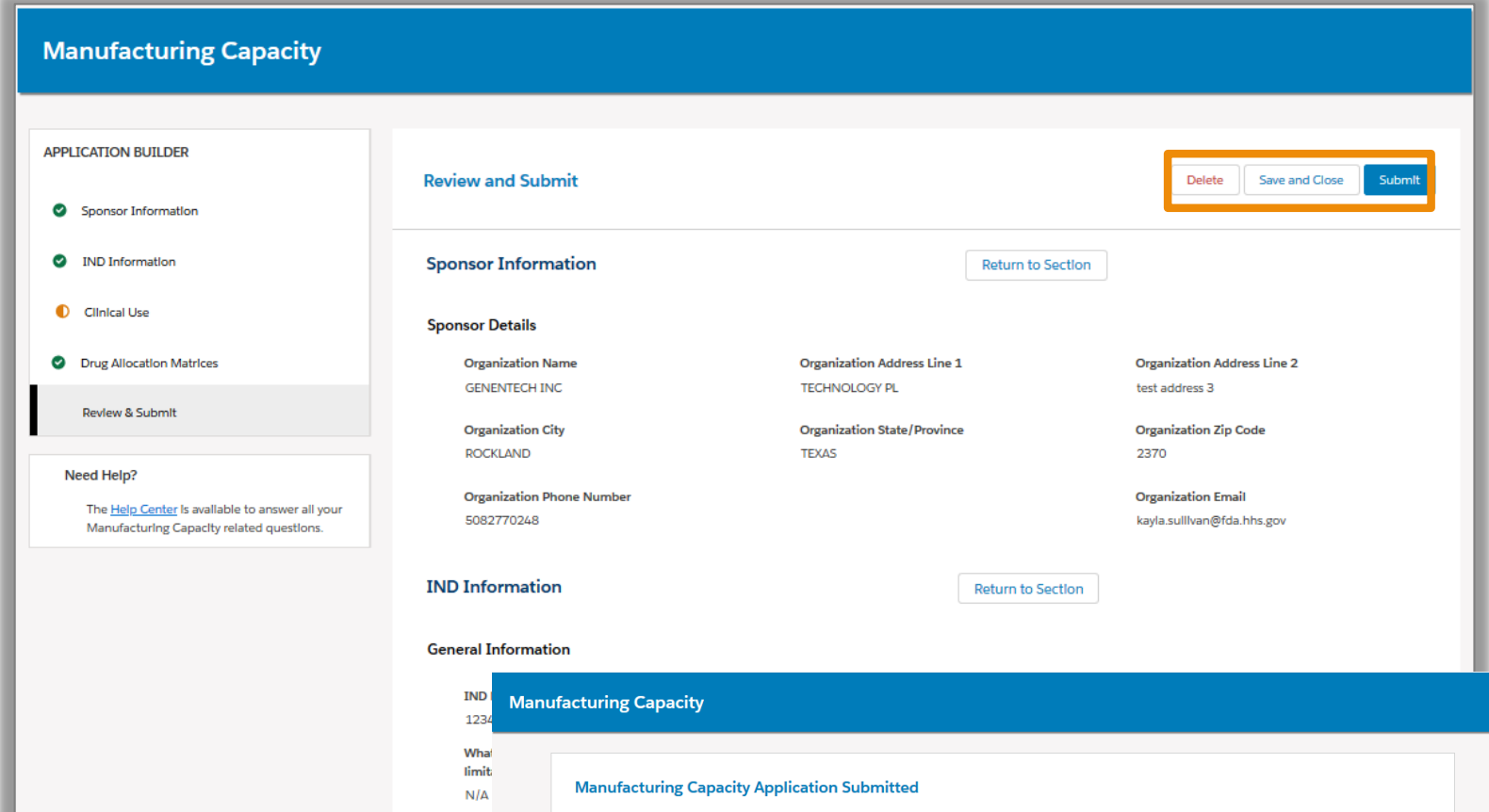
Review and Submit

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.

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.



Technical Support and Resources

CDER NextGen Portal Support & Resources

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

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.

Portal Video Tutorial

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