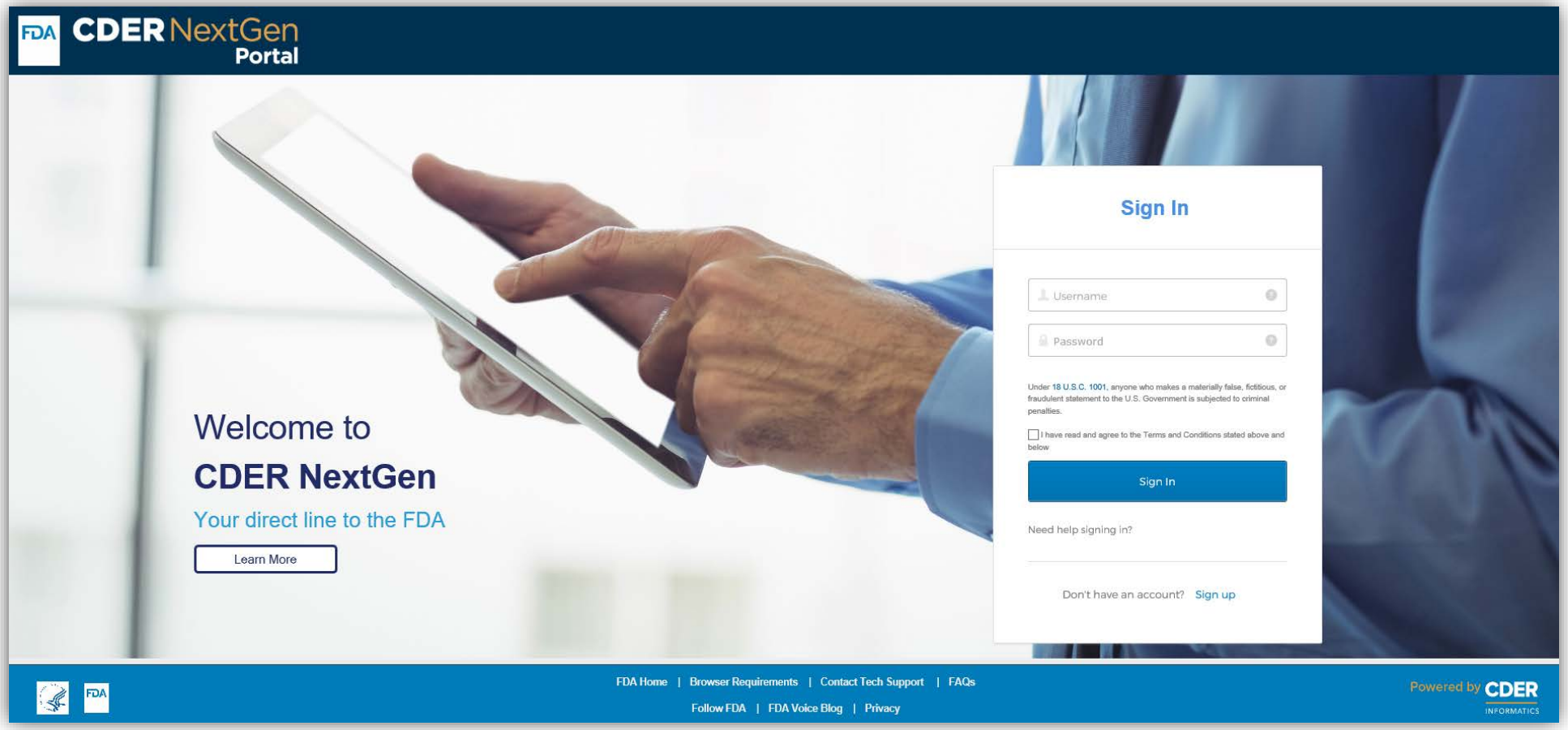
Manufacturing Capacity Reference Guide



Click here to access the CDER NextGen 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.

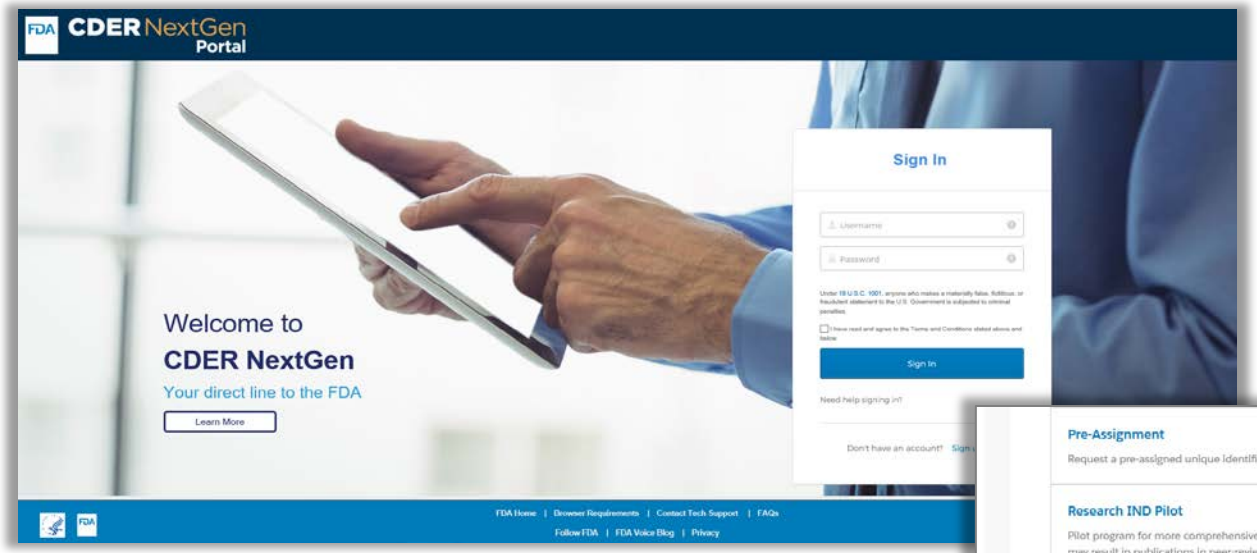
Manufacturing Capacity submissions are voluntary, however, CDER strongly encourages sponsors and/or manufacturers to submit information in support of the COVID-19 response.

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

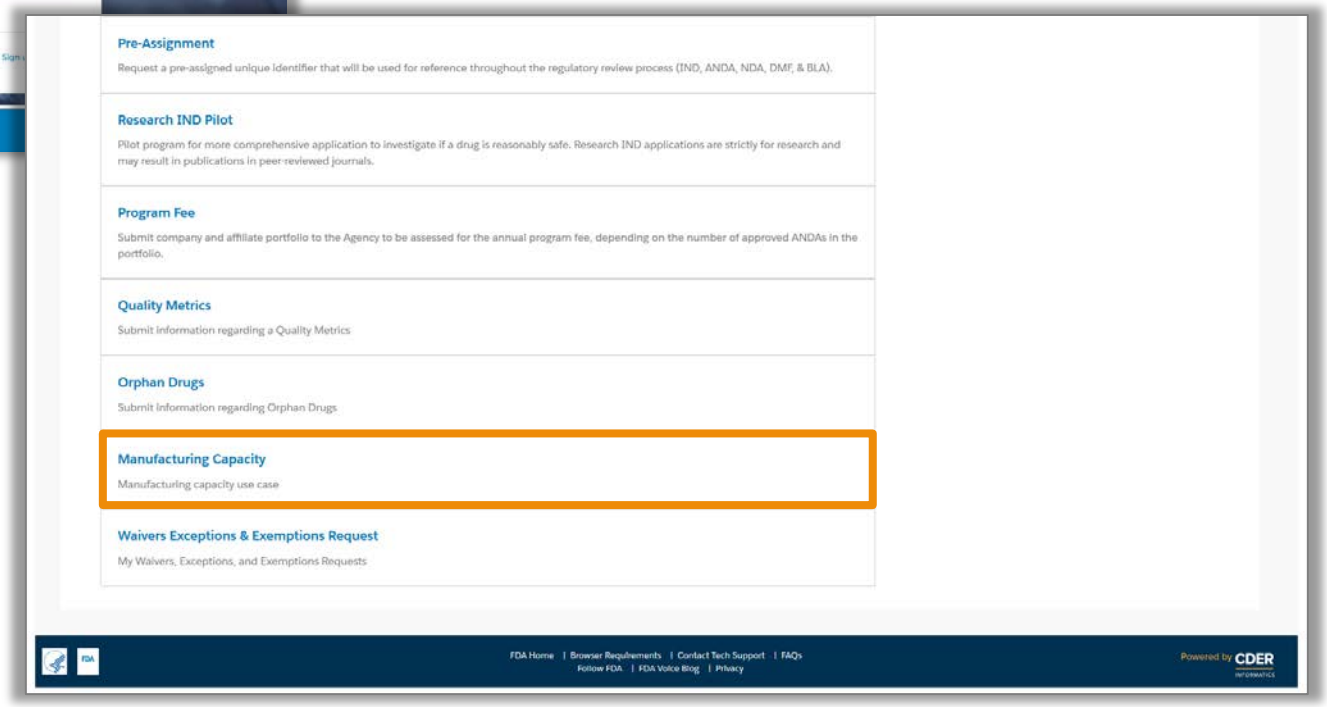
For business assistance, contact the Regulatory Project Manager assigned to the IND associated with this submission.

Manufacturing Capacity

CDER NextGen Portal Homepage



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



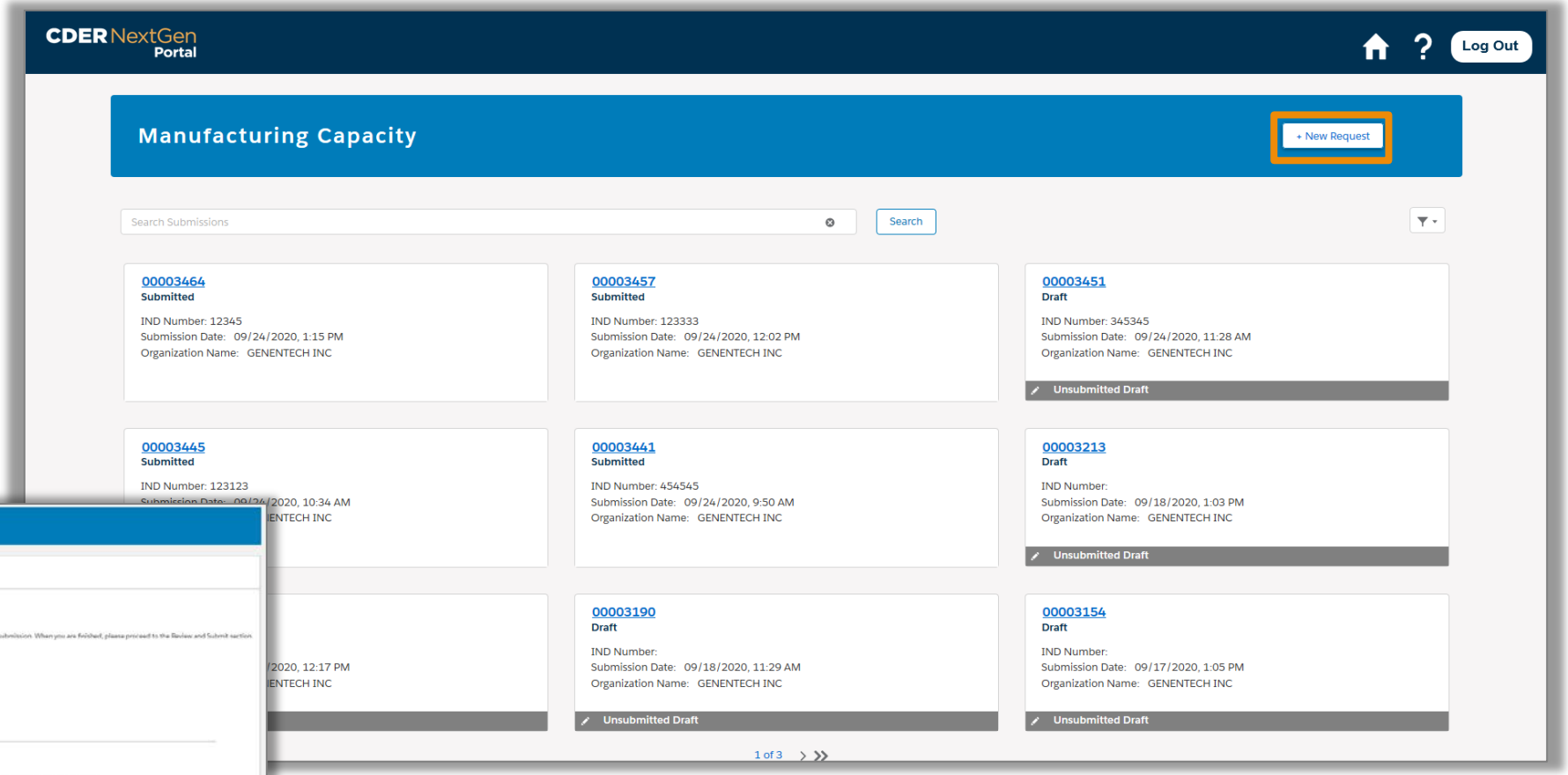
Manufacturing Capacity

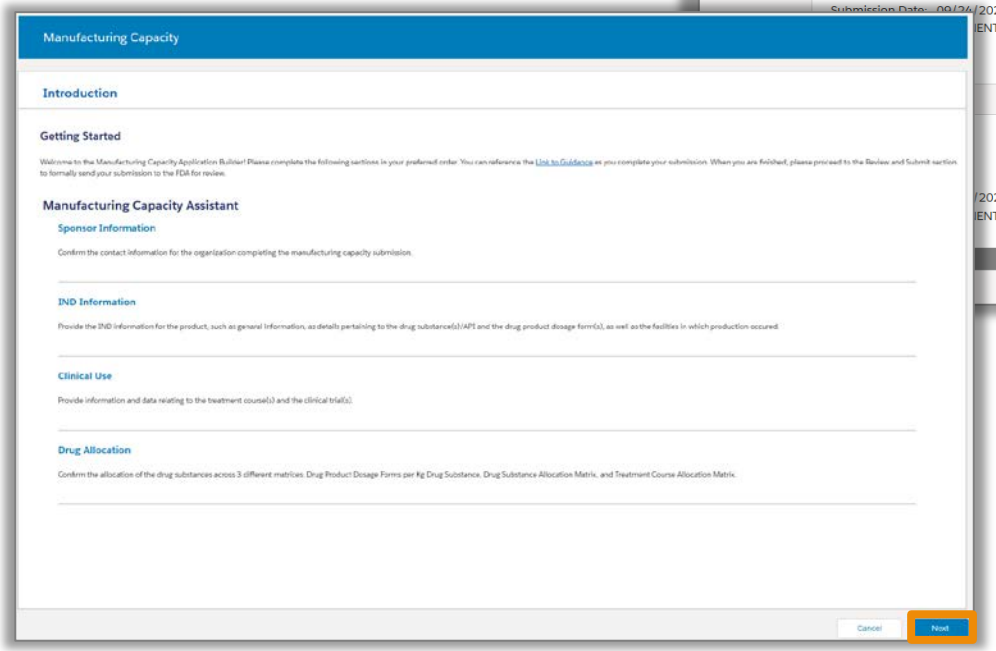
Submit a New Submission

Step 2. Select **New Request**.

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

Step 4. Click **Next**.





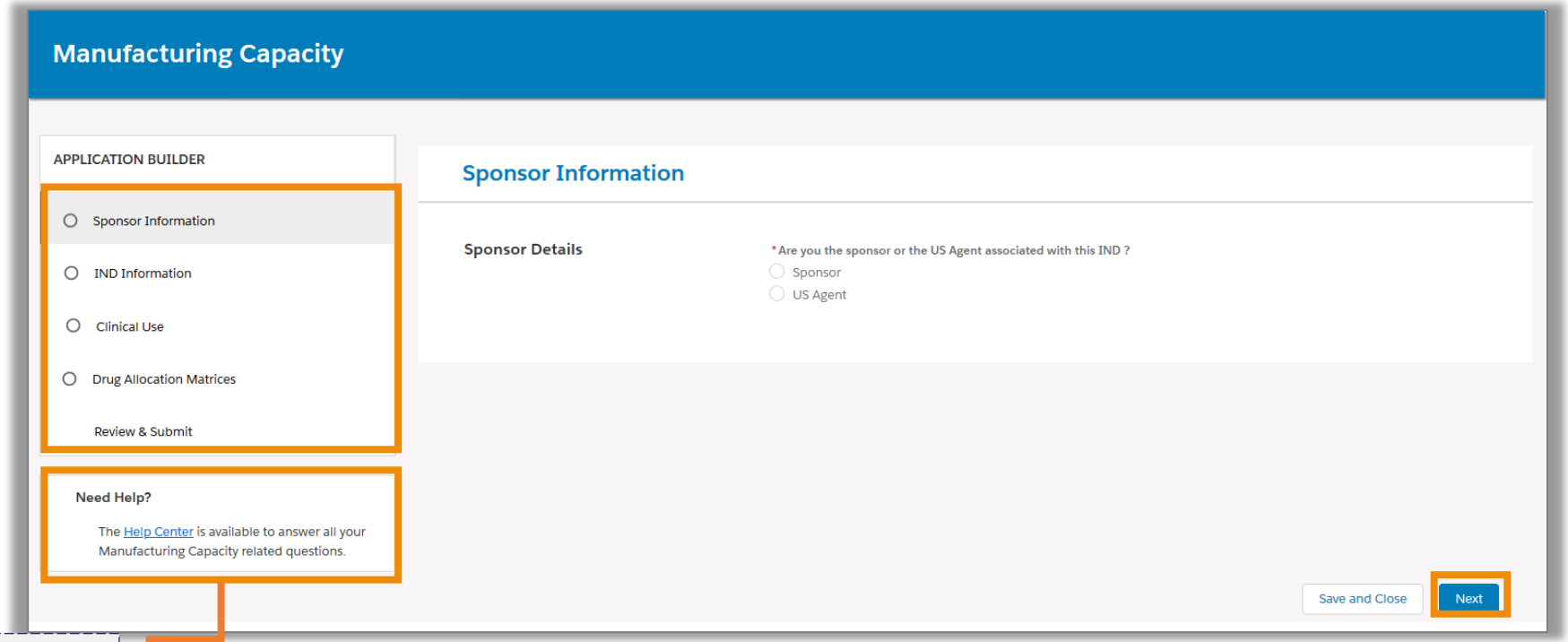
Manufacturing Capacity

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**.

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

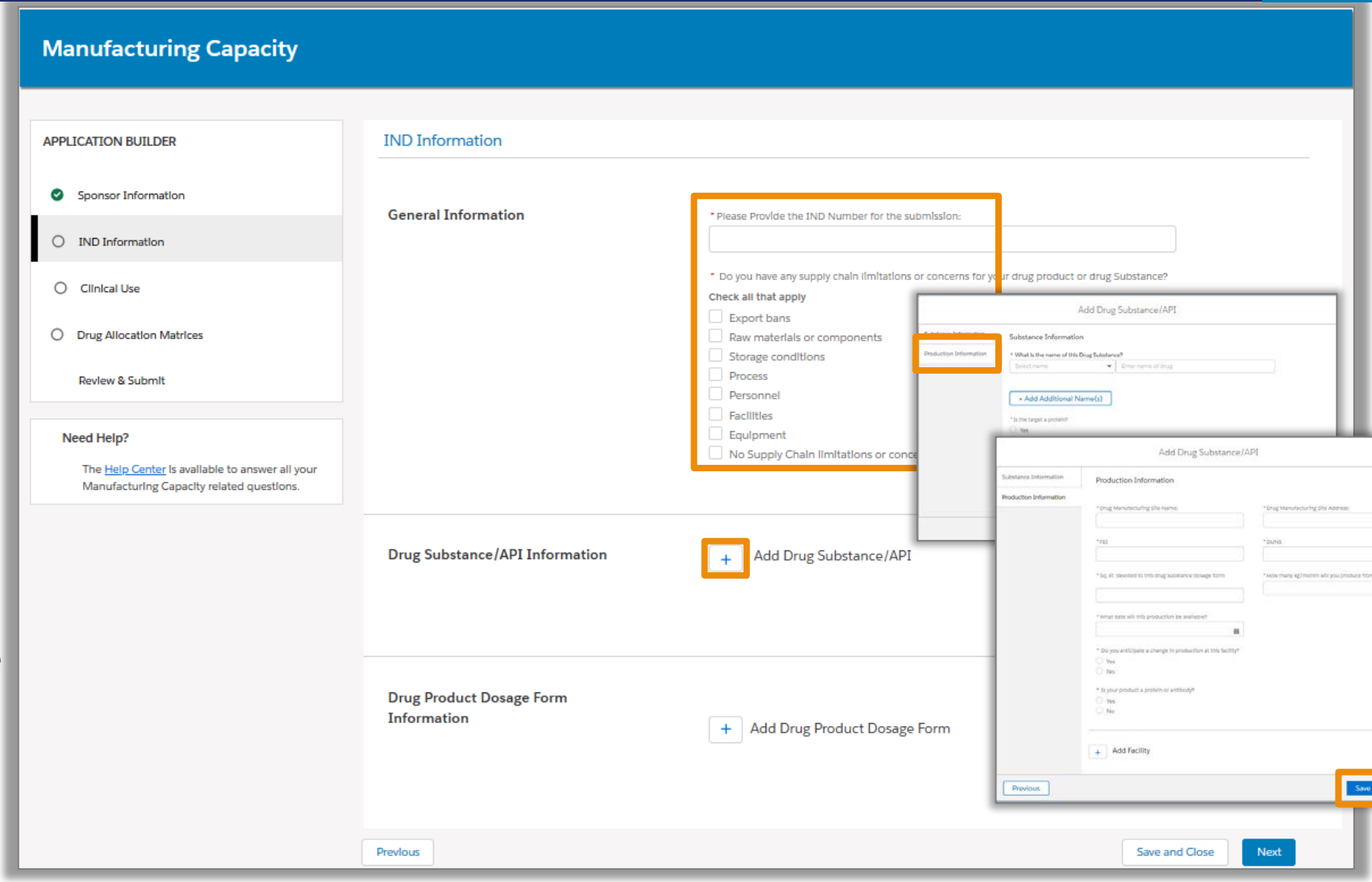
IND Information

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

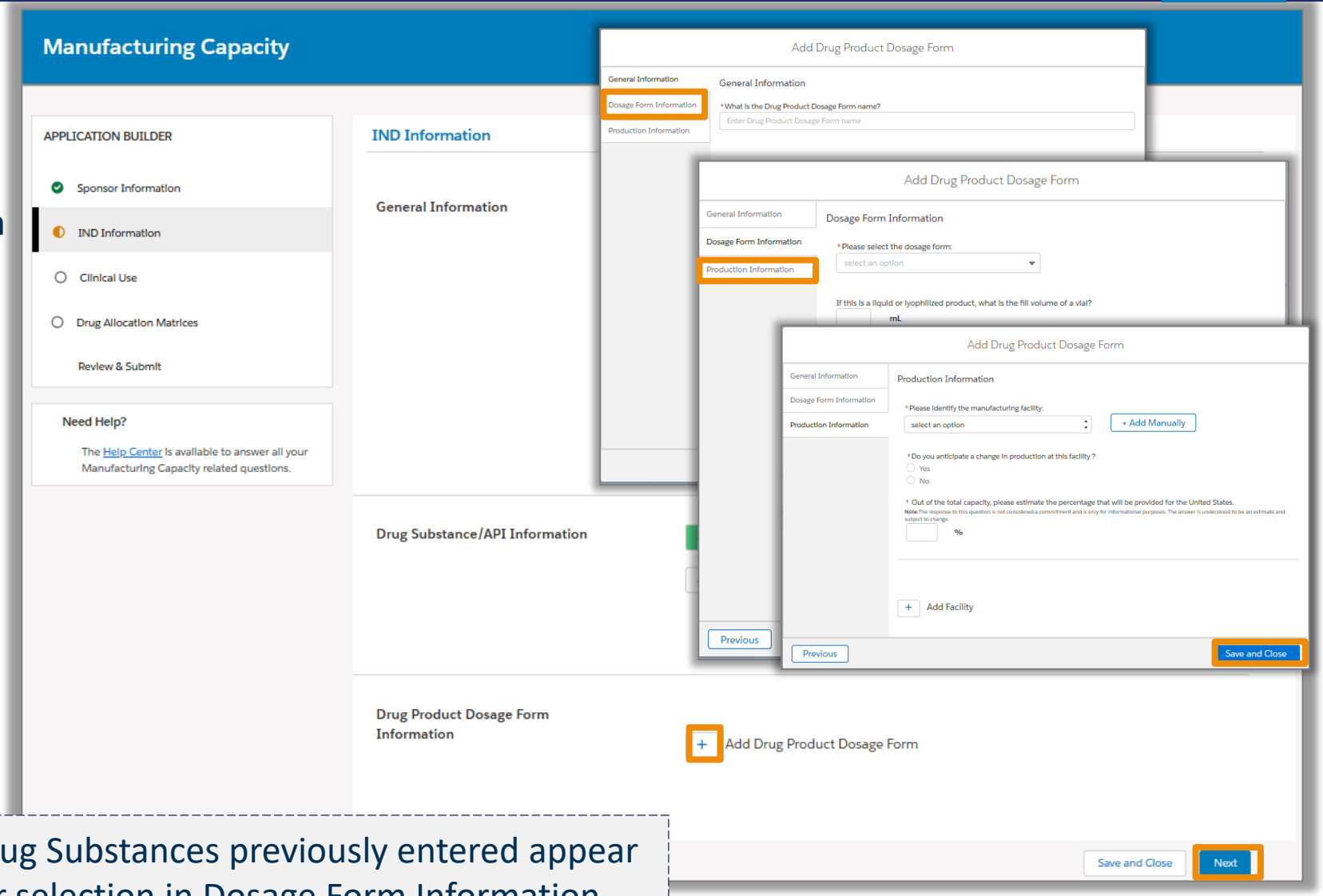
IND Information

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. Click **Next** or **Production Information.**

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

Step 14. Click **Next.**



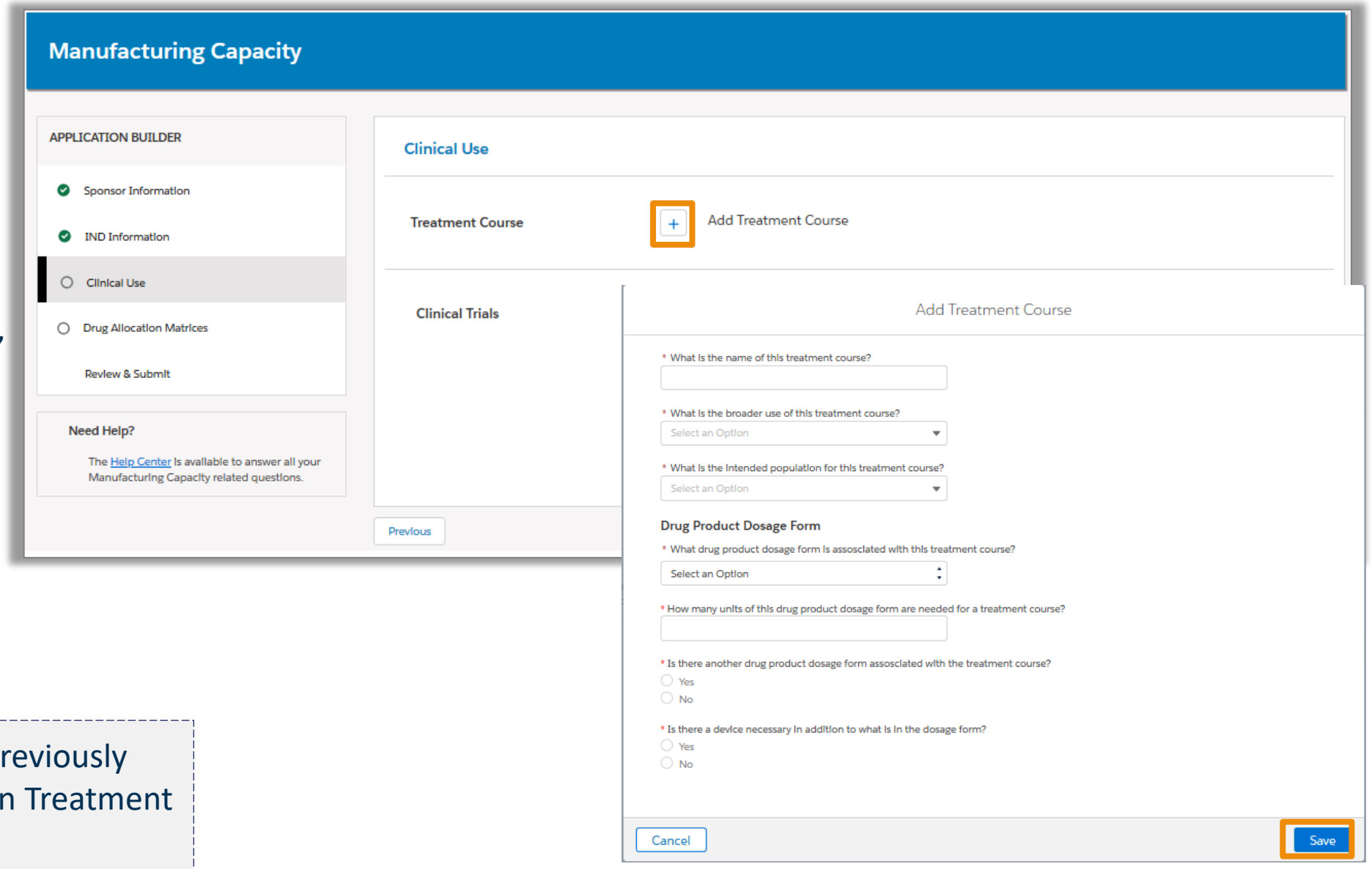
Drug Substances previously entered appear for selection in Dosage Form Information section.

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.



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

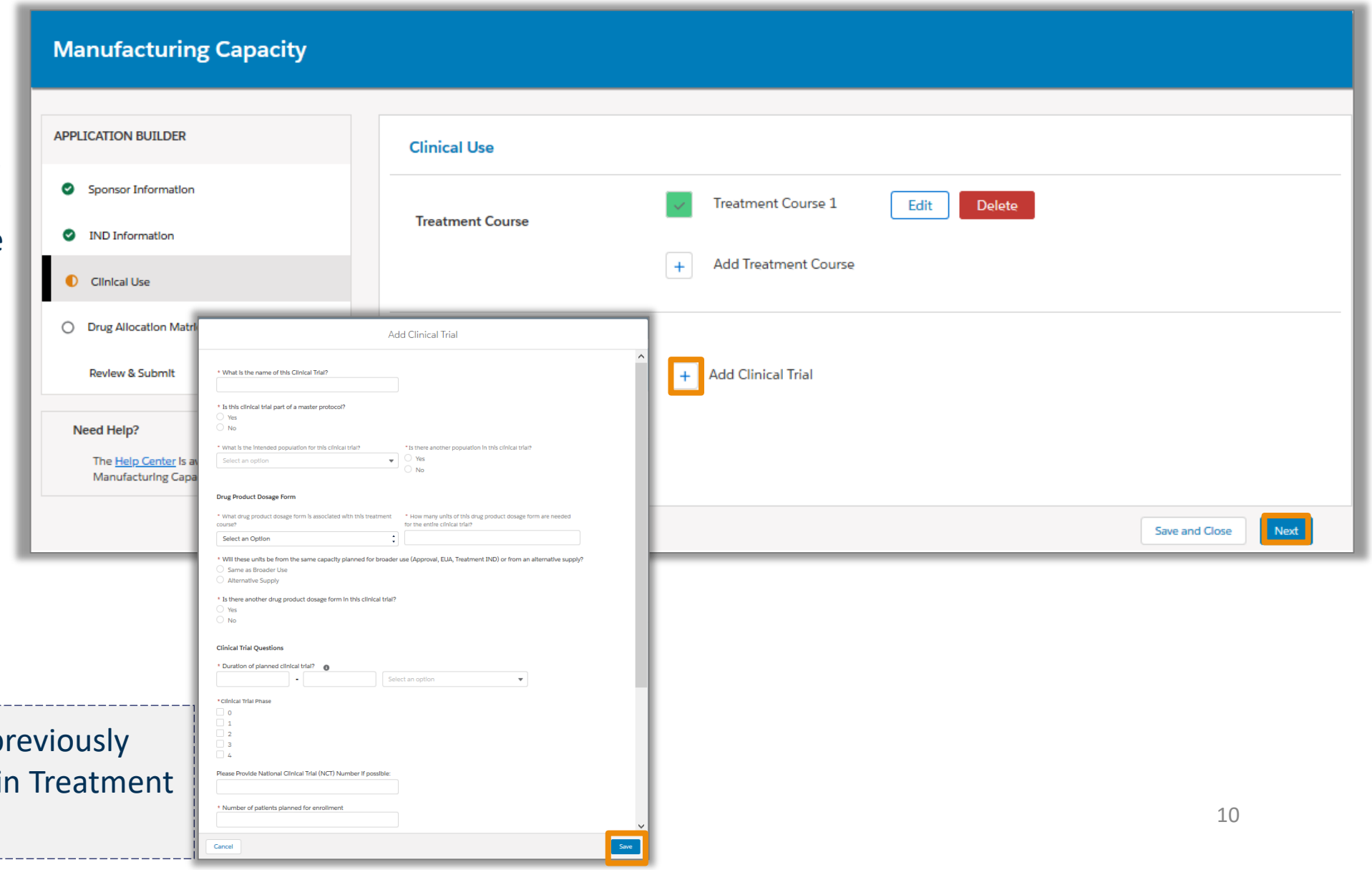
Manufacturing Capacity

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.

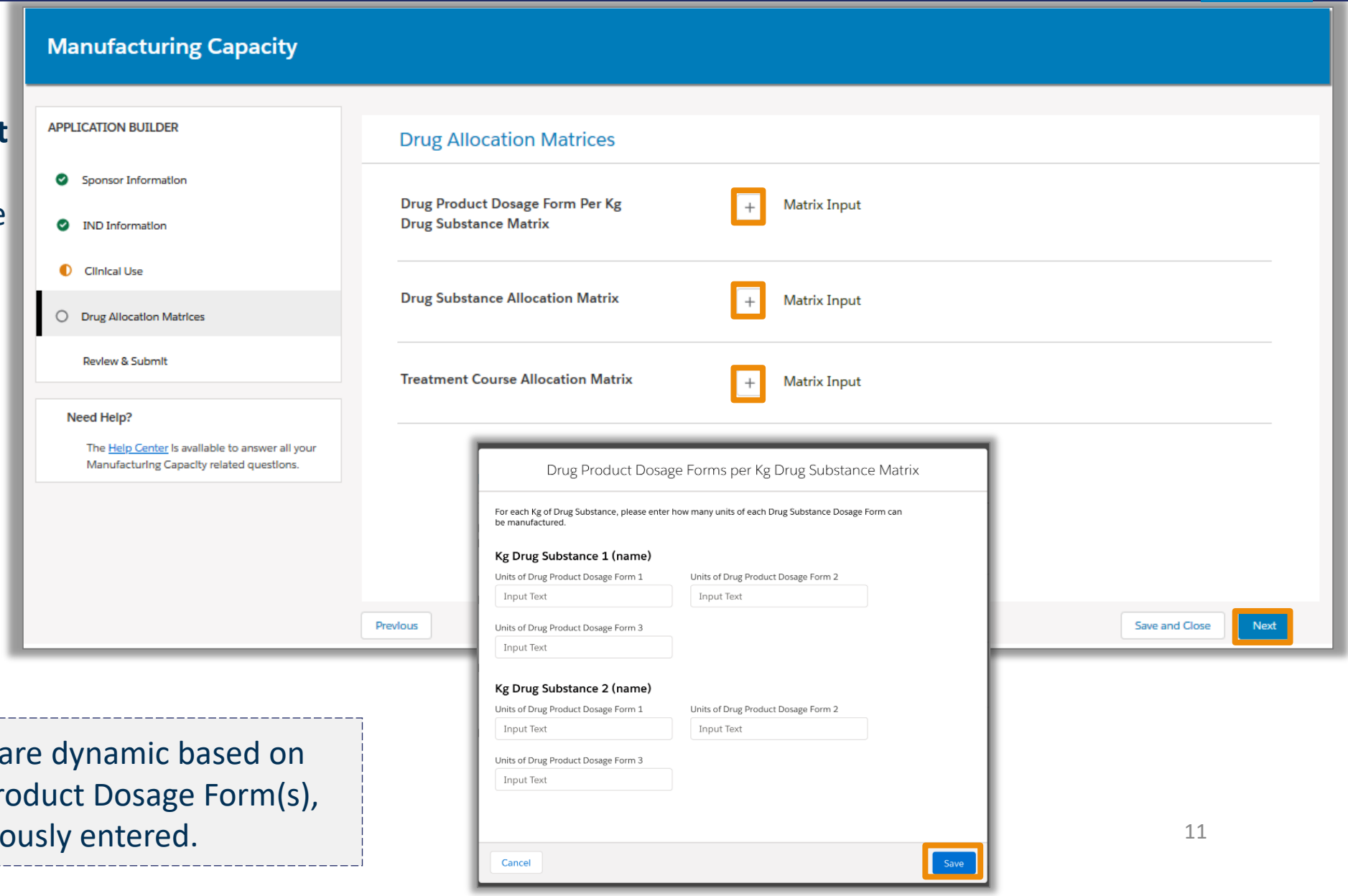
Manufacturing Capacity

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**.



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

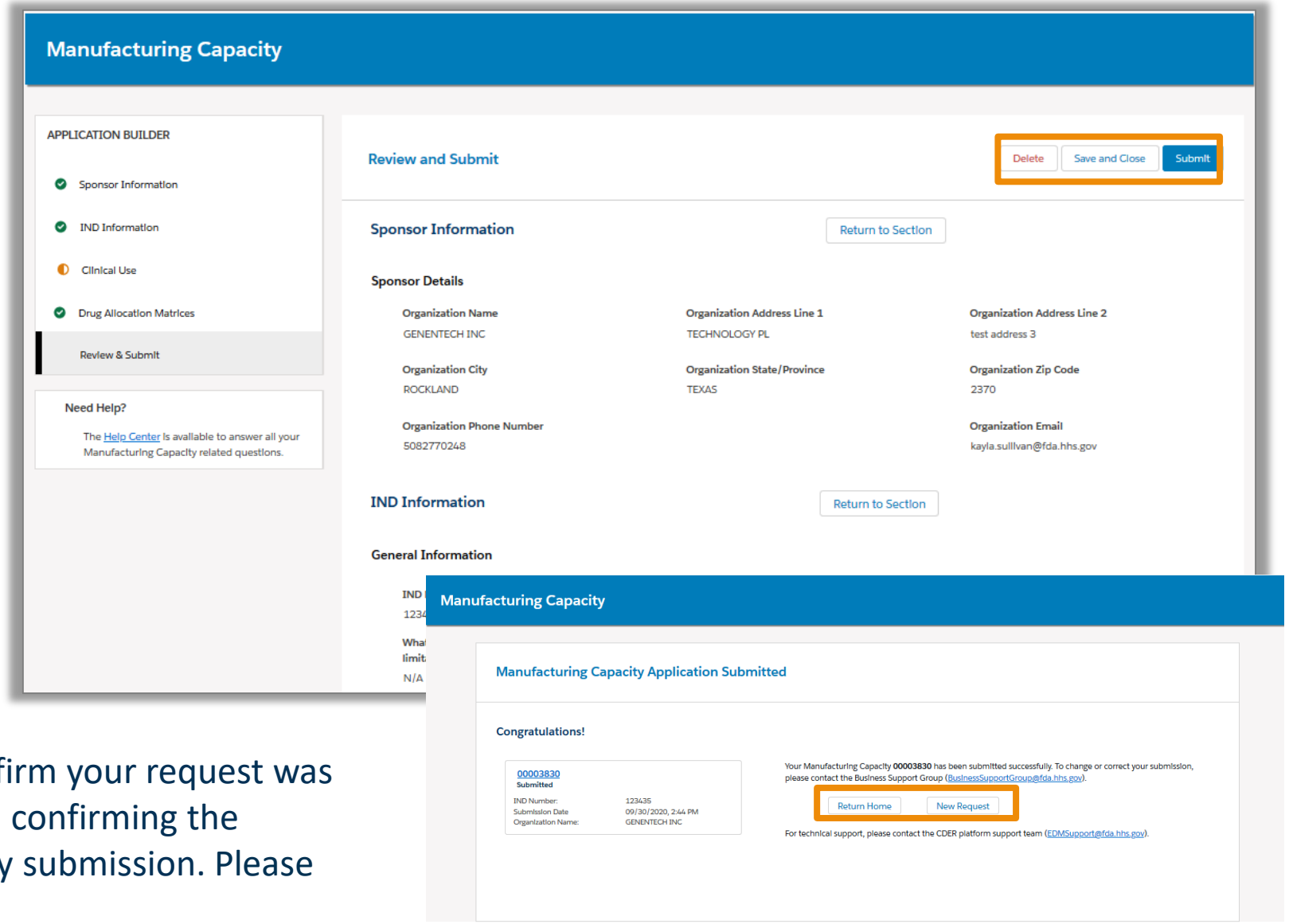
Manufacturing Capacity

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.

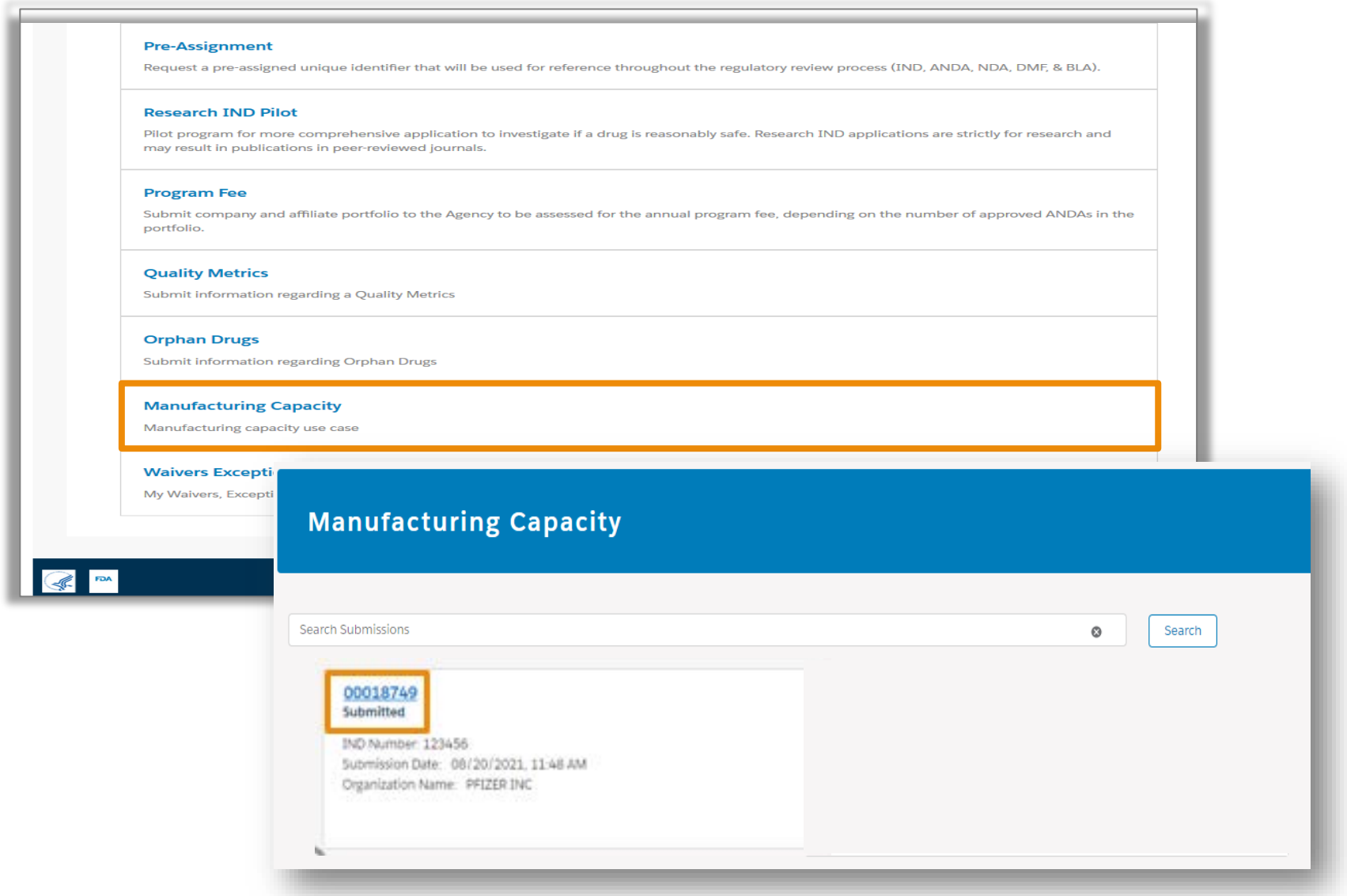
Cloning Capability

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.



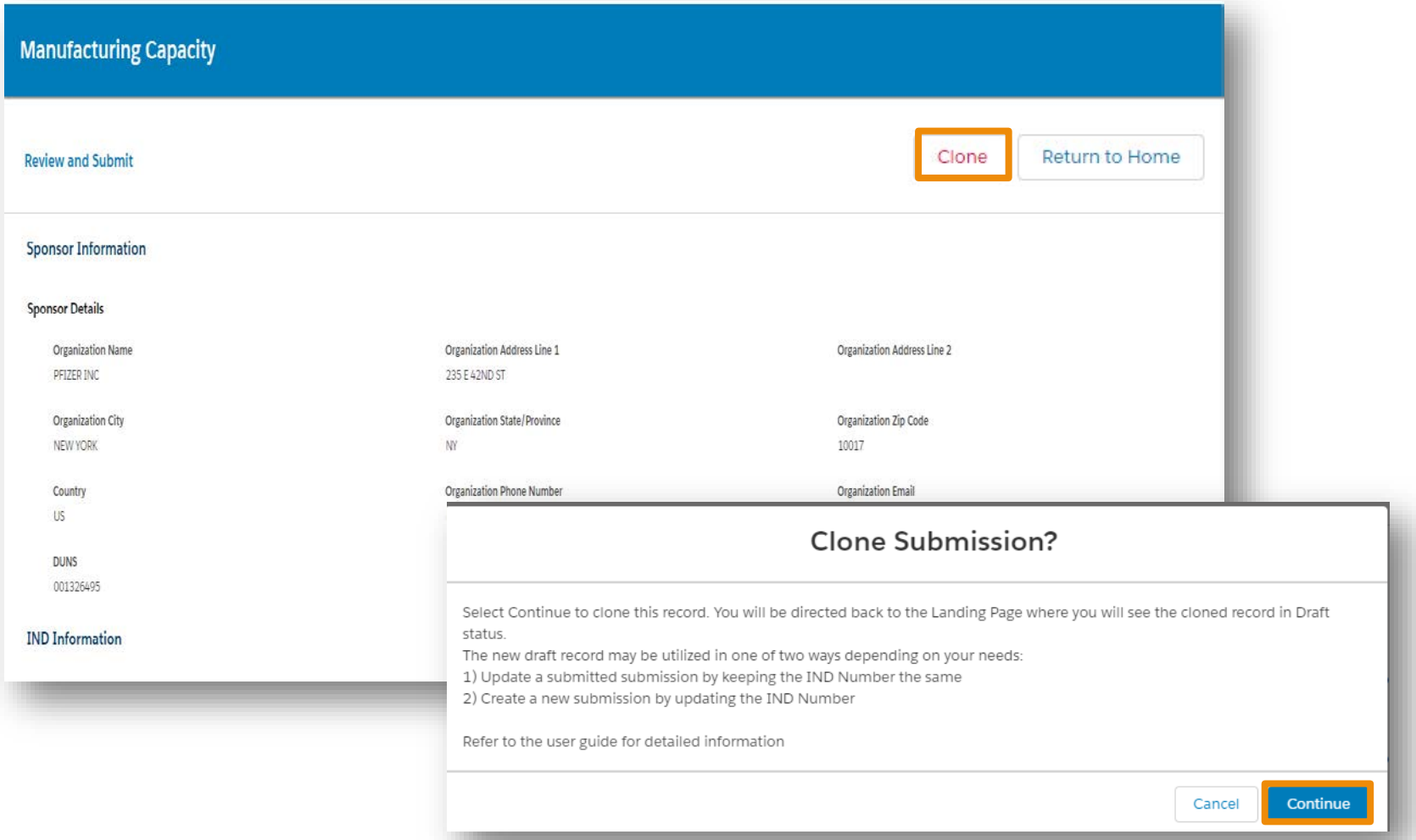
Note: The Cloning Capability can be used to update information on an existing submission by keeping the IND number the same, OR to clone an existing submission with similar attributes but different IND.

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.



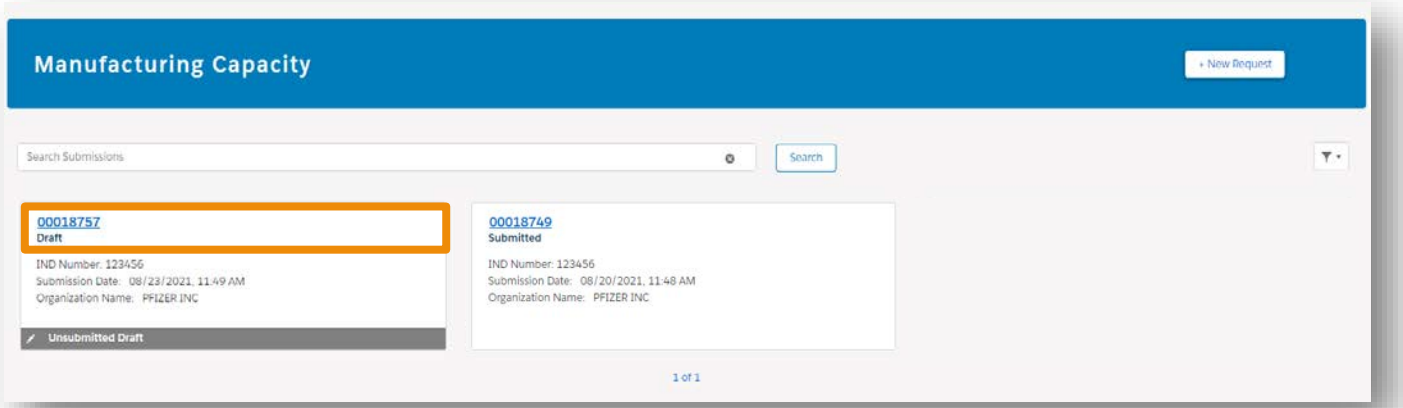
Manufacturing Capacity

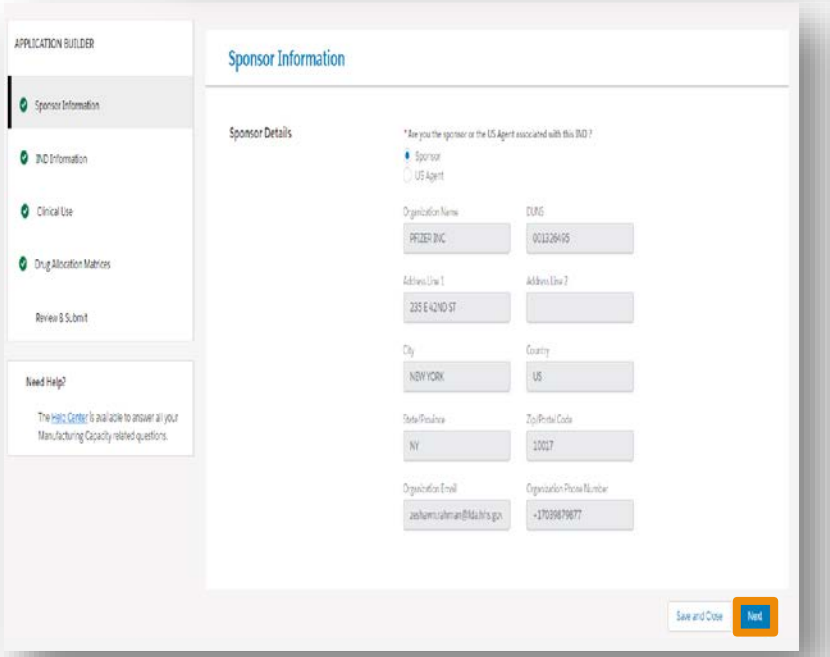
Cloning Capability

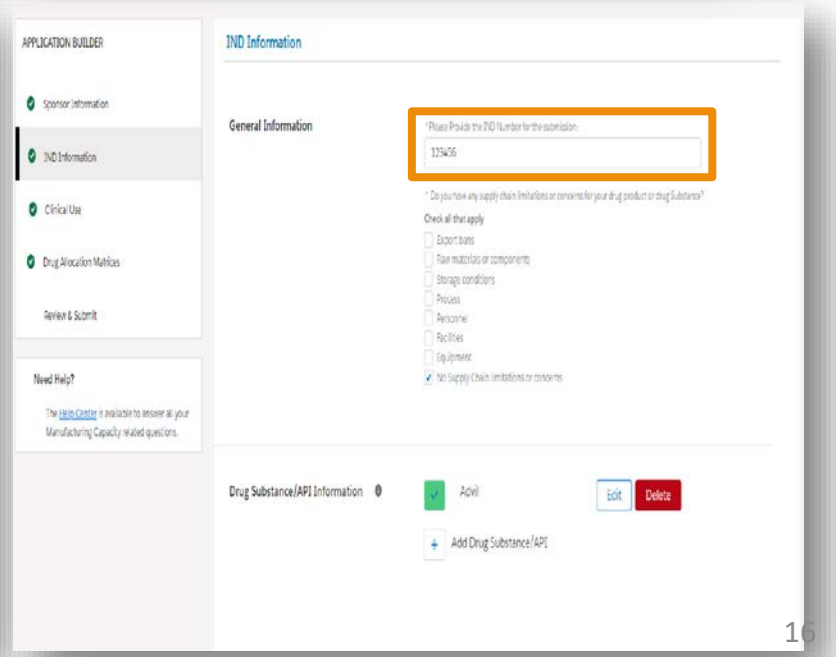
Step 5. Click on the draft application that you would like to clone.

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.





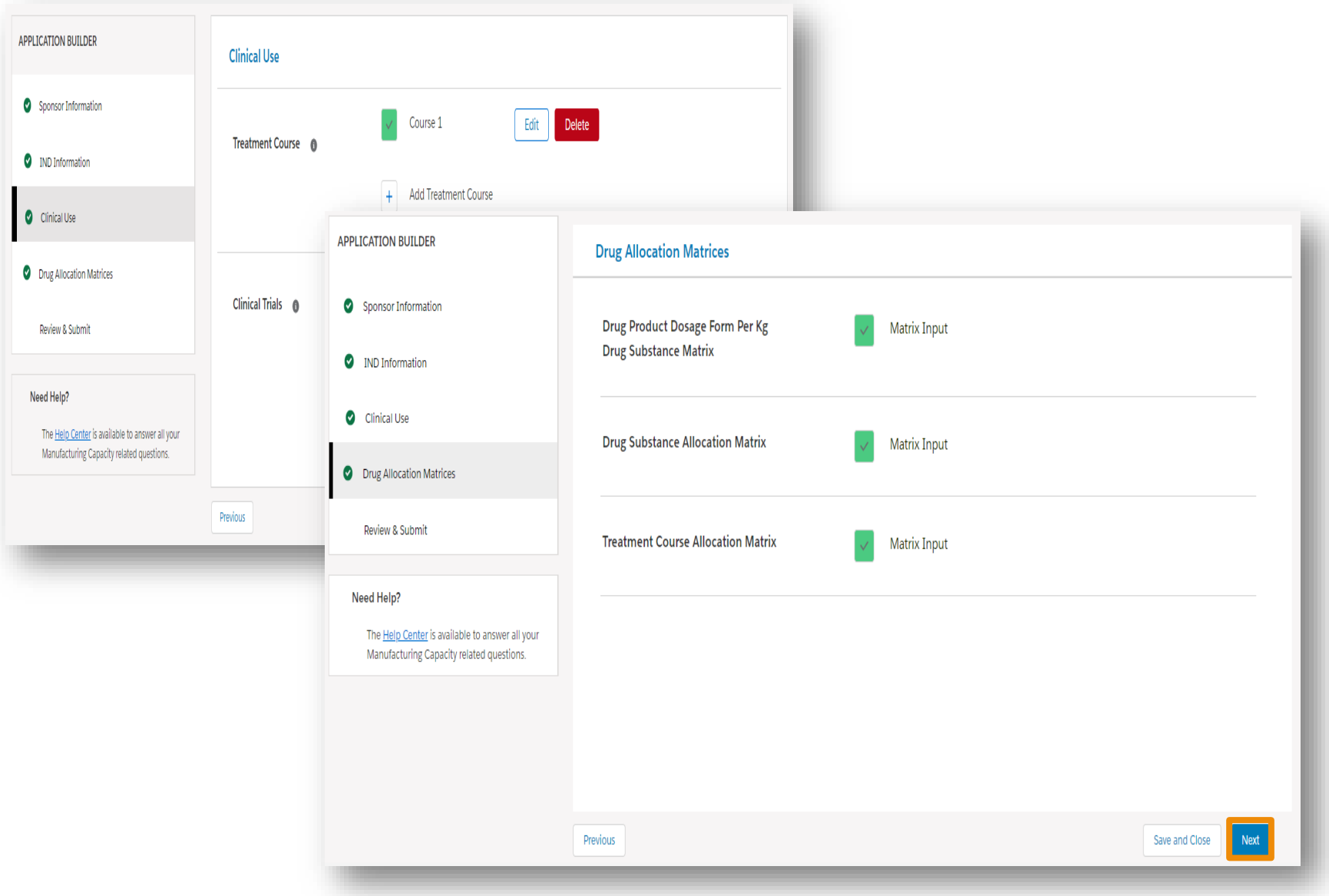


Manufacturing Capacity

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.**

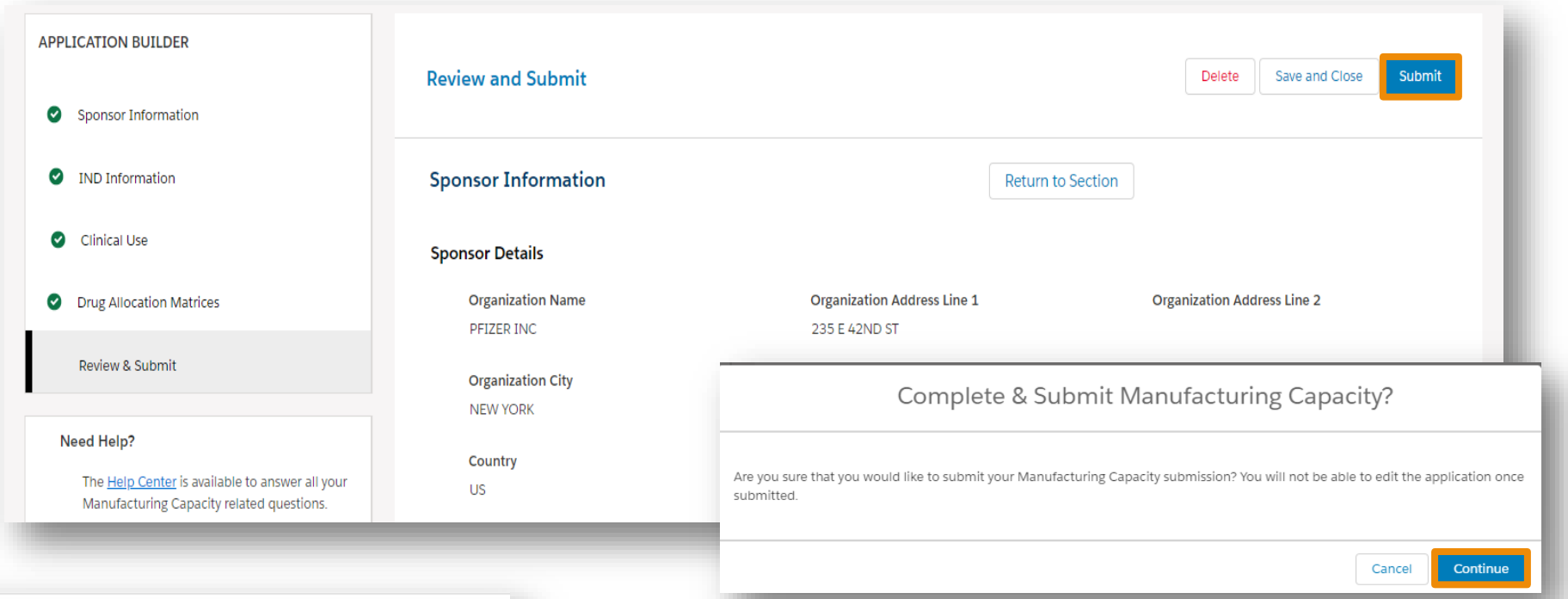


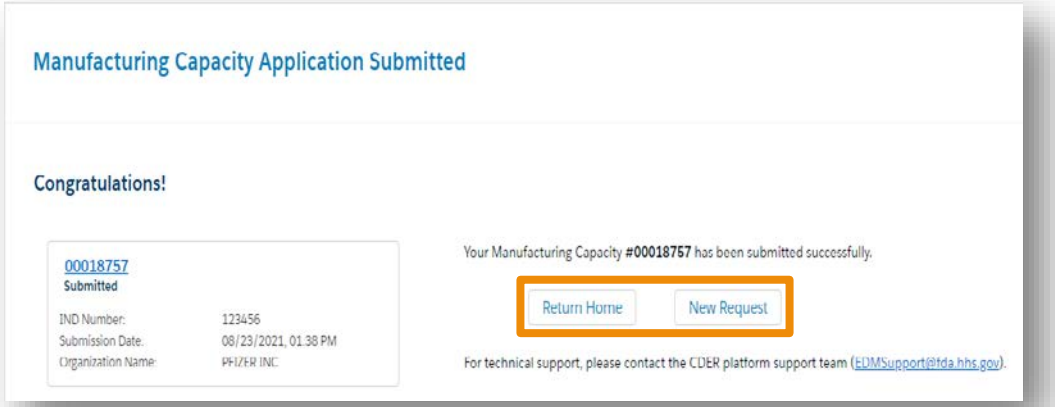
Manufacturing Capacity

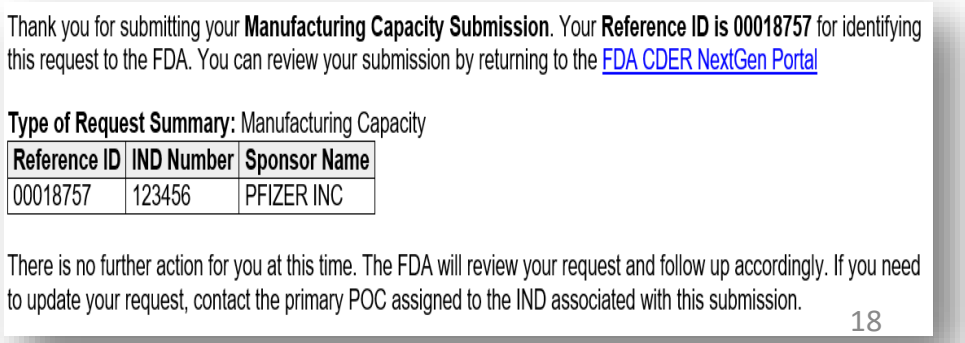
Cloning Capability

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.

CDER NextGen Portal Video Tutorial

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