CDER NextGen
Portal

Frequently Asked Questions

CDER NextGen Portal: Manufacturing Capacity

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The following questions and answers are those that are most frequently asked and answered by the Center for Drug Evaluation and Research (CDER).

Submitting Manufacturing Capacity

1. **Why do certain fields automatically populate when the Sponsor is selected as opposed to the US Agent?**
If you are the sponsor of the IND, certain fields populate automatically. If you are the US Agent, you could be representing one or more sponsors and therefore must specify the sponsor information associated with this particular IND.

2. **How do I delete a Drug Substance/API, Drug Product Dosage Form, Treatment Course, Clinical Trial, or Matrix?**
You can delete an entered Treatment Course and/or Clinical Trial, by clicking the Delete button next to the entry. You cannot delete the Drug Substance/API, Drug Product Dosage Form, or Matrix information, but you can modify the information by clicking Edit.

3. **Can I request an update to my Manufacturing Capacity submission(s)? If so, how can I update the submission?**
The cloning feature may be utilized to update a previous record. To update a previous submission, please generate a cloned draft of the submission, edit it with updated information and keep the IND number the same. Please see page 2 for more information on Cloning a Manufacturing Capacity Submission.

4. **Can I save my draft and continue working on it later?**
   Yes, you can save your draft by clicking "Save and Close" at any time. You can view your saved draft(s) by selecting your submission on the landing page.

5. **Can the FDA see saved requests?**
   No, the FDA cannot see any saved requests. Only information that has been submitted will be seen and reviewed by the FDA.

6. **What happens once I submit a request?**
   Once a Manufacturing Capacity has been submitted, you will receive an e-mail confirmation. You also could view your submitted request on the landing page by clicking the confirmation number.

Cloning a Manufacturing Capacity Submission

7. **What does the "Clone" button do?**
   The "Clone" button may be found on the Summary page of any previous submission. Cloning a submission will copy all data into a new Manufacturing Capacity submission that will appear on the home screen in "Draft" status.

8. **Can I clone a submission with a "Draft" status?**
   No, only a Manufacturing Capacity that has been submitted may be cloned.

9. **Where do my cloned submissions go?**
   The user will be directed back to the Landing Page where they will see a new submission with the cloned data in "Draft" status.

10. **How do I update Manufacturing Capacity submission(s) using the cloning feature?**
    After generating a "Draft" status submission with previously entered information, the draft record can be edited and resubmitted. Keep the same IND number to update the submission.

11. **If one of my submissions already contains information needed for a new IND submission, can my information be pre-populated?**
    Yes, you may use the "Clone" button that appears on the "Summary" page on any submitted record. Using the clone feature will copy all information from a submitted record into a new draft record. That new draft record can be edited as needed. For a new submission, please update the IND number before submitting.

Troubleshooting Tips

12. Which browsers does the application support?
CDER NextGen Portal officially supports Mozilla Firefox Version 45 and above, and Google Chrome version 58 and above.

13. Are there any steps I can take if I run into technical issues during the registration process before contacting support?
If you experience technical issues during registration, try restarting your browser and clearing the cache. If you continue to experience issues, contact CDER Platform Support at EDMSupport@fda.hhs.gov.

14. I am having issues registering for the CDER NextGen Portal, what do I do?
For guidance on registering for the CDER NextGen Portal, click the Learn More button on the CDER NextGen Portal home page to locate the User Registration Guide and video and/or contact EDMSupport@fda.hhs.gov.

Contact Information

15. I'm having a technical issue, who do I contact?
For all technical support, contact CDER Platform Support at EDMSupport@fda.hhs.gov.

16. I'm having issues with my submission and I have questions about the guidance to submit, who do I contact?
For business assistance, please contact the primary POC assigned to the IND associated with this submission.