CDER NextGen

Portal

Frequently Asked Questions

CDER NextGen Portal

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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).

General Questions

1. What is the CDER NextGen Portal?

The CDER NextGen Portal is a website for Industry to submit information to the FDA.

Requesting a Login

2. When requesting a login, what phone number should I enter?

For your phone number, put either your individual direct line and extension or your individual work cell phone number.

3. I didn't get an email to Activate my account after registration. What should I do?

If you did not receive an email titled "FDA CDER NextGen Portal- Login Request Received," please send an email to CDER Platform Support (EDMSupport@fda.hhs.gov) requesting the email to be resent.

4. The activation link in the email is expired, what should I do?

If you attempt to open the activation link and are greeted with the below screen stating that your activation link is no longer valid, select "Request a new token", then input the email address in which you would like support to contact you, along with a brief message stating that you need a new activation link.

5. I am leaving my company and will no longer need access to the Portal. What should I do?

Email CDER Platform Support (EDMSupport@fda.hhs.gov), and your replacement Portal representative before your last day of work.

Logging In

6. What is my username?

Your username is the e-mail you used when you created your login.

7. What do I do if I forgot my username?

Your username is usually your work e-mail address. If your work e-mail address is not working as your username, check your e-mail and locate the e-mail titled "Welcome to CDER NextGen Portal". This e-mail contains your username. If you cannot find this e-mail, please e-mail technical support (EDMSupport@fda.hhs.gov).

8. What do I do if I forgot my password?

Navigate to https://edm.fda.gov to access the FDA CDER NextGen Portal. On the login page, click "Forgot Password". A Forgot Password screen will appear and will request your e-mail address. Once you enter and submit your e-mail, you will receive an e-mail titled "FDA CDER NextGen Portal – Password Reset". The Password Reset e-mail will have a link to access your security questions.

9. What do I do if I forgot my security question answers to reset my password?

If you do not remember your security question answers for password reset, please e-mail technical support (EDMSupport@fda.hhs.gov).

About Multi-Factor Authentication

10. What is Multi-Factor Authentication (MFA)?

Multi-factor authentication (MFA) is a security mechanism in which individuals are authenticated through more than one required security and validation procedure. MFA seeks to decrease the likelihood that others can access your data. It enhances the security of your information by using an additional factor to verify your identity when you attempt to access the CDER NextGen Portal.

11. Why do I need to use MFA?

Passwords are becoming increasingly easy to compromise. For additional security, many systems are choosing to adopt MFA because it allows an additional layer of protection for

the system and its data. Multi-Factor Authentication adds a second layer of security to your account to make sure that your account stays safe, even if someone else knows your password.

12. Am I required to use MFA?

Once you have enrolled in MFA, you will be required to use multi-factor authentication when logging into the CDER NextGen Portal.

Using Multi-Factor Authentication

13. How does Multi-Factor authentication (MFA) Work?

Once you have signed up for MFA, when you attempt to access the Portal, you will be prompted to enter your username and password as usual (the first "factor"). You will then be taken to the MFA screen where you will be prompted to send a One-Time Passcode to the email address associated with the FDA CDER NextGen Portal account (the second "factor").

14. How long does it take to enroll/register in MFA?

FDA CDER NextGen Portal will automatically enroll you in MFA with the email address used to register the login. If you experience technical issues, please contact CDER Platform Support (EDMSupport@fda.hhs.gov).

15. How do I activate my account if I'm a new user or an existing user?

Please refer to the Reference Guide: CDER NextGen Portal Account Registration and MFA Enrollment Process document for instructions.

16. Do I need to have a smartphone to use MFA?

No, you can use a smartphone if it has access to the corporate email address in which you used to register.

17. How often will I have to log in using MFA?

You will not be required to log in using MFA every time you access FDA CDER NextGen Portal, you will however be prompted for MFA the first time and any subsequent login the system deems appropriate.

Troubleshooting Tips

18. Which browsers does the application support?

FDA CDER NextGen Portal officially supports Mozilla Firefox Version 45 and above, Microsoft Edge, and Google Chrome version 58 and above.

19. 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, prior to contacting CDER Platform

Support please try restarting your browser and clearing the cache.

Contact Information

20. I'm having a technical issue, who do I contact?

If you are experiencing a technical issue, please email CDER Platform Support at EDMSupport@fda.hhs.gov.

Security

21. Are there certain requirements I must meet while creating a password?

Yes, while creating a password you must meet the following criteria/requirements:

- 8 Characters minimum
- 1 Lower Case Letter
- 1 Upper Case Letter
- 1 Number (0-9)
- 1 Symbol (e.g., !@#$%^&*)
- Does not contain part of username
- Does not contain first name
- Does not contain last name

22. Do I only have access to certain use cases within the CDER NextGen Portal?

Yes, you only have access to certain uses cases. If you would like to request access to other uses cases, you will need to reach out to the EDM Support Team (EDMSupport@fda.hhs.gov).

23. Do I ever have to reset my password?

Yes, you will need to reset your passwords every 60 days.

24. What if I continuously enter my login incorrectly?

If you enter your credentials incorrectly five times your account will be locked, and you will need to reach out to EDM Support Team (EDMSupport@fda.hhs.gov) to unlock your account.

25. What types of Personally Identifiable Information (PII) is needed to register for the CDER NextGen Portal?

You will need to provide first name, last name, phone number, email, and answers to security questions.

26. How does CDER NextGen Portal and the FDA protect my account?

The FDA CDER NextGen Portal has a dedicated team to monitor any malicious behavior to proactively protect all accounts from any hacks or attempted unauthorized access.

27. **Do the users of CDER NextGen Portal have to adhere to specific terms and conditions?**

Yes, upon signing into the CDER NextGen Portal, you must always agree to the terms and conditions. These include but are not limited to confirming you understand that any false, fictitious, or fraudulent statements to the U.S. Government are subject to criminal penalties.