Reference Guide: CDER NextGen Portal Account Registration and MFA Enrollment Process

https://edm.fda.gov/
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Introduction

Welcome to CDER NextGen Portal

This guide provides the essential information you need to request an account with CDER NextGen Portal. The sections described below cover creating and activating an account, as well as enrolling in and using the Multi-Factor Authentication process. For technical support, email CDER Platform Support staff at edmsupport@fda.hhs.gov.
Requesting a Login
Register to create a Login

This section describes how to complete the first step in the access request process: submitting a login request.

**Step 1.** Navigate to CDER NextGen Portal by accessing: https://edm.fda.gov

**Step 2.** Click Sign up.

⚠️ When signing up please ensure you are using one of our supported browsers. These browsers include Internet Explorer, Google Chrome, and Mozilla Firefox. Please also ensure your browsers allow for the use of third party cookies. If you have any issues enabling third party cookies, please contact your IT Support.
Register to create a Login

**Step 3.** Enter in your Personal Information: First Name, Last Name, Email Address, Office Phone Number and extension, if applicable.

**Step 4.** Review the Terms and Conditions for the site.

**Step 5.** Confirm that you agree to the Terms and Conditions by selecting the box next to “I have read and agree to the Terms and Conditions stated above.”

**Step 6.** Click **Submit**.
Register to create a Login

**Step 7.** After clicking submit, you will be navigated to a confirmation message stating that your account has been created and that you need to check your email to complete the login request process.

Your account has been successfully created. Please check your email for the next steps.

If you do not receive the email or for any questions and support, contact the CDER Platform Support.

(EDMSupport@fda.hhs.gov)
Create your Account

Upon clicking the link, you will be prompted to set up your new password and secure your profile.

**Step 8.** You will now be able to Enter your password, Select a Forgot Password question and select a security image.

**Step 9.** Click Create My Account.

If you are not automatically redirected to the CDER NextGen Portal home page, you may navigate there manually by opening your browser and entering https://edm.fda.gov.
User Login
Logging into the Portal for the First Time

**Step 1.** Navigate to CDER NextGen Portal by going to: [https://edm.fda.gov](https://edm.fda.gov)

**Step 2.** Enter your email address as the Username.

**Step 3.** Enter your new password.

**Step 4.** Confirm that you agree to the terms and conditions of the site by selecting the checkbox.

**Step 5.** Click **Sign In**.
Multi – Factor Authentication

**Step 6.** Click **Send Email.**

**Step 7.** Navigate to your email to receive your authentication code (this email may take a couple of minutes to arrive).

**Step 8.** You should have received an email similar to the below email.
Multi – Factor Authentication

**Step 9.** Enter code.

**Step 10.** Click **Verify**.
Profile Management
Review Profile Information and Select Organization

Once you verify your code, you will be directed to the Review Profile Information page. The following steps cover reviewing your profile information.

Step 11. Review that your information is correct, Click Next.

NOTE

If you would like to make any changes to your profile information, please contact CDER Platform Support (EDMSupport@fda.hhs.gov) for assistance.
Review Profile Information and Select Organization

Step 12. Input either your Company Name or DUNS number in the search bar.

Step 13. Click Search.


Step 15. Click Select Organization.
Review Profile Information and Select Organization

**Step 16.** Once you have highlighted and selected your Organization, click **Save & Continue.**

**Step 17.** Once you’ve selected Save & Continue, you will need to log out and log back in. Please select log out on the top right corner of the screen.
Review Profile Information and Select Organization

**Step 18.** Once you log back in, you will land on the portal home page.
Migrating Your Account
Activate Migrated Account

This section provides guidance for existing portal users on how to activate their migrated account.

**Step 1.** Once your account has been migrated, you will receive the below activation email.

**Step 2.** Please click on the activation link in the email or copy and paste it to your browser.

![Email Example]

**NOTE**

This email will be sent from noreply@okta.com. If you do not see it in your inbox, please check your spam and junk mail folders for it.
Activate Migrated Account

Step 3. You will now be prompted to do the following;

- Enter your new password
- Select a Forgot Password question
- Select a security image

Step 4. Click **Create My Account**.

If you are not automatically redirected to the CDER NextGen Portal home page, you may navigate there manually by opening your browser and entering [https://edm.fda.gov](https://edm.fda.gov)
**Activate Migrated Account**

**Step 5.** Once you land on the CDER NextGen Portal home page, Enter your email address as the Username.

**Step 6.** Enter your new password.

**Step 7.** Confirm that you agree to the terms and conditions of the site by selecting the checkbox.

**Step 8.** Click **Sign In**.

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**NOTE**

If you are not automatically redirected to the CDER NextGen Portal home page, you may navigate there manually by opening your browser and entering [https://edm.fda.gov/](https://edm.fda.gov/)
Multi – Factor Authentication

**Step 9.** Click **Send Email.**

**Step 10.** Navigate to your email to receive your authentication code (this email may take a couple of minutes to arrive).

**Step 11.** You should have received an email similar to the below email.

Hi John Smith,

You are receiving this email because a request was made for a one-time code that can be used for authentication. If you did not make this request please contact FDA CDER Platform Support immediately.

Please enter the following code for verification.

510948

For technical support, contact the FDA CDER Platform Support Team at FDASupport@fdagov

**Please do not reply directly to this message. This is an automatically generated email and replies will not be monitored.**
Multi – Factor Authentication

**Step 12.** Enter code.

**Step 13.** Click Verify.
Review Profile Information and Select Organization

Once you verify your code, you will be directed to the Review Profile Information page. The following steps cover reviewing your profile information.

**Step 14.** Review that your information is correct, Click **Next**.

NOTE

If you would like to make any changes to your profile information, please contact CDER Platform Support ([EDMSupport@fda.hhs.gov](mailto:EDMSupport@fda.hhs.gov)) for assistance.
Review Profile Information and Select Organization

Step 15. Verify your organization affiliation and ensure it is correct, click **Save and Continue**.

Complete Registration

Organization Information

Organization Selection

**Existing organization you are affiliated with**

<table>
<thead>
<tr>
<th>Company Name</th>
<th>Company Address</th>
<th>DUNS</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABC Industry</td>
<td>123 DGFH Road, Rockville, MD 20852</td>
<td>0011223344</td>
</tr>
</tbody>
</table>

Step 16. Once you have verified your information you will be prompted to log out and log back in.

*If you need immediate assistance, please contact CDER Platform Support at CDERSupport@FDA.HHS.gov.*
Review Profile Information and Select Organization

**Step 17.** Once you log back in, you will land on the portal home page.
Resetting your Password

**Step 1.** Navigate to [https://edm.fda.gov](https://edm.fda.gov) to access the FDA CDER NextGen Portal.

**Step 2.** On the login page, click “**Need help signing in**”. The “**Need help signing in**” link will expand and display the option “Forgot password?”. 
Resetting your Password

**Step 3.** A “Reset Password” screen will appear requesting your email address. Upon clicking the "Reset via Email" button, the screen will display a message that an email has been sent to you. You will receive an email titled “FDA CDER NextGen Portal – Password Reset Request Received”.

![Reset Password Screen](image1.png)

![Email Sent Screen](image2.png)
Resetting your Password

Step 4. The Password Reset email will have a link to access your security questions. Once you click the link, answer the security question then click “Reset Password”.
Resetting your Password

**Step 5.** Once you have correctly answered your security question, you will be prompted to input a new password. Click “Reset Password” when done entering a new password.
Reseting your Password

**Step 6.** After resetting your new password, you will be navigated to Portal home page where you will login with your new password.
Portal Training Videos

The "Training Videos" contains 1-4 minute video clips on how to complete submissions for events on the portal.

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 user guides and FAQs.

Technical Support

For all technical support, contact CDER Platform Support at EDMSupport@fda.hhs.gov.

CDER NextGen Portal Support & Resources

The CDER NextGen Portal (https://edm.fda.gov) has many resources for support.