ORA Data Exchange (DX) Training Resources

e-Learning Course Series

Summary

ORA Data Exchange (DX) e-Learning courses are integral components of the ORA DX training resources. The short and easy to understand format of the e-Learning courses allows users to acquire needed information in a quick manner. This Knowledge Article (KA) focuses on e-Learning courses related to the ORA DX systems, specifically the ORA Partners Portal (ORAPP). Topics include an overview of current e-Learning categories, the e-Learning catalog describing current courses and descriptions, how to access an e-Learning course, and contact information if additional information is needed. Soon, KAs will be located in ORAPP for access and reference.

e-Learning Course Overview

The ORA DX training team designed and developed e-Learning courses with the user's time and needs in mind. These courses are designed to deliver key information in a concise duration (10 minutes or less). New courses are developed as and when new data sharing capabilities are introduced, or current data sharing capabilities are enhanced in the ORA DX Systems. The ORA DX training team strives to maintain the e-Learning courses for consistency and accuracy as the ORA DX systems evolve.

For user convenience and ease of search, e-Learning courses have been organized on ORAPP into four categories:

- **ORA DX Overview** – This category of courses introduces users to the overall ORA DX Program, DX systems overview, and DX onboarding information.
- **Inventory Data Sharing** – In this category users will find e-Learning courses related to inventory data sharing such as firm search, firm history, and inventory reconciliation.
- **Inspection Data Sharing** – This category contains courses related to the inspections data sharing such as non-contracted inspections.
- **Sample Data Sharing** – Final category containing e-Learning courses pertaining to the Sample Collection, Sample Receipt and Analysis domains.

e-Learning Course Catalog

Shown below is the catalog of current e-Learning courses with IDs, name, description, and date published. The e-Learning courses can be accessed on ORAPP Training Page.

Course ID	Course Name	Description
ORA DX Overview Category		
ELDXOV1	ORA Data Exchange (DX) Program Overview	Overview of the ORA DX program, vision, systems, and capabilities including regulatory partner participation and responsibilities
ELDXOV2	ORA Data Exchange (DX) Onboarding Overview	Overview of the onboarding process for the ORA DX systems including regulatory partner responsibilities
ELPPOV1	ORA Partners Portal (ORAPP) Overview	Overview to access, navigate, and log in to ORAPP including First Time Login instructions

Course ID	Course Name	Description
ELSSOV1	**NEW** - System to System Overview	Overview of System-to-System (NFSDX), an ORA DX system
Inventory Data Sharing Category		
ELDXFS1	Firm Search and Firm History	Overview of the ORA DX Firm Search and Firm History capabilities, including FDA and State-to-State firm searches using NFSDX, and instructions to perform a firm search and view firm history in ORAPP
Inspection Data Sharing Category		
ELPPNC1	Non-Contracted Inspections Overview	Overview of the Non-Contracted Inspections (NCI) capability in ORAPP
ELPPNC2	Non-Contracted Inspections Submission	Instructions to perform NCI submission using the NCI Excel Template in ORAPP
ELPPNC3	Non-Contracted Inspections Submission Errors, Correction, and Resubmission	Instructions to view and correct NCI submission errors and conduct resubmission in ORAPP
Sample Data Sharing Category		
ELPPSC1	Sample Collections Overview	Overview of the Sample Collections capability for state collected samples in ORAPP
ELPPSC2	Sample Collections Guidance Materials Overview	Overview of the Sample Collections Guidance Materials to support data entry using the Sample Collections Excel Template in ORAPP
ELPPSC3	Sample Collections Submission	Instructions to perform a Sample Collections submission using the Sample Collections Excel Template in ORAPP
ELPPSC4	Sample Collections Errors and Correction	Instructions to view and correct Sample Collections submission errors in ORAPP
ELPPSA1	**NEW** - Sample Receipt and Analysis Overview	Overview of the Sample Receipt and Analysis capability for FDA or state collected samples in ORAPP
ELPPSA2	**NEW** - Sample Receipt and Analysis Guidance Materials Overview	Overview of the Sample Receipt and Analysis Guidance Materials to support data entry using the Sample Receipt and Analysis Excel Template in ORAPP
ELPPSA3	**NEW** - Sample Receipt and Analysis Submission	Instructions to perform both Sample Receipt and Sample Analysis submission using the Sample Receipt and Analysis Excel Template in ORAPP
ELPPSA4	**NEW** - Sample Receipt and Analysis Errors, Correction, and Resubmission	Instructions to view and correct Sample Receipt and Analysis submission errors and conduct resubmission in ORAPP

Table 1: Current e-Learning Courses

U.S. FOOD & DRUG
ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS (ORA)

ORA Data Exchange (DX)
Knowledge Article #4
June 2023

How to Access e-Learning Courses

Users can access an e-Learning courses while logged in to the ORAPP or via the public Training Page.

Access an e-Learning course while logged in to ORAPP

1. Navigate to the ORAPP home page.

2. Select **Login.**

3. Select **Accept** the agree to the disclaimer.
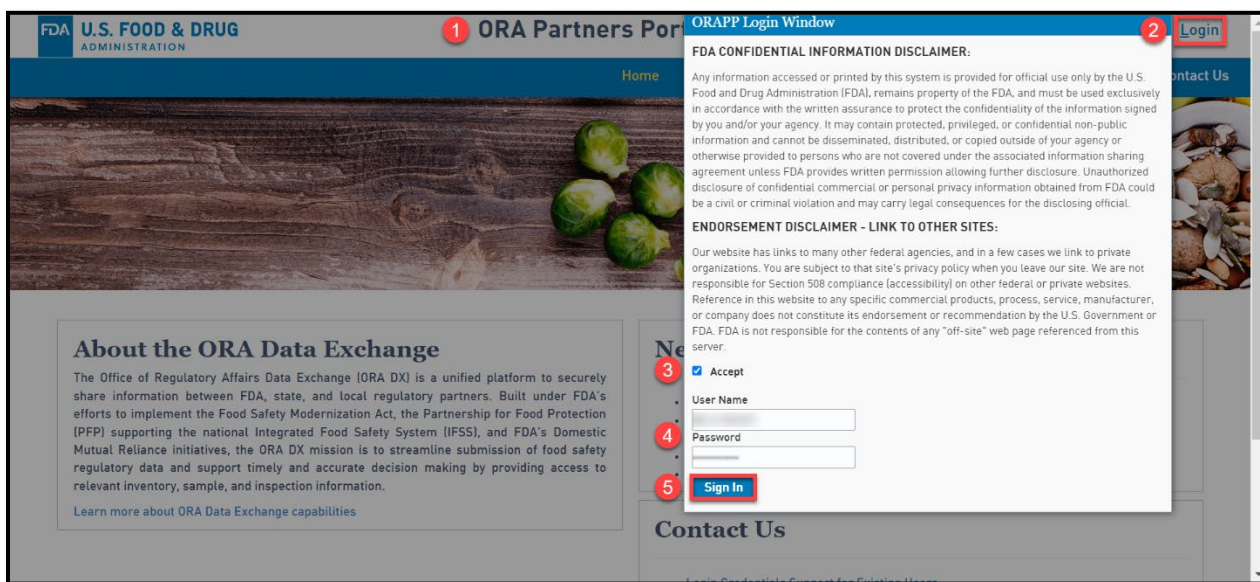
4. Type in the **User Name** and **Password.**

5. Select **Sign In**.

Figure 1: Log in to ORAPP

6. Select **Training** at the menu bar.

7. Select **e-Learning** on the submenu. The e-Learning page is displayed.
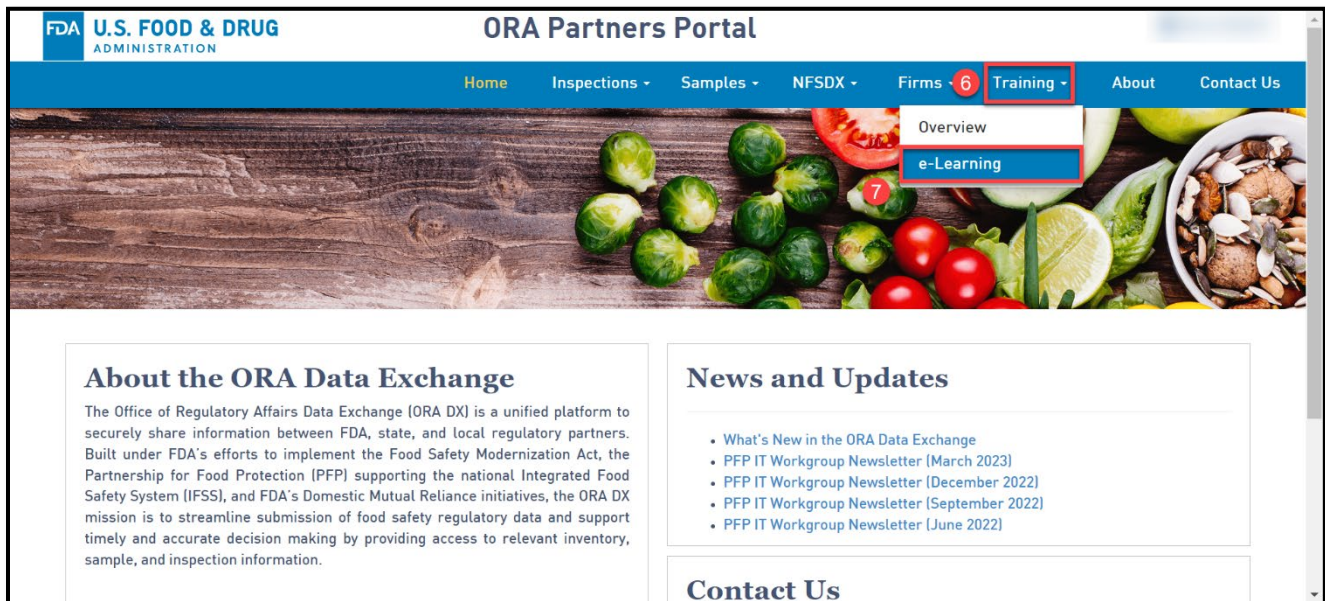
Figure 2: Navigate to the e-Learning Page

8. Click on an e-Learning course category to expand it. The various courses and their corresponding details are displayed.

9. Select the **Launch** button beneath the desired course, to open it.
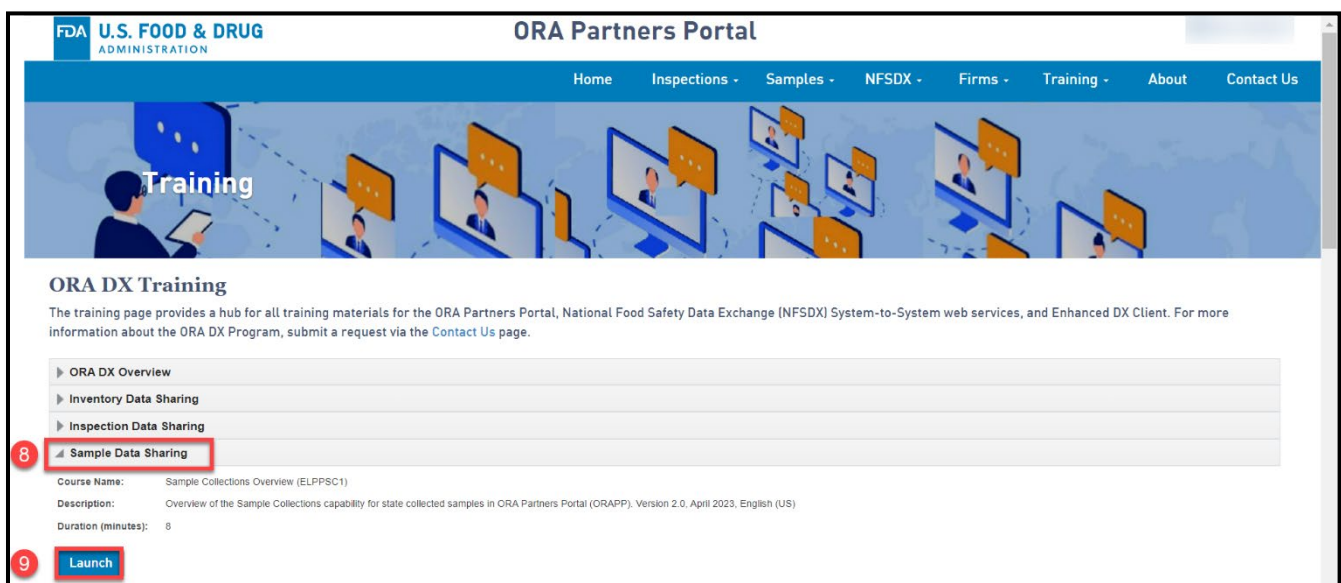
Figure 3: Select and launch an e-Learning course

Access an e-Learning course using the Public Training Page (not logged in to ORAPP)

1. Navigate to the [ORAPP home page](#).

2. Select **Training** on the menu.

3. Select **e-Learning** on the sub-menu. The e-Learning page is displayed.
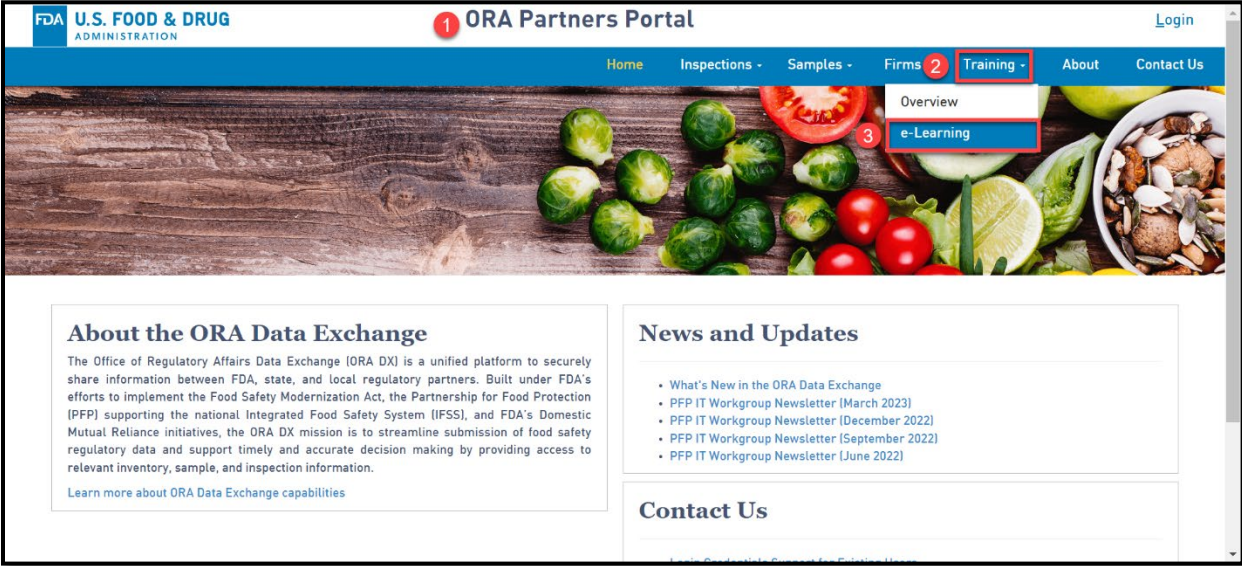
Figure 4: Navigate to the e-Learning Page

4. Choose your **State** from the dropdown list.

5. Type in the name of your **Organization**.

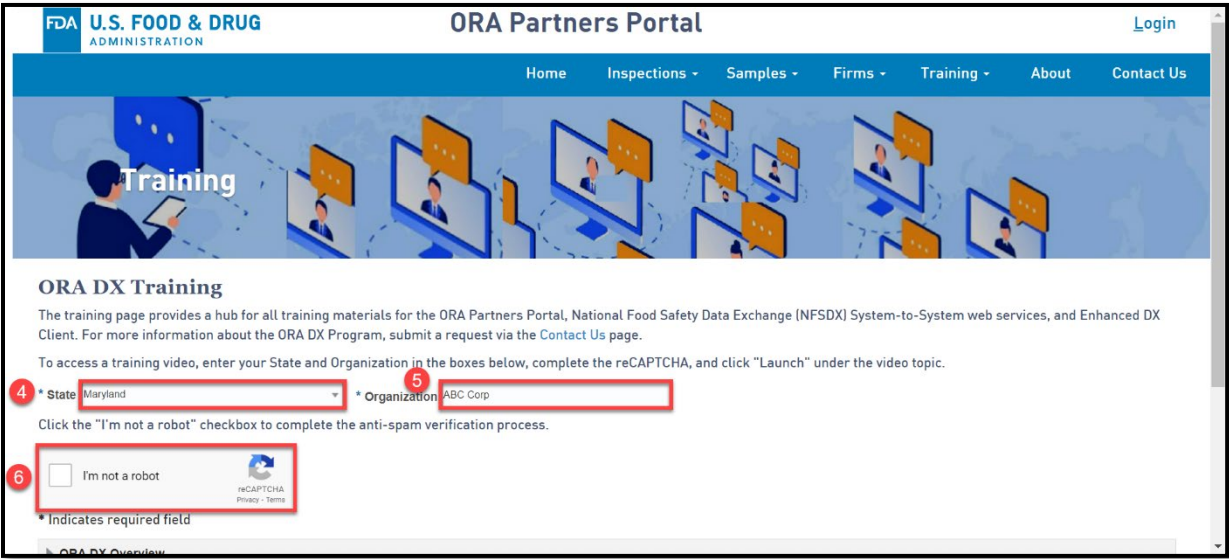6. Select the **I'm not a robot** checkbox for the reCAPTCHA security verification.

Figure 5: Input state and organization information

7. Upon security verification, expand the e-Learning course category by clicking on it. The various courses and their corresponding details are displayed.

8. Select the **Launch** button beneath the desired course, to open it.

Figure 6: Authenticate and access an e-Learning course

> ***Note:*** For security purposes, reCAPTCHA verification is required each time an e-Learning course is previewed or accessed. An e-Learning course needs to be launched within one minute of the verification completion.

Contact Us

The ORA DX Training Team would love to hear from you to continuously improve ORA DX training to support regulatory partners. We invite you to contact the ORA DX Training Team via the ORAPP Contact Us Page for any of the following:

- ORA DX training inquiries and support
- Request an Instructor-led course, e-Learning course, or Knowledge Article
- Provide feedback on ORA DX training