ORA Data Exchange

Regulatory Partner Onboarding Handbook

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1. INTRODUCTION

The purpose of the Onboarding Handbook is to describe the ORA Data Exchange (DX) onboarding process for regulatory partners.

1.1. DX BACKGROUND

The FDA Office of Regulatory Affairs (ORA) has developed the DX program under PFP Information Technology (PFP IT) workgroup (WG) initiative to support the goals and vision of the national Integrated Food Safety System (IFSS) as mandated by the Food Safety Modernization Act (FSMA). The PFP IT WG collaborates with regulatory partners to implement a seamless data exchange in support of the IFSS and FSMA mandates to advance food safety. The ORA DX program has implemented the following two electronic data exchange solutions for a bidirectional unified platform to securely share information between regulatory partners and FDA:

- System-to-System Services (also known as National Food Safety Data Exchange (NFSDX))
- ORA Partners Portal (ORAPP)

The above two systems incrementally and continuously evolve providing enhanced DX capabilities to eliminate double data entry and increase timely regulatory decision making by providing access to relevant inventory, sample, and inspection information. The ORA DX also includes the Enhanced DX Client which supports the submission of sample data (i.e., collection, receipt and analysis data) only to FDA.

2. PARTNER ONBOARDING PROCESS

The partner onboarding process is a series of activities for a regulatory partner to become a DX user. These activities are conducted by FDA and regulatory partner. The onboarding activities start once a regulatory partner decides to participate in any ORA DX capability and internal FDA approval is obtained. Once a partner has been onboarded, onboarding activities may need to resume if the partner decides to pursue additional DX exchange capabilities.

The DX System-to-System and Partners Portal participation requires a Food and Feed 20.88 agreement between FDA and regulatory partner. The 20.88 Food and Feed agreement enables sharing of confidential information with states, counties, and partners. Typically, regulatory partners (state agencies) already have this agreement in place.

2.1. Pre-Onboarding Activity: ORA DX Overview Meeting

The Data Exchange (DX) Outreach Coordinator normally conducts a DX Overview meeting with interested regulatory partners. During this pre-onboarding activity the DX program and capabilities information is shared. The partners will also have an opportunity to ask questions and discuss their interest in the DX program. This meeting is typically non-technical in nature.

2.2. System-to-System (NFSDX) Onboarding

In addition to the 20.88 agreement, for the System-to-System capabilities an Interconnection Security Agreement (ISA) and Memorandum of Understanding (MOU) are also required. The purpose of the ISA is to document the terms and conditions of the data exchanged between the

System-to-System Services, owned and managed by FDA, and the state system. The MOU establishes a management agreement between FDA and the state regarding the connection between partner and FDA systems. It also establishes the terms for collaboration between FDA and the state, including designated managerial and technical staff. Both these agreements are required before Preproduction and Production credentials can be provided.

The onboarding for System-to-System capabilities is more extensive due to various system to system integration activities. These activities start with planning and kickoff activities between FDA and partner, followed by development and testing activities by the partner. All these activities wrap up with production roll-out. The following graphic provides a high-level view of the process.

Figure 1: System-to-System (NFSDX) Integration Onboarding Process

The following table provides the high-level step-by-step onboarding activities. The activities described are usually completed sequentially, but some steps can be performed out of order, in parallel or may be optional. Also, FDA shares additional details (as applicable and as needed) during ad-hoc Integration Touchpoint meetings and via email with the regulatory partner to support the integration activities. For the Enhanced DX Client onboarding, the FDA assists state labs with installation and some of the onboarding activities below are not applicable.

Step #	Description	Owner
	Planning and Kickoff	
1.	Communicate interest in DX Program and/or System-to-System capabilities.	Regulatory Partner
2.	Conduct DX Overview meeting and share the Partner Engagement Package with regulatory partner. ***Partner Engagement Package includes*** *DX Overview Presentation, Partner Onboarding Handbook, ORA DX Workgroup Meeting Invites, etc.*	FDA
3.	Have additional meetings and discussions as needed to determine capabilities being pursued by regulatory partner.	FDA
4.	Share the Integration Package(s) and data exchange agreements with regulatory partner.	FDA

Step #	Description	Owner
	Integration Package includes *Capability Integration Guides, Integration Guide Supplements, XML Schema Definition Files, WSDL, etc.*	
5.	Plan, schedule, and conduct technical meetings with regulatory partner's technical team to walkthrough technical aspects and documentation.	FDA
6.	Plan the integration activities for the regulatory partner (state agency) system.	Regulatory Partner
Development and Testing		
7.	Complete the development, testing, integration and UAT activities for the regulatory partner system. (Includes: data mapping, web service client development, configuration, etc.)	Regulatory Partner
8.	Establish preprod credentials, create test scripts for integration testing, distribute to the regulatory partner, and verify at least one preprod submission.	FDA
Production Roll-Out		
9.	Plan the regulatory partner production rollout timeline.	Regulatory Partner and FDA
10.	Configure regulatory partner system for production integration.	Regulatory Partner
11.	Confirm operational readiness for integration in production.	FDA
12.	Conduct Production Integration meeting as needed to test actual submission and verify there are no production issues.	FDA and Regulatory Partner
13.	Provide post-production support to the regulatory partner to support the data exchange via System-to-System integration.	FDA

Table 1: High-level Step-by-Step Activities for System-to-System Integration Onboarding

2.2.1. System-to-System Onboarding Meetings

After the pre-onboarding meeting, there are various meetings that are conducted between FDA and regulatory partners to support the activities listed in the Table 1 above. Some of these meetings may be merged or become optional based on the in regulatory partner's needs. The following table outlines these meetings.

Meeting	Purpose	Frequency	Participants
Partner Interest and Decision	Discuss information related to DX onboarding, System-to-System and ORAPP capabilities.	Ad-hoc	Regulatory Partner and FDA
Technical Overview	Overview of technical documents and topics related to System-to-System integration.	Ad-hoc	Regulatory Partner and FDA
Integration Touchpoint	Discussion regarding technical aspects of System-to-System integration and onboarding questions.	Ad-hoc	Regulatory Partner and FDA
Production Integration	Discussion to determine operational readiness for production integration.	Ad-hoc	Regulatory Partner and FDA
Sample Data Sharing – IT Implementation Phase	Discussion between FDA and regulatory partners about topics relevant to the sample data sharing IT implementation.	Monthly	Sample data sharing work group meeting participants which includes regulatory partners (state labs) and FDA
Ad-hoc meetings	Meetings to share additional information and provide clarification for onboarding activities.	Ad-hoc	One or more regulatory partners and FDA

Table 2: System-to-System Onboarding Meetings

2.3. ORA Partners Portal Onboarding

The onboarding process for ORAPP is more straightforward since regulatory partners are not required to perform IT development. The following graphic provides the high-level onboarding process.

Figure 2: ORAPP Onboarding Process

The following table provides the high-level step-by-step onboarding activities. The activities described are usually completed sequentially, but some steps can be performed out of order, in parallel or may be optional.

Step #	Description	Owner
1.	Regulatory partner communicates interest in DX Program or requests access to ORAPP capabilities.	Regulatory Partner
2.	Plan, schedule, and conduct DX Overview meeting with the regulatory partner. ***Note:*** *This meeting is optional.*	FDA
3.	Verify partner has active Food and Feed 20.88 agreement and provide approval for regulatory partner access.	FDA
4.	Provide user information (agency, name and email address) to FDA.	Regulatory Partner
5.	Establish user credentials and distribute it to regulatory partner.	FDA

Table 3: High-level Step-by-Step Activities for ORAPP Onboarding

2.3.1. Training and Support

The DX Training Team provides training courses for the ORA DX systems' users (regulatory partners) and FDA. The training focuses on the various data exchange capabilities within the two systems noted above. The trainers walkthrough how to use specific capabilities and explains how it can support specific data exchange purposes. The courses are conducted virtually (on-demand, interactive or lecture).

3. PARTNER OFFBOARDING PROCESS

There may be instances where a regulatory partner no longer requires access to the DX capabilities. In these cases, the regulatory partner works with FDA on offboarding activities. The following sections provides information about offboarding for the System-to-System and ORAPP capabilities.

3.1. System-to-System Offboarding

Regulatory partners would need to inform FDA about the intent to discontinue usage of any or all data exchange capabilities for System-to-System. It must be noted that FDA provides system credentials per regulatory partner so that the partner system can be configured for System-to-System data exchange. So, regulatory partners should inform FDA only if the entire DX capability usage is discontinued. It is not required to notify FDA when individual state agency users are offboarded from the regulatory partner system. Upon confirmation, FDA will disable the state credentials and notify the requestor.

3.2. ORA Partners Portal Offboarding

Regulatory partner should inform FDA the intent to discontinue use of ORAPP user account. A request to deactivate the user account should be sent to FDA. FDA would then proceed with deactivating the account and notify the requestor.

4. CONTACT INFORMATION

Should you have questions, requests, or issues related to the ORA DX Program, please send an email to Appsdesk@fda.hhs.gov.