1. Introduction

The Regulatory Exchange Platform Secure (REPs) is an IT portal that was originally developed in 2018 by the Pan American Health Organization (PAHO) to facilitate the exchange of information between participating MDSAP Auditing Organizations (AOs) and Regulatory Authorities (RA).

In November 2022, the ownership and operation of REPs was transferred from PAHO to the U.S. Food and Drug Administration (FDA). This procedure was updated to reflect that transition and establish new procedures consistent with FDA IT governance policies.

2. Purpose/Policy

The purpose of this document is to define policies and procedures for the user account management of all non-FDA REPs users.

3. Scope

This procedure applies to all MDSAP Regulatory Authority (RA) users and Auditing Organization (AO) users.

4. Definitions/Acronyms

REPs – Regulatory Exchange Platform – secure

AO – Auditing Organization

RA – Regulatory Authority

5. Authorities/Responsibilities

Auditing Organizations:
Designate a person(s) to serve as the roles of the AO Official Contact Person, AO Submitter and AO Client Manager role.

AO Official Contact Person:
Responsible for determining their auditing organization's users, user roles and for submitting user account requests.

Regulatory Authorities:
Designate a person(s) to serve as a RA Approver, RA Master List Manager and REPs Account Manager

RA REPs Account Manager:
Responsible for determining their RA's users, user roles and for submitting account change requests.

6. Procedures

6.1 The AO Official Contact Person or RA REPs Account Manager is responsible for determining, maintaining, and managing their organization's user accounts and roles.

6.2 Account provisioning should follow the principle of least privilege and user access and roles should be granted on an as needed basis.

6.3 User accounts are authorized per individual user only. No guest, anonymous, group or temporary accounts are permitted.

6.4 All accounts must use an official email address from their organization.

6.5 In the event where a user is no longer an employee of their organization or no longer requires access to REPs, the AO Official Contact Person or RA REPs Account Manager must notify the FDA by submitting an account deactivation request to the FDA MDSAP Helpdesk at mdsap.support@fda.hhs.gov within 5 calendar days.

6.6 The AO Official Contact Person or RA REPs Account Manager is required to perform a review their organization's user access and permissions on a

periodic basis. The FDA MDSAP REPs team may also provide an user access report on for review.

6.7 All user access change requests are to be submitted by filling out the MDSAP AU P0033 REPs User Account Request form and submitting the complete forms to FDA MDSAP REPs Helpdesk at mdsap.support@fda.hhs.gov.

6.8 **REPs User Roles:**

Note: Users may have multiple roles listed below:

AO User Roles and Descriptions

a. ***AO Submitter*** - Creates and submits audit report packages. Can add documents to audit report packages and make modifications to audit report packages.

b. ***AO Client Manager*** - Creates new facility requests to be added to the Master List. Can create facility modification and withdrawal requests. Can generate Master List report of all facilities.

c. ***AO Read-Only*** - View and search AO's Master List of facilities and audit report packages.

RA User Roles and Descriptions

a. ***RA Master List Manager*** - Approves facility creation, modification, and withdrawal requests. Can create, modify, and deactivate facilities in the Master List

b. ***RA Approver Role*** – Reviews submitted audit report packages and can add a final classification to audit report packages. Can change the submission status of an audit report package

c. ***RA Read-Only*** – Can view all facilities in the Master List and view all audit reports packages

d. **RA Ad-hoc Reporting** – Can create custom reports in the Ad-hoc Reporting module

7. Forms

MDSAP AU F0033 REPs User Access Request Form

8. Reference Documents

REPs User Guide

9. Document History

VERSION NO.	VERSION DATE	DESCRIPTION OF CHANGE	AUTHOR NAME/PROJECT MANAGER
001	2019-03-06	Initial Release	Michael Chan
002	2022-01-03	Revised entire document to include the interim use of Box during the REPs downtime	Michael Chan
003	2022-11-21	Removed the interim use of Box and re-established the use of REPs. User account request process updated to FDA processes. Added reference to new REPs User Request Form F0033.	Michael Chan

Version Approval 003

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CHAIR, MDSAP RAC