

<ENTER COMPANY LOGO>	<b>WORK INSTRUCTION</b>	<b>Document Reference</b> [Document Number] <b>Revision:</b> [00]
	<b>TITLE</b> Use of Adobe Sign for the Application of Electronic Signatures	<b>Effective date</b> [Effective Date]

**APPROVALS:**

Name	Signature	Date

**REVISION HISTORY:**

Revision	Name and Date	Summary of Changes
00		

**Instructions on completing this document**

*(Please remove this table when finished modifying this document.*

*This table is provided for informational purposes only.)*

The instructions in blue text within this document are meant to provide clarifications related to the information in each section and/or to prompt the author to provide company-specific information. The blue text must be deleted once this document has been modified to reflect the company's processes and practices.

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## 1.0 PURPOSE

The purpose of this work instruction is to establish a process for the application of electronic signatures using Adobe Sign.

## 2.0 SCOPE

This work instruction describes the steps required to apply 21 CFR Part 11 compliant electronic signatures to PDF documents (.pdf) using Adobe Sign. Other document file types must be converted to PDF format before the user can apply their electronic signature.

<Note: This template pertains to the use of Adobe Sign to apply 21 CFR Part 11 compliant signatures to controlled documents. If Adobe Sign is also being used to sign non-regulated documents, revise this section to include instructions related to the process that applies to these documents.>

## 3.0 DEFINITIONS

<Revise this section to include all acronyms and terms used in the document.>

### 3.1 Acronyms

Term	Definition
EDMS	Electronic Document Management System

### 3.2 Terms

Term	Definition
Account Administrator	An Adobe Sign user with the ability to define account settings in the system.
Document	A file in PDF format that is distributed for signature.
Electronic Record	Any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system. (Ref. [1])
Electronic Signature	Computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature. (Ref. [1])
Group	An entity in the system to which distinct configuration settings may be applied. Users are assigned to groups.

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<b>Term</b>	<b>Definition</b>
Group Administrator	An Adobe Sign user with the ability to define group settings in the system.
Recipient Group	Two or more Signers to whom a signature task is assigned.
Record	A document that has been signed by all required Signers.
Sender	A user within the Adobe Sign account with the privileges to send documents to Signers for the application of electronic signatures.
Signer	An Adobe Sign user (internal or external to the Adobe Sign account) who has been sent a request to apply an electronic signature.

## 4.0 RESPONSIBILITY

<This section details all roles covered by this Work Instruction. If your company uses different roles/titles or will assign tasks differently, modify this section to reflect those role assignments and tasks. Once you have modified this section, review the document in its entirety to ensure that the roles are consistent throughout the document.>

### 4.1 Account Administrator

- Grants access to Adobe Sign for new users
- Changes access provided to existing users
- Deactivates users in Adobe Sign
- Maintains the account configuration settings
- Creates groups in Adobe Sign

### 4.2 Group Administrator

- Maintains the group configuration settings
- Maintains and periodically reviews the User Access List for Adobe Sign

<Note: Depending on how groups are managed in Adobe Sign, the same user(s) may be assigned the Account Administrator and the Group Administrator roles.>

### 4.3 Sender

- Sends the request for signature to authorized Signers
- Downloads the signed record and its audit report from the Adobe Sign portal
- Transfers the signed record and its audit report to the repository for final records

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#### 4.4 Signer

- Reviews and approves document(s) in Adobe Sign via the application of an electronic signature

## 5.0 PROCEDURE

### 5.1 Account Administration

#### 5.1.1 Granting User Access

A new user access is granted access to Adobe Sign based on an approved request for access. The request is maintained via <specify how requests will be documented (e.g. logical security procedure)> and request approval is obtained from <specify role(s) responsible for approving requests and, if applicable, add to roles listed in Section 4.0>. The approved request for access includes at a minimum the following information:

- Full name
- Email address
- Role / privilege(s) (Signer, Sender, Group Administrator, Account Administrator)
- Assigned group
- Confirmation that the user's email address is not associated to a user in any Adobe Sign account (within the organization or external)

All users for whom access to Adobe Sign is requested, regardless of the user's assigned role, must meet the requirements outlined in <insert reference to procedural control governing electronic signatures> to allow for the individual to apply electronic signatures to documents subject to regulatory oversight.

<Note: It is recommended to restrict Adobe accounts exclusively to email addresses assigned by your organization. This measure will facilitate the control over the uniqueness of email addresses. This measure also aims to facilitate the control over the access privileges granted to users and the configuration settings applied when the system is utilized.>

User access is granted <specify when i.e. when an approved request is received by the Account Administrator OR on the date indicated within the approved request>. Per the approved request, the new user is manually added to the Adobe Sign account by the Account Administrator or automatically through synchronization with the organization's identity provider.

Once the new user is added to the account, the user receives an email notification with instructions for user account activation. The user is prompted to set up a password which along with the user's email address will serve as credentials to access Adobe Sign.

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### 5.1.2 Changing User Access and Access Deactivation

Any changes in the level of system access, including access deactivation, can be requested by the user or by the user's direct supervisor, by sending a request to the Account Administrator. The request is maintained via <specify how requests will be documented> and request approval is obtained from <specify role(s) responsible for approving requests and, if applicable, add to roles listed in Section 4.0>.

The Account Administrator changes access or deactivates user access to Adobe Sign based on an approved request <specify when i.e. when an approved request is received by the Account Administrator OR on the date indicated within the approved request>

### 5.1.3 Account/Group Management

The Account Administrator is responsible for configuration settings for the Adobe Sign account. The configuration is maintained in accordance with <insert reference to procedural control governing configuration management>.

The Account Administrator creates groups in Adobe Sign based on an approved request to create a new group. The request is maintained via <specify how requests will be documented (e.g. change control procedure)> and request approval is obtained from <specify role(s) responsible for approving requests and, if applicable, add to roles listed in Section 4.0>.

Upon creation of a new group, the group will inherit settings that reflect the Account settings which can be modified by the Group Administrator.

## 5.2 Group Administration

The Group Administrator is responsible for configuration settings for the group they are responsible for. These settings include, but are not limited to, the preferred time zone setting for the group, identity verification requirements for the application 21 CFR Part 11 compliant electronic signatures, and predefined list of reasons for signature from which Signers must choose. The configuration is maintained in accordance with <insert reference to procedural control governing configuration management>.

The Group Administrator maintains the User Access List for Adobe Sign which documents the privileges assigned to authorized Adobe Sign users. User Access List for Adobe Sign contains at minimum the following information for each authorized user:

- Full name

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- Email address
- Assigned role/privilege(s) (Account Administrator, Group Administrator, Sender, Signer)
- Assigned group
- User status (Active/ Inactive)

Multiple users may be assigned the Group Administrator role with a given group. A Group Administrator must be a member of the group for which group administrator privileges are assigned.

Users assigned the Sender role must be assigned to a group which is configured for the application of 21 CFR Part 11 compliant electronic signatures since the Sender's group settings are applied when a document is sent for signature.

The Group Administrator periodically reviews the User Access List for Adobe Sign to ensure that appropriate access rights are maintained.

### 5.3 Sending Documents for Signature

Documents may only be sent for signature by an individual who is identified as a Sender on the User Access List for Adobe Sign. The Sender initiates the request for signature via the Send page in the Adobe Sign portal.

#### 5.3.1 Identify Signers

The Sender assigns Signers by entering the Signer's email address as it is documented on the User Access List for Adobe Sign. If applicable, the Sender may assign a single signature task to a Recipient Group which includes multiple Signers. The task is executed by the first member of the Recipient Group to successfully apply an electronic signature.

If the Sender selects the option to apply signatures sequentially, the system enforces the application of the signature in the order in which the Signers' email addresses were specified by the Sender. If the option to apply signatures sequentially is not selected, the Signers are notified of their signature tasks in parallel and they may apply their electronic signatures in any order.

#### 5.3.2 Specify the Authentication Method

Within the Send page in the Recipients section, the Sender enters the Signer's confirmed email address and selects authentication method available in the drop-down field next to recipient's email address.

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If the Signer is an internal user, the system is configured to select the default authentication method. This will allow the Signer to authenticate himself using corporate credentials.

If the Signer is an external user, the Sender must choose one of the following authentication methods:

- Adobe Sign authentication: This method can be used when the Signer is known to have an existing Adobe ID. This will allow the Signer to authenticate himself using his Adobe ID and password.
- Phone authentication: This method can be used when the Signer's phone number is known and capable of receiving SMS notifications. This will allow the Signer to authenticate himself using his email address and verification code.

### 5.3.3 Attach Document for Signature

The Sender attaches a PDF document to the request for signature and may also include any a message to the Signers within the request. Adobe Sign has been configured to automatically embed a text into each request for signature informing the signer of the legally-binding nature of his electronic signature.

Once the document for signature has been attached, the Sender may preview the document and insert a single predefined signature field (Signature or Signature Block) associated to each Signer. The positioning of the predefined signature field is the location in the document where the Signer's electronic signature will be applied. If no predefined signature fields are specified, the Signers apply their respective signatures within system generated signature fields that are positioned at the end of the document and associated to the Signer's email address.

## 5.4 Application of Electronic Signatures

Signers are notified that they have been requested to sign a document via email notification. This email includes a hyperlink to the document for signature. An Internal Signer may also access the document via the Adobe Sign portal. Signers must provide valid Adobe Sign credentials to view the document whether attempting to access the document via the email hyperlink.

The Signer reviews the document and if the Signer agrees with the document's content, the signature application process is initiated. The Signer selects the appropriate signature field and is required to provide a reason for signature from a predefined list that is specified in the group's configuration settings. The Signer must provide valid credentials (based on the authentication method selected by the Sender) to successfully sign the document.

Following the application of the Signer's signature on the document, a message will be displayed informing them that they have successfully signed the document.

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<Instructions related to the delegation process must be removed from this document if this functionality is not enabled for the group that is configured for the application 21 CFR Part 11 compliant electronic signatures.>

If desired, the Signer's signature task may be delegated to another Signer. The Signer who wishes to delegate the assigned task must provide the email address of an alternate Signer as it is documented on the User Access List for Adobe Sign.

### 5.5 Record Generation and Retention

Once the document has been signed by all the required Signers, an email notification containing a hyperlink to the signed record is sent to the Sender and all the Signers. Upon accessing the signed record, the Sender and Signers may also access the audit report associated to the signed record.

The Sender is responsible for downloading the signed record and along with the audit report from the Adobe Sign portal. The Sender transfers the signed record and its audit report to <insert location for record storage, such as Electronic Document Management System (EDMS)>. The signed record and audit report are retained in accordance with <insert reference to procedural control governing record retention and archiving>.

## 6.0 REFERENCES

Document Number	Document Title
Document Number	<enter title of procedural control governing configuration management>
Document Number	<enter title of procedural control governing record retention and archiving>

## 7.0 EXTERNAL REFERENCES

- Ref. [1] U.S. Food and Drug Administration, Code of Federal Regulations, Title 21 Part 11, Electronic Records; Electronic Signatures, 1997.