# CTO

**Doc. No: CTO_QMS_SOP_023**

**Title: Using Electronic Signatures**

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**Approval(s):**

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## Document History

| Version | Date | Author | Comments |
|---|---|---|---|
| 1.0 | 09-Dec-2015 | Elena Amandola | This document replaces the SOP for Electronic Signature (GITI_CO_SOP_004) |

## Convention

Some words must be used in a standard way, as defined below:

- **Must (has / have to):** this must not be ignored
- **Should:** this may be ignored, but must be justified
- **Can:** this may be ignored, without any justifications

**Dates** should be stated in the **form** "dd-mmm-yyyy", e.g. 01-Aug-2015

## Explanation / Definition of Terms

The terms and definitions are published in the CTO Quality Manual available in the QMS Document Repository.

## Publication

This document must be published in the CTO QMS Document Repository, accessible via the CTO IGM intranet.

# Table of Contents

# 1 Purpose

This document describes how to apply an Electronic Signature. Electronic signatures, compliant with 21 CFR Part 11, can be used instead of handwritten signatures for GxP records. For GxP records, electronic signatures are legally as binding as handwritten signatures.

This document describes the steps to take for CTO associates to sign GxP documents by using an electronic signature, in accordance with Novartis external and internal GxP regulations.

It supports the requirements and processes described in the SOP for CTO QMS *Electronic Records and Electronic Signatures*, as referenced in the CTO Quality Manual [1].

Training on this SOP is mandatory for all CTO personnel.

# 2 Scope

## 2.1 In Scope

This document applies to:

- all CTO GxP-relevant documents that are signed electronically.
- all persons who (plan to) perform electronic signatures on these documents.

**NOTE:** electronic signatures using Novartis standard tool and methodology (PKI) can be used only within the Novartis environment. If a document shall be signed by person outside of Novartis, the document must be signed with a handwritten signature only.

## 2.2 Out of Scope

Any document type not specified in section 2.1 is considered Out of Scope for this SOP

# 3 Roles and Responsibilities

Roles and responsibilities related to this document are:

| Role Name | Description |
|---|---|
| SOP Owner | The person (or designate) responsible to:<br>• Execute the SOP and drive continuous improvement<br>• Ensure that the SOP is included into the CTO training management process<br>• Ensure that the SOP is managed according to approved procedures (e.g. document management and records management) |
| SOP Executer | The person that executes the procedure and records the findings. This person should be trained to perform these duties. |

| | |
|---|---|
| CTO IGM | The organization that approves execution and adherence to the compliance requirements documented in the CTO Quality Manual [1] |

# 4 Procedure

## 4.1 General Instructions

Before a person performs an electronic signature a "Certificate of Understanding" has to be signed:

> I, the undersigned, understand that execution of an electronic signature function on a Novartis computer system has been certified to the United States Food and Drug Administration by Novartis Top Management to be the legally binding equivalent of my traditional handwritten signature.
>
> I also acknowledge that I understand that it is prohibited to share components of my electronic signature such that my signature could be executed by another individual. Such components may include, but are not necessarily limited to, computer passwords or unique identification tokens such as electronically encoded ID cards.

**NOTE**: The Certificate of Understanding may be signed electronically.

## 4.2 Migrating documents with Hybrid Signatures

A document may be signed by both handwritten and electronic signatures only by applying the following processes, and according to an approved methodology (e.g. PKI). A document with a hybrid signature must be migrated from one format to the other, preferably to electronic format.

## 4.3 Migration to electronic format after a Handwritten Signature

1. Prepare a document.
2. Hand write the signature on paper.
3. After a defined number of handwritten signatures are given on paper, the document including the page with handwritten signatures is scanned, and the scanned document is verified "locally" via electronic signature. The "local" person who verifies the scanned document has to check the scanned document against the handwritten signed paper document for consistency.
    - The following verification statement should be used: "*With this signature I certify that the electronic document is an accurate, complete and legible transcript of the original document and that the document is migrated from paper to electronic format*."
4. The verified document is signed electronically.
    - In case the "local" person verifying the document performs the role of the next foreseen Approver, only one electronic signature is needed. In this case, the following verification/approval statement should be used: "*With this signature I*

*certify that the electronic document is an accurate, complete and legible transcript of the original document, and I approve the document.*"

5. With the electronic signature obtained in steps 3 and/or 4, the document is considered to be migrated from paper to electronic format. The official GxP record is the electronic document. Only the electronically signed version has to be stored in a defined storage location and must be available for audit/inspection purposes during the retention period.
6. **IMPORTANT**: The paper copy must be kept for one week following the migration to electronic format. This is to ensure that the electronic copy is backed up. After one week, the document containing handwritten signatures must be destroyed.

**NOTE:** The 3-step process detailed below is **not allowed**.

1. Prepare a document.
2. Hand write the signature on paper.
3. The document is scanned; the scan is sent via e-mail and subsequently electronically signed without verification of the original hand-signed signature(s).

## 4.4 Migration to electronic format, when a Handwritten Signature is the last signature on a Hybrid Document

It is strongly recommended that if the last signature on a *Hybrid Document* is a handwritten signature, someone "locally" verifies the signature and migrates the document to an electronic format.

**NOTE**: If this is not possible, proceed to Section 4.5

1. Prepare a document.
2. Sign the document electronically.
3. After a defined number of electronic signatures are given, the document is printed out for handwritten signatures. Check the validity of the electronic signatures printed on the document, hand write a statement on the printout that the electronic signatures are valid and sign and date the statement.
    - The following verification statement can be used: "*I certify that the electronic signatures are valid.*"
4. The verified electronic document is approved on paper.
    - In case the verifying person is also the next foreseen Approver, only one handwritten signature is needed. In this case, the following verification/approval statement should be used "*I certify that the electronic signatures are valid and I approve the document.*"
5. After the last handwritten signature is given on paper, the document including the page with electronic and handwritten signatures is scanned, and the scanned document is verified "locally." The "local" person who verifies the scanned document has to check the scanned document against the hand-signed paper document for consistency. (It is not necessary to verify the electronic signatures, which was done in step 3.)
    - The following verification statement should be used: "*With this signature I certify that the electronic document, which contains both electronic and handwritten*

*signatures, is an accurate, complete and legible transcript of the paper based document.*"

6. With the electronic signature obtained in step 5, the document is considered to be migrated from paper to electronic format. The official GxP record is the electronic document. Only the electronically signed version has to be stored in a defined storage location and must be available for audit/inspection purposes during the retention period.

**NOTE**: The paper version must be kept for one week following the migration to electronic format. This is to ensure that the electronic copy is backed up. After one week, the document containing handwritten signatures must be destroyed.

### 4.5 Migration to paper format, when a Handwritten Signature is the last signature on a Hybrid Document

**It is strongly recommended not to keep paper-based hybrid documents**. If paper based copies of hybrid documents are to be kept as the official version of a document, it must be known before the signature method changes from electronic to hand-signed.

1. Prepare a document.
2. Sign the document electronically.
3. After a defined number of electronic signatures are given, the document is printed out for handwritten signatures. Check the validity of the electronic signatures printed on the document, hand write a statement on the print out that the electronic signatures are valid and sign and dates the statement.
    - The following verification statement can be used: "*I certify that the electronic signatures are valid.*"
4. The verified electronic document is approved on paper.
    - In case the verifying person is also the next foreseen Approver, only one handwritten signature is needed. In this case, the following verification/approval statement should be used "*I certify that the electronic signatures are valid and I approve the document.*"
5. With the handwritten signatures obtained in steps 4 and/or 5, the document is considered to be migrated from electronic to paper format. The official GxP record is the paper based document. Only the paper based document has to be stored in a defined storage location and must be available for audit/inspection purposes within a reasonable time frame during the retention period.
6. The electronic document must be destroyed immediately after the document is fully approved.

## 5 Controls and Monitoring

This section defines controls and monitoring related to the SOP. Controls and monitoring related to the current SOP are performed within the procedure steps, 4.1 – 4.5, above.

# 6 References, Attachments, Abbreviations/Acronyms

## 6.1 References

| # | ID | Title |
|---|---|---|
| [1] | CTO_QMS_QM_001 | CTO Quality Manual |

## 6.2 Abbreviations / Acronyms / Terminology

Abbreviations and acronyms for CTO are found on the CTO Quality Manual

| Terminology | Description |
|---|---|
| CTO Quality Management System | An effective pharmaceutical quality system that is based on the CTO Quality Manual [1] |
| PKI | Public Key Infrastructure |