**Purpose** The purpose of this Standard Operating Procedure (SOP) is to provide instructions to follow good documentation practices. This applies to all:

* Good Manufacturing Practices (GMP) and Good Distribution Practices (GDP) operations documented on paper and/or within electronic records
* XXXXXX staff, contractors, temporary workers, and consultants that support GMP/GDP operations

**Roles & Responsibilities**

**Table of Contents**

**Procedural Requirements**

The following roles have specific responsibilities called out in this procedure:

|  |  |
| --- | --- |
| **Role** | **Responsibility** |
| Area Management | Ensure all staff provide official record of signature and initials |
| Quality | * Ensure documentation is completed and signed/initialed and dated as required * Support staff as necessary * Approve documentation as required |
| Staff | * Complete official record of signature and initials * Apply requirements in this procedure during execution of   documentation tasks |
| Document  Management Services (DMS) | Manage completed [FORM-451082](https://amgencdocs.veevavault.com/ui/%23doc_info/702908?state_type=steady_state__v) for archival |

This procedure contains the following topics.

|  |  |
| --- | --- |
| **Topic** | **See Page** |
| [General Requirements](#_bookmark0) | 2 |
| [Recording Information](#_bookmark1) | 6 |
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The following requirements must be adhered to while following this procedure:

* Good Documentation Practices requirements covered in other process or site specific procedures must be followed.

Effective

* Procedures must be used to support the execution of tasks at the point of use and using the appropriate media (eg, PC, HMI, iPAD/Tablet, Paper)
* For electronic records, use secure computer-generated, time-stamped audit trails to independently record the date and time of the operator entries and actions that create, modify, or delete electronic records.

## Data Integrity & ALCOA +

**Requirements**

The following requirements must be adhered to for all GMP and GDP paper and electronic documentation and records, including supplemental information (eg, attachments):

* Documentation and records must demonstrate data integrity to ensure data is complete, consistent, and accurate throughout the data lifecycle.
* †††1 Documentation and records must adhere to the ALCOA+ (attributable, legible, contemporaneous, original, accurate +) principles. The table below provides a description and examples of each principle.

**Note:** Examples below are not intended to be all inclusive. Additional scenarios may apply.

Effective

|  |  |
| --- | --- |
| **Principle** | **Description / Requirement** |
| **A**ttributable | Documents and records must identify the individual that performed a recorded task and when the task was performed. This also applies to any changes made to records (eg, corrections, deletions, changes). |
| **Example 1:** A paper record documenting test results includes the initials and date of the individual who executed the test.  **Example 2:** A controlled form and attachment are prepared on behalf of someone else. The form and attachment indicate who completed them and include the initial and date of the completer. | |
| **L**egible | Information/data must be legible. It must be readable and unambiguous for it to be understandable and of use. This applies to all information that would be required for the document/record to be considered complete, including all original records or entries. |
| **Example 1:** A controlled document is downloaded. The header, footer, and watermark do not overlap with the content. The font size makes the document easy to read.  **Example 2**: Dates have been recorded consistently and in a format that makes the day, month, and year clear (eg, 1 Jan 2020). | |
| **C**ontemporaneous | Evidence of actions, events, or decisions must be recorded as they take place or at the end of a series of steps which can’t be broken up. The evidence must also be recorded in the order (ie, sequence) required. |
| **Example 1:** Production activities/events, test results, and verification of controls are documented immediately at the time of identification.  **Example 2:** A record is approved after all required entries are completed. | |
| **O**riginal | The first-capture of information, whether recorded on paper (static) or electronically (usually dynamic, depending on the complexity of the system) |
| **Example 1:** Validation test results are recorded directly on the current, effective version of the protocol.  **Example 2:** A paper record is uploaded into a computerized system. The electronic copy is verified for completeness and approved as a “true copy”. | |
| **A**ccurate | Records must be a truthful representation of facts. |
| **Example 1:** Transcribed data included in a Report in the document management system is verified and approved by a qualified data verifier.  **Example 2:** Results of completed actions are recorded on a form as they take place. This serves as an accurate attestation of what was done. | |

Effective

## Data Integrity & ALCOA +

**Requirements,**

cont’d

|  |  |
| --- | --- |
| **Principle** | **Description / Requirement** |
| Complete | Documents and records must include all information that would be critical to recreate an event. |
| **Example 1:** All required fields of a form are completed or are appropriately marked with a “N/A”. **Example 2:** A paper record is uploaded into a computerized system. To approve the electronic copy as a True Copy, the approver must confirm the copy is complete. If the original paper record was 4  pages, the electronic copy must also have 4 pages with the same information for it to be approved as a True Copy. | |
| Consistent | Information must be created, processed, and stored in a logical manner that has a defined consistency. |
| **Example 1:** A SOP reviewed and approved in the document management system provides instructions on how to consistently execute a GMP process.  **Example 2:** The record retention schedule defines the retention period for all documents and records to ensure like documents/records are retained for the same period of time. | |
| Enduring | Documentation and records must be kept in a manner such that they exist for the entire period during which they might be needed. This means that they must remain intact and accessible as an indelible/durable record throughout the record retention period. |
| **Example 1:** Written entries are in ink, which is not erasable, and will not smudge or fade during the retention period.  **Example 2:** Paper records are archived in secure locations to prevent damage and loss. | |
| Available | Documentation and records must be available for review at any time during the required retention period, accessible in a readable format to all applicable personnel who are responsible for their review. |
| **Example 1:** The effective and final versions of the controlled documents maintained in the document management system are accessible to all staff that require access to execute their job responsibilities.  **Example 2:** Paper records stored in an off-site storage facility are tracked in a validated system to ensure records are readily and easily accessible. | |

## Official Record of Signatures & Initials

Area Management is responsible for ensuring an official record of signature and initials is maintained for all direct reports and contingent staff that support GMP/GDP operations. [FORM-45108](https://amgencdocs.veevavault.com/ui/%23doc_info/702908?state_type=steady_state__v)2 is the official record of the authorized wet signature and initials for each staff member as it will appear on all GMP/GDP documents.

†††2 Staff must:

1. Complete [FORM-45108](https://amgencdocs.veevavault.com/ui/%23doc_info/702908?state_type=steady_state__v)2 using handwritten entries before applying any handwritten signatures/initials on any GMP/GDP documentation.
2. Forward the completed paper form to DMS.
3. Update signature form (on file with DMS) when changes occur to signature or initials (eg, name change, signature change due to injury).

## Signature Authority & Delegation Important Concepts

Refer to the following important concepts on signature authority and delegation:

* + Signing for information (via signature or initials) is confirmation that the information is accurate and complies with GMP/GDP requirements.

Effective

* + Signatures may be delegated to others per the restrictions listed below or where there is proof of being assigned as the designee.
    - The Site Head has signature authority for all departments except Quality.
    - Operations must not sign for more than one group or department on any single document.
    - The Quality Site Head has default signature authority for all Quality Operations.
    - Departmental peers with the same level or higher have signature authority for each other provided each has the same job function, or where there is proof of delegation.
    - Qualified Person signature authority may only be designated to another Qualified Person.

*Continued on next page*

## Performed by, Review & Approval of Documents or Tasks

The following requirements must be adhered to when performing, reviewing and approving tasks or documentation:

* A trained staff member performing a task may not approve, verify, or review his or her own individual actions. However, the trained staff member may review an entire document that contains their individual specific entries, where multiple entries are documented and review of the entire contents of the document is required (eg, batch record [BR] page reviews, logs/logbooks, equipment use records [EURs]).
* Each task/step/set of steps performed must be signed/initialed and dated by the staff member that completed that task/step/set of steps.
* Performed By, Recorded By, Reviewed By, Witnessed By, and Verified By entries must have:
  + Initials or signature
  + Date
* Designees signing a paper document must also print the name of the person whom they are signing for (eg, <signature> for <printed name of person signing for>).

Effective

* Documents/records that require approval must be performed per the following:
  + Print and apply wet signature/date, or
  + Apply electronic signature/initial in quality system that is validated for the business process and intended use

## Training Activities

A staff member in training (trainee) performing a task must sign/initial and date (where applicable) the document or record, in addition to the required trained staff member.

# Recording Information

**General** Record information on paper and within electronic records as follows:

* + - Print/download FORM>Serialized documents from CDOCS with serialization by downloading the Working Copy or per site procedure and record information.
    - Print/download FORM>General documents from CDOCs via Viewable Rendition and record information.
    - Record information in the current, effective version of the paper or electronic controlled document (eg, executable forms, forms, multiple entry forms).
    - Record information at the time of execution or as soon as possible to the real time (eg, at the completion of a series of connected steps) unless otherwise stated in the governing controlled document.
    - †††3 Document production events and process control actions immediately upon identification of the event.
    - Use clear and unambiguous language.
    - Ensure equipment and materials are uniquely identified (eg, labeled or tagged) and documented per the requirements of the governing controlled document or validated quality system.

Effective

* + - Complete all fields and comment sections in the order identified, unless otherwise specified or if there are established alternatives (Refer to: [Handling Blank Spaces](#_bookmark4)).
    - When raw data is saved in both paper and electronic form, the electronic data shall be taken as the original data. The printed piece of data cannot substitute the electronic original record.

## Restrictions Do not:

* + - * Record information before performing the action
      * Backdate information or initials/signatures
      * Use erasable ink or non-waterproof ink
      * Use annotation tools that can overwrite the data in electronic records
      * Use ditto/quotation marks (“) to document repeat information
      * Use pencil
      * Use scratch papers, loose papers, sticky notes (“post it”) to record GxP information
      * Record information anywhere other than the controlled document/system
      * Write on the back of a page, unless the document is double-sided
      * Write over text
      * Cross out data making it unreadable
      * Sign or initial another staff member’s name
      * Discard or destroy records, system files (unless backed-up/archived) or original data (unless retention period has expired per [FORM-492487](https://amgencdocs.veevavault.com/ui/%23doc_info/2025906?state_type=steady_state__v))
      * Perform tasks under another user’s electronic credentials (unless under training with trainer supervision).

## Paper Records Only

 A paper record consists of static data (ie, paper or pdf). A paper record may be electronically signed via a validated electronic signature system and/or a handwritten signature/initial applied.

1. Record information in a paper record following the instructions below:
   * Use indelible black or blue ink when recording on paper or black or blue font color when recording on a PDF; colors other than blue or black may be used only for marking up drawings
   * Date and initial/sign your own information/comments
   * Ensure handwriting is legible

## Electronic Records Only

 An electronic record consists of dynamic data within a computerized system (eg, an electronic record which the user and reviewer/approver can interact).

1. Record information in an electronic record ensuring the information is clearly attributable to the person who entered the information and:

Effective

* + The electronic system is validated for the intended use, and
  + Electronic signature functionality is validated and provides appropriate authentication and traceability to the specific person who signed the record

## Printouts & Photocopies of GMP/GDP

**Controlled Document Requirements**

1. The following requirements must be met for printouts, photocopies and downloads of GMP/GDP controlled documents and forms used for data entry:
   * must be printed using the current effective version
   * must be printed at the time of use (signature pages do not need to be printed)
   * entries must be legible
   * must have the same effective date as the current effective electronic version.

Printed documents must match the effective date of electronic version at the time of the first data entry

* + Completed forms and partially complete forms must be retained (ie, not destroyed) according to record retention policies and [FORM-492487](https://amgencdocs.veevavault.com/ui/%23doc_info/2025906?state_type=steady_state__v)
  + Incomplete or erroneous documents/forms must be kept and attached to the replacement document along with written justification for their replacement and page numbering as Page X of X
  + Unused documents (ie, blank forms, blank protocol pages) must be destroyed in a confidential waste bin or shred bin

1. All other GMP controlled documents must:
   * Be legible
   * Have the same effective date as the electronic version
   * Be discarded once the printed version is no longer valid

*Continued on next page*

## Data Entry for GMP/GDP

**Controlled Documents and Forms**

1. Download and/or print GMP/GDP documents and forms per the following:

|  |  |
| --- | --- |
| **If FORM is printed from...** | **Then ...** |
| CDOCS with Document type Operational>Form>Serialized | Download a Working Copy (per block below) and print  **or**  Print on serialized paper per site procedure |
| CDOCS with Document type Operational>Form>General or any other document type | Download Viewable Rendition and print  As appropriate, numbered sets of blank forms may be issued, bound (eg, Equipment use logs). |
| Other system (eg, CMMS, LIMS) | Print form per local or system procedures |

1. Execute documentation per requirements in section [Printouts & Photocopies of](#_bookmark2) [GMP/GDP controlled document requirements](#_bookmark2)

## Downloading a Working Copy in CDOCS

Download a Working Copy in the Document Management System (CDOCs) per the following:

1. Locate the effective version of the FORM > Serialized.

Effective

1. Select “Download Working Copy” from the action menu.
2. Enter the number of copies required (limit 50).
3. Click Continue.
4. Open the notification “Your Controlled Copies Have Been Prepared”.
5. Click the link “Link to download Package: here”.
6. Double click to open the Working Copy of document. The Working Copy contains the following:
   * Watermark identifying document as Working Copy
   * Footer identifying:
     + Date retrieved
     + Retrieved By
     + Serialized Copy #

*Continued on next page*

## Recording Objective Evidence

**Recording comments**

1. Record evidence in the manner required per approved/effective protocol, form, method, etc. For example:
   * Numeric value
   * Pass/Fail
   * As Expected/Not as expected
   * Acceptable/Not Acceptable
2. Record objective evidence per the following instructions:
   * Record all test results per requirements of approved/effective protocol, form, method, etc.
   * Tick marks ( or X) may be used for checkboxes indicating Pass/Fail.
   * Sign and Date all result printouts

 Printouts or screen prints showing acceptable results constitute record of result.

1. Record information where it is clearly visible in the appropriate place per the following table:

Effective

|  |  |
| --- | --- |
| **If sufficient room...** | **Then ...** |
| is provided | Record information in the place provided and sign/initial and date entry, as required |
| Not provided | * Write a reference character (eg, letter (a) or number (1)) beside location for entry to refer to the information * Record the information where it is clearly visible, labeling it with the same reference character used for the entry and initial and date entry |

1. Write comments in clear and legible manner (eg, through the use of error codes).
2. Initial and date all comments.
3. Identify comments clearly using reference characters (eg, letter (a) or number

(1)) and refer to the location within the document where the comment applies.

1. Ensure that comments documented in Batch Records are co-initialed and dated by Quality either per page or per comment.

*Continued on next page*

## Handling Blank Spaces Requirement

Provide a comment in paper records when Not Applicable or N/A is entered for a required field. The comment must be initialed and dated.

 Writing “N/A” is not required if there are N/A check boxes for single or multiple spaces.

## Handling Blank Spaces

Effective

Address blank spaces or non-applicable information as follows:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **For** | **Then** | **Example** | | |
| Multiple lines or fields where the information in each field is repeated  **RESTRICTION:** Does not apply to:   * Initials/signatures * Dates * Raw data, including captured or measurement data such as gauge   readings or specifications | 1. Use an arrow to identify identical information that is repeated between the first and last lines. 2. Enter your initials and the current date beside the arrow. |  | | |
| Fields with multiple checkboxes or options | Mark the checkbox/option(s) that apply |  |  |  |
| Areas or fields where a N/A  checkbox is included | Mark the box as needed |  | | |
| A single line or field where data is not applicable | 1. Enter “N/A” on the line or field where data is not applicable. If field is required, enter a reference character and add a comment. 2. Enter your initials and the current date beside the “N/A”. |  | | |
| Multiple lines or fields where data is not applicable | 1. Enter a single, diagonal line across all lines or fields where data is not applicable. 2. Enter “N/A” across the lines. 3. Enter your initials and the current date. 4. For full pages, add an additional comment such as “intentionally left blank” or “no further entries” or similar to explain the blank space. 5. Sign and date the page. |  | | |

*Continued on next page*

## Numbers, Measurements, & Calculations

Use the following instructions to record numbers, measurements, and calculations when specific SOPs, Batch Records, or laboratory methods do not already provide.

* Record values/results to the full precision (number of significant figures) provided by the acceptance criteria, specification, release limit, or data source (instrument) unless otherwise specified in the governing controlled document or validated system
* Record a zero (0) before a decimal point when the value is less than one (eg, 0.75 not .75)
* Use the same abbreviated units of measure required by the effective controlled document. Abbreviated units are as follows:

|  |  |
| --- | --- |
| **Unit of Measure and Abbreviation** | |
| Gram = g | Microliter = L |
| Kilogram = kg | Milligram = mg |
| Liter = L | Milliliter = mL |
| Microgram = g or mcg | Millimole = mmol |

* Use significant figures, as follows, by recording:

Effective

* + Every non-zero digit in a measurement (eg, the numbers 12.3, and 1.23 have three significant figures)
  + All zeros between non-zero digits (eg, the numbers 10.03, and 1.003 have four significant figures)
  + Zeros at the end of a number and to the right of a decimal point (depending on the precision of the measuring device) (eg, the numbers 670.0, 67.00, and 6.700 have four significant figures)
* Round numbers as below:

|  |  |  |
| --- | --- | --- |
| **If the digit beyond the last required**  **significant figure is…** | **Then round** | **Example:** |
| < 5 | Down | 21.4 becomes 21 if only 2 significant  figures are required |
| ≥ 5 | Up | 21.5 becomes 22 if only 2 significant  figures are required |

* + Round to the significant figure of the acceptance criterion when reviewing results for comparison to an acceptance criterion
  + Round only the final results from calculations (not interim results) when performing chain or multiple calculations
  + Record manual calculations as needed before performing a step/task and for all steps within the calculation
  + Use only validated spreadsheets when spreadsheets are used for calculations

*Continued on next page*

## Dates and Times

Record dates and times per the following instructions:

* + - Express all dates so that the day, month, and year is clearly understood. Refer to the following for recommended date formats:

|  |  |  |
| --- | --- | --- |
| **Format** | **US (MM/DD/YYYY)** | **European (DD/MM/YYYY)** |
| Numeric | 06/01/2020 | 01/06/2020 |
| Alphanumeric | Jun 01 2020 | 01 JUN 2020 |

* + - Never back date
    - Document time using hours, minutes, and seconds (if required) in a consistent and unambiguous format. Use colons (:) or dots (.) as separators. Examples include:

|  |  |
| --- | --- |
| **Military (24 hour)** | **Meridian (12 hour)** |
| 0850 | 8:50 am |
| 1750 | 5.50 pm |
| 16:00:03 | 4.00.03 pm |

* + - Use only XXXXXX calibrated timing device or a site-approved timing device (eg, network master clock synchronized to a standard computer clock such as those in DeltaV, LIMS, or MAXIMO systems) to document time-critical GMP/GDP operations or procedures

Effective

* + - Use the same timing device to record start and end times
    - Electronic records have the date and time stamp generated by the computer at the time of operator entry and action that creates, modifies, or deletes electronic records

**Note:** Printed information from computer related systems may have non-European format dates or times, provided these are consistent within that system.

## Handling Blank Spaces Requirement

Provide a comment in paper records when Not Applicable or N/A is entered for a required field. The comment must be initialed and dated.

 Writing “N/A” is not required if there are N/A check boxes for single or multiple spaces.

## Handling Blank Spaces

Effective

Address blank spaces or non-applicable information as follows:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **For** | **Then** | **Example** | | |
| Multiple lines or fields where the information in each field is repeated  **RESTRICTION:** Does not apply to:   * Initials/signatures * Dates * Raw data, including captured or measurement data such as gauge   readings or specifications | 1. Use an arrow to identify identical information that is repeated between the first and last lines. 2. Enter your initials and the current date beside the arrow. |  | | |
| Fields with multiple checkboxes or options | Mark the checkbox/option(s) that apply |  |  |  |
| Areas or fields where a N/A  checkbox is included | Mark the box as needed |  | | |
| A single line or field where data is not applicable | 1. Enter “N/A” on the line or field where data is not applicable. If field is required, enter a reference character and add a comment. 2. Enter your initials and the current date beside the “N/A”. |  | | |
| Multiple lines or fields where data is not applicable | 1. Enter a single, diagonal line across all lines or fields where data is not applicable. 2. Enter “N/A” across the lines. 3. Enter your initials and the current date. 4. For full pages, add an additional comment such as “intentionally left blank” or “no further entries” or similar to explain the blank space. 5. Sign and date the page. |  | | |

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# Attaching and Affixing Supplemental Information

## Requirements for Supplemental Information

 Supplemental information is any information or data that is being added (ie, attached or affixed) to an existing and approved:

* paper document or record, or
* electronic document or record
  1. ALCOA+ principles must be applied when attaching or affixing supplemental information.
  2. Supplemental information must be approved in one of the following ways:
     + As part of the approval process of the document/record, the information is attached/affixed where approval signature (ie, system signature) signifies that the supplemental information is complete and correct, or

 On its own using a validated e-sig system

## Affixing Supplemental Information

|  |  |
| --- | --- |
| **If..** | **Then ensure …** |
| Information is being added to an existing page | * All data on the page is readable and original data is not obstructed * Information is affixed in a way that if it was removed, it would be known that it was removed. Examples include:   + Write across the attachment and the page using a unique means of identification   + Initial and date across both the attachment and page interface   **Picture 1:**  Sign/initial and date across the edge of the printout   * Tape used to secure the information does not contact any printed   or handwritten information |
| Attaching or Affixing a Label | The label is defaced in such a way to:   * Ensure the label may not be used or reused * Not obliterate relevant information |

Affix required supplemental information (eg, filter integrity test results, labels) to a document as follows:

Effective



# Correcting, Adding, and Rewriting Information

## Correcting Information

For paper records, correct recorded information per the following instructions:

1. Draw a single line through the entire incorrect entry (including numbers and dates) and initial and date.
2. Document the reason for the change by writing it out or add the appropriate error code per the following table:

|  |  |
| --- | --- |
| **Error Code** | **Meaning** |
| CE | Calculation Error |
| DE | Data Entry Error |
| EE | Entry Error |
| IE | Illegible Entry |
| LE | Late Entry |
| TE | Transcription Error |
| WO | Write Over |

1. Write the correct information where it is clearly visible in the appropriate place per the following table:

Effective

|  |  |
| --- | --- |
| **If ...** | **Then ...** |
| Sufficient room beside the lined out entry | Write the correct information beside the lined out entry and initial and date entry |
| Not enough room beside the lined out entry | * Write a unique reference character (eg, asterisk, letter (a), or number (1)) beside the lined out entry to refer to the correct information. * Write the correct information where it is clearly visible, labeling it with the same reference character used for the incorrect entry, and initial and date the entry   **Note**: Correct information should be placed on the same page as the correction. |

1. Ensure a verification, approval, or review of the corrected entry if the original entry required verification, approver, or review.
2. For electronic records, correct recorded information for critical fields identified by the system data integrity assessment, per the following instructions:
   * change can only be made by the authorized personnel
   * change must be attributable to person making the change
   * date must be recorded

*Continued on next page*

## Correcting an Approved Record

Correct recorded information per the following instructions:

* Consult with Quality to determine if a quality system record is required (eg, change control, deviation) if the error impacts the results, performance of a step and/or task
* Make any corrections to an approved document through the document management system or other Quality system

## Restrictions Do not:

* + Erase, obliterate or delete raw data, system files (unless backed-up/archived) or original entries
  + Dispose of original entries or pages of raw data if an error occurs, including attachments of bound pages
  + Use correction fluid or tape
  + Cross out or obscure raw data or original entries

Effective

## Managing Missing Information

Use the following table to address missing information:

*Continued on next page*

|  |  |
| --- | --- |
| **If the following is missing** | **Then** |
| Task-related signature/initials | 1. Sign or Initial as needed. 2. Use the Late Entry error code (LE). 3. Initial, date, and provide an explanation for the late entry   EXAMPLE: For work performed on dd/mm/yyyy   1. Consult with Quality determine if the late entry requires a deviation per [SOP-428250](http://edmquality.amgen.com/edmquality/component/main?__dmfClientId=1400164423961&__dmfTzoff=-120). |
| Retrievable information | 1. Record the missing information. 2. Add a comment, including the following information:    * The GMP/GDP verifiable source used to retrieve the information    * An explanation for the omission or late entry 3. Include a copy of the retrieved information, if available    * Notify Quality before using and/or filing information from a photocopy.    * Initial and date the photocopy. |
| Information that cannot be retrieved from another GMP/GDP document, record,  or validated system | Consult with Quality to determine the required actions and determine if a deviation is required per [SOP-428250](http://edmquality.amgen.com/edmquality/component/main?__dmfClientId=1400164423961&__dmfTzoff=-120). |

## Rewriting/ Recreating & Transcribing Information (Excluding BRs and Related Attachments)

Documents may be rewritten, re-created or information transcribed for the following reasons:

* Information is unclear/illegible
* An incorrect form or document was used
* The document is irreparably torn or damaged
* The original is lost or misplaced Perform the actions per the following table:

Effective

|  |  |
| --- | --- |
| **If ...** | **Then ...** |
| Rewriting/recreating a document | 1. Obtain Quality’s approval by obtaining their signature on the first page of the rewritten/re- created document. 2. Determine if a deviation is required per   [SOP-428250](http://edmquality.amgen.com/edmquality/component/main?__dmfClientId=1400164423961&__dmfTzoff=-120) to justify the rewrite/re-creation.   1. Identify the document as “Rewrite” or “Re-creation”. 2. Provide an explanation for the rewrite/re-created document. 3. Reference the GMP/GDP sources used for the rewrite/recreate. 4. For paper documents, attach the original document to the rewritten/re-created document when   available (eg, for damaged, torn, or illegible original documents). |
| Transcribing Information | 1. Identify the information as “Transcription” 2. Provide an explanation for the transcription. 3. Reference the source for the transcription. |

**Email Usage** Email can be used to communicate GMP/GDP decisions impacting regulated activities if accompanied by documented approval of decision. Decision must be attached as unalterable \*.PDF containing signatures and dates.

## Email Restrictions

Do not use email to:

* + Record GMP/GDP related raw data
  + Record initial observation with respect to product safety and quality
  + Record document approval
  + Document GMP/GDP related outcomes, results or assessments
  + Add comments and/or annotations to draft documents
  + As attachments to Quality Systems (eg, QMTS, CCMS) unless email is used to communicate GMP/GDP decision as listed in [Email Usage](#_bookmark6) section, or to document notifications to or from external parties.

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**Faxes** Documents showing GMP/GDP decisions may only be faxed if they contain a handwritten signature and date of signature.

**Note:** Faxes may be scanned into the document management system as records for retention and future reference.

## Handling Copies Received via Fax or Email

1. Identify the document as “Copy”.
2. Control the copy as original documentation and archive per site procedures, eg. Fill finish forms in \*.PDF format that are shared between sites.

**Email Usage** Email can be used to communicate GMP/GDP decisions impacting regulated activities if accompanied by documented approval of decision. Decision must be attached as unalterable \*.PDF containing signatures and dates.

**Requirements** The following requirements must be adhered to when creating memos:

* + Memos must be in paper form or as an electronic record
  + The information in a memo must be clearly attributable to the person who wrote or entered the information

**Usage** Memos may be used:

* + To record events, issues, and data
  + As supporting documentation for approved documents

Memos may be created in the following ways:

* + Created and approved in the document management system with electronic signature.
  + Created in paper form with ink signature and date. As needed, paper form can be imported to the document management system and approved as a record.

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**Content** Memos must be addressed to responsible individuals and include:

* + Distribution list
  + Reference to any related copies
  + Specific title, product name and/or lot reference (as applicable)

**Signatures** The memo author must sign and date the memo.

**Archival** File the memo with a specific batch file or subject file when no batch is associated with the memo, as applicable, in accordance with XXXXXX’s Records Retention Schedule per [FORM-492487](https://amgencdocs.veevavault.com/ui/%23doc_info/2025906?state_type=steady_state__v).

**Note:** Paper memos may be imported and approved in the document management system as records for retention and future reference.

**Requirements** The following requirements must be adhered to when creating memos:

* + Memos must be in paper form or as an electronic record
  + The information in a memo must be clearly attributable to the person who wrote or entered the information

**References** The following documents are critical and necessary to perform the SOP

|  |  |
| --- | --- |
| **Document** | **Title** |
| [FORM-451082](https://amgencdocs.veevavault.com/ui/%23doc_info/702908?state_type=steady_state__v) | Multi-Site: Staff Signature Sheet |

**Resources** The following internal documents provide additional information:

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|  |  |
| --- | --- |
| **Document** | **Title** |
| [FORM-492487](https://amgencdocs.veevavault.com/ui/%23doc_info/2025906?state_type=steady_state__v) | XXXXXX’s Records Retention Schedule |
| [SOP-428250](https://amgencdocs.veevavault.com/ui/%23doc_info/2022418?state_type=steady_state__v) | Multi-Site: Deviation and Corrective Action Preventative Action (CAPA) Process |

**Definitions** The table below includes terms used in this SOP and its definitions.

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|  |  |
| --- | --- |
| **Term** | **Definition** |
| Backdate | Record a prior date or time. |
| Critical Data | Any process value or test measurement obtained to evaluate process parameters and or specifications. Examples include: time, date, pH, conductivity, weight and temperature. |
| Data | Information derived, created or obtained from raw data (eg, a reported analytical result). Data can be static (ie, paper or pdf) or dynamic (eg, an electronic record which the user and  reviewer/approver can interact with). |
| Data integrity | The extent to which all data are complete, consistent, and accurate throughout the data lifecycle in alignment with ALCOA+ principles. |
| Designee | Person who performs, signs, or approves a task in the absence of the intended staff. This person has similar experience, training, and responsibilities. |
| N/A | Abbreviation used to indicate that something is “not applicable.” Writing out “Not Applicable” or abbreviating it as “N/A” or “NA” are acceptable practices.  This abbreviation is not to be confused with “Not Available,” which means that information was  not found, does not exist, or was not provided when required. “Not Available” is not to be abbreviated as “N/A.” |
| Original record | Data as the file or format in which it was originally generated, preserving the integrity (accuracy,  completeness, content, and meaning) of the record. Examples include original paper records of manual observations and an electronic raw data file from a computerized system. |
| Performed By | Initials or signature of a person executing an operation or task, usually the “operator” or “analyst” |
| Raw data | Original records and documentation, retained in the format in which they were originally generated (ie,, paper or electronic) or as a ‘true copy**’** |
| Recorded By | Initials or signature of a person recording data while someone else is executing an operation or task |
| Re-creating | Re-writing a new record from a verifiable source to replace the original |
| Reviewed By | Initials or signature of a person examining a task, document, or record in order to confirm its accuracy and completeness |
| Significant Figures | Significant figures (or digits) are all digits in a measured number that are known for certain plus one digit that is estimated. Significant figures depend on the precision of the measuring device. In a number, the “significant figures” are the figures that denote the exactness of the quantity  being measured. |
| Transcribing | Transferring information from one record or system to another document |
| True copy | An exact verified copy that preserves the content and meaning of the original record |
| Verified By | Initials or signature of a person confirming or witnessing that a task, operation, calculation, or procedure has been performed per written instructions and accurately documented |
| Witnessed By | Initials or signature of a person observing in real time that a task or operation is being performed per written instructions and accurately documented |

**Abbreviations** The table below includes acronyms and abbreviations used in this SOP.

|  |  |
| --- | --- |
| **Abbreviation** | **Definition** |
| ALCOA | Attributable, Legible, Contemporaneous, Original, Accurate |
| BR | Batch Record |
| GMP | Good Manufacturing Practices |
| GDP | Good Distribution Practices |
| HMI | Human Machine Interface |
| PC | Personal Computer |
| SOP | Standard Operating Procedure |

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Document Approvals for SOP-423329, V9.0 Approved Date: 15 Oct 2021

|  |  |
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| Quality Approval | Carlos Monteagudo |
| Outcome: Approve | [(cmonteag@XXXXXX.com)](mailto:(cmonteag@amgen.com) Quality |
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