

Good Documentation Practices

Document Types

Good documentation practices (GDP) apply to many documents and demonstrate conformance to requirements for a variety of quality systems: internal customers, external customers, International Standard Organization (ISO), and/or the Food and Drug Administration.

Record	Format	Requirement
Calibration Documentation	Calibration Vendor Documentation, Forms, Laboratory Notebooks	21CFR820.72, 21CFR211.194
Manufacturing Records	Forms	21CFR820.184, 21CFR211.192
Maintenance Records	Logbooks, Vendor Documentation	21CFR820.70, 21CFR211.67
Validation Protocol	Reports	21CFR820.75, 21CFR211.110
Corrective Action Investigation	Forms, Memoranda	21CFR820.100, 21CFR211.100
Material Traceability Log	Vendor Documentation, Certificates of Analysis/Conformance	21CFR820.60, 21CFR211.188
Engineering Change Requests	Forms	21CFR820.70, 21CFR211.110

Document Numbering

Documentation is traditionally identified with a unique number so that all pieces of a single document are identified. Providing evidence of compliance to standards can be complex because the information is collected from many people; therefore, document numbering ensures that any gaps can be easily detected and corrected.

Document Numbers and Revision

- All documents shall have a unique document number. This is typically issued by a document control department or person.
- Every page of a document shall be marked with the page number as well as the total number of pages in the document. If a document is a single page, this section is often omitted.
- All documents shall have a revision level. Letters, numbers, or custom notation can be followed per the standard operating procedure (SOP).

- Different numbering and revision levels are common for documents when they are in a draft state, routing for approval, or final approved state.

Document Effective Dates

- All documents shall have an effective date. It is very important that old documents are not used when new documents are issued.
- The approved date notation, European or English, shall be identified in a procedure. Otherwise, local conventions are assumed.

Optional Document Features

- Documents may have a title. This is preferred to enable personnel to find documentation when needed.
- Documentation lists are advisable as they assist personnel and auditors in retrieving exactly what was specified.
- Documents may have a confidentiality statement. This precludes competitors from obtaining such documentation from a Freedom of Information (FOI) request.

Document Changes

All documentation changes must be carefully documented, reviewed, and approved. Uncontrolled changes can have a substantial impact on a company's ability to demonstrate compliance to their specific standards.

Corrections/Additions

- Additions shall be inked in.
- All corrections or additions shall be initial and dated.
- Only personnel who have already been approved to author or make changes to documents can correct or add to documents.

- Corrections shall be made by a single line.

Comments

- Non-typographical error corrections or additions indicating a change in data or acceptance status require a comment.

Approval

- Typographical error changes or additions do not require approval.
- Non-typographical error changes/additions are routed through a full document change control.

Document Signatures

All documentation used to provide evidence that standards are being followed must be signed and dated.

Origination

- All documents shall be signed by the originator.
- A legal signature is a first initial and last name. The complete first name may be used as well.
- No signature pads, scanned signatures, or duplicated original signatures shall be used to replace a handwritten signature by the person signing.
- Documents shall be signed in permanent ink.
- Signatures shall be kept throughout the life of the document.
- The local date shall be used to date documents.

Review

- All documents requiring verification shall be signed by the person verifying
- Documents requiring approval shall be signed.
- An approved list of designees, originators, and reviewers shall be maintained.

Designees

- If a designee is to be used, then that person signs his/her name, adds the words "signing for," and adds the original printed name of the approver.
- Designees must have the knowledge, skills, and abilities to perform the assigned authorship, verification, or approval activity.

Dates

- A legal date is comprised of a month, day, and year, although not necessarily in that order. Local conventions are assumed unless otherwise specified in an SOP. Time is not required.
- Postdating (entering a date in the future) is not permitted
- Backdating (entering a date on a day after the entry was made or the task was performed) is not permitted

- If the local time is used as part of the signature, it shall be assumed to follow the local time unless otherwise indicated.
- If times are required, procedures identifying approved guidelines for documenting date and time (military, AM/PM) shall be defined.
- Changes to documents after an origination, review, or approval date/signature has been applied, such as resulting from a review process, must be rerouted for approval.
- Documents that have not been completed and signed off are still considered drafts and do not need to be maintained as part of the document change history.

Definitions

FDA	Food and Drug Administration
ISO	International Standards Organization
GMP	Good Manufacturing Practices as described in 21CFR210 and 21CFR211.
QSR	Quality System Regulation as described in 21CFR820.
GDP	Good Documentation Practices are a collection of standard practices, procedures, and policies that industry has adopted over the years. While there is no specific requirement called GDP, requirements can be extracted from the Quality System Manual, 21CFR820.40 Document Controls, 21CFR211 Subpart J Records And Reports.
Verification	Verification means confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.
SOP	Standard Operating Procedures. These are established when they are both written and approved.
Forms	Data collection sheets usually accompanying a standard operating procedure.
Laboratory Notebooks	Permanently bound notebooks with unique page numbers where results of inspections and test procedures are documented. They are most commonly found in laboratories and research and development environments..
Vendor Documentation	Any certificates, forms, or other documentation supplied by vendors to demonstrate that they have completed a specific regulated task. The most common form of vendor documentation would be calibration certificates.
Designee	A person who has been given the authority to sign for another person. This must be established in a standard operating procedure. This person must have the knowledge, skills, and abilities to perform the same quality of review as the original signatory.