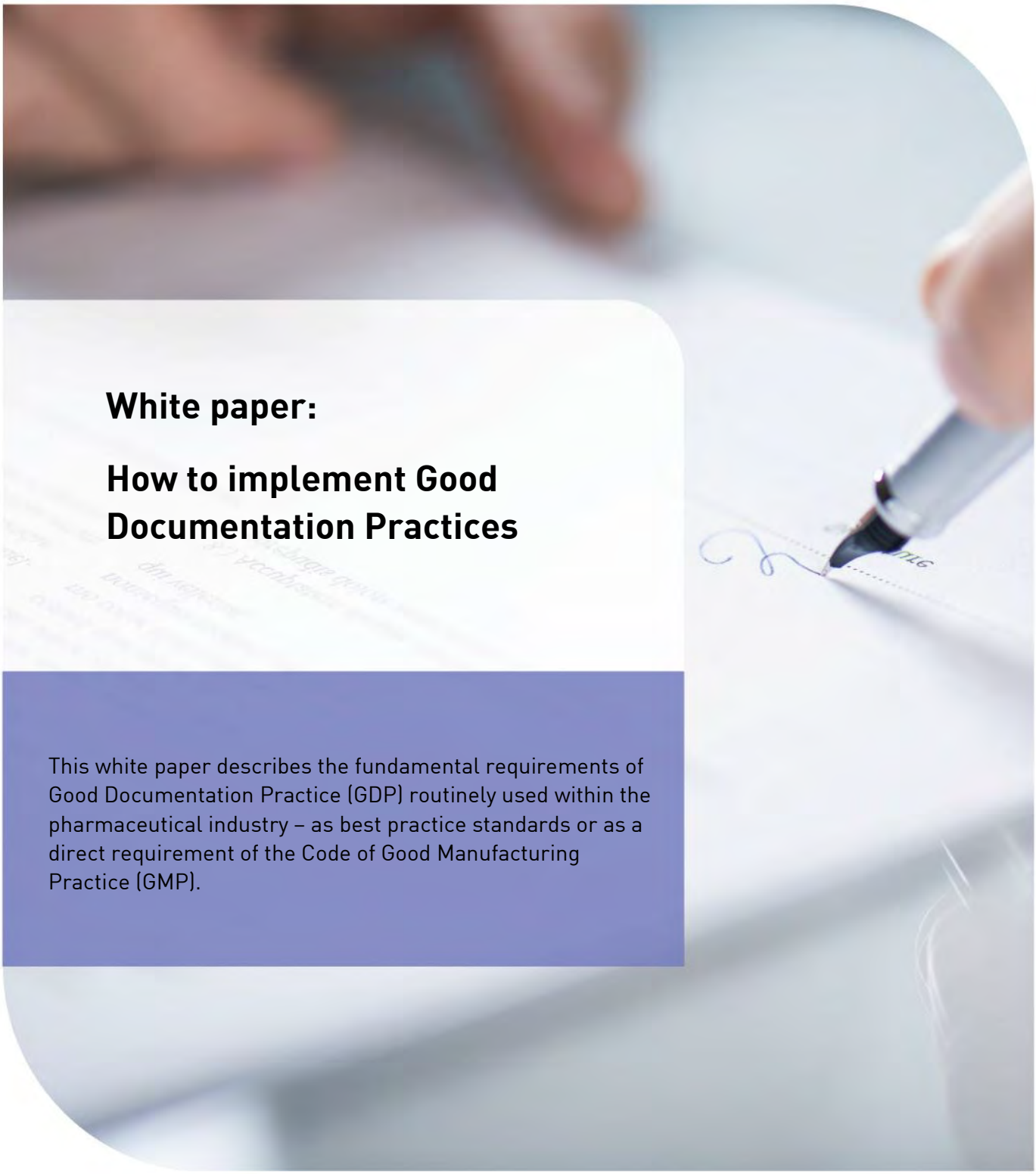


White paper:

How to implement Good Documentation Practices

This white paper describes the fundamental requirements of Good Documentation Practice (GDP) routinely used within the pharmaceutical industry – as best practice standards or as a direct requirement of the Code of Good Manufacturing Practice (GMP).

PharmOut®

MKT_TMP200_01_r06

Why are document standards important?

In a GMP environment documentation needs to meet certain requirements to ensure product quality and product safety. If an instruction or record is poorly documented, then the manufacture or Quality assurance/control of a product can be negatively impacted, potentially reducing patient safety.

The GMP regulations from PIC/S, FDA and EU all include mandatory sections on documentation. Documentation provides both:

- Information on when, where, who, why and how to complete tasks, and
- Evidence proving that the tasks have been completed as they should be.

Consequently, the standard of documentation within a company can directly impact the level of success in manufacturing quality products that are safe as well as success during audit situations.

The basics of GDP

To meet industry standards, it is critical that all documentation follows GDP when it affects:

- GMP processes
- material or product identity, quality, purity, strength and safety
- the validated state of GMP product manufacture, facilities, equipment, computer systems and testing methods.

It is recommended that your company has a policy or procedure outlining the expected GDP standards, particularly for those requirements that may be unique to your company – for example, using a specific pen colour or when and how to use scanned documents/records as original data.

Documentation is a valuable resource

Documentation may be divided into:

- documents – procedural or instructional documentation, and
- records – evidence of compliance.

Refer to EU GMP Chapter 4 for further information on different types of documents. Both documents and records are an invaluable communication tool for any business.

Benefit	Description	Form of documentation
Provide background history	Information storage point for anyone to access. Information can be added at any time, providing a full history.	Record
Preserves learning and knowledge	Reference for future use or a means to communicate information to others. Particularly important to ensure that knowledge is not lost when an employee leaves.	Document
Protects intellectual property	Evidence of an idea or a finding including the date and the responsible person.	Record
Provides legally valid evidence	Documents events, processes, ideas, communications etc. which can show that something did or did not happen.	Record
Ensure the quality and consistency of processes/activities/manuf-acturing	Provides the same critical information and training to all relevant employees, to ensure the quality and safety of the product.	Document

Different types of documents and records

Documentation and records used throughout the manufacturing process, as well as supporting processes (e.g. Quality Control or Quality Assurance), must meet the basic requirements of GDP. These include (but are not limited to):

- Batch Record Forms
- Bills of Materials (BOMs)
- Specifications
- Policies
- Protocols
- Standard Operating Procedures (SOPs)
- Work Instructions (WIs)
- Test Methods
- Checklists
- Forms/Log sheets
- Training Assessments
- Electronic and hardcopy Quality records (e.g. non-conformance, corrective and preventative actions, internal inspection, change control, training records etc.)
- Certificate of Analyses (CoA) or Certificate of Compliance (CoC)
- Technical transfer reports
- Validation documentation

General requirements

The following requirements should be applied to all documentation within the GMP environment.

General elements	GDP requirements
Clearly written documentation	All documents must be accurate and written in a manner that prevents errors and ensures consistency. If documents are to be used together, e.g. an SOP and a form, then each should reference the other. Ensure there is traceability between two or more documents/records using formal document numbers or record identification.
Using indelible ink	All records must be filled out in indelible ink for long term legibility. Do not use pencil or ink that can be erased. Colour should be specified by the company GDP procedure; often this is limited to blue or black because historically copy/scanning technology was limited in reproduction quality. However, this is less of a factor with the advent of high resolution scanners and colour copiers.
Legible handwritten entries	A document is unusable if it cannot be read, so care must be taken to ensure that handwriting is legible. All entries must be made at the time the tasks are performed and should be legibly signed and dated. The same is true of electronic documents and records – language should be clear and unambiguous.
Reviewing and approving	Documents and records should be reviewed by someone who did not perform the task to ensure that the information is correct and accurate. A signature and date by the reviewer/approver confirms that a review has taken place.
Staff signatures	Handwritten signatures must be unique to the individual and listed within the site signature register to ensure that the signature is traceable to a member of staff (or contractor). Staff are not permitted to sign for another member of staff unless delegated. Signatures must never be forged. The management of the signature record should be governed by a procedure and routinely reviewed so that it remains current – new staff should sign the signature register during induction, the signature register must indicate the date staff exit the company. Electronic signatures must meet the same general documentation requirements – refer to EU Annex 11: Computerised Systems or PIC/S Annex 11: Computerized Systems for additional regulatory requirements.

General elements	GDP requirements
Signed delegation of responsibility	In the event that a critical member of staff is absent for a time, they must delegate responsibility to another qualified person. The delegation must be either: • proceduralised in a document (SOP, WI etc.), or • documented with names of all people involved and signed by the person that is delegating their responsibility. The delegation should also be approved with the signature of a more senior member of staff.
Page numbering	GMP documents should have page numbers using the following standard 'X of Y' to indicate the total number of pages in a document.

Records must be permanent

Traceability of records in the GMP environment is of critical importance so that:

- the company can prove they are compliant to the Code of GMP and to their own processes and procedures
- the root cause of a non-conformance or a justified customer complaint can be identified
- corrective or preventative actions can be implemented and their effectiveness checked over time.

It is imperative that records are accurate and any changes or amendments are made in a complaint manner.

General requirements

No	Requirement
1	Deliberately amending or destroying GMP records to hide or falsify data is fraud.
2	Do not discard a GMP record just because you might have made a mistake, it is still required for traceability.
3	It is not acceptable to discard GMP records for any reason unless the retention period expiry is reached.
4	Loose unofficial papers, notes and uncontrolled documents that can easily be lost or changed without appropriate approval do not meet GDP requirements.
5	Do not use notebooks/legal pads with easily removed pages, scrap paper or post-it-notes to record GMP information.

Record control

Your site GDP procedure should describe the types of workbooks/notebooks that may be used – typically these are hard-covered with sown/sturdy binding; avoid spiral bound workbooks or logbooks as pages may be removed.

In an emergency, if no official means to record an observation is available, then:

- Initial, date and provide a comment on the paper record of the observation and attach to the official hardcopy record as soon as possible.
- Transcribe and attach the data to the official record and annotate 'Transcribed, see attached original'. The transcription must be signed and dated by the Preparer and filed/stored together with the original record.
- The data must be checked for accuracy by a second staff member.
- Investigate why an official record was not available at the time. Implement corrective actions so that the same situation may not arise again, e.g. create a form for the record, amend the procedure, change the process so that the record is captured electronically etc..

Using true copies

Sometimes there is a need to use a copy of an original document or record, e.g. attaching a copy of a report to a non-conformance record. So that it is apparent that the record is not the original:

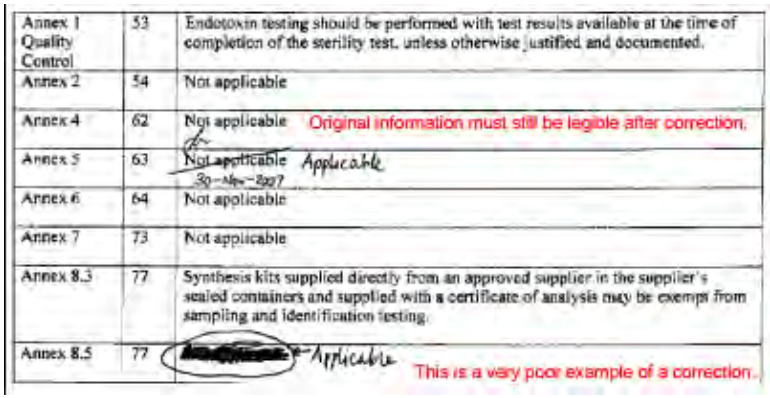
- Stamp or write on the front of the copied documentation, 'True Copy'.
- Sign and date the 'True Copy' amendment.

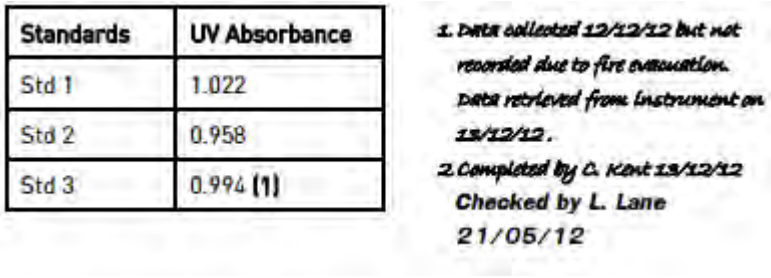
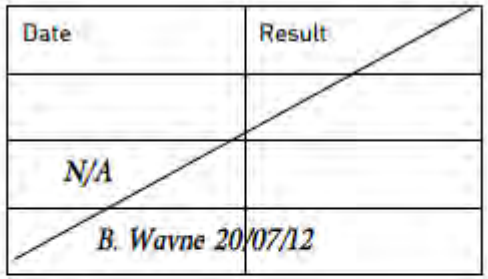
Modifying records in a compliant manner

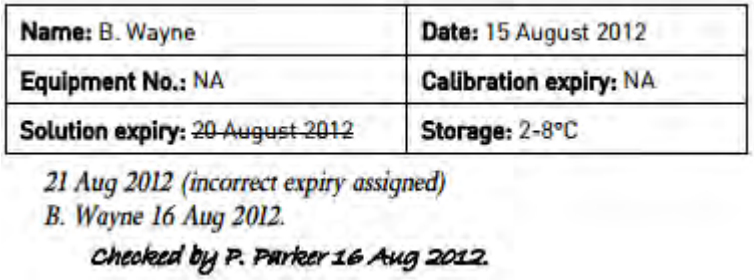
The company GDP procedure should stipulate how data or entries may be amended. This should include details on:

- Any standard abbreviations used, e.g. 'not applicable' (NA or N/A) etc.
- Unacceptable practices, e.g. using 'ditto' marks (") to indicate the same entry as above, leaving empty fields in a form, etc.
- Who is responsible for checking documentation amendments or general GMP compliance of logbook pages over time.

The following requirements outline the ways in which handwritten entries may be amended.

Handwritten Corrections	GDP requirements	Example
Making a legible correction	If a correction needs to be made, the original record must still be legible: Make a single line through the error – never use correction fluid, multiple cross-outs or marker pen to obscure the original record. Record the correction close by – numbering corrections is acceptable when space is limited. If the record becomes too congested with corrections, an attachment may be used, however the original record must indicate the number of pages attached and the attachment reference the record it is related to. Provide a brief comment why the change is required (as appropriate). Initial the change so that it is clear that the correction is deliberate. Record the date of the correction next to the initials so that there is a record of when the change was made.	

Handling omitted data	If an entry was omitted and must be made at a time later than the activity was performed then: Clearly indicate the date the activity was performed and the date the activity is recorded on the documentation. Document an explanation to substantiate the entry and the reason for the delay in recording. Sign and date the change.	
Completing all fields on a record	All fields on a record should have an entry, even if it is 'N/A'. Alternatively, multiple blank spaces/rows/columns on a record must be marked out with a single line across the whole field/space. This: • ensures that the record cannot be added to at a later date without appropriate checking or approval • indicates that not completing a field/space is deliberate. Marking out a larger space or whole page may be completed with a diagonal line. Use 'N/A' above the line (or other standard response indicated in the site GDP procedure) and sign and date to shown that the field/space is not applicable. An explanation may be required why the field/space is 'not applicable'.	 **Name:** B Wayne — **Date:** 15 August 2012 **Equipment No.:** NA — **Calibration expiry:** NA **Solution expiry:** 20 August 2012 — **Storage:** 2-8°C

Checking corrections	Corrections or amendments may be made after the content of the record has already been checked. Therefore, the correction must also be checked by the same person who checked the rest of the document. The checking analyst should: • Review the change and ensure that it has been made in a complaint manner – clear, legible, accurate, original entry is still visible etc. • Review the change with respect to the content of the rest of the document • Sign and date the correction. Important: Correction dates occurring after the last date that the record was checked are not compliant.	

Recording numbers

The following requirements outline the ways numbers should be recorded.

Recording numbers	GDP requirements
Decimal numbers	The company GDP procedure should stipulate any specific requirements for recording data. In general, if a decimal value is a fraction of 1 then a zero must be placed before the decimal point. Example: Record 0.98 rather than .98 The number of decimal places to be recorded should be outlined in a procedure. Example: When a specification limit is 2.55 - 2.85 and the result is 2.7, then record the result as 2.70 and not 2.7.
Rounding	The company must indicate how any rounding is to be performed and the results recorded. Consider the number of significant figures of the specification and the error of the instrument/equipment, rounding averages etc.
Dates format	Record dates following common practice of the country, such as Day/Month/Year (Australia) or Month/Day/Year (USA). Because of differences between countries, it is recommended that the month is denoted by its first 3 letters for clarity. Example: 11/03/12 or 11/03/2012 or 11 Mar 2012. This is particularly relevant for multi-national companies where different date formats are traditionally used. A corporate policy should cover multi-national date formats so that there is consistency in records and prevents confusion between different sites.
Time format	Record time in 24 hour format (00.00 – 23.59) or denoting am or pm. Example: 1 pm or 13.00 Record a period of time in hours and minutes. The site GDP procedure should indicate when to use 24 hour increments. Example: 1 hr 36 min or 1:36 hours or 96 min.

Dealing with attachments and printouts

The following requirements must be met when attaching records and printouts to GMP documents.

Handling attachments	GDP requirements
Attachments to forms	Attach one record to another (for example if a report is to be attached to a form): • Staple the attachment to the record; paperclips are not acceptable. • Cross-reference the record and the form with each other, e.g. the record references the report number and the report references the record number
Attachments to workbooks/logbooks	Secure the attachment to the appropriate page of the workbook/logbook – use tape or staples, glue or paperclips are not acceptable • Do not obscure any data on either the workbook page or attachment. • Ensure sufficient identification on the attachment to ensure traceability in the event it becomes separated (cross-referencing) • Indicate on the original document that there is an attachment. • Sign and date both the workbook and attachment.
Thermal printouts	All printouts made on thermal paper must be copied before attaching to a report or filing. Indicate 'copy of original 'or 'true copy,' on the copy and initial and date. Do not tape over information on thermal paper as the tape will cause the data to rapidly fade. After making a copy, secure the original and the copy with the report.

Using scanned documents

Scanned documents, converted to pdf files, are very useful for companies or department operating across different locations. However, the company should indicate how to treat scanned documentation and other compliance requirements associated with electronic media (refer to PIC/S Annex 11: Computerized Systems).

Scanning documents	GDP requirements
Obtaining approval signatures	Obtaining approval signatures from staff located at different sites/locations/ time-zones can be completed using scanning rather than hardcopy: • Print the document to be approved • Sign and date the hardcopy and then scan the hardcopy with the signature. • The pdf file of the scan is emailed to the appropriate signatories, who each print out the pdf file, sign and date their signature field, and then re-scan the document and email back to the preparer. • The preparer receives a pdf file from each signatory indicating their approval. • Attach the signatory page from each approver to the original, hardcopy with the preparer's hardcopy signature. • Indicate on the front page the number of attached signature pages. • File all the pdf files in the same storage folder as per the company policy for electronic versions.
Access to pdf and MS Word versions	Generally, pdf versions of documentation can be accessed by staff because they are not able to be changed (without specific software). However, MS Word files (or equivalent software) can be changed and so should have limited access for most staff (unless other security functions are enabled).

Communication styles used in GDP

The following table contains suggestions for communication styles useful for GDP.

Actions	How they help
Using words that everyone can understand (reduce jargon or abbreviations)	Unfamiliar words reduce the reader's understanding of what is written. It can also interrupt their flow of learning if they need to search for the meaning of a word. Therefore, jargon or abbreviations should be avoided if possible, unless well known to the audience. Definitions of jargon or abbreviations should always be included in the document for reference. This is most effectively done by included the definitions in a table format, at the start or end of the document. There is often company-specific jargon that develops within a company or on a site that may be very confusing to outsiders or new staff – prepare a list of these terms that is easily accessible and include within the induction procedure and for audit situations.
Using words with unambiguous meaning	The English language is full of descriptive words which can have different meanings depending on the context, the understanding of the reader and even cultural differences. For this reason, words should be chosen very carefully.
Using whitespace	Ensure that the contents of the document are not squeezed into a smaller area just to limit page numbers. Documents with small margins and no spaces between paragraphs and headings can be difficult to look at, hard and slower to read. Space the contents out so that the type/font is easy to read for all users (consider the overall audience age, or potential colour blindness or dyslexia).
Providing enough detail to make sense of it in the future	When creating a document, consider the context in which the document may be used in the future and whether the reader has enough background information. However, too much non-critical information can also detract from the document and make it too wordy.
Using pictorial or graphical aids (including tables)	Many people remember information best when there is a strong visual prompt, such as a diagram. When the document has to be wordy, consider using tables to structure the information so it is less overwhelming to the reader.

Actions	How they help
Previous experience and expectations	The level of detail, written style and type of document should all be ruled by the documents target audience.
Consistent wording to avoid confusion	Referring to something by two different names, even if only slightly different, can be confusing.
Consistent styles templates	Consistency with styles will give any document a greater sense of professionalism.

Sources

Links used within this document are prone to change. Please refer to the appropriate source for the most recent information. We endeavour to keep an up-to-date record of information at www.pharmout.net

PharmOut is an international GMP consultancy serving the Pharmaceutical, Medical Device and Veterinary industries. PharmOut specialises in PIC/S, WHO, United States FDA, European EMA, and Australian TGA GMP consulting, engineering, project management, training, validation, continuous improvement and regulatory services.

Our team includes international GMP experts who have previously held leadership roles within regulatory bodies.

For more information please visit www.pharmout.net or contact us at info@pharmout.net.

PharmOut Pty Ltd, ABN: 85 117 673 766, Unit 10, 24 Lakeside Drive, Burwood East, Victoria 3151.
Ph: +61 3 9887 6412, Fax: +61 3 8610 0169, Email: info@pharmout.net Web: www.pharmout.net