The Evaluation of the Good Documentation Practice Error Using the WHO's ALCOA Principles

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***Abstract*—This study discusses the problems faced at the company about good documentation practice errors; this is due to the absence of work instructions to double-check the documentation carried out. This study aims to reduce good documentation practice errors in plasma production areas by evaluating the implementation. The methods used in this study are interviews, surveys, and evaluations using Garret Rank methods. The study concludes that the rank factor causing documentation error in the first rank is the correction factor, the second rank is the legibility factor, the third is the wrong information factor, and the fourth is the incomplete factor.**

***Keywords*—good documentation practice; error; garret rank; ALCOA**

I. INTRODUCTION

Good Documentation Practice (GDP or GDocP) is a systematic procedure for receiving, reviewing, approving, dispensing, recording, storing, and filing documents—all to deliver safe and effective drugs and medical devices (Egnyte, 2022). This research location is in a company that produces contact lenses and eye surgery tools, namely PTC. The company has used a documentation system to make contact lenses according to GDP standards by providing clear and accurate product information. The World Health Organization (WHO) states that all medical device manufacturers should implement the ALCOA principle in their GDP. ALCOA stands for Attributable, Legible, Contemporary, Original, and Accurate. These basic ALCOA principles and the related GDP outlook that ensure data reliability are not new, and much high- and mid-level normative guidance exists (World Health Organization, 2016).

Therefore, every PTC employee is given an understanding of ALCOA+ and DI to carry out the documentation process based on the established GDP principles. PTC sets writing standards to make the data accurate and that there are no misinterpretations when reading product information. The running product information can be written on the DHR (Data History Record). DHR is a collection of data from the initial process of making soft lenses to the final process. Consumers can know this data to provide detailed and accurate information without any corrections during the documentation process. The correction can affect consumer confidence in the company's products. The company classifies the correction made by the operator as a form of GDP error. In the plasma area, GDP errors can cause the status of an active product to change to hold or be delayed. This hold status requires a lengthy repair time to return the material status to be active again. Basically, the factors causing the GDP error can be reduced or even eliminated. This study will evaluate the GDP error and analyze solutions that can be implemented to increase GDP in the Plasma area.

GDP is an effort to ensure products are of good quality and easily traceable (Kasoju & Ye, 2021). Documentation is left behind in a company or organization after a product is released or sold to the general public. Hence, the most important thing is the completeness of accurate and correct documentation. Based on this, it can be concluded that documentation related to products in organizations or companies needs to be stored using the GDP method. Guenther et al. (2015) explain several things that must be considered in the GDP method so that documents can be archived properly as follows:

a. Practice documentation clearly
   The process of documenting practice uses tools that produce firm and clear documents. If the document is a hard file, use ink that does not fade easily and quality paper. As for documents stored in soft files, they must be arranged in neat folders.
b. Documentation practice is done in a readable manner
   If documentation is done using a pencil or pen, the written results must be easy to read. Correcting documents using correction fluid or crossing the wrong part by drawing a line is prohibited.
c. Documentation practices produce documents that are easily searchable
   Documentation related to important activities or matters must be dated, marked, and signed. The original document must be signed and dated if there is an error.
d. Documentation practices produce detailed documents.

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The information contained in a document must be complete by writing down details. If there is a calculation, it can be written in full, starting from statements, questions, and answers.

Several causes of GDP error, according to Taschner (2020), are as follows: a) documentation is not compiled based on a certain period; b) error corrections in documents are not signed or dated and are not accompanied by reasons for the corrections made; c) too many uses of correction fluid or other camouflaging tools; d) error using ink, this is caused by ink not in accordance with the procedure so that the data is not readable; e) records are inaccurate and the information written differs from the original data; and f) data in the form of tables, charts, or other audit trails are not well documented.

II. RESEARCH METHOD

The data collection method is a statement about the nature, activities, and circumstances. Data is collected to obtain information needed to achieve research objectives (Haliza & Sumarna, 2023). This study uses primary data to compile comprehensive information using the survey to fill the rank of each element of GDP and interview (Sumarna, 2022). Collecting data in evaluating opportunities to improve GDP uses two stages of the method: interviews and evaluation. In the first stage, interviews are questions and answers orally directly to obtain first-hand (primary) data; the question items are:

- Is the role of GDP very important in the manufacturing area;
- What causes on-hold GDP;
- What will have an impact if there is an on-hold GDP;
- How to implement GDP in the Documentation process;
- After implementing a double check on each documentation, is the trend on hold of GDP still high;
- Who has the right to apply the GDP principle in the work area;
- Why does employee documentation have to use permanent ink;
- If there is on hold GDP and the employee doing the documentation is absent, who is the person entitled to make corrections to the GDP;
- Why is a reviewer needed in a document.

The second stage is the evaluation stage which uses the Garret Rank to calculates percentages to determine the ranking of several types of factors Rajasekaran & Thirumagal (2022). The GDP factor will then be ranked by respondents based on the frequency of events that often occur resulting in a GDP error. The formula below is for determining the Garret Rank. Rij are the rangking given by respondents and Nj are the factors based on the rangking from respondents. All stages in this study are summarized in the study framework in fig. 1 below.

$$\text{Percent Position} = (100\ (Rij - 0.5))/\ Nj \qquad (1)$$

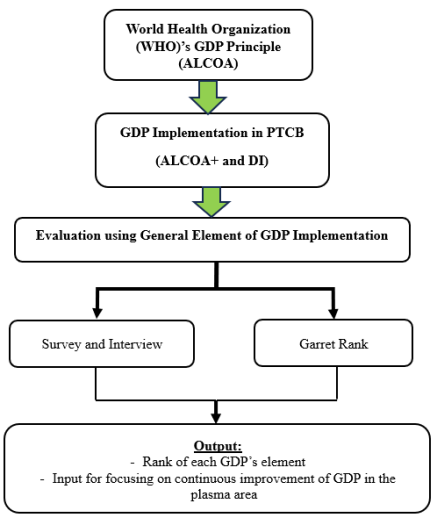

Fig. 1. Study Framework

III. RESULT AND DISCUSSION

The aim of the implementation of GDP is to obtain a solid judgment, the supporting data set must be credible and comprehensive. GDocP should be followed to ensure all paper and electronic records, enable the full traceability of GDP activities. The evaluation of what factors often cause errors to occur in the manufacturing area. Data processing was carried out by collecting votes for twenty respondents consisting of seventeen operators and three-line leaders. The respondents filled in the ranking according to the situation in the field regarding the factors that most often occur as the cause of errors. Following are the survey results obtained from GDP error.

TABLE 1. DATA OF RESPONDENTS

No.	Factors	Ranks given by respondents			
		1	*2*	*3*	*4*
1	Correction	7	11	2	0
2	Imcomplete	1	3	8	8
3	Legibility	6	4	5	5
4	Wrong information	6	2	5	7
	Total respondents	20	20	20	20

Based on Table 1 above, the authors can explain that rank 1 on the correction factor is obtained from the number of respondents' responses. From 20 respondents there were 7 respondents who agreed to choose the correction factor to rank 1 as the GDP error factor that often occurs. For rank 2 on the correction factor, there are 11 respondents who agree that the correction factor is second rank as the cause of the GDP error. This applies to the 4th factor. Rank 1 on the incomplete factor obtained from the number of respondents' responses. From 20 respondents, there was 1 respondent who agreed to choose the incomplete factor to be ranked 1 as the GDP error factor that often occurs. For rank 2 on incomplete factors, 3 respondents agree that incomplete factors are ranked 2nd as the cause of GDP errors. This applies to the 4th factor. Likewise, the explanation of the ranking of the legibility factor and misinformation also applies to the explanation of the correction and incomplete factors.

TABLE 2. GARRET VALUE FROM RANKS

No.	100(Rij-0.5)/Nj	Calculate Value	Garret Value
1	100(1-0.5)/4	12.5	73
2	100(2-0.5)/4	37.5	56
3	100(3-0.5)/4	62.5	44
4	100(4-0.5)/4	87.5	27

Based on Table 2 above, it can be explained that the table is a conversion process from ranking 1-4 to get the value of the Garret rank. Then, the value of each ranking above can be processed into the following table. Based on Table 3 below, it can be explained that the ranking correction factor 1 is obtained from the calculation of ranking one from the correction factor (in Table 1) multiplied by the garret value number 1 (in Table 2). Next, for rankings 2 to 4, follow the formula calculated for ranking 1. After incomplete ranking, factor 1 is obtained from calculating ranking one on incomplete factors (in Table 1) multiplied by Garrett value number 1 (in Table 2). Furthermore, for rankings 2 to 4, follow the formula calculated for ranking 1. For the legibility factor, ranking 1 is obtained from ranking 1 on the legibility factor (in table 1) multiplied by Garret value number 1 (in table 2). Furthermore, for rankings 2 to 4, follow the formula calculated for ranking 1. For the misinformation factor, ranking one is obtained from the calculation results for ranking one on the misinformation factor (in Table 1) multiplied by the Garrett value number 1 (in Table 2). Furthermore, for rankings 2 to 4, follow the formula calculated for ranking 1. After the multiplication results of the four rankings for each factor are obtained, they can be added and written in the total column. The total can be divided by 20 (total respondents) to find out the average value.

TABLE 3. DATA PROCESSING OF GARRET RANKS

No.	Factors	Ranks given by respondents				Total	Average
		1	2	3	4		
1	Correction	511	616	88	0	1215	60.8
2	Incomplete	73	168	352	216	809	40.5
3	Legibility	438	224	220	135	1017	50.9
4	Wrong information	438	112	220	189	959	48

From Table 3 above, the total and average values of each GDP error factor can be obtained. After the author gets the results of processing the data on the garret rank, it can be seen that rankings 1 to 4 are based on the average values contained in Table 4. The highest average values of the incident factors explain that these factors are ranked 1. The smallest average of the above factors is the last rank (rank 4). So of the four factors, if sorted, the first rank is the correction factor, the second-ranking is the legibility factor, the third is the wrong information factor, and the fourth is the imcomplete factor. The author can sort these rankings based on the average.

From the interview section, get some findings to the types of GDP errors that occur in the production section are as follows:

a. Correction, namely error factors such as errors that occur when correcting data and correcting the data is wrong, it is called the type of GDP error correction.

b. Legibility is an error factor that occurs due to writing of data that is not clear and cannot be read by other people, this can occur due to bad writing tools.
c. The wrong information is an error in input data that is wrong in doing documentation. This can happen because the personnel does not read the headings in each column on the form, so they only do work based on habit or memory.
d. Incomplete, namely the error factor, because incomplete data is filled in by the operator or employee who documents the form.

Based on WHO principles (World Health Organization, 2016), health and medical device manufacturers should follow GDocP to adjust risks to the precision, comprehensiveness, consistency, and reliability of the data during their entire period of function–throughout the data life cycle. Employees have to follow GDP to ensure data integrity. The WHO's ALCOA principle requires that documentation be attributable, legible, contemporaneously recorded, original, and accurate. These significant characteristics are used together in both paper and electronic records. The "attributable" principles refer to information captured in the record so that it is specifically identified as the data source. The "legible, traceable, and permanent" principles refer to the need for readable and understandable data that gives a clear view of the sequencing of steps or events. The record in GDocP activities can be completely reconstructed by the person analyzing these records at any time through the records retention period. The "contemporaneous" data refers to data recorded when produced or observed. The "original" data refers to the first or source capture of information and all following data that must be fully reconstructed in the GDP activity. The requirements of original data in GDP are:

- Original data should be reviewed;
- Original data are valid, and checked copies should be retained;
- Original data records should be comprehensive, timeless, quickly retrievable, and readable during retention.

The last one is the "accurate" principle, which means data or information is correct, upright, complete, valid/ authentic, and credible in PTC's plasma production area using the paper record method. We will discuss specifically each ALCOA principle that PTC can implement.

A. Attribution
The "attribution" of activity can be implemented using initials, full handwritten signature, personal seal, date, and (if needed) time. A risk management consideration for attribution on GDP is using a personal seal to sign documents. It obliges additional risk management controls, such as handwritten dates and procedures, that require storage of the seal in a safe location with limited access only to the allowed individual.

B. Legible, traceable, permanent
The legible, traceable, and permanent principle controls that can be aptoed for paper records include (but are not limited) to:
- Use permanent or indelible ink;
- No use of pencil or deletion;
- Use of single-line cross-outs to record changes with name, date, and reason recorded;
- No use of dark correction fluid or otherwise blur the record;
- Controlled release of bound, paginated notebooks with sequentially numbered pages (for example, X to Y style page);
- Controlled release of sequentially numbered copies of blank forms;
- The paper records filed by exempt and controll paper archives;
- Keeping of paper/ink that fades over time.

C. Contemporaneous
Contemporaneous principle applied in paper records through use of:
- Written procedures, training, review, audit and self-inspection controls. The aim is to make sure that worker records data entries at the time of the activity directly in official controlled documents;
- Procedures need activities that record the date of the activity and time in paper document as well if it is a time-sensitive term;
- Good document design. The aim is to encourages good practice. The documents should be perfectly designed and the give availability of blank forms in document;
- Recording of the date and time of activities using synchronized time sources (such as using facility and computerized system clocks) which cannot be changed by unauthorized worker. If possible, data and time recording in manual activities (for example counting) should be done automatically.

D. Original
The company or organization may decide a fully electronic approach to consent more efficient of the record review and storage. Controls for review of original paper records can be implemented in:
- Written procedures, training, review, audit and self-inspection controls to ensure that worker conduct an suffice review and approval on original paper records;

- For written review procedures require worker to evaluate changes made into original information on paper records (such as changes documented in cross-out or data correction). So we ensure these changes are properly documented, justified with valid evidence and can be investigated (when is required).
- Signatures to ensure that worker understand their responsibility as reviewers or approvers;
- A procedure describing the actions must be taken if data review notice an error or omission. This procedure should provide data corrections or clarifications;
- Compliant attitude which can provide visibility of the original record and audit-trailed traceability from the correction.

Controls for storage of original paper records or true copies of original paper records such as:

- Controlled and secure storage areas, including paper record archives;
- Make a position for a paper archivist(s) who is independent in GDP operations;
- Indexing of records to permission ready retrieval;
- Periodic tests to verify the ability to retrieve archived paper records;
- The provision of suitable reader equipment when required, such as microfiche or microfilm readers if original paper records are copied as true copies to microfilm or microfiche for archiving;
- Written procedures, review and audit, and self-inspection of processes defining conversion of an original paper record to true copy should include the following steps:
  - A copy/copies is/are made of the original paper record(s), preserving the original record format, the static format, as required, for example photocopy and scan.
  - The copy/copies need to be compared with the original record(s) to determine if the copy preserves the entire content and meaning of the original record and no data are missing in the copy.
- The verifier documents the verification in a manner securely linked to the copy/copies, indicating it is a true copy.

Concern should be providedd in continuity of the entire the original hand-signed paper records. In particular when the handwritten signature is an important essential the whole integrity and plausibility of the record.

E. Accurate

Managing the accuracy of data in paper records can be implemented regularly in:

- Validation of analytical methods;
- Validation of production processes regularly; and
- Review of GDP records.

IV. CONCLUSION

In PTC, the GDP errors happen for some factors: the first rank is correction, the second rank is legibility, the third rank is wrong information, and the last rank (fourth) is incomplete. To meet the requirements of GDP, processes, and procedures must be put in place and monitored. Training users on the importance of GDP and how to follow it is also essential. Electronic documentation systems can help to streamline the document management process, facilitate more accessible information sharing between each division, provide real-time data access, and minimize the risk of errors. Ensuring compliance with the implementation of GDP requires a comprehensive rapprochement to document and commitment to continuous improvemee of the best practices for ensuring this compliance include conducting regular audits, maintaining good communication, implementing electronic documentation systems, providing training, and establishing a document review process.

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