IMPLEMENTATION OF THE GOOD DOCUMENTATION PRACTICE IN MANUFACTURING AREA

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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 adding work instructions, namely, double-checking each documentation. The methods used in this study are observational research methods and documentation. The study concludes that the company already has SOPs for good documentation practice and has followed them in accordance with the standards that have been written.

Keywords: *good documentation practice, errors*

INTRODUCTION

Good Documentation Practice (GdocP or GDP), also known as Good Record Keeping Practice (GRK), is a set of internationally accepted guidelines that ensure the correctness, integrity, and correctness of data collected during the research, development, manufacture, and testing of pharmaceuticals and medical devices (Egnyte, 2022). PTCB is one of the global companies dedicated to advancing eye care through research and innovation and is engaged in the medical device sector. The GDP system plays a big role in companies, especially when documenting products. The World Health Organization (WHO) states that the GDP principle ALCOA stands for Attributable, Legible, Contemporary, Original, and Accurate (World Health Organization, 2016). The GDP principles applied in PTCB are ALCOA+ and DI. The + sign is Consistent, Enduring, Complete, and Available, while DI stands for Data Integrity.

Until now, corrections are still found in scribbles to correct errors when the operator is carrying out the documentation process. GDP error is a form of error when writing

ISSN: 2303 – 2790
Bengkalis, 27 September 2023

documentation data. In each area of the company production process, the GDP error greatly impacts the ongoing cycle time (product completion time). If there is an additional throughput time, of course, it can have an impact on the cost and output produced. There are several factors for the occurrence of GDP errors, namely the use of non-standard writing instruments (resulting in writing being overwritten), carrying out documentation without reading the headings in the columns (resulting in data that does not match the column headings) and not double-checking the documentation.

It is expected to reduce throughput time losses resulting from GDP errors by evaluating GDP. The formulation of the problem used in this study is applied to problem-solve as described in the background, namely: how to evaluate the GDP error in the Plasma production area, and what solutions can be implemented to increase GDP in the Plasma area. The aims and objectives of conducting this research are as follows: evaluating GDP errors in the documentation process in the Plasma area.

A good documentation process consists of a stable system for further review of documents using clear identification of changes and revisions made, availability and distribution of documents as needed, readable and easily identifiable, preventing unwanted things and properly archiving previous documentsGDP can keep documents safely stored physically or electronically and avoid loss of documents due to human negligence, nature, and problems with the devices used. In the document filing process, the GDP method uses the principles of complete, accurate, original, sustainable, durable, easily accessible, concise, easy to read, easy to track, and easy to control

In good documentation practices, usually, there are still some errors in document writing. These errors can be interpreted as GDP errors. It is an error that occurs when the document writing process is carried out. The occurrence of a GDP error causes the cycle time or the time the product is completed to be delayed. If the GDP error occurs, it is necessary to have a throughput time which causes problems in cost and output. GDP errors can make products that are being processed hampered, and initially, the product status is in an active process being held or delayed. The hold status in product production requires quite a long time to return the status of the material to be active

ISSN: 2303 – 2790
Bengkalis, 27 September 2023

again. Thus, the author can explain GDP requirements based on general elements (Bhattacharya, 2014) such as the following table.

Table 1.

General Provisions for Implementation GDP

General Element	GDP Requirements
Clearly Written Documentation	All documents must be accurate and written clearly with the aim of preventing errors in writing the contents of the document. Identify two or more documents and records using document numbers or record identification.
Using permanent ink	The entire history of the record must be filled in with permanent ink so that the writing can be seen in the long term. Don't use pencils or ink that can be easily erased. Color must be determined by the GDP procedures of a company; like blue or black ink. Because the history of copy/scanning technology is limited to production quality. The consistent use of blue and black ink on GMP documentation provides a more professional perception of the company.
Legible Handwritten Entries	A document cannot be used if the writing is unclear or even unreadable, therefore it must be ensured that the handwriting is legible. All entries must be made at the time of documentation and must be signed and dated. The same goes for electronic documents and records, the language must be clear and unambiguous.
Reviewing and approving	Documents and records should be reviewed by someone who did not do the paperwork to ensure that the information is true and accurate. A signature and date by the reviewer/approval are required for the purpose of confirming that the review process has been carried out. Documents or records that are not completely signed may not be used in any work or be considered evidence of work that has not been completed.
Signed Delegation of Responsibility	If a member of staff is temporarily absent, they should delegate responsibility to an employee who is qualified to provide the signature. The terms of a delegation are procedural in documents (Standard Operational Procedure, Work Instruction), or documented with the names of everyone involved and signed by the person who delegated their responsibilities. The delegation must also be approved with the signature of a more senior member of the staff.
Staff Signatures	The handwritten signature must be unique to the individual. Staff are not

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Bengkalis, 27 September 2023

	allowed to sign other staff members except delegated and signatures cannot be forged.
Page Numbering	GDP's documents should have page numbers using "X to Y" format to indicate the total number of pages in a document.

Throughput time is defined as the amount of time spent in the production process of each product. Processes included in the throughput time category are time spent continuously or actively as well as free time or waiting time during the production process. Suthar & Deshpande (2014) This throughput time can occur based on competition in the market or errors in GDP correction. Taschner & Charifzadeh (2020) explained that the lower the throughput time, the more efficient the production time of a product. This is because the same output (product) can be produced with less input (time). Throughput time consists of two parts which include productive time and unproductive time. This includes processing time (turning raw materials into finished goods), inspection time (checking raw materials as they are processed into finished goods), movement time (moving goods from one department to another and entering and leaving the manufacturing area), and queuing time (waiting for processing, inspection, and moving). Thoughtput time can be measured by measuring time using several stages first. Buer et al. (2019) said that when a company wants to perform calculations using this method, the data that must be prepared include defined system boundaries and use the ingredients list to calculate the longest value stream. The first step taken to calculate the throughput time is to determine the boundaries of the system in which the throughput time must be measured. The determination of this system limit depends on the available data or documents. In order to perform this calculation, data is needed regarding input and output levels as well as Work-In-Process (WIP) levels. Second step, if a product within a company consists of assembled components it must be matched to the WIP based on the individual contribution of the components. The WIP of each component must be changed and adjusted according to the amount of the final product.

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RESEARCH METHOD

The research object is the target to be achieved in order to get a solution to the problems that occur because the research object is something that is of concern in research. The object of this study is to obtain data in a more focused manner, which explains the idea in a scientific way with certain goals, and valid, and reliable variables. (Haliza & Sumarna, 2023). This study using primary data that will compile comprehensive information. Primary data collected use observation (Sumarna, 2022). The object of study is the document/data related to GDP implementation.

Collecting data in evaluating opportunities to improve GDP in the Plasma production area uses two stages of the method, namely observation and documentation. The first stage is observation which is a data collection method that is carried out by observing directly what has happened so that the data needed at the research site can be retrieved. The observation stage is carried out when observing work situations and problems faced by the company to be used as a problem formulation at the beginning of the research. Observation results are also used to describe GDP practices that occur in the plasma production area which will be outlined in the discussion. The second stage, documentation is the collection of data that can be seen directly from the sources of documents related to research.

RESULT AND DISCUSSION

GDP helps to ensure that all processes are traceable and also consistent that the finished product is of the highest quality level and meets all regulatory requirements. According to Bhattacharya (2014), the common elements in the implementation of GDP consist of several factors, namely documentation that is written clearly, using permanent ink, handwritten entries that can be read, reviewed, and authorized, signed delegation of responsibilities, page number and staff signature. In the discussion below, GDP practices based on the above elements will be explained in the plasma production area. The practice of implementing GDP is produced by interview and observation methods. The following wil be discuss based on general elements of GDP:

a. Clearly written documentation

ISSN: 2303 – 2790
Bengkalis, 27 September 2023

In the plasma production area, there is an MSFF (Material Shop Floor Form) document. This document is used for the production section of the plasma area. Documents will be filled out by plasma personnel who have their respective qualifications because some forms can only be filled in by qualified personnel in certain zones in the plasma area. This document is made by qualified personnel in zone B, namely the Cassette unloading section, after carrying out the documentation, this form is given to the line leader for confirmation. This form can be done by any plasma personnel, and form can be filled in after completing the line clearance. The data that is filled in such as date, shift, start time, name, and employee ID. The following columns will be filled in by documentation personnel to complete all documents after one PO has been completed in the plasma area. In carrying out documentation, personnel must write down any data or information clearly and can be read by others. This form is completed by the document personnel and will be submitted to the line leader, then after the line leader checks the entire documentation it will be submitted to the data entry personnel to carry out the key in the data process on the computer.

b. Using permanent ink

In carrying out documentation on each form, it is mandatory to use permanent ink and as for the colors that have been determined, namely blue and black ink and liquid ink is not permitted because liquid ink fades more easily on paper, and pencil is not permitted because it is easily erased and data is easily replaced. These provisions are made so that documents can be stored properly and data can still be read until the retention time specified in these forms.

c. Legible handwritten entries

Every employee who performs documentation must write down each word/number clearly according to the writing standards set by the company. This is done so that people who read are not mistaken in interpreting each document.

d. Reviewing and approving

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Bengkalis, 27 September 2023

Documents must be signed by the person doing the job, not allowed to sign someone else's work. And some documentation is required for confirmation by the line leader, and there are documents that require approval from the process head.

e. Signed delegation of responsibility

If an error or incomplete data is found in the document and the operator performing the work cannot be present on that day, only the process head can make corrections to the document which will later be given information that the document on behalf of the operator was carried out by the process head.

f. Staff signatures

As a control in each document requires a minimum of two authorizations from different divisions.

g. Page numbering

Each page of the document already uses the "X to Y" format page numbering. So that it can track if there are incomplete or missing document sheets.

Key components to implementing GDP system are SOPs, batch records, change control procedures, and document control. Following GDP helps individual organizations and the industry establish consistent practices that reduce misinterpretations, minimize miscommunication, and improve product quality.

CONCLUSION

Based on the discussion that has been described by the author, it is concluded that the company already has the implementation of Good Documentation Practice (GDP) and is implemented in every job/activity in the company. However, there are still some GDP errors found in the production area, especially the plasma area, therefore the authors provide a solution to reduce GDP errors. The suggestion is that in doing work related to documentation, it is better to double-check after doing the documentation. This will be used as work instructions in the production area, thus in the future it is expected that GDP errors will be found in the documentation less and less. Thus creating good and correct documentation and increasing consumer confidence in the products to be sold and reducing the throughput time in processing products.

ISSN: 2303 – 2790
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ISSN: 2303 – 2790
Bengkalis, 27 September 2023