Standard Operating Procedure

Title: Good Documentation Practice

Department	**Quality Management**		**Document no**	**QMS-165**	
Title: Good Documentation Practice					
Prepared by:		Date:		Supersedes:	
Checked by:		Date:		Date Issued:	
Approved by:		Date:		Review Date:	

1.0 DOCUMENT OWNER

Technical/Quality Manager

2.0 PURPOSE

Good documentation constitutes an essential part of any quality system. Clearly written documentation prevents errors from spoken communication and permits tracing of batch history.

The purpose of this SOP is to provide guidelines and establish rules for documentation practices at the GMP site.

3.0 SCOPE

This procedure applies to all documents within the GMP facility relating to the manufacturing, processing, packaging, storing, testing and controlling of pharmaceutical products, components and raw materials. This includes documentation relating to equipment and validation.

4.0 RESPONSIBILITY \ BUSINESS RULES

4.1 Responsibilities

It is the responsibility of the site quality team to ensure that the requirements of this SOP are followed.

It is the responsibility of all Department Managers / Designees to train employees on this procedure and monitor compliance during the review and verification of documents.

It is the responsibility of each staff member to follow the requirements of this SOP.

4.2 Training

Before carrying out this procedure, operators must have successfully completed GMP Training modules such as “Introduction to GMP” and “Documentation and Record Keeping” where available.

Operators will be trained by a trained person in this Standard Operating Procedure (SOP) and this is to be documented in the Staff Training Records. The trainer will demonstrate the procedure involved in undertaking tasks associated with this SOP. This may involve several interactive demonstrations between trainer and trainee.

Retraining in this SOP is required at least every 3 years unless this SOP is updated to a new edition.

5.0 PROCEDURE

5.1 General Requirements

5.1.1 All handwritten entries are in black or blue permanent ink. Felt tip pens, fountain pens, pencils, etc., are NOT permitted.

iii. **D-M-YY**, e.g. 02 March, 2022 = 2-3-22

iv. **D/M/YY**, e.g. 02 March, 2022 = 2/3/22

v. **DD/MMM/YYYY**, e.g. 02 March, 2022 = 02 MAR 2022

vi. **DD/MMM/YY,** e.g. 02 March, 2022 = 02 MAR 22

5.3.2 The time format may be either of the following:

- AM/PM, e.g. 8:00AM

- 24-Hour clock, e.g. 0800 for 8:00AM or 2000 for 8:00PM.

Note: Same time format should be used within a document.

5.3.3 When recording time, do not use fractions. For example, 30 minutes or 0.5 hours instead of ½ hour.

5.4 **Initials**

5.4.1 Use initials and signatures consistently on all cGMP documentation. Always use the initials and signatures you provided on the Signature and Initial list.

5.4.2 Signature (or initials) on cGMP documentation indicates who performed or approved the information in the step and/or document.

5.5 **Handling Blank Spaces**

5.5.1 As a general rule, blank spaces are not permitted on completed documents. If an entry does not have to be made in a specific instance on a document, use the notation “N/A” meaning (Not Applicable).

Note: N/A refers to “Not Applicable”. No other acronyms should be used unless explained. “Not Available” or other notations should be fully spelled out.

5.5.2 If an entry space does not have a data entry because it is for start-up or end of production, then a phrase “Start Up” or “End of Production” or similar phrase, is used.

5.5.3 If a table or most of a table is left blank, include a single diagonal line across the blank part of the table (from bottom left to top right or from top left to bottom right); write N/A and initial and date.

5.5.4 If a narrow cell in the table is left blank, putting N/A in the cell is enough there is no need to sign and date due to space constraint.

5.5.5 If instructions are given to skip a step, or portion of a step, line through that portion, initial and date. No explanation is necessary, because the explanation is supplied within the documentation instructions.

5.5.6 All written comments must be dated and initialled.

5.6 **Data Entry**

5.6.1 Only record data directly onto the official document.

It should be apparent that the entry was made after the fact. If there is an original source for the data, a notation should be added as an explanation.

5.8.9 If a correction is made to a record after its approval then a re-approval is required.

Example: Correction made on a shop order after approval of Expiry date from QA.

5.9 **Use of Printouts and Other Additional Documents**

5.9.1 All pertinent printouts are included in the official documents, i.e. scale / balance printouts, temperature charts, etc.

5.9.2 All printouts are signed / initial and dated, contain the ID number of the instrument, location of the instrument, if portable, and lot number and product name or product code associated with the printout.

5.10 **Use of Copies**

5.10.1 Only use an original to make copies. DO NOT make copies from a copy.

5.10.2 Copies of Standard Operating Procedures are provided by the Document Control Officer.

5.10.3 Copies of batch record documentation, e.g. Manufacturing Instruction and Packaging Shop Order etc., are issued by the Planning Department using the “Batch Document Management System”.

Manufacturing Instruction and Packaging Shop Order must be authorised by Manufacturing Compliance, Production and Quality Assurance.

- If additional copies are needed, the Planning Department will reissue the document(s) needed.

- The original issued document must be kept with the batch documentation with appropriate annotations provided. The reason for the re-issuance must be given.

