



Good Documentation Practices PharmSystem Technologies

Keywords: batch record, documentation errors, corrections.

Section C.02.011 Manufacturing Control of Food and Drug Regulations states as follows: “Each batch processed is effectively governed by individually numbered manufacturing order prepared by qualified personnel from the master formula by such means as to prevent errors in copying or calculation and verified by qualified personnel”. A pharmaceutical company has to comply with GMP and provide adequate proofs to regulatory bodies and customers that demonstrate a state of control of the manufacturing process and comply with the BPRs and written procedures during all activities related to the manufacturing of the products. All documents are considered as legal binding evidence of compliance with GMP. In practice this means if you did not write it down, you did not do it and also you did do what you wrote down.

Usually the common documentation errors included:

- Missing initials and dates.
- Missing signature and dates at the time the activity is performed.
- The “write over” and the “scribbler”.
- Data entries that do not correspond to the batch record instructions.
- Writing a note that activity was performed on one day and signed for on other day.
- Training not documented as required in SOP.
- Blanks on batch production records.
- Pre-recording of data.
- Incomplete references.
- Review not signed.
- Document not completed in all sections.
- Adding data and correcting entry of another person.
- Illegible writing.
- Too many corrections.

If data entries are missing or incorrect we cannot determine what occurred that may have led to a quality issue with a product. This could lead to reject a batch or not be able to prevent the problem from happening again. If the product is released this could put patient at risk and result in an expensive recall of the product. Data should be entered at the time the activity is performed. If you delay entering data you may forget to enter it at all or you may make an incorrect entry from memory.

Data must be entered clearly and legibly. All entries should be dated and signed by the person making entry. It is the responsibility of that person who completed a critical step, to ensure the entry is verified by another person. Corrections should be done by the person who made the original entry at the time of the error. If it is impossible the person should inform the

appropriate people (Supervisor or QA) and make late entry. Transcriptions must be checked by a second person and kept with original crossed out data record or referencing it.

To prevent the documentation errors you should do as follows:

- Training.
- Well designed BPRs and worksheets.
- Restrict access.
- Policy SOP.
- Adequate resources.