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Can the author of a GMP document also act as its reviewer?

Ask our Experts

3 minutes reading time

Is there a normative source for the fact that the reviewer of a document cannot be the same person who prepared it?

Expert answer from a GMP inspector:

The "four-eyes principle" is an essential pillar of quality assurance in the GMP area. The necessity of a dual control principle for documents should be decided on the basis of risk considerations and is applied in particular to all documents required by regulatory authorities (e.g. manufacturing instructions/records or test instructions/records). In my opinion, all instructions and the corresponding records that serve to provide evidence of conformity with GMP requirements and the functioning of the QMS are subject to approval.

I would expect that a company-internal SOP or equivalent document would specify which documents are to be authorised at least according to the "four-eyes principle" or the "six-eyes principle" (author, reviewer, approver).

Although the EU GMP Guide does not contain any formal procedures for document authorisation that I am aware of, a number of references to the "four-eyes principle" and to review can be found:

EU GMP Guide, Chapter 4:

Principles: *"Suitable controls should be implemented to ensure the accuracy, integrity, availability and legibility of documents."*

4.2 *"Documents should be designed, prepared, reviewed, and distributed with care."*

4.21 c: *"Identification (initials) of the operator(s) who performed each significant step of the process and, where appropriate, the name of any person who checked these operations;"*

EU GMP Guide Annex 13, Article 33:

"The operation should be performed in accordance with GMP principles, specific and standard operating procedures and under contract, if applicable, and should be checked by a second person."

211.100 (a) des CFR FDA requires the involvement of the Quality Control Unit in the preparation of records:

"These written procedures, including any changes, shall be drafted, reviewed, and approved by the appropriate organizational units and reviewed and approved by the quality control unit."

Clause 4.2.3 of ISO 9001 regulates the control of documents and formulates clear requirements. According to DIN EN ISO 9000, a document is considered controlled if its life cycle is defined in all sub-steps (preparation, review, approval, distribution, withdrawal of old versions) and can be traced at any time.

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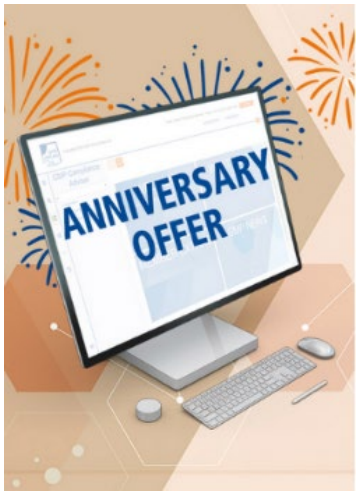

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