Quality – GDP (Good Documentation Practice) Rules

Your Objectives:

At the end of the lesson, you will be able to list, explain, put into practice, and follow all Good Documentation Practice rules.

Watch this video first: https://www.youtube.com/watch?v=55Oj5ghLC5o

Accurate documentation is an important _____ in the quality assurance system. All types of pertinent documents are fully specified in a manufacturer's quality management _____. Documentation may be completed in one of several formats: on paper-based, _____-based and/or photographic media, notwithstanding. The aim here is to control, monitor and _____ *all* activities in the established documentation system, whether these pertain directly or _____ to the quality aspects of a product. The quality management system should include sufficient _____ as is required/prescribed and should be sufficiently coherent to everyone involved. This serves to consider a satisfactory documentation of different _____ and _____ of observations and to be able to show a continuous application of given requirements.

Basically, there are two types of _____ : There are certain regulations (instructions, requirements) and there are protocols, or reports. Good documentation practice should be applied to the respective documentation type.

Appropriate controls like internal and [ ] auditing should also be introduced to ensure the availability, accuracy, [ ], and accuracy of the [ ]. Instructions on how to complete the documents should be error-free and should always be made available in writing, whereby the term "in writing" is intended to mean “recorded or documented in the media”. The ensuing completed documents should also be reproducible in a format that is human-readable.

Our own most common Good Documentation Practice rules are:

- If in doubt, ask!
    - Legible [ ]:
        - An illegible document is useless, so you need to be sure, in the case of a handwritten document, that the handwriting is legible. All entries must be entered the moment the work steps are carried out—clearly identified and dated. This, of course, also applies to [ ] documents, which must also be grammatically clear and unambiguous.
- Sign in black or blue and use indelible ink.
- Use the desired date and time format:
    - Use (DD)(MM)(YYYY) to avoid confusion between European and US date formats
    - Use military-standard time to avoid confusion between 12- / 24-hour time indications.
- Sign off only your performed steps with your initials and current date.
    - Use “N/A” in empty fields, to indicate that content was not forgotten &/ to [ ] any subsequent entries.
- Follow all rules for error correction:

- Strike through an [ ] with one line only and provide correction, include the date, your initials and, in most cases, the reason for your [ ];
- Do not obliterate errors (no erasing, blotting out, etc.);
- Use any error codes if/ where necessary.

- Page numbering Good Manufacturing Practices documents should be numbered using the following standard:
  - 'X' out of 'Z' for indicating the total number of pages within the document.

Good Documentation Practice Quiz:
https://quizizz.com/admin/quiz/5d259112a60254001a60e972/good-documentation-practice

Aufgabe Lückentext:

Folgende Wörter bitte in den Lückentext einfüllen.
Jedes Wort kommt einmal vor.
Bitte Gross- und Kleinbuchstaben beachten.

aspect, correction, detail, documentation, documents, electronically, electronic, external, evaluations, error, handwriting, indirectly, legibility, prevent, processes, record, system