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 <u>available</u> 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:

  o Strike through an [ ] with one line only and provide

    correction, include the date, your initials and, in most cases, the reason for your

    [ ] ;

  o Do not obliterate errors (no erasing, blotting out, etc.);

  o Use any error codes if/ where necessary.

- Page numbering Good Manufacturing Practices documents should be numbered using the following standard:

  o '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