If It Was not Documented, It Was Not Done

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Introduction

- Who Am I?
- What's in it for you?

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Presentation Aims/Outcomes

This presentation will provide you with the following knowledge:

- Why it is necessary to document everything?
- The differences between a well written and poorly written document.
- The impact of not following procedures.

An Apocryphal Story

At one time there were three monkeys locked in a room. This room also contained a banana, suspended by a cord from the ceiling in the centre of the room. Whenever one of the monkeys grabbed the banana, all the monkeys were subjected to an icy cold shower. After several repetitions of this shower, no monkey in the room would touch the banana.

One of the monkeys was removed and a new monkey added in his place. The new monkey saw the banana and moved towards it. The other two set upon him with violence, preventing him from getting the banana. The new monkey quickly learned that it was not permitted to touch the banana.

A second of the original monkeys was then removed, and a new monkey replaced him. The newest monkey attempted to get the banana, but the other two taught him the 'banana policy'. Soon he also knew the banana must not be touched. Finally the last of the original monkeys was removed and replaced with a new monkey, who was also taught the wisdom of avoiding the banana.

Now there is a fresh and tasty banana suspended from the ceiling of the room and three monkeys. None of these monkeys have ever been subjected to an icy cold shower, but all three will enthusiastically enforce the 'banana policy' event though none have any idea why it exists or if it is still useful.

- The moral being, make sure you know why you are doing what you are doing the way you are doing it and if you can see how to do it better, update the practice.

Why does everything need to be documented?

- In order to reproduce a previous experiment exactly, or to consistently test products or obtain samples in the same way in the future, a written procedure is needed. Person A and Person B following the same test procedure separated by 10 years, should both be able to follow a method in exactly the same way and get the same result without trying to figure out what, exactly is needed to be done.

The 3 rules of Good Documentation Practice (GDP)

The following 3 rules are attributed to the FDA and sum up most auditor's attitudes to documentation.

1. If it was not documented, it did not happen.
2. If it was documented, but poorly, it did not happen either.
3. Do not forget rules 1 and 2.
4. If what you did was dodgy and you did not document it , it did infact happen.

What makes a good document?

- A step by step document that contains everything and leaves nothing to chance.
- If you refer to ‘cheat notes’ while preparing or conducting a test, then arrange for the notes be placed into the document you are officially using.
- A good document should also be clear, as brief as practicable and leave nothing open to interpretation.

What makes a poor document?

- Non sequential – jumps all over the place
- Assumes too much
- Inconsistent formatting
- A document where 10 analysts would conduct 10 different tests with 10 different results.

The Impact of Not Following Procedures

- Difficult, if not impossible to retrace a process where not followed, or deviations not recorded. Akin to poor documentation.
- Cannot prove to a regulator or auditor that a task was correctly carried out
- Products could be declared adulterated resulting in a recall or worse

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Citations Resulting From Poor GDP

The following are audit observations known as FDA 483's (you do not want these if you make drugs for the USA):

- Batch production records do not include complete information relating to the production and control of each API batch.
- Method validation documentation did not include appropriate data to verify that the analytical method produced accurate and reliable results.
- Laboratory equipment calibration was not adequately documented.
- Unsubstantiated Claims
- Overstatement of Efficacy
- Misleading Risk Presentation
- Lack of Adequate Directions for Use
- Omission of Material Fact

Conclusion

You will now know the following:

- Why it is necessary to document everything?
- The differences between a well written and poorly written document
- The impact of not following procedures.

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References / Appendix

- FDANewsInfo070316 Documentation for Manufacturing and Control Records
- Further Reading:
  - "Eliminating the Gobbledygook" by Kathy Walsh
  - https://paulyeatman.net.au/index.php/2020/02/10/controlled-documentation-identifying-what-goes-into-a-policy-a-sop-and-an-oi/
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  - https://paulyeatman.net.au/index.php/2016/09/05/standard-operating-proceedure-vs-operator-instruction/