GOOD DOCUMENTATION PRACTICES

A QUICK GUIDE TO TIPS, TRICKS, AND COMMON PITFALLS

The use of Good Documentation Practices (GDP) is a a critical requirement for successful pharmaceutical or medical device development and approval .Yet GDPs are still being overlooked. Here are the most prevalent mistakes that continue to delay products to market.

NAVIGATING THE FUNDAMENTALS

Good Documentation Practices are essential to successfully bring therapies or medical devices to market. GDPs is the cornerstone to Good Manufacturing Practiecs (GMP) and ensures that regulatory compliance record requirements are met.

There are two fundamental rules to GDP recordkeeping:

1. If it's not signed and dated, it's not documented.
2. If it's not documented, it wasn't done.

While these two fundamental rules may appear simple at first, when applied, many companies still experience issues surrounding GDP. In this article, the following common pitfalls will be discussed in further detail.

- Time Date Stamps
- Significant Digits
- Corrections
- Blank Fields

NPG

TIME DATE STAMPS

Time date stamps are imperative to building an accurate record or timeline for a sequence of events when manufacturing your product. For this reason, time date stamps are one of many facets subject to scrutiny when executing any sort of official testing.

All protocols must be fully approved prior to the execution of any test activities. After the protocol is approved, all operators executing the protocol must have documented training. During execution, all steps are signed and dated at the time the work is completed. Results are recorded on the date work is performed using approved data sheets (not on scratch paper or sticky notes.) In addition, supporting documentation e.g., equipment records, sterilization reports, work order builds, etc. should be correctly filled out with time date stamps for all activities. All supporting documentation should then be attached to the report when the report is routed for approval.

Date formats are dependent on company guidelines, however, best practice default is a format that explicitly states the day, month, and full year:

DD-MMM-YYYY (ex: 14-DEC-2020).

Training Document

Doc #123-56-897	Rev. A	Pkg Validation & Stability Testing Protocol
Section	Instructor: John Smith *SIGNATURE*	Date: 22-DEC-2023, Duration: 30 mins

"I understood the material that was shown to me and its relation to my job."

Employee ID#	Name	Signature	Date
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SIGNIFICANT DIGITS

While the term “significant digits” or “sig figs” may seem like a blast from the past back to your high school chemistry days. Significant digits play a major role in GDP. The resolution for significant digits will be established within the protocol and also by the measuring equipment/system used to capture the data. Therefore, the lowest significant digit can dictate the resolution for the entire study. It’s also important to keep in mind that test equipment can have more resolution than needed and the report writer should be mindful of how many significant digits to report (for example, many Instron machines can report up to 4 significant digits for tensile strength). It should also be noted that it is best practice for inspection records and data to be recorded using decimals and not fractions.

Sample	Visual Inspection (Pass/Reject)	Tensile Result lbf/in	Sample	Visual Inspection (Pass/Reject)	Tensile Result lbf/in
1	Pass	2.2886	26	Pass	2.2897
2	Pass	2.3931	27	Pass	2.7651
3	Pass	3.5319	28	Pass	2.8951
4	Pass	2.7819	29	Reject	2.0347
5	Pass	2.2634	30	Pass	2.5619
6	Pass	2.7231	31	Pass	3.0127
7	Pass	2.4312	32	Reject	2.1124
8	Pass	2.5916	33	Pass	2.6713
9	Pass	2.3179	34	Pass	2.5432
10	Pass	2.2617	35	Pass	2.9876
11	Pass	2.9617	36	Pass	2.8643
12	Pass	3.4169	37	Pass	3.0319
13	Pass	2.7163	38	Pass	2.3393
14	Pass	3.0162	39	Pass	2.8234
15	Pass	3.9163	40	Pass	2.5362
16	Pass	2.9974	41	Pass	2.7836
17	Pass	2.7842	42	Pass	2.4166
18	Pass	2.4164	43	Pass	2.2719
19	Pass	2.5655	44	Pass	2.9876
20	Pass	3.0197	45	Pass	2.3332
21	Pass	2.6795	46	Pass	3.0096
22	Pass	2.8162	47	Pass	2.4732
23	Pass	3.4165	48	Pass	3.8791
24	Pass	2.3493	49	Pass	3.0997
25	Reject	2.1797	50	Pass	2.4079

CORRECTIONS

It’s natural for mistakes to happen. Corrections ton documents must be performed in a specific format per GDP.

- Fully cross out entire incorrect entries using the CLIDE method:
- CLIDE (Correct, [single] Line, Initial, Date, Explain)

~~22 °C~~ 24 °C Joe Bloggs 23/10/2015

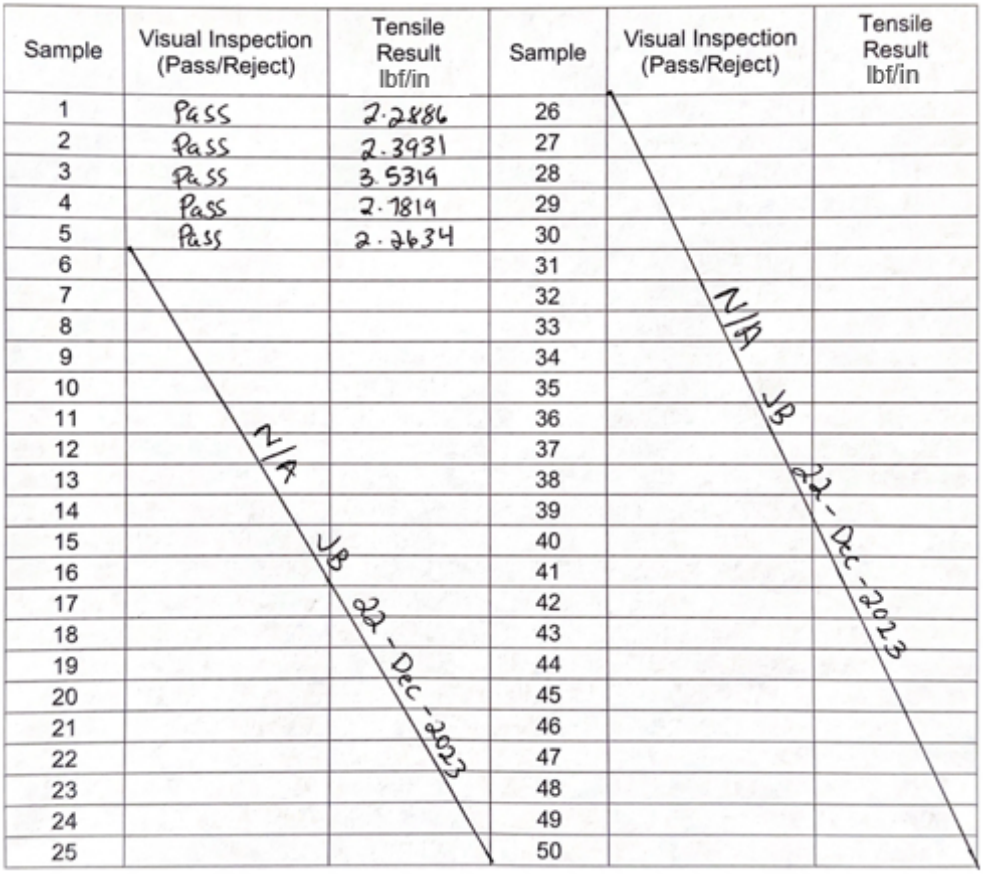
JB 22-Dec-2023
Need to correct temperature Joe Bloggs 22-Dec-2023

- Do not overwrite text.
- Never use correction fluid (white-out).
- Never use ditto marks for repetitive entries.
- All comments must be reviewed and dated.

BLANK FIELDS

When populating a form or record never leave a cell or line blank. In the instance where data or information is not available, it's best to follow the format below to ensure that GDP practices are being met.

- N/A and cross out form entries that are not relevant, or where information is not available.
- For sections with form entries that are in a tabular format, a single line can be used to mark all spaces and N/A can be written along the line.
    - Remember to initial and date.



In conclusion, Good Documentation Practices act as a foundation to bringing medical devices to the market. If a form wasn't signed and/or dated then it wasn't documented, and if something wasn't documented then the activity technically never happened. To best avoid common issues with GDP it is recommended that you set aside time to fully review documents, both for the content, and to ensure that proper GDP techniques were utilized in origination of the information. Think of the four-eyes principle when reviewing documentation where two separate people must approve the activity (the one who performs the task, and the one who signs off). Follow the guidelines outlined in this article for a more seamless process of getting new therapies to market.