CleanTech Systems, Inc.

GDP - Good Documentation Practices Training for Cleanroom Employees

CleanTech Systems

Why is Documentation so Important ?

- **It's the Law- there MUST be a paper trail.**
- "If it's not documented it's not done," is a phrase often repeated in this industry.
- It is documented evidence that provides a history of the specific cleaning and disinfection steps taken in support of quality manufacturing of drug products, medical devices and/or biologics products.

Regulations- Who is the FDA?

- **The Food and Drug Administration (FDA)** is the agency responsible for regulating drug products, medical devices and/or biologics in the United States. They have ultimate authority to give out penalties, fines or close a company down for failures that impact quality manufacturing processes.

Regulations- What is cGMP?

- **Good Manufacturing Practice or cGMP** is a term the FDA uses to refer to a system of controls, testing and management of drug products, medical devices and/or biologics.

Regulations- What is cGMP?

- An essential part of GMP's is the DOCUMENTATION of every aspect of the process, activities, and operations involved with drug products, medical devices and/or biologics manufacturing.
- If the documentation showing the conditions under which the product was made and tested is not correct and in order, then the product does not meet the required specification and is considered CONTAMINATED.
- This can be a huge financial loss and public embarrassment to the manufacturer.

Regulations- What are SOP's?

- **Standard Operating Procedures or "SOP's" are** detailed, written instructions. The SOP's purpose is to achieve uniform and consistent safety, quality and effectiveness of a specific function.

Regulations- What are SOP's?

- FDA and GMP requires that all organizations involved in drug products, medical devices and / or biologics manufacturing have appropriate SOP's in place in order to conduct manufacturing and assure compliance with FDA regulations.

  We must follow these "quality" documents.
- The lack of written SOP's and/or the failure to follow them is the biggest reason the FDA gives out fines.
- Log Sheets are a part of SOP's and reflect the satisfactory completion of the instructions in the SOP's.

Regulations - SOP's

- **What are Standard Operating Procedures or "SOP's"?**

These are detailed, written instructions to achieve uniform safety, quality and effectiveness of a specific Function. The FDA requires all organizations involved in drug products, medical devices and/or biologics manufacturing to have appropriate SOP's in place in order to conduct manufacturing and research operations, and to assure compliance with the current regulations. The presence of these quality documents is essential when inspections take place since the most frequent reported deficiencies during Inspections are the lack of written SOP's and/or the failure to adhere to them.

Log Sheets are a part of SOP's and reflect the satisfactory completion of the instructions that compose the SOP's.

- ***SOP's are not open for questioning!***

Data Entry on Log Sheets

- CTS Employees that have been trained in GMP are responsible for recording GMP data. It is not acceptable to record GMP data without going through our customer's GMP SOP Training Program.
- Entries must be made using black or blue pens with indelible ink (no pencils, no Gel pens or markers). All entries must be legible.
- Entries must be made on the day the task has been completed or performed.

Data Entry on Log Sheets II

- Fields and sections that are not used must be marked out by striking out the field with a single line, initial, reason for strike out and dating per the Corrections section of this training.

Corrections

- **Corrections -** Changes made to records must be performed in such a manner that the original entry is CLEARLY legible.
- Use of correction fluid (such as Whiteout) or correction sticker is not permitted.
- Writing over the original entry is not permitted. The entire original entry is to be struck out with a single line.
- Corrections made to an entry within a document must be initialed, dated, *and must include a reason for the change.*

Corrections II

- Entries are not to be made once a completed document has been reviewed and approved.
- If a document becomes difficult to read due to getting wet or to the nature of or the number of changes required, a new copy of the document may be used to report the entries originally made which may include the changes needed.
- All changes and entries reported must be explained and a reason for transferring the entries onto a new copy of the document must be entered.
- The original version of the document must be retained and attached to the new copy.

Writing Dates

- Dates must be recorded as day, month, and year.

  The following format is the only acceptable format :

  DD-MMM-YY (for example, 06-Dec-12)

Writing Times

- All times are entered using the military standard and refer to local time (USA East Coast): Eastern Standard Time or Eastern Daylight Saving Time.

- The following are the only acceptable formats to record times:
  - For 09 AM, enter 0900 or 09:00
  - For 09:15 AM, enter 0915 or 09:15
  - For 09 PM, enter 2100 or 21:00
  - For 09:15 PM, enter 2115 or 21:15

Types of Signatures

- Performer (Performed By) The person who performs instructions described in a document must enter the required information in the spaces designed for the corresponding entries. Identification of the performer must include the initials or full signature (as defined by the document being used) and include date and/or time, as required by the document.
- The Performed By and the Reviewed By signature cannot be the same person.

Types of Signatures II

- Data Entry Verification (Verified By) Verifies an activity has taken place via eyewitness observation at the time of the cleaning as required and indicated by the pre-approved document.
- Data entry verification must occur at the same time the activity takes place, by a second person who signs or initials and dates each entry.

Types of Signatures III

- Data Entry Check (Checked By) confirms the data entries (only) are correct via visual check. Not the work itself.
- The data entry check can be done after the performer action.

Potential Costs of Log Sheet Errors

- Loss of Work and Contract- Self & Co
- Hiding potential contaminated product- Public Health
- Severe penalties and fines for the Customer