Developing a Sample Tracking System for an FDA Regulated Process in a cGMP Manufacturing Facility

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Abstract

Cytoimmune Therapeutics was looking for a sample tracking form for their new biomedical treatment. The company budget was considered, and an affordable custody form system was developed to record data following FDA guidelines and biomedical samples specifications. This form was adjusted to be implemented in a cGMP manufacturing facility. The tools selected for the sample tracking system were Microsoft Word for the software and barcodes for the identification system for their affordability and applicability. The sample tracking system was tested and received positive feedback from both teams (laboratory and manufacturing teams), principally the manufacturing team who are responsible for providing the recorded information to the FDA.

Introduction

Cytoimmune Therapeutics is a clinical-stage biopharmaceutical company founded in 2019 in California, with headquarters in Monrovia, California. The company established a current Good Manufacturing Practices (cGMP) manufacturing facility in Toa Baja, Puerto Rico, to support the production of its cancer treatment, which is now in the final trial stages. This type of facility is known for operating under FDA guidelines.

To obtain FDA approval for the manufacturing process, the company needed to implement a sample tracking system to document the trajectory of the treatment vials. This documentation was required because the treatment involves biomedical samples that must be refrigerated under specific conditions. If a vial is left at room temperature for a prolonged period during manufacturing, it must be discarded and cannot be distributed to patients.

The objective of this project was to develop a sample tracking system for an FDA-regulated process in a cGMP manufacturing facility. The project involved evaluating identification methods, designing a tracking form, and verifying its functionality during initial manufacturing trials.

Literature Review

The purpose of sample tracking is to understand the what, where and why of samples. An efficient sample tracking system is expected from well-organized laboratories and facilities. Some of the information that must be included in a sample tracking system includes the properties of the sample (name, unique ID, where it was derived from, volume, etc.), the location of the sample, any activities or assays that the sample has been a part of, and the status of a sample at any given time. All this information must be included in the sample tracking form [1]. Among the tools that enable this level of control and traceability, barcode identification has emerged as a practical and scalable solution.

The barcode identification system is known to be useful for inventory management. Companies are using this system for warehouse management. Barcodes provide a cost-effective and standardized method for inventory control, offering rapid identification and minimal error rates in regulated environments [2].

Methodology

For the project, the DMADV (Define, Measure, Analyze, Design, Verify) methodology was followed. This consisted of the following steps:

1. Define: The problem of this project was defined as the need to develop a sample tracking system for an FDA regulated process in a cGMP manufacturing facility.

2. Measure: All FDA regulations that applied to the specific type of sample that was manufactured in this facility were reviewed and studied. Samples for the treatment conditions, restrictions and requirements were reviewed. A spaghetti diagram of the trajectory of the sample was developed to identify areas and personnel in contact with the manufactured vials.

3. Analyze: After gathering all FDA regulations, sample information, requirements and diagrams to trace sample trajectory from beginning to end limitations were identified. The software system for the tracking process selected was Microsoft word with a shared form for all personnel involved in the process. The identification system selected to identify each vial was barcodes.

4. Design: After studying the process, sample information and systems, the system was checked to see if it met cybersecurity criteria, if it was reliable tracking information, reliable for data transfer and had reliable storage of data. For the identification process, barcodes were selected because each vial was identified with a unique ID, and it was compatible with the software to store the data. Barcodes were a cost-effective and efficient alternative for the company. Afterwards, the selected software system and ID systems were designed and adapted with all the specifications for the studied process. Table 1 summarizes the sample trajectory through each area of the facility, including the personnel responsible and the corresponding custodian manager.

5. Verify: After the software system was designed with the specifications of the process following FDA regulations and making it compatible with the identification system, it was tested. During the first batch of the treatment the sample tracking system was tested.

Table 1. Sample trajectory by area and custodian manager.

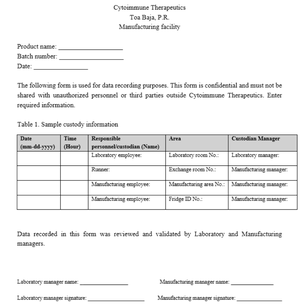
Responsible personnel/custodian	Area	Custodian Manager
Laboratory employee	Laboratory	Laboratory manager
Runner	Exchange room	Manufacturing manager
Manufacturing employee	Manufacturing area	Manufacturing manager
Manufacturing employee	Fridge	Manufacturing manager

Results

The tools selected for the sample tracking system were Microsoft Word for the software and barcodes for the identification system. During the first batch, the trial system served its purpose and all data for samples custody for the first manufactured batch was recorded. After the first trial, the form was revised to add some information. This includes the manufacturing manager and laboratory manager's signatures at the end of the manufacturing process, and time and date for custody change. This with the purpose of recording the amount of time the sample spent in each area. This helps to track the temperature and other conditions to which the sample was exposed.

The data included in the final version of the form shown in Figure 1 was product name, batch number, date; a table to indicate responsible personnel/custodian, area, custodian manager, hour of custody change (times ample was received); and spaces for the signature of the manager of each area (manufacturing and laboratory managers) to be filed after a batch is completed to validate all information that was reviewed after production.

The sample tracking system received positive feedback from both teams (laboratory and manufacturing teams), principally the manufacturing team who are responsible for providing the recorded information to the FDA. The manufacturing facility is ready to be evaluated by the FDA to obtain approval for the next phase of the treatment and allowed approved manufacturing.



Cytoimmune Therapeutics
Toa Baja, P.R.
Manufacturing facility

Product name: _____
Batch number: _____
Date: _____

The following form is used for data recording purposes. This form is confidential and must not be shared with unauthorized personnel or third parties outside Cytoimmune Therapeutics. Enter required information.

Table 1. Sample custody information

Date (mm-dd-yyyy)	Time (Hour)	Responsible personnel/custodian (Name)	Area	Custodian Manager
		Laboratory employee:	Laboratory room No.:	Laboratory manager:
		Runner:	Exchange room No.:	Manufacturing manager:
		Manufacturing employee:	Manufacturing area No.:	Manufacturing manager:
		Manufacturing employee:	Fridge ID No.:	Manufacturing manager:

Data recorded in this form was reviewed and validated by Laboratory and Manufacturing managers.

Laboratory manager name: _____ Manufacturing manager name: _____
Laboratory manager signature: _____ Manufacturing manager signature: _____

Figure 1. Sample Tracking form

Conclusions

The final version of the form was designed using Microsoft Word for budget purposes. This form could only be accessed by custodians and area managers. It will be stored in SharePoint while the IT team works on a secure database system to store this data outside a cloud. During the form designing procedure a lesson learned was that not all pharmaceutical products have the same requirements. In this case the form had to contain more information because the treatment is composed of biological products. This adds to the condition's requirements, which limits the team to not follow previous treatments or existing forms for non-biological treatments.

For future work, it is suggested that the manufacturing team review all other FDA requirements before requesting approval from FDA to ensure the company complies with all requirements, so the approval process is shorter. Furthermore, the presented form should be reviewed, updated, and approved periodically as FDA requirements might change or require information changes.

References

[1] Lab Key (2023, October 27) *What is Sample Tracking?* https://www.labkey.com/what-is-sample-tracking/

[2] McCue, I. (2022, September 4). *Behind barcodes: How they work*. Oracle NetSuite. https://www.netsuite.com/portal/resource/articles/inventory-management/barcode.shtml