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VIEW POINT

Improving Efficiency In Quality Assurance Documentation Cell With Lean Thinking

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The pharmaceutical industry is regulated by regulatory agencies like the U.S. Food and Drug Administration (FDA), the European Union (EMEA), WHO and the Ministries of Health of various countries and guidelines such as the Good Practice (GxP) guidelines. The GxP guidelines are primarily Good Laboratory Practice (GLP), Good Clinical Practice (GCP) and Good Manufacturing Practice (GMP), ensuring the quality of the processes leading to the final product. The pharmaceutical industry has to comply with regulations from the law and health authorities. This article provides an insight into how lean thinking concepts like 5S can help the Quality Assurance Documentation cell of a Pharmaceutical company and can increase its efficiency of document upkeep, storage, archival, distribution, presentation and retrieval.

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What Is 5 S?

The most important tool used in lean thinking is the **5S system.** The idea is that a messy workplace, storage place, desk, etc makes it hard to find documents or any other important things and can result in accidents or mistakes.

5S is a tool to create system and order in a company's work culture. At the same time, 5S expresses the attitude in an organization towards the structure and the system.

With the introduction of the 5S work culture, the work places, shelves, the floor, racks etc. are clearly marked. Every tool or part has a "home" where the component is placed and is clearly identified. Other tools and parts are removed and are stored in the designated position.

5S Stands For

1. Sort: Sort the work place into 'in use' and 'not in use'.
2. Set in order: Put items in the system.
3. Shine: Procedure for cleanliness.
4. Standardize: Procedure for how to leave the workplace.
5. Sustain: Ingraining into culture.

Advantages Of Using 5S

- Improves ergonomics.
- Improves safety – no disorders.
- Improves quality _ of storage and identification when needed.
- Gives pride to the work place.
- Easier to take over.
- Reduces changeover times.
- Gives a visible overview of the work place – tools, parts, fixtures etc.
- Time spent on searching is reduced.
- Reduces demand for space.
- Improves productivity.

Activities Of The Quality Assurance Documentation Cell In A Pharmaceutical Company

1. Document Distribution

At the time of distribution of a document, necessary entries are made in the

document control register which has information about Document name, Document number, Issued by, Received by, Retrieved document no.(if any), Number of copies retrieved, Destroyed by, Date, Checked by details.

2. Batch Manufacturing Record / Batch Packaging Record

- Master copies of the Batch Manufacturing records are kept in the documentation cell and the photo copies of the master copy are issued for regular production on request and for approval by Quality Assurance. All sheets of the photo copies are signed and dated by QA Personnel.
- The executed /completed batch records are submitted back to QA for review.
- After review of the records and QC analytical results, QA releases the batch (Product) for sale.
- All the completed and reviewed batch records are archived in the documentation cell.
- All batch records are retained at for five years after the shelf life of the product.

3. Validation protocol / Report / Summary

- The original copy of the validation protocols/qualification documents such as the Equipment Qualification Protocol/Reports are compiled by QA in the respective qualification files like Design Qualification, Installation qualification, Operational qualification, Performance qualification. Visit reports (if any) are also maintained by QA and are issued to the respective departments along with the qualification files when required.

- After completion of validation, the Protocols and Reports along with the QC results and the Summary report, are prepared and filed by the QA department in the respective validation records.

4. Specifications

- All specifications of Raw material / Packing material / intermediate and finished products are set up by the QC and are authorised by QA. Original documents are filed in the respective master files of the QA Department with a "MASTER COPY" seal in green colour on the text side (backside) of the page.
- Controlled copies of specification are issued to the QC department with a "CONTROLLED COPY" seal in red colour on top of each page on the printed side.

5. Standard Operating Procedure

- Master copies of SOP are filed in the QA department in the respective files with a "MASTER COPY" seal in green colour on the non text side (backside) of the page.
- Different stamps are used for circulating SOP to the concerned departments, either with a "CONTROLLED COPY" seal in red colour or a "DISPLAY COPY" seal in blue colour on top of each page on the printed side as per the need.

6. Third Party Documents Like Technical Agreements, Audit Reports , Compliance Responses Etc

- Separate files are maintained for party/agency.

7. Art works

All documents related to artwork approval, including the specimen samples, are filed and controlled by the QC and QA departments.

8. Stability samples

Details of stability reports are maintained and the records are archived by the QA documentation cell.

9. Log Books : The following log books are maintained

- **Production Department**

- Equipment Operation
- Equipment Cleaning
- Planned Preventive Maintenance of Equipment.
- Temperature and Humidity
- Pressure Differential
- Balance Calibration
- General House Keeping
- Pesto Flash
- Issue and control of stereos
- Issue and control of Punches and dies
- Intermediate log
- Overprinting of Packaging Materials

- pH meter log
- Transfer pump and Transfer line log
- Utility Department
- Purified Water Plant Operation
- Purified Water Plant Regeneration
- Planned Preventive Maintenance of AHUs and Compressed Air

- **Quality Control Department**

- Instrument Operation and cleaning
- Volumetric Solutions
- Reference Standard
- Working Standards
- Reserve Sample
- Control Sample
- Glass ware calibration
- Calculation sheet
- pH meter
- water monitoring log
- Autoclave Calibration
- Sub culturing and destruction of sub culture
- Media Stock Register
- De-fumigation checks log
- Media Preparation
- Media destruction
- Growth Promotion test
- Plate exposure
- UV lamp log
- Raw materials analysis

10. Training Record

The training records of individual personnel are retained till the last record, which has to be signed by them when they expire their date.

The Training Records consist of:

- The Annual Training Schedule
- Training modules
- Individual Training records
- General Training record
- Material/Visual aids/Literature used for Training

11.In addition ,QA also maintains Following Records

- Packing specification
- Monthly reports
- Annual reports
- Medical check-up record
- Pest control record
- Market complaints
- Instrument calibration(External agency)
- Change controls
- Deviations
- Out of specification records

12. Document Retrieval

Revised documents are issued only after retrieval of the superseded Control copy and Display copy from the concerned department. The superceded Master Copies are retained with the "OBSOLETE COPY" stamp in black colour for future reference and the other copies (Controlled and Display copies) are destroyed. A record of issue of documents and retrieval and destruction of the superceded documents, are maintained.

13. Retention of Documents

All documents are retained for at least one year after the expiry of the finished products.

Aim

The main aim of this study was to increase the efficiency and space and to improve the turnaround time for the Document Issuance, Document Retrieval and Document Archrivals for the Quality Assurance Documentation Cell of the Pharmaceutical Company.

General Challenges Observed In The Documentation Cell

1. Increased manpower is required to maintain the documents.
2. Identification, location and retrieval of the documents in the Documentation Cell.
3. Tracking of documents in circulation
4. Delay in document issuance.
5. Space constraints in the Documentation cell

In view of the number of documents handled and the quality of maintenance, it has become increasingly important to follow some proven methodology so that the system works by itself and with desired efficiency. One such method could be the use of the 5S system. How the concept can be implemented, is described below:

Changes done in the Documentation Cell as per the 5S system

Sort: Sort out the work place into four categories a)"in regular use", b) "not in regular use", c) obsolete and d) for destruction.

- Redesign and physically segregate the racks /shelves depending on the volumes and space utilization.
- Identify the documents and arrange each file with a unique number for easy access. for example: Apex documents like Site Master File, Validation Master File, layouts, etc. can be stored separately under category A (which is not in regular use). Documents like Batch manufacturing records, Analytical work sheets, and Standard operating procedures can be stored under category B (which are used frequently).
- Obsolete documents can be placed on higher racks as such documents are normally used for reference purposes.
- Documents for destruction should be reviewed and stored on a separate rack under lock and key so that they can be sent for destruction in bulk.

Set In Order: Put Items In System.

- The labelling /identification system should be designed to have clear classification and ease of understanding. This should be extended to the individual rack and column/shelf.
- The document locator list should be prepared and displayed on each rack so as to know which documents are placed on which of the racks .

Shine: Procedure for cleanliness.

- Develop a new standard operating procedure (SOP) for detailing out the arrangement, numbering system, location allotment, receiving, itemisation/identification, placement, storage, retrieving, issuance and destruction of documents.

Standardize: Procedure For 'How To Leave The Workplace'.

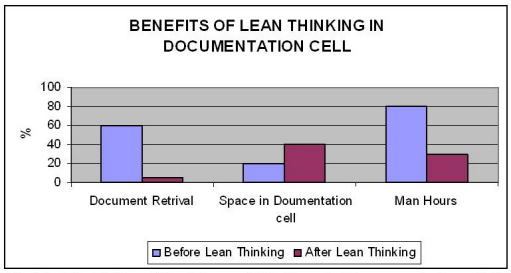
- Allotment of time slots for the document in and out-system, issuance and receiving so that everyone's time is saved. Moreover, priority can be given in advance so that documents which are required, are pulled out and are kept ready for reference photocopy or for any other use.
- Reconciliation of the document based on issuance and the receiving record should be done at a certain frequency so that nothing is missed out and all documents are placed at the locations assigned as per the identification number allotted.

Sustain: Ingraining Into Culture.

- Training for all those who are responsible for the document call, The concept, procedures, advantages, dos and donts and safety and security measures should be imparted in order that the compliance is observed throughout and the system works efficiently of its own.
- Validation of the documentation system by challenging the overall document cell systems and mock trials .The turnaround time could be a measurable parameter for assessing the efficacy of the system implemented.

Results

[Table/Fig 1]Some data was collected after the application of lean thinking through the S5 project and that has resulted in several benefits in terms of Documentation Cell efficiency which was measured, retrieval time, space utilization and the man hour utilization. It was noted that there were space problems to store the same volumes of documents, which were addressed by orderly arrangements and by placing the numbered files vertically in the racks. Storage of obsolete documents separately also contributed to more space.



(Table/Fig 1) Benefits of Lean Thinking in Documentation Cell

Segregation of documents which are used frequently and which are not used so frequently, helped in the fast retrieval of the documents from the racks. It was found that locating ,retrieval and issuance of the documents was consuming lesser time as compared to when the documents were not arranged as per S5 concepts. The number of persons working in the documentation cell reduced and there was no impact on the efficiency on the working .Although some

procedures were added, which were not in practice before.

A labelling system and location list available at each rack, simplified the storage techniques. A document locator list of all the individual items in alphabetical order, is posted on the compactor. The locator sheet details the rack and shelf on which a document is located. The locations are clearly identified, allowing a staff person to walk straight to the location to retrieve the desired document.
New personnel transferred to the document cell were able to perform the job after reading the SOP describing the documentation practices.

It was observed that the understanding among the various operating groups increased and team work prevailed .Priority was defined by production and QC based on the production plan for the next two days and the required documents were arranged in advance, thus reduced the waiting time .In addition, the documents required for regulatory submissions such as specifications, batch records and stability data were also provided as per the plan before the due date, through better planning and interaction.
Reconciliation of documents made it easy to find the missing slot. The documents were arranged at the designated (predefined) location. There were no missing documents and if at all any document was kept back to its location, it was perused or the reasons for not getting the same back were known and was notified for.

Orderly placement of documents in the shelves resulted in better space utilization at the workstations. The staff members could get the required ones when required. Adopting such practices made the workspace (s) clean, presentable and less cluttered.

Conclusion

Maintaining a good document cell suiting the requirements of a Pharmaceutical Industry has been a challenging job. There are a number of documents which need to be referred, used, photocopied, updated and filed on regular basis. In case the documents are not identified, located and placed properly, there are chances of misplacement and more time is required for retrieval of the documents, which ultimately results in inefficiency and poor productivity. Also, the work stations look untidy with lot of documents kept on it. This finally leads to confusion and mistakes.

In a regulatory governed environment, a document cell which works under the Quality Assurance department, has to be developed in such a manner so that upkeep, storage, archival, distribution, presentation and retrieval systems have very little room for inefficiency. This development can be brought in when the procedures followed are trouble free and flawless. This also requires a cultural change, which has shown to be achieved by implementation of the S5 concept as described above.

The implementation is simple and if practiced regularly, yields better returns and improves the overall output without any cost impact or investment. Such practices are also of great importance in handling higher volumes of documents which are generated with time, especially for those organisations which are in the business in regulated markets. Finally, the methodology adopted has proven to bring about cultural change, which will be profitable in the long run.

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