

Lean Approach to Quality Control Laboratory of Pharmaceuticals

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Introduction

Generally quality control laboratory in a pharmaceutical company is the rate limiting point to deliver product to customer. Because, products are tested in quality control laboratory after production and if the products meet required criteria, then the products are released to market or customer. Most of the time, lots of sample are waited in queue to be tested. Lead time varies for test of sample of a product or group of products. The goal of lean approach in QC lab is to use less effort, fewer resources and less time to test incoming samples.

Lean philosophy was developed in Toyota motor company after World War II in an effort to more production with less resource.

The basic underlying concept of Lean was to eliminate any operations that did not add value to the company's product or service from the standpoint of final customer.¹

Later this philosophy was being adopted in different areas such as manufacturing, IT system. Quality control laboratory of Pfizer's in Puurs, Belgium applied lean philosophy and they reduced 25% lead time for testing of their eight major products. And then, lean approach was rolled out in all site of Pfizer's of the world.²

This example can be taken and implemented in quality control laboratory of pharmaceutical company.

Lean Approach in QC Laboratory

Specify Value

Value can be defined as a capability provided to customer at the right time at an appropriate price, as defined by

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the customer. Identify value-adding and non-value-adding activity in laboratory. For documentation, controlling, archiving and planning of analyst's work, huge time is consumed in QC lab which in some extent not adds value. To manage these activities, laboratory information management system software can be used.

Value Stream Mapping

Testing process flow of individual product can be analyzed to eliminate any non-value adding activity. To analyze it, it is not always give optimum solution if it is analyzed by only supervisor or manager or in-charge. To eliminate waste from process flow, input to be taken from personnel who are involved with the process. As an example, when analysts give input in logbooks after completion of all tests, it takes some extra time which is a waste. If logbook entry is performed during the run time of equipment, it will not take extra time. Moreover, logbook should be kept with equipment, not in a shelf of the corner of laboratory which will reduce extra movement to take logbook. Except this, layout of laboratory should be

designed to reduce extra movement for tasks. Generally all data are checked by an independent analyst after completion of analysis. If this job is performed only one or two person, there must be a waiting to check the data which is also a waste. More persons can be involved or even every analyst can be involved to check data of each other.

Create Flow and Pull

Sometimes it is observed that work load is not well distributed among analysts. Someone has high work load than other. It varies testing lead time which hampers the flow of product toward customer. Good uses of personnel and equipment have to ensure to overcome it. Generally analysts wait for a group of sample (as much number as possible) for campaign analysis (analysis of samples from different batches of same product). It increases lead time for analysis. To reduce the lead time, sample number for campaign analysis should be kept as minimum as possible to maintain the flow in optimum level. Use of lab at optimum level is also important to reduce lead time. Total work-load can be

distributed to lab capacity on daily basis equally, not higher work loads on a day or lower on another day.

Pull is interpreted as testing according to customer priority. Generally it is observed that an analysis plan is affected by urgent inclusion of analysis of a product and which is recurring situation. It also increases lead time for analysis. Dedicated analysts can be assigned for urgent analysis which will not affect regular plan. Regular analysis plan should be in a manner to follow FIFO.

Seek Perfection

As value is specified, value streams are identified, wasted steps are removed, and flow and pull are introduced, then process to be continued until a state of perfection is reached in which perfect value is created with no waste. Lean transformation can not be possible overnight; it needs time to be adopted. To monitor progress, a daily KPI (Key Performance Indicator) can be introduced.

References

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