



TQM OF PHARMACEUTICAL: IMPORTANCE, RECENT ADVANCEMENT AND APPROACHES

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Abstract:

Quality of pharmaceuticals has always important area of concern for regulatory agencies across the globe in order to maintain the quality and facilitate production of pharmaceutical preparation without batch to batch variations and hence maintaining the same therapeutic effectiveness with the advent of total quality management a new vista has opened for assured quality of pharmaceuticals. Total quality management being a multidimensional approach essentially requires adherence to quality practices in all areas of pharmaceutical production. Application of various approaches and practices viz. quality by design, quality risk management, six sigma approach along with following regulatory guidelines in all facets may lead to practical realization of this concept. This article presents a brief review of existing industrial practices of total quality management with special emphasis on recent advancements as well as importance of TQM in Pharmaceutical Production.

Keywords: TQM, Good manufacturing practices, Quality, Quality design, Quality management, Quality Assurance,

1. Objective:

Review of recent trends and approaches toward TQM with reference to Pharmaceuticals

Importance of TQM in Pharmaceutical



2. Introduction:

Total Quality Management is a system to satisfy the customer. TQM leads to continuous development in quality of the product by the involvement of the employee and management. TQM is a managerial approach used by pharmaceutical manufacturer in ensuring pharmaceutical product meets the required quality with regards to their uses. As the pharmaceutical product are lifesaving drugs so it is very crucial to maintain the quality of overall production to cope up with problems arises after that. It is a potentially beneficial approach approach to manufacturing pharmaceutical product, as it ensures they exceed customer's expectations in relation to quality standard, efficiency and also effectiveness.

Pharmaceutical industry is a very vital segment of our health care system, which deals with manufacturing and marketing of pharmaceuticals and biological products and medicinal devices, used for the diagnosis and treatment of diseases as well as conducts research for development of new products for human welfare.

The quality in the pharmaceutical industry has become a very important topic. Since the world has gathered together to harmonize its practices and guides and the launching of the FDA current good manufacturing practices – the cGMP; for the 21st century – there has been a growing awareness for the significance of the quality of the pharmaceutical products. It is important to know that the importance of TQM in Pharmaceutical as well as the recent advancement in pharma companies to improve the overall quality of the product.

3. Research Methodology:

The above research is based on conceptual nature. In order to find out the basic view of the main problem researchers uses the secondary data specifically. To understand the nature and background of the problem researcher referred various books, journals, articles, news papers,



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seminar/conference abstract, reports of various committees. Along this he collects material by browsing various website and view expressed by experts on blogs.

4. Importance of TQM in Pharmaceutical:

Pharmaceutical manufacturer plays a key role in the system of health care and for that case, they are heavily regulated by the relevant authorities since; any slight mistake in pharmaceutical manufacturing can have fatal consequences. In this case, pharmaceutical manufacturer need to maintain and improve continuously on their products through Total Quality Management system process implementation. Some importance of TQM in Pharmaceutical are as follows.

1. Handling:

Container opening, proper sealing, highly active, toxic material should be handle with proper handling equipment, so that that should not lead to any accident. Highly sensitizing material such as cephalosporin, cephalosporin should handle in separate production area. Highly active or toxic API like certain steroids, should be manufactured in a dedicated area and using dedicated equipment. That is possible when organization is following the proper TQM norms.

2. Storage:

To prevent damage and deterioration of the API and complete formulation, it is important to store the raw material as well as final formulation. It quality is not maintain for the storage of this then it becomes difficult and creates the critical health issues. Environmental Conditions, Clean, Tide and required storage temperature should be maintain by TQM.

3. Packing:

Many of the Pharmaceutical agents has the ability to shows the reaction with the packaging, packing material, that completely change the characteristics of the API and formulations. It is important to maintain the Quality of Packing material as well the proper labelling on the same. The material used for packing must comply with the norm and as per the requirements of API and other contents.



4. Facilities & Equipment:

Location, design and construction of building should be suitable for the type and stage of manufacture involved, protecting the product from contamination including cross contamination and protecting operator and the environment from the product.

5. Sterile Area:

Personal suffering from an infectious disease or having open lesion on the exposed surface of the body should avoid activities which could compromise the quality of API. Smoking, eating, chewing, and storage of food can be restricted to designated area and separated from production or control areas. So it most important to maintain the quality of this to ensure quality of API.

6. Labelling:

Labelling is important part as it contains all information related to preparations, so outer labelling as well as product labelling can be complied with the quality norm and dosage and cautions as well.

7. Computerized System:

Computer system should be designed so that unauthorized entry in restricted and important area is prohibited, so that pharma companies can maintain the security and quality of preparations. A back up system is important to maintain the data which is related to preparations and important.

5. Recent Trends in TQM wrt Pharma:

Looking in to today's techno world it is important to adopt some new technology for production of pharmaceutical products. Many of time go9ing manually may leads to the wrong product and formulation. Various automated approaches are used in many industries for maintaining quality at different stages of a process. These are part of TQM approach as these automated approaches decrease requirement of sampling and testing at various stages as these analyzers and probes gave automatic reading at every operation and give information on computer that ongoing process is under control or not so help in increase productivity by decreasing in process sampling



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and testing. Few of such automated techniques as well as new methods trending in future for real time quality management are given below

AOTF Multiplexed Analyzer:

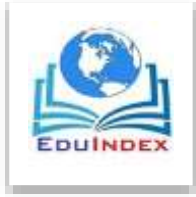
The acousto-optic tunable filter (**AOTF**) is an electro-optical device that functions as an electronically tunable excitation filter to simultaneously modulate the intensity and wavelength of multiple laser lines from one or more sources. Brimrose's rugged and high performance on-line AOTF NIR process spectrometers deliver fast-responding and multi-component analysis for a variety of process applications throughout the pharmaceutical, food & dairy, chemical, polymer, petrochemicals, agricultural, pulp & paper, wine industries and military.

CIP and WIP probes:

Rather than using a older technology we should adopt new technology to improve the quality. Up to the 1950s closed systems (pipes, vessels, process equipment) were disassembled and cleaned manually. This method usually meant spending a lot of time for some industries that needed frequent internal cleaning of their processes (beverage, brewing, processed foods, pharmaceutical, and cosmetics). The advent of CIP (Clean-in-Place) & Wash in Place (WIP), e.g. a method of cleaning the interior surfaces of closed systems without disassembly, has really benefitted such industries.

The advantages of this method are like, improved safety for workers involved in production of potential dangerous compounds, faster cleaning, reduced water usage, less labor spending, repeatable operations, possibility to include a programmed cleaning cycle that is fully automated (employing PLC, sensors, valves) with recirculating detergent and rinse solutions.

Intelligent Packaging:



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Sensors are used in packaging to collect information of the package and its content. ... Indicators can provide visual, qualitative (or semi- quantitative) information about the packaged food by means of a color change. An indicator leads to a color change (e.g. different color intensities or irreversible diffusion).

Fibre optic sensors for presence of product in packing:

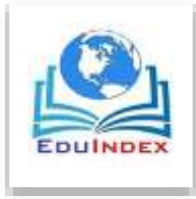
It consists of an amplifier and a fiber optic cable. These sensors sense the presence of product in the packaging e.g. in tablet packing if any cavity in the pack is empty, then it will give signal that there is absence of product in the cavity. In automated operations, it stops the process if this problem occurs regularly. It is easy to handle and having very high switching frequency⁴².

Mass encryption technology

It is a technique to provide a unique digital identity to every product generated by a computer-based encryption engine. Digital encryption is much more secure because it every can be given its own unique code. The encrypted code is denoted with 16-digit alphanumeric code, printed on packaging during manufacture and therefore provides each medicine with the unique identity. A major advantage of this technology is that consumer can simply verify the authenticity of the drug with the help of codes printed on blister pack, or by entering the code online into an internet site or via SMS

Data integrity

In 2016, after observing a series of violations involving data integrity, the FDA published “Data Integrity and Compliance with CGMP Guidance for Industry. As a result, data integrity and addressing the regulatory requirements were key themes at pharma quality management. A strong indicator that achieving data integrity has been a major challenge for the entire



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pharmaceutical industry is also the fact that the ISPE GAMP reacted quickly and published a practical guide on “Records & Data Integrity” in March 2017.

This guide provides a great overview on procedural, behavioral, and technology aspects of data integrity and lifecycle management. A key take away is that technology may be part of the problem, but it's also part of the solution.

Quality oversight and metrics

Quality metrics are considered to be an effective instrument for monitoring quality systems and driving improvements in GxP areas. However, the increased externalizing of critical operations makes it challenging to deliver accurate and comparable data.

The concern around keeping full quality oversight including CMO and 3PL activities was subject of a number of conference presentations. For example, at the Bio manufacturing Strategy Meeting, I hosted a roundtable discussion on how to ensure a strong quality and compliance focus with CMOs, partners, and suppliers.

Pharma 4.0

The concept of Pharma 4.0 continued to gain traction in 2017. Technologies are seeing ahead for pharmaceutical manufacturing to the next level. The ultimate benefit of Pharma 4.0 will be the transformation from automated (but inflexible) mass product supply into a highly adaptive set of manufacturing capabilities to produce individually tailored products. Rather than focusing on the customized productivity, focus is given on both part mass production for cost reduction as well as the customization for customer oriented product. They propose a Quality 4.0 framework to help companies improve and modernize their existing quality management systems. Although this concept is not just about technology, LNS argues that “those that apply the technology to



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greatest effect will be the innovation leaders of tomorrow.” ISPE hosted a number of conferences and workshops on the subject of Pharma 4.0 last year

Workforce transformation

To cope up with the technology change, company has to move for workforce transformation as per requirements and skill required. Moving the pharmaceutical industry to a “4.0” maturity level will require new kinds of employee profiles and qualifications with more skillful people. The “Workforce of the Future” initiative introduced by ISPE, includes a variety of members from top pharmaceutical companies. It identified that in the next five to 10 years, the industry will need a highly skilled workforce with competencies that differ from the past.

The initiative is planning to work with the industry and academia to develop university curricula. During the initial phase with nine selected universities, they identified a number of potential gaps in university curricula as follows, Combination products and delivering systems, Robotics and automation, IT data management, including data analysis, modelling, statistics, and data visualization, Regulatory sciences, including cGMP and GMP hands-on training, Project management, including risk management in manufacturing processes (biotech and small molecules) and related cost analysis, Process analytical technology to achieve real-time release. It is must to focus on competence of the people and hired the same as well as provide the training required.

Industry cloud for life sciences

By adopting a cloud-based quality management system, companies can streamline processes by creating a single source of truth for all stakeholders. This enables quality professionals to access real-time information, creating operational efficiencies and achieving greater visibility for more



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informed decisions across the supply chain. The industry cloud has the potential to modernize and unify quality management by enabling new ways of working for global teams.

6. Conclusion:

TQM is the most effective tool in quality management of pharmaceuticals. It is recommended strictly by many regulatory agencies but still it is not completely implemented in all the industries especially in India. As India is one of the largest exporters of pharmaceutical products across the globe, strict implementation of TQM is need of the hour in Indian context. Despite of extensive advancement in product development for real time online production and packaging monitoring, their limited utilization by majority of industries remains a major area of concern. In view of producing high quality medicines. Number of innovations has been done in the field of Pharmaceutical for the purpose of improving overall quality of the production as pharmaceutical product are closely related to the life of the people

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