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RESEARCH ARTICLE

QUALITY METRICS AND QUALITY KPI OF PHARMACEUTICAL INDUSTRY- A REVIEW OF GAP IN EXISTING PRACTICES

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ABSTRACT

Quality metrics are used throughout the pharmaceutical industry to monitor quality systems, processes and drive continuous improvement efforts in drug manufacturing. Quality Metrics (QM) are the refined and systematic representation of Quality- Key Performance Indicators (Q-KPI) during manufacturing operation. These can used to identify, where performance of quality management is good and meeting desired standards or where performance requires amendment.

Objective: The purpose of this study is to identify the quality key performance indicators (KPI) and how comprehensively these are used during pharmaceutical manufacturing and distribution operations.

Method: The exploratory method has been used for study through data available on regulatory websites and secondary data in articles of other researchers.

Result: KPIs shall be enabler to describe the performances measures for Quality in pharmaceutical industry

Conclusion: The Quality-KPI are used as tool to maintain quality of pharmaceutical products. It is important to identify and track KPI for Quality in pharmaceutical industry during manufacturing and distribution operations.

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INTRODUCTION

A key component of this work relates to evolve and effectively invigilate the quality performance in pharmaceutical manufacturing and distribution operations. Quality is a fundamental requirement of pharmaceutical, throughout operation in its business periphery. The requirement to adhere to quality specifications is being tightened by regulatory agencies on day by day. It is therefore, becomes imperative for pharmaceutical enterprise to explore Quality-Key Performance Indicators (Q-KPI) to measure and maintain the quality health of the organization. Pharmaceutical Quality System is driven by standards of Good Manufacturing Practices (GMP)' and Good Distribution Practices (GDP)' with supporting concept of GXP. The deployment of quality professional and experts are more in manufacturing plant, as compared to any other sectors of pharmaceutical operations. GXP is a general notion used for 'Good Warehouse Practices, Good Automation Practices, Good Engineering Practices' etc.

In the year 2015, United States Food and Drug Authority (FDA) brought about Nonbinding Recommendations entitled 'Request for Quality Metrics Guidance for Industry'. This may be considered as a development in pharmaceutical world to explore the Quality-Key Performance Indicators (Q-KPIs) during manufacturing operations. USFDA aspires to use these quality metrics, as an instrument to identify risk-based factors that could increase or decrease inspection frequency and that could potentially be predictive of drug supply disruption. Key performance indicators (KPIs) are an essential means in this process as they measure the manufacturing and distribution alike to have reliable information on current and desired standards. KPIs are used to identify where performance of quality management is good and meeting desired standards, and where performance requires improvement. KPIs, which are specific and measurable elements of quality management of pharmaceutical operations, can be used to assess the overall quality of product. They are measures of performance, based on standards determined through evidence-based studies of data. KPIs promote accountability of pharmaceutical manufacturer by facilitating comparisons with its stated objectives or targets of an organization.

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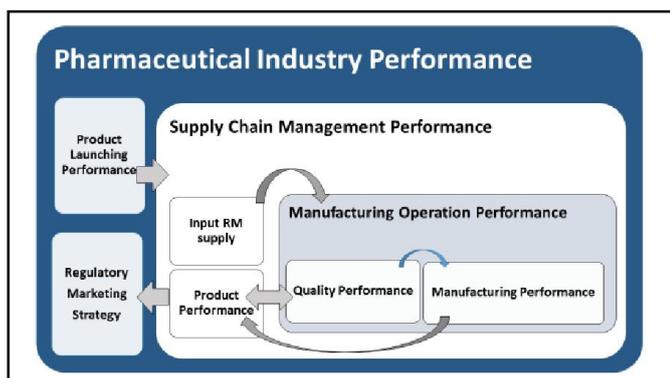
Further, they promote accountability towards drug regulatory agencies. An aim of Q-KPI is to determine which factors motivate the personnel enough to respond to improve KPIs.

DISCUSSION

Pharmaceutical Quality System is the set of infrastructure, processes, procedures and resources used to manufacture pharmaceutical products in accordance with applicable regulations. This entails establishing standard operating procedures, work instruction, quality control, quality assurance and quality improvement for achieving consistent drug product quality. The objective of a Quality System is to demonstrate consistency in product realization, establishing and maintaining a state of process control and facilitate monitoring across the product lifecycle stages.

The term 'Quality Metrics (QM)' has been recently popularized by FDA with an intention to strengthen its inspection process for pharmaceutical industry. The concept is focused to pharmaceutical manufacturing operations and controls. In pharmaceutical enterprise operations, it is decisive to do activities right the first time (RFT), every time without a risk of failure and without incurring extra costs caused by material losses and rejected batches. KPI is used to facilitate the improvement of performance through benchmarking, which makes it possible for organizations to document the quality of product they deliver against that provided by similar pharmaceutical organizations.

KPIs also facilitate benchmarking process to highlight improvements in quality. The benchmark processes help to identify wherever there are opportunities for improvement or where improvements have already occurred as a result of positive changes. Once an organization has established effective Metrics and Q-KPI, the benchmarking becomes stress-free.



Importance of KPIs in pharmaceutical industry

Pharmaceutical manufacturing and distribution process performance management have to provide the tools for the tracking of quality and production parameters. A focus on quality leads to fewer recalls, lesser complaints and quality related regulatory observations. The use of quality key performance indicators (Q-KPI) promotes responsible practices and quality driven organizational culture.

Review of Regulatory Approach

The FDA uses the term Quality Metrics, which intends to use the data to further develop its risk-based inspection scheduling, to identify situations in which there may be a danger for drug supply disorder, to improve the efficiency and effectiveness of institutional inspections, and to improve FDA's evaluation of drug manufacturing, distribution and control operations. Through nonbinding references entitled 'Request for Quality Metrics Guidance for Industry', the FDA expects that the initial use of the metrics will be to consider a lesser surveillance inspection frequency for incumbent firms. Apparently, FDA aims to carefully review data submitted in response to its requests of quality metrics, to help inform decisions about additional quality metrics data requests the Agency may make in the future. FDA plans to evaluate whether data reported by manufacturers is correct, true, valid and represents its understanding of the specific quality data desired.

Quality Metrics (QM) and FDA aspirations

The metrics were identified as being objective, subject to inspection and a decisive aspect in assessing the overall effectiveness of a PQS, within reasonable limits, and in a reasonable manner, while avoiding an undue reporting load. FDA trusts that these quality metrics, provide important information about operational reliability and quality culture. The following set of quality metrics that FDA assess based on industry reporting was developed with stakeholder input.

Using the data described in the following section, FDA may reckon the following quality metrics for each product and establishment, wherever applicable

- Lot Acceptance Rate
- Product Quality Complaint Rate
- Invalidated Out-of-Specification (OOS) Rate
- The number of product quality complaints received for the product.
- The number of lots attempted which are released
- The APRs or PQRs were completed within 30 days of annual due date for the product.
- APRs or PQRs required for the product.

Quality-KPI during manufacturing and distribution operations

There are several Quality KPIs identified for pharmaceutical operations. Important Q-KPIs are listed as under, include positive KPIs as well as negative ones:

- Corrective Action Preventive Action (CAPA) undertaken
- Market complaint
- Number of recalls
- Deviation reported
- Quality Risk
- Change Controls
- Training Program

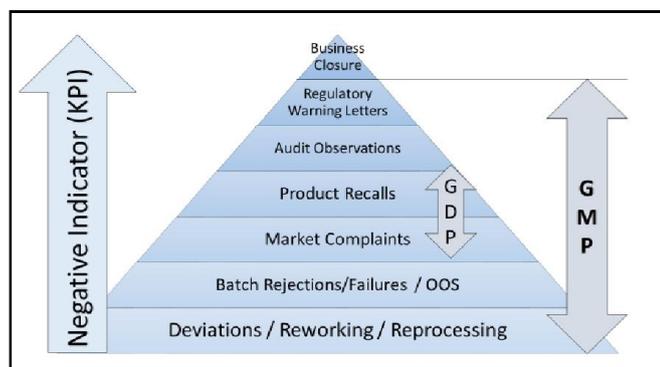
- Internal Audit Program
- Cases of temperature excursions
- Counterfeit cases reported
- Product Mix-up in pharmacies
- Product mix up during shipment

RESULTS

In order to establish Q-KPIs in pharmaceutical industry a holistic approach as adopted that included the activities under the purview of Good Manufacturing Practices (GMP) and Good Distribution Practices (GDP). Following Q-KPIs were identified:

- Deviations from instructions laid down in standard operating procedure or batch cards
- Reprocessing and reworking
- Batch failures and subsequent rejections due to out of specification (OOS) results
- Market complaints received after product release from plant
- Product recall, either voluntary or regulatory instructed
- Audit observations and non-compliances reported
- Regulatory warning letters
- Business closure

There is enhanced role of GDP to ensure compliance to facilitate the dispositioning of market complaint and product recall.



Success Factors of Q-KPIs

- Qualified resources
- Management commitment
- Training and continuous improvement strategies
- Automation
- Open communication system

KPIs during Manufacturing (Quality Metrics)

- The number of batches for which raw material dispensed for production.
- The number of rejected batches of the product, rejected during in process activity or after manufacturing
- The number of pending release for more than 30 days.
- The number of Out of Specification (OOS) results for the product, including stability studies testing.

- The number of lot release and stability tests conducted for the product.
- The number of Out of Trend (OOT) results for lot release and stability studies tests for the product which are invalidated due to laboratory error.

KPIs should be supported by

- Top management's commitment to continually improve the system
- Information sharing with transparent approach
- Notification processes for reporting the quality performance against expectations
- Proactive risk assessment to predict potential risks and apply appropriate risk management and mitigation techniques
- Customer complaint handling mechanism and product recall management (if necessary)

Conclusion

Pharmaceutical enterprise must ensure that their quality strategy is aligned with regulatory requirement for quality, holistically during manufacturing and distribution of products. Quality Key Performance Indicators (Q-KPI) are by and large conceptualized during manufacturing, but the identical actions are significantly missing during distribution, thus the gap in existing operational practices of pharmaceutical sector is evident. A set of effective KPI comprising of overall strategy should be formulated for manufacturing and distribution operations. Lack of integrated manufacturing, distribution, quality and overall compliance in a single solution impacts the ability to consistently deliver quality products that is compliant with regulatory norms.

Recommendation

In order to plug-in the existing gap in practices, there is a need to foster an unified approach to establish quality key performance indicators, allowing pharmaceutical entrepreneur to ensure a seamless quality performance throughout manufacturing and distribution.

Abbreviations:

APR: Annual Product Review
 CAPA: Corrective Action and Preventive Action
 CFR: Code of Federal Regulations
 CGMP: Current Good Manufacturing Practices
 GDP : Good Distribution Practices
 KPI: Key Performance Indicators
 OOS: Out of Specification
 PQR: Product Quality Review
 QA: Quality Assurance
 QRM: Quality Risk Management
 QMS: Quality Management System
 USFDA: United States Food and Drug Administration

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