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Review Article

Importance of Quality Metrics: A Review

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ABSTRACT

"Quality metric" is the measure of the effectiveness of systems associated with the manufacture of pharmaceutical products, including the pharmaceutical quality system. This is widely used in industry and they are potentially used to reduce drug shortages and it is the common language to gauge progress around quality. Quality Metric may include elements such as customer satisfaction, supplier performance, manufacturing defects, complaints and many other internal and external processes. It should focus on effectiveness and measure that the right things are being done correctly. Quality Metrics are difficult to establish but provide excellent insight into the health of the quality system, the use of quality metric data leads to further development of FDA'S risk based inspection schedule and to identify situations in which there may be a risk for drug supply disruption, to improve the efficiency and effectiveness of establishment inspections, to also improve FDA'S evaluation of drug manufacturing and control operations. It can be used to assist segment sites for risk based inspection schedule and also assist to segment product and individual product manufacturer based on risk. The key points in quality metrics are keep it simple, improve objectively and segmenting sites/products and also evaluating quality systems. Share the quality goals across the organisation and establish quality performance metrics based on linkage to organisational objective

Keywords: FDA, Quality metrics

INTRODUCTION

Quality Metrics is measurement of quality, where companies measure performance against quality standards to determine whether they are meeting expectations. By tracking quality metrics, we can reveal the weakness in a process or product which notifies a business of the necessity to correct areas of deficiency quickly. At its basis, FDA plans to use its authority to collect records "in advance of or in lieu of" an inspection, under section 704(a) (4) (A) of the FD&C Act to gather various quality metrics data records. This study is important for Greater visibility and transparency between industry and regulators, ability to identify drifts earlier to drive audit/inspection schedules, Risk based approach to inspections, increasing consistency of metrics. The quality metric also encourages pharmaceutical manufacturers to conduct robust quality measurements on their own products. By having quality metric data will allow it to "improve efficiency and effectiveness" of the inspection. Quality metrics is used primarily for reducing inspection frequencies.

The objective of this is to establish and collect these metrics which provide various stakeholders – from industry to regulators – with greater insight into the state of quality at a given manufacturing facility, and allow stakeholders to better anticipate and address quality issues while simultaneously reducing unnecessary regulatory burden.

DISCUSSION

What is Quality Metric?

An objective measure of the quality of a product or process

Quality is the fitness for intended use of the product, relevant to patients

Product (and/or process) segmentation

An objective measure of the quality of a site

Quality is measure of site's ability to manufacture products fit for intended use

Site segmentation (can include a build of product/process scores)

An objective measure of the effectiveness of systems associated with the manufacture of pharmaceutical products, including the pharmaceutical quality system

On site evaluation of quality systems

Why do we need Quality Metrics?

Metrics are used to drive improvements and help businesses focus their people and resources on what's important. The range of metrics that companies can employ vary from those that are mandatory – for legal, safety or contractual purposes to those that track increases in efficiency, reductions in complaints, greater profits and better savings. Overall, metrics should reflect and support the various strategies for all aspects of the organization, including finance, marketing, competition, standards, or customer requirements and expectations. Metrics indicate the priorities of the company and provide a window on performance, ethos and ambition.

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Metrics proposed by stakeholders

Metric	Possible Definitions
Lot acceptance rate	Number of lots rejected/Number of lots attempted
Product Quality Complaint Rate	Number of quality complaints/ (Number of units released/1 million)
Confirmed Out-Of-Specification (OOS) rate	Number of confirmed Out-Of-Specification (OOS)/ Number of release tests conducted
Recall rate	Number of product recalls / Number of lots released

How data is collected from industry for measuring of quality metrics and reported?

Ultimately, metrics will help to tell the organization:
Where it has been
Where it is heading
Whether something is going wrong
When the organization reaches its target[1]
Examples of Potential Metrics
Batch Failure Rate
Right First Time
OOS/ Laboratory Failure Investigation Rates
Methods for calculating Quality Metrics
Lot Acceptance Rate
Product Quality Complaint Rate
Invalidated Out-of-Specification (OOS) Rate
Annual Product Review Rate or Product Quality Review (PQR) on Time Rate
Lot Acceptance Rate = 1 – x (x = the number of specification-related rejected lots in a timeframe divided by the number of lots attempted by the same establishment in the same timeframe).
Product Quality Complaint Rate = the number of product quality complaints received for the product divided by the total number of lots of the product released in the same timeframe.
Invalidated Out-of-Specification (OOS) Rate = the number of OOS test results for the finished product invalidated by the establishment divided by the total number of OOS test results divided by the total number of tests performed by the establishment in the same timeframe.
Annual Product Review (APR) or Product Quality Review (PQR) on Time Rate = the number of APRs or PQRs completed within 30 days of annual due date at the establishment divided by the number of products produced at the establishment[2].
The implementation and collection of metrics data, including potential mechanisms for collection, frequency of reporting, and level of reporting requirements for organizations, sites, and individual products
It has been proposed that all metrics data be reported annually by product sponsors
The reporting will be conducted in an organizational level, however each organisation would collect and report data for each product and manufacturing site.
As the implementation of manufacturing metrics will involve new processes and practices for both industry and the agency, participants suggested the establishment of a "safe harbor" provision for reporting metrics during the first phases of implementation
FDA would collect data and resolve any major issues in their collection and analysis, without industry concern regulatory action from this initial data[3]
Final Words
Quality assurance and control play an essential role in the pharmaceutical manufacturing process, by ensuring that patients are provided with medications that are safe, effective, and produced at a high level of quality.
Metrics data collection and analysis may also help mitigate or reduce quality-related drug shortages and recalls, by allowing for early identification of products at risk for quality failure
For industry: The use of quality metrics promotes responsible practices and quality driven corporate culture.
For the public: A focus on quality leads to fewer recalls and quality related shortages.
For the FDA: Industry achieves and is rewarded for quality, without extensive regulatory over sight[3].

CONCLUSION

Quality metric provide basis to improve risk based principles to determine the appropriate reporting category for post approval manufacturing changes and by collecting this data we can identify, establishment that may pose significant risks to consumers such as risk from unsafe products and drug shortages.
Quality metrics are widely used throughout the pharmaceutical industry to monitor quality control systems and processes, and many of the components that inform those metrics (e.g., data on process capability output or statistical process control) are collected and maintained as part of cGMP compliance.[3]

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