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RESEARCH ARTICLE

IDENTIFICATION OF PHARMACEUTICAL QUALITY METRICS: PHARMACEUTICAL INDUSTRY

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ABSTRACT

Quality metricsare essential metrics for any pharmaceutical industry and assuring customers/patients are provided with safety/identity/strength/purity/quality drug products with zero defect. Pharmaceutical quality metrics identification is complex, involving numerous metrics that influence the performance of a pharmaceutical quality system. Pharmaceutical quality metrics are paramount established Real-Time Governance and visualization of deteriorated quality trends to the senior management. Through this management shall draw action points/corrective & preventive actions to the painful areas/area of improvements/non-compliances.Quality metrics display of the department's information which need to achieve one or more objectives; consolidated and arranged in a single frame so that the information can be monitored effectively by management at a glance.

Objective:
The purpose of this study is to identify the pharmaceutical quality metrics and bymonitoring the strategy of pharmaceutical industry which can check on department's activities in order to achieve service-level targets and operations.

Methods:
Interview with pharmaceutical industry employees has been used for primary source of data. And the exploratory method has been used for study through data available on regulatory websites and secondary data in articles of other researchers.

Results:
Total 68 quality metrics are determined as essential quality metrics for pharmaceutical industry.

Conclusion:
Through quality metrics visualizations pertaining to all departments can be monitored effectively & take necessary actions if needed and mitigate the quality risk .and achieve connect-communicate-collaborate with all stakeholders of organization.

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INTRODUCTION

As per Peter Drucker, the two most important quotes in business management are (1)

- "If you cannot measure it, you cannot improve it." And
- "Leadership is doing right things"

Quality metrics are less understood and implemented in the pharmaceutical industry to monitor quality risk of the site and as a continuous improvement tool for quality. The pharmaceutical industry visualization shall be though only quality metrics. First a thorough understanding of the current pharmaceutical industry practices about quality metrics analysis and through many interviews of both management and shop floor personnel an initial starting point quality metrics developed/identified to increase visualization of quality levels (low/medium/high) in the pharmaceutical industry. That initial thought was that if the quality can easily be quantified through quality metrics, that will adjust behavior in order to meet those expectation of quality and thus performance will improve overall. Finally, the question if improving (quantification and qualitative) visualization of quality through quality metrics will in fact improve performance of pharmaceutical industry and empower personnel. Quality metrics shall be evaluated for continuous improvement of quality as well as significantly increase compliance to regulatory requirements. Recommendations for increasing regulatory compliance to laid down standards of regulatory and delightof customer also be proposed. In the year 2015, United States Food and Drug Authority (FDA) brought about Nonbinding Recommendations entitled 'Request for Quality Metrics Guidance for Industry' (2). Quality metrics are measurements of the value and performance of products, services and processes. The following are common examples.

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Customer Satisfaction: In many cases, it is appropriate to measure the quality of a product or service by the quantifying customer opinions. The most common way to do this is simply to ask customers to rate their satisfaction. For example, there is no better way to measure the quality of a meal beyond asking the customer if it was good.

Failure Rate: The reliability of products as measured by the probability of a failure over a period of time. For example, a robot might have an annual failure rate of 0.1% indicating that 1 out of 1000 units fail in a year.

Quality Control: Quality control is the sampling or testing of manufactured units or delivered services. For example, a hotel might randomly sample rooms that have been cleaned to make sure that the room is in the expected condition. This can then be tracked as a quality metric such as the percentage of rooms that met the hotel's standards.

Defect Rate: The quality of processes or project work can be measured with a defect rate. For example, the number of defects per 1000 lines of code can be considered a quality metric.

Objectives of study

- To find out the pharmaceutical quality metrics recommended in pharmaceutical regulatory websites, interview with pharma industrial personnel and secondary data in articles of other researchers.
- To find out whether pharmaceutical quality metrics are good for pharmaceutical industry for real time governance for visual display of the department's information which need to achieve one or more objectives; consolidated and arranged in a single frame so that the information can be monitored effectively by senior management at a glance, which may provide key insights of Department activities.

RESULTS

The primary data has been collected in the year 2017 from 83 managers. The managers were from European Medicines Agency (EMA), United States Food and Drug Administration pharmaceutical firms with several years of experience (5-25 years). They were selected on the basis of their seniority within their organization and also their willingness to participate in the research. Eighty three (83) managers were invited to participate; however, the two managers did not respond despite one follow up, and therefore, the 81 managers that did respond provide a 97.59% response rate, and those characteristics collected are presented in Table 2.

Data collection & Interpretation

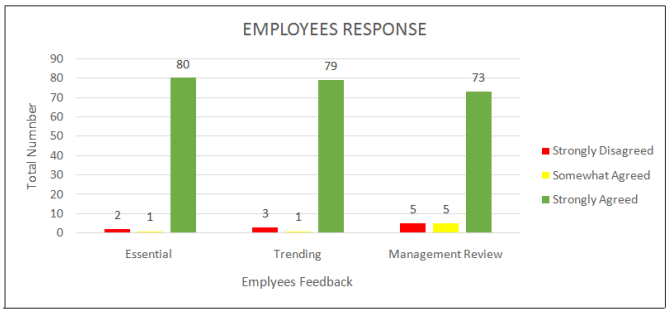
The employees were asked to identify quality metrics and were asked to rate their answers under three categories, "Strongly Agree", "Somewhat Agree". The focus was on the view whether quality metrics are important for pharmaceutical industry. In the first question, the employees were asked whatwere their views on the quality metrics essential requirement. Maximum number of employees (80/83) Strongly Agreed that the quality metrics are paramount to pharmaceutical industry. In the Second question, the employees were, asked whether they trending of quality metrics is compulsory? Maximum number of employees (79/83) Strongly Agreed to the fact that quality metrics are paramount to pharmaceutical industry. In the finalquestion it was asked from the employees whether management review on quality metrics periodically benefit the performance of pharmaceutical firm? Maximum number (73/83) Strongly Agreed quality metrics are paramount to pharmaceutical industry. If we see intotality, majority of employees have agreed to the fact that quality metrics, trending and periodic participation of management during review of quality metrics has definitely affected the performance of pharmaceutical firm. Tabulated the above information in Table:1.

Table 1. Employees response to quality metrics

Quality Metrics	Strongly Disagreed	Somewhat Agree	Strongly Agreed	Total
Essential	2	1	80	83
Trending	3	1	79	83
Management Review	5	5	73	83

Source: Primary Data.

Random interviews were selected to encourage the interviewees to discuss openly and freely their individual and their organisations approach of quality metrics, tabulated data in Table: 2. These interviews are taken orally, and remote pharmaceutical sites taken care by telephonic. The interviews on average lasted around 50 min. All interviews were documented with participant consent and the data being analysed using a standard manual systematic process consisting of familiarization with the data, generation of initial codes, identification of themes with grouping, mapping and interpretation was used. A flow diagram of the data collection process is shown in Figure 2.



Source: Primary Data.

Figure 1. Responses of the employees

As a company identifies its goals and designs quality metrics to measure compliance with those goals, it should expect to introduce additional implementation tools to improve the metrics and help realize its goals.

The three most important factors to consider when designing quality metrics are:

Customer Focused: The metrics for a Management, quality manager, and regulatory agency will all be different. Management is concerned with quality metrics like announcement of regulatory inspection, Recall of drug from market, Market complaints, Batch Failure, etc. A quality manager would like quality metrics would visualize quality risk time-to-time (High-Medium-Low), Open quality

notifications, CAPA effectiveness, customer satisfaction, etc. The metrics for an Regulatory agency should be even more focused: non-compliances w.r.t. defined regulatory standards, Adulteration of Drug Products, Contamination Levels, etc.

The important quality of quality metrics effectiveness are clearly aligned with the metrics, and the metrics are aligned with the quality vision of an organization. Religiously and timely these quality metrics shall report or presented to senior management for effective deriving of action plan and mitigation of quality risk.

S means "SPECIFIC": Must be specific and targeted to avoid misinterpretation or dilution.

M means "Measurable": Must be able to collect quantifiable, measurable data.

A means "Actionable": Must be reasonably attainable so that the workforce isn't discouraged.

R means "Realistic": Must be cost-effective, and must measure things relevant to the business.

Table 2. Socio demographics of study participants

S. No.	Organization Name#	MNC / Domestic	Export	No. of Employees	Location	No. of Participants	Gender	Job Title Range	Years of Experience
1	A	Domestic	Europe USA ROW*	1000+	Hyderabad India	15	Male: 12 Female: 3	• Senior Vice President • Senior Manager • Manager	8 to 25
2	B	Domestic	Europe ROW*	500+	Pune, India	16	Male: 14 Female: 2	• Managing Director • Manager	5 to 30
3	C	Domestic	Europe USA ROW*	2000+	Goa, India	18	Male: 13 Female: 5	• Senior General Manager • Manager	8 to 20
4	D	Domestic	Europe USA ROW*	1500+	Goa, India	21	Male: 17 Female: 4	• Senior General Manager • Manager • Assistant Manager	5 to 20
5	E	Domestic	Europe USA ROW*	740+	Chennai, India	10	Male: 8 Female: 2	• Senior General Manager • Manager • Assistant Manager	5 to 18
6	F	MNC	Europe USA ROW*	23000+	Hyderabad India	3	Male: 2 Female: 1	• Assistant General Manager • Senior Manager • Manager	8 to 15
TOTAL						83	Male: 66 Female: 17		

Source: Primary Data. *ROW –Rest of World; Organization Name# - Confidential information

Figure 2. Flow diagram of the data collection process

Table 3. University of california performance measures (5)

Measure of	Measures	Expressed as ratio of
Efficiency	Ability of an organization to perform a task	Actual Input / Planned Input
Effectiveness	Ability of an organization to plan for output from its processes	Actual Output / Planned Output
Quality	Whether a unit of an work was done correctly	Number of units produced correctly / Total number of units produced
Timeliness	Whether a unit of work was done on time.	Number of units produced on time / Total number of units produced
Productivity	The amount of a resource used to produce a unit of work	Outputs / Inputs

Evaluation of Quality Metric

Many resources on the design of quality metrics suggest the SMART acronym as a good tool for evaluating the effectiveness of quality metric (4).

T means "Timely": Time-horizon of data capture must match that of the ability to respond.

The last three characteristics (S-M-A) are particularly important for the decision-making metrics deployed and

implemented in pharmaceutical industry. The quality metrics must be relevant and lead to timely actions to be "smart" enough to influence the day-to-day operations. In addition, the metrics must be able to be influenced by the managers/employees and they must be able to have the authority to make those changes.

The following questions shall use and to measure the quality of a metric evaluated:

- Is the metric objectively measurable?
- Does the metric include a clear statement of the end results expected?
- Does the metric support customer requirements, including compliance issues where appropriate?
- Does the metric focus on effectiveness and/or efficiency of the system being measured?
- Does the metric allow for meaningful trend or statistical analysis?
- Have appropriate industry or other external standards been applied?
- Does the metric include milestones and/or indicators to express qualitative criteria?
- Are the metrics challenging but at the same time attainable?
- Have those who are responsible for the performance being measured been fully involved in the development of this metric?
- Has the metric been mutually agreed upon by you and your customers?

Table 3. Department wise – Quality metrics (6)

Quality Department: Quality Metrics	Production Department: Quality Metrics
1.Adverse Event Rate	1.Batch Failure Rate
2.Analytical Invalid Rate	2.Batch Reject Rate by Product
3.CAPA Effectiveness Rate	3.Batch Reject Rate by Site
4.Confirmed OOS Rate by Product	4.Batch Yield Rate
5.Confirmed Out of Trend	5.Equipment Qualification Rate
6.Contamination Rate	6.Lots on Hold
7.Contract Manufacturing Batches Release Rate	7.Lots Pending More Than 30 Days
8.Contract Stability Testing / Manufacturing / TestingSites Controls	8.Lots Rejected
9.Critical Investigations Rate	9.Number of Lots Attempted
10.Customer Service Measures Recall Procedure	10.Number of Out of Specification Results For Lot Release
11.Deviations Rate	11.Packing Material Rejection Rate
12.Temperature Excursion Rate	12.Process Validation Rate
13.Field Alerts Rate	13.Raw Material Rejection Rate
14.GMP Letter Withdrawal	14.Right First Time Rate
15.Internal Audit Rate	15.Right Second Time
16.Invalidated Out of Specification Rate	16.Risk Assessment of Equipments Rate
17.Investigation Free Lots Rate	
18.Lead Times for Investigations	
19.Lot Acceptance Rate	
20.Major Change Control Rate	
21.Methods Revision Rate	
22.Number of Recalls	
23.Number of Warning Letters	
24.On Time Internal Audit Rate	
25.Pharmacopeia Updates Rate	
26.Product Non-Quality Complaint Rate	
27.Product Quality Complaint Rate	
28.Quality System Effectiveness	
29.Recall Rate	
30.Regulatory Inspections Rate	
31.Reject Rate	
32.Repeat CAPA Rate	
33.Repeat Deviations Rate	
34.Rework / Re-Processing	
35.Risk Mitigation Plans	
36.SOP Revision Rates	
37.Specification Revision Rate	
38.Supplier Complaints	
Engineering Department: Quality Metrics	Human Resource Department: Quality Metrics
1.Adherence to Preventive Maintenance Schedule	1.Employee Satisfaction Rate
2.Percentage Overdue Preventive Maintenance Rate	2.Employee Turnover Rate
3.Unplanned Down Time Rate of Equipment	3.Organizational Health Metrics
4.Unplanned Maintenance Rate of Equipment	4.Percentage of Quality Staff
5.Utilities Qualification Rate	5.Percentage of Temporary Workforce
	6.Safety Accidents Rate
	7.Training Effectiveness Rate
	8.Training Roll Out Rates
	9.Human Error Rates

The University of California provides classification of performance metrics as summarized in Table: 3. These questions and classifications reinforce the connection-communication-collaboration between customers expectations and design of quality metrics.

DISCUSSION

Little research is available on the pharmaceutical industry quality metrics. Pharmaceutical industry quality metrics are the

senses of quality and we can link this kind of sensations and usethose metrics as a capacity to anticipate and that anticipation is also a very important as a part of quality leadership skills. Indeed, this method has developed and that practices in some of the pharmaceutical companies are a way of developing perception as well as then analyze and really put together the relationships understanding the relationships of the different components of the given situation. So then the firm can project, recreate a new environment that will help people feel better, know themselves better about quality. FDA plans to launch its quality metrics data initiative in January 2018 by opening an electronic portal (e-portal) to collect data on certain manufacturing processes electronically from biopharmaceutical companies. The aim is to identify and reward those firms able to demonstrate that their operations can consistently produce high-quality products and thus merit reduced regulatory oversight. Yet as the metrics program nears implementation, industry is pushing back, voicing concerns about the scope of FDA's data requirements, the timing of the program's launch, and what the agency will do with the resulting information (3). The notion of introspection being absolutely critical and introspection is not only intellectual it's also understanding where we are and quality levels and that helps with building good quality products, it helps with communication to management. Quality metrics are authentic, engage the management, capacity to deliver quality product time-to-time, overall brings connect-communication and collaboration to the mission, and plays a role of like a mirror, reflects and send back your image. This study underlines identifying pharmaceutical industry quality metrics which in-turn give real time governance, visualization of quality risk (Low-Medium-High) and interested organizations can make informed decisions regarding best implementation of quality metrics. Quality metrics directly and indirectly connect-communicate-collaborate organization towards one quality standard throughout the organization. In nut shell encourages pharmaceutical firm to implement quality metrics beyond the metrics described in this paper expected to maintain the process in a state of control over the life of the process, even as materials, equipment, production environment, personnel, and manufacturing procedures change.

Conclusion

The above study gave the views of the pharmaceutical regulatory websites, interview with pharma industrial personnel and secondary data in articles of other researchers on the pharmaceutical quality metrics good for pharmaceutical industry. 83personnel (66 male: 17 female) from the pharmaceutical industry were interviewed (Table 2). The saturation point for the interviews was reached after 83 interviews.

The consolidated output of the qualitative research comprised the identification of 68 quality metrics. These 68-quality metrics again classified department wise to empower and make responsible for their action and ways of working to retrospective time-to-time. Tabulated department wise quality metrics in Table: 3. However, assurance was provided to the interviewees that confidentiality would be respected.

Recommendation

The recommendations of this study is that the point of view of the pharmaceutical regulatory bodies has not been considered. The reason was that the pharmaceutical regulatory bodies published limited pharmaceutical quality metrics and determined to be implemented. The second recommendation was that the area covered regarding Indian multinational pharmaceutical companies. The study could have broadened its view if foreign multinational pharmaceutical companies covered. However, it was felt that the quality metrics is good for pharmaceutical companies having direct influence on accessing risk of quality and time-to-time steer the decisions to mitigate non-compliances, quality risk and strengthen quality systems.

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