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QUALITY METRICS IS GOOD FOR PHARMACEUTICAL INDUSTRY

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ABSTRACT

Today's pharmaceutical industry must deal with regulatory oversight, inspections/audits, new technologies and soaring of drug prices. It is imperative that pharmaceutical industry adopts some form of business strategy to manage the vast amount of information available. Most popular and regulatory enforced is the quality metrics implementation. Is this best / good for the pharmaceutical industry? The answer to this question is that it depends on the pharmaceutical industry. This paper focuses on identifying pharmaceutical industry quality metrics which in-turn give a visualization of quality where we are and where we have to go i.e. visual displays that will guide pharmaceutical industry to improve quality into the drug product and to stabilize the economy of the country and unmet needs of 7+ Billion people to access quality medicines. Making effort for interested organizations can make informed decisions regarding best implementation of quality metrics. The exploratory method has been used for study through data available on regulatory websites, interview with pharma industrial personnel and secondary data in articles of other researchers. Quality metrics, directly and indirectly, connect-communicate-collaborate organization towards one quality standard throughout the organization. In nutshell encourages the 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.

KEYWORDS

quality, metrics, pharmaceutical, influence, good, visual displays.

JEL CODES

M1, M14.

INTRODUCTION

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

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

Quality metrics are less understood and implemented in the pharmaceutical industry to monitor the 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 the performance of pharmaceutical industry and empower personnel. Quality metrics shall be evaluated for continuous improvement of quality as well as significantly increase compliance with regulatory requirements. Recommendations for increasing regulatory compliance to laid down standards of regulatory and delight of 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.

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.

LITERATURE REVIEW

Jan Paul Zonnenberg (2014) provided analysis US FDA issues warning letter to a pharmaceutical company that directly address and make accountable to the Management of the company and not his employees for deviating the quality norms and GMP (3). Andrew Harrison, Susan J. Schniepp (2015), stated in his research article, effective implementation of a quality culture requires hand-to-hand hold between management and employees. Designing and defining of roles and accountability are the initial steps for quality culture for assuring quality drug product for unmet needs of the world population. The pharmaceutical firm had to take responsibility to provide technical training and ensuring adequate resources for performing discharging duties effectively (4). Jennifer Markarian (2017), has described in his research that "Cynicism had to be rid off and with optimistic quality, metrics had to be chosen as a quality tool (5). Jill Wechsler (2017), reveals that the US FDA and Pharmaceutical Industry also acknowledge the importance of an organization quality culture for assuring the quality of the drug product. The gap identified in his research was quality culture is visible and directly proportional how management holds the employees and empower but no tools available how to measure and document (6). Carmen Medina (2017) found in his research, all countries drug regulatory bodies confirmed quality system shall be compliant to the laid down guidelines. Deficient and lack of quality complaint tools and techniques result in audit findings and hefty fines and penalty (7).

Life Health (2013) found interesting finding in his Survey of Quality Assurance Executives found that Quality Assurance teams are looking for quality performance metrics to demonstrate training effectiveness (8). Jill Wechsler (2017) in his article 'FDA Quality Metrics Initiative Challenges Manufacturers' states that 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. He found companies who able to demonstrate operations consistently produce high-quality products shall be rewarded (9). United States Food and Drug Administration (2016) proposed quality metrics through draft guidance, 'Submission of Quality Metrics Data' to support their risk-based inspection program and used throughout the drugs and biologics industry to monitor quality control systems and processes and drive continuous improvement efforts in drug manufacturing (2). Dr. Mike Long (2016) in his article briefed standardize quality metrics as one tool, but not the only tool, for prioritizing levels of effort and scrutiny for drug manufacturers. He concluded impact to industry could potentially be minimal. Organizations that already have a mature collection of data that is already required as a part of regulations have a leg up on other organizations that do not. Smart application of effort good

reporting structure will also be important in implementation. However, organizations that currently do not have a good handle on these will feel a significant impact (13).

NEED FOR THE STUDY

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 nutshell encourages the 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.

OBJECTIVES

1. 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.
2. 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 needs 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.

METHODOLOGY

The research methodology involved is a combination of data available on pharmaceutical regulatory websites, interview with pharma industrial personnel and secondary data in articles of other researchers. The participants for this study were managerial of a pharmaceutical industry; therefore, the study did not require ethics approval. The primary data has been collected in the year 2017, the interviewees were all at a managerial level within their respective organizations and were regarded as being experienced personnel. They were from the European Medicines Agency (EMA), US FDA approved organizations 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 1.

DATA COLLECTION & INTERPRETATION

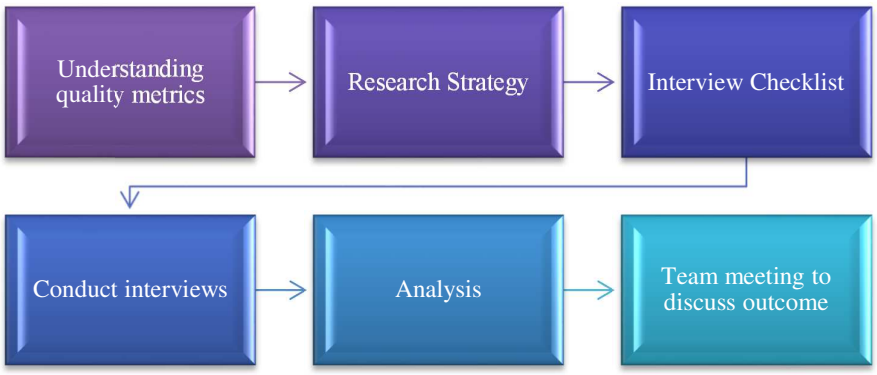
Random interviews were selected to encourage the interviewees to discuss openly and freely their individual and their organizations approach of quality metrics. These interviews are taken orally, and remote pharmaceutical sites are taken care by telephonic. The interviews on average lasted around 50 min. All interviews were documented with participant consent and the data is analyzed 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 1.

TABLE 1: 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 1: FLOW DIAGRAM OF THE DATA COLLECTION PROCESS



SUGGESTIONS

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 the announcement of regulatory inspection, Recall of the drug from the 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 a 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.

Following are the interesting themes derived from the interviews based on the quality culture, philosophy and size of the organization:

1. Cultural influences, in particular in the larger organizations
2. The number of employees in the organizations impacts the number of quality metrics selection.
3. In big pharmaceutical firms, you have more employees working, and therefore, it is important to know the selection of quality metrics depend.
4. Analytical and Logical Approach to Quality Metric: The use of an analytical and stepwise selection of quality metric was apparent. The potential advantage that such approaches may add transparency to the decision-making process was evident.
5. Subjective and Personal Considerations of Quality Metrics:
   Personal preferences relating to the subjective interpretation of the quality metrics were identified. The individual human element of a person's beliefs, the values important to that person and their preferred approach were evident. Subjective factors such as opinion, experience, trade-off tolerance and preference are part of the quality metrics.
6. Frameworks and Analytical Approach to Quality Metrics: The use of frameworks to assist with the quality metrics review process and the use of analytical and stepwise decision-making approaches were raised by the interview participants. They commented on the potential that such approaches may add transparency to the visualization of the quality process.
7. Qualification and Experience in Previous Decision-Making: Bias based on a person's previous experience in quality metric selection was apparent from the interviewees. It was evident that past experience in quality metric selection and previous exposure to similar challenges are important factors for both individuals and organizations.
8. Impact Analyses of Quality Metrics: The value in identifying good and bad quality metrics was mentioned as was the need and value of reviewing and examining the impact of visualization of quality outcomes.
9. Quality Metrics Audit Trail: The value of maintaining an audit trail for important quality metrics was considered critical for visualization of quality. Transparency in the process and the potential for better predictability in future judgments were linked to having a record/audit trail of previous successes.
10. Individual versus Corporate Decision-Making: There is a difference between the corporate quality metrics and that of the individual. We have a good understanding of how a committee makes a decision, but we do not necessarily understand how individuals on that committee have made their own decision.

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 (10).

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.
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 measure the quality of a metric evaluated:

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

The University of California provides a classification of performance metrics as summarized in Table: 2.

TABLE 2: UNIVERSITY OF CALIFORNIA PERFORMANCE MEASURES (11)

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

These questions and classifications reinforce the connection-communication-collaboration between customers expectations and design of quality metrics.

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 the pharmaceutical industry. 83 personnel (66 male: 17 female) from the pharmaceutical industry were interviewed (Table 1). 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.

TABLE 3: DEPARTMENT WISE – QUALITY METRICS (12)

Quality Department: Quality Metrics	Production Department: Quality Metrics
1. Adverse Event Rate 2. Analytical Invalid Rate 3. CAPA Effectiveness Rate 4. Confirmed OOS Rate by Product 5. Confirmed Out of Trend 6. Contamination Rate 7. Contract Manufacturing Batches Release Rate 8. Contract Stability Testing / Manufacturing / Testing Sites Controls 9. Critical Investigations Rate 10. Customer Service Measures Recall Procedure 11. Deviations Rate 12. Temperature Excursion Rate 13. Field Alerts Rate 14. GMP Letter Withdrawal 15. Internal Audit Rate 16. Invalidated Out of Specification 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	1. Batch Failure Rate 2. Batch Reject Rate by Product 3. Batch Reject Rate by Site 4. Batch Yield Rate 5. Equipment Qualification Rate 6. Lots on Hold 7. Lots Pending More Than 30 Days 8. Lots Rejected 9. Number of Lots Attempted 10. Number of Out of Specification Results For Lot Release 11. Packing Material Rejection Rate 12. Process Validation Rate 13. Raw Material Rejection Rate 14. Right First Time Rate 15. Right Second Time 16. Risk Assessment of Equipments Rate
Engineering Department: Quality Metrics	**Human Resource Department: Quality Metrics**
1. Adherence to Preventive Maintenance Schedule 2. Percentage Overdue Preventive Maintenance Rate 3. Unplanned Down Time Rate of Equipment 4. Unplanned Maintenance Rate of Equipment 5. Utilities Qualification Rate	1. Employee Satisfaction Rate 2. Employee Turnover Rate 3. Organizational Health Metrics 4. Percentage of Quality Staff 5. Percentage of Temporary Workforce 6. Safety Accidents Rate 7. Training Effectiveness Rate 8. Training Roll Out Rates 9. Human Error Rates

LIMITATIONS

The limitations of this study are 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 limitation 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 are good for pharmaceutical companies having a direct influence on accessing the risk of quality and time-to-time steer the decisions to mitigate non-compliances, quality risk and strengthen quality systems.

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