RESEARCH ARTICLE

IDENTIFICATION OF PHARMACEUTICAL QUALITY DASHBOARD-PHARMACEUTICAL INDUSTRY

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ARTICLE INFO	ABSTRACT
	This paper describes and demonstrates pharmaceutical quality dashboard, is a visual display of the pharmaceutical industry critical quality metrics information to steer industry to meet quality vision and overall performance of your firm, set objectives, consolidated and arranged in a single frame so that the quality metrics can be monitored effectively by senior management at a glance and promoting transparence throughout the organization. Despite the availability of robust quality systems in-place and in-use, it does not mitigate quality risk and non-compliances. Therefore, this study proposes a research model that support management monitor and steer their quality metrics throughout the continuous improvement cycles. 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 for developing quality dashboard to be included in a measurement framework for systems strengthening. More than 83 participants, who represented 05 different organizations working to design and roll-out of quality dashboard. The quality dashboard framework and indicators will help guide pharmaceutical industry in ways that will have lasting results. **Objective:** The purpose of this study is to identify the pharmaceutical quality dashboard which will give new level of comfort with their visualization of overall quality risk of firm and analytic abilities. The dynamic, interactive pharmaceutical quality dashboard have helped keep management and internal/external stakeholders about the time-to-time quality performance indicators. **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:** After several data pharmaceutical quality dashboards evaluation, finally prototype pharmaceutical quality dashboards designed and developed which is cost effective, feasible, no special training required for roll-out, customizable, easy to use, eye-catching and drive management to meet quality mission for pharmaceutical industry. **Conclusion:** Through pharmaceutical quality dashboards, overall quality risk shall be visualized, quantified and do qualitative analysis pertaining to all departments effectively & take necessary actions if needed and mitigate the quality risk with connect-communicate-collaborate with all stakeholders of organization.

INTRODUCTION

As per Peter Drucker, the two most important quotes in business management are (Dave, 2017)

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

Pharmaceutical quality dashboard isless understood and implemented in the pharmaceutical industry to monitor overall quality risk of the firm, as a continuous improvement tool for quality, and steer the firm towards meeting quality vision and cater 7+ billion of people with quality drug products.

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First a thorough understanding of the current pharmaceutical industry practices about quality dashboard analysis and through many interviews of both management and shop floor personnel an initial starting point quality dashboard 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 dashboard, 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 dashboard will in fact improve performance of pharmaceutical industry and empower personnel. Quality dashboard 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' (US, 2016).

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, and those characteristics collected are presented in Table 2.

Data collection & Interpretation

The employees were asked to quality dashboard is essential for pharmaceutical industry to steer towards compliance and meet quality vision and were asked to rate their answers under three categories, "Strongly Agree", "Somewhat Agree" and Strongly Disagreed. The focus was on the view whether pharmaceutical quality dashboardis important for pharmaceutical industry. In the first question, the employees were asked whatwere their views on the pharmaceutical quality dashboard is essential requirement. Maximum number of employees (80/83) Strongly Agreed that the quality dashboardis paramount to pharmaceutical industry.

In the Second question, the employees were, asked whether they implementation of pharmaceutical quality dashboard is mandatory? Maximum number of employees (79/83) Strongly Agreed to the fact that pharmaceutical quality dashboardis paramount to pharmaceutical industry to implement and roll-out assuring in-pace and in-use. In the finalquestion it was asked from the employees whether management review on pharmaceutical quality dashboard periodically benefit the performance of pharmaceutical firm? Maximum number (73/83) Strongly Agreed pharmaceutical quality dashboard are paramount to pharmaceutical industry. If we see intotality, majority of employees have agreed to the fact that pharmaceutical quality dashboard, implementation, trending and periodic participation of management during review of pharmaceutical quality dashboardhas definitely affected the performance of pharmaceutical firm. Tabulated the above information in Table 1.

Random interviews were selected to encourage the interviewees to discuss openly and freely their individual and their organisations approach of pharmaceutical quality dashboard, 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.

Intention to improve existing methodologies used, the following research question is addressed in this paper:

Which pharmaceutical quality dashboardintegrate with quality metrics on-order to support the continuous improvement cycles and mitigate quality risk?

The following sub questions should be answered to address the main question:

- What requirements and recommendations can be defined for the pharmaceutical quality dashboard?
- How pharmaceutical quality dashboard should look and how to design?
- Which conclusions and final recommendations can be made for pharmaceutical quality dashboard?

Pharmaceutical quality dashboard not only visualize quality metrics, but also derives action points which are pain areas to the organizations which require immediate attention of senior management to roll-out corrective and preventive actions, escalate deficiencies in the product, process, people, procedures and customers. Pharmaceutical companies through pharmaceutical quality dashboard shall steer and anticipate and mitigate quality risk and non-compliances.

Integration

Quality Risk Visualization (Low-Medium-High):

A pharmaceutical quality dashboard is designed to summarize quality metrics in a comprehensive and appropriate manner.

Analysis

In many cases it is hard to recognize overall quality risk based on a single and ad hoc base. Therefore, it is required to monitor the changes over time and conduct a trend analysis. Useful to incorporate are historical information, actual values and the target measures.

Functionality

Customer Perception

For pharmaceutical industry customer is patient, who required quality drug product for wellbeing. So, the pharmaceutical quality dashboard shall be in-line with patient interest to mitigate risk in product and exceeding regulatory expectations.

Feasibility

Besides meeting quality requirements, it shall talk about pain areas to the organizations which require immediate attention of senior management to roll-out corrective and preventive actions, escalate deficiencies in the product, process, people, procedures and customers.

Senior Management

Workflow monitoring

A senior management is vital to religiously evaluate the pharmaceutical quality dashboard and take proper and constructive decisions to mitigate quality risk in the product/process/systems. Well informed and timely decisions shall save life of people

Table 1. Employees Response To Pharmaceutical Quality Dashboard

Pharmaceutical Quality Dashboard	Strongly Disagreed	Somewhat Agree	Strongly Agreed	Total
Essential	2	1	80	83
Implementation	3	1	79	83
Management Review	5	5	73	83

Source: Primary Data.

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Figure 1. Responses of the employees

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

Table 3. Pharmaceutical Quality Dashboard Structure

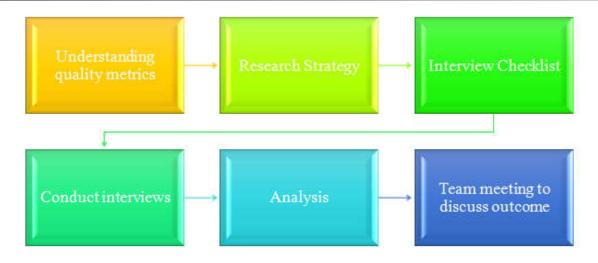|	Drug Product	Drug Product Quality Risk
What is managed?	Information Drug product life cycle	Quality metrics like, deviations, out-of-specifications, failures etc..
How is it managed?	Connect-communicate-collaborate of cross-functional teams Integrating and partnership with key suppliers	Corrective Actions Preventive Actions Upgrading vendors and process
Why manage it?	World to provide 7+ billion people with access to high quality medicine	Through visualization of quality risk Pooling and summarizing quality metrics
What is success?	Delighting customer Regulatory approvals Product approvals	Quality system works No non-compliances Exceeding regulatory norms

Figure 2. Flow Diagram of The Data Collection Process

Alerts & Warnings

For deriving and roll-out corrective & preventive actions, all cross functions teams should be alerted when a quality risk rated as HIGH or deteriorate trends occur.

Accountability

For example, deteriorate quality metric observed, senior management shall identify the action points and roll-out corrective and preventive actions to further deteriorate of quality metric.

Technology

Quality Metrics

The main constituent of pharmaceutical quality dashboard are quality metrics and it is a building block. These should comply to SMART principle (Doran, 1981).

Virtual Access & Periodical Evaluation

For strict implementation and in-place and in-use, senior management has to lead with ownership by providing training about benefits to all employees.

Top 5 Must Have Quality Management Metrics for the Executive Dashboard (Matthew, 2012),

- Cost of quality
- Overall equipment access
- Percentage of products in compliance
- On time and complete shipments
- New product shipments

Characteristics of Pharmaceutical Quality Dashboard (Core Dash Board, 2017)

- All the visualizations pertaining to all departments fit in a single screen.
- It displays the department's quality metrics performance indicators that can be monitored.
- Indicators such as filtering and drill-down can be used in dashboard; department's quality metrics performance indicators actions which also include lag & lead performances wise etc.

- The dashboard can be accessed by the senior management to monitor effectively & take necessary actions if needed.
- The data gets automatically updated without any assistance from the user. The frequency of the data updating will vary with the departments. Dashboard data gets updated on a daily basis.

DISCUSSION

Little research is available on the pharmaceutical industry quality dashboard. Pharmaceutical industry quality dashboard 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 (Jill, 2017). 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 dashboardare 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 dashboard which in-turn give real time governance, visualization of overall quality risk (Low-Medium-High) and interested organizations can make

informed decisions regarding best implementation of quality decisions and corrective & preventive action. Quality dashboard directly and indirectly connect-communicate-collaborate organization towards one quality standard throughout the organization. In nut shell encourages pharmaceutical firm to implement quality dashboard 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

83 personnel (66 male: 17 female) from the pharmaceutical industry were interviewed (Table:1 and Table:2). The saturation point for the interviews was reached after 83 interviews. The consolidated output of the qualitative research comprised with the framework of pharmaceutical quality dashboard. Here elaborates these more in-depth of pharmaceutical quality dashboard and gives a brief overview of possible features derived from theory and interviews. The following key requirements form the foundation to put continuous control into practice:

Recommendation

Furthermore, the theoretical model of pharmaceutical quality dashboard is not empirically tested and quantitatively validated. This means that this model needs further research before it can be reliably applied to pharmaceutical industry.

Overall, it can be determined that the outcomes of this study are valid and reliable within the pharmaceutical industry perspective. But additional research and empirical study is necessary to generalize the findings to reliable theories and apply them.

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