

INTERNATIONAL JOURNAL OF RESEARCH IN COMMERCE & MANAGEMENT

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STEERING THE PHARMACEUTICAL INDUSTRY THROUGH QUALITY DASHBOARD

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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 transparency throughout the organization. All cross-functional departments quality metrics are integrated into the pharmaceutical quality dashboard and all critical quality metrics are visualize which may provide insights of quality risk and a further area of improvements. This is paramount as high-quality data has become a strategic resource to make well-informed decisions and steer the pharmaceutical industry smoothly and achieve its quality mission i.e. connect-communicate-collaborate the world to provide 7+ billion people (1) with access to high-quality medicine. 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 a 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 the quality dashboard. The quality dashboard framework and indicators will help guide pharmaceutical industry in ways that will have lasting results.

KEYWORDS

quality, dashboard, steering, pharmaceutical, transparency, framework.

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INTRODUCTION

As per Peter Drucker, the two most important quotes in business management are (2)

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

The impact quality has on a pharmaceutical industry success is often well understood. However, the pharmaceutical industry had no standard operating procedure/framework, traditionally struggled to establish metrics that can easily represent the effectiveness of quality in the organization (3). Quality Dashboard is less understood and implemented in the pharmaceutical industry to monitor the quality risk of the site and as a continuous improvement tool for quality. Steering pharmaceutical industry through quality dashboard is an innovative way of operating business to safeguard quality and avoid recalls, batch failures of drug products. First a thorough understanding of the current pharmaceutical industry practices about quality dashboard and through many interviews of both management and shop floor personnel an initial starting point quality dashboard developed/identified to steer pharmaceutical industry 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. The pharmaceutical quality dashboard is complex, involving numerous quality metrics that influence the performance of a pharmaceutical industry. The starting point for identifying quality metrics for its measurement is better conceptual clarity on what a pharmaceutical system is, including its key quality metrics and performance objectives. This paper reviews a wide range of earlier work in defining and conceptualizing pharmaceutical quality dashboard and its strengthening, as well as relevant insights from the pharmaceutical industry literature to highlight common themes and insights.

REVIEW OF LITERATURE

According to Philip Crosby (1995), "Quality is Still Free" understood that the employees are a real source for the quality non-compliances, it is a myth. Employers do and adhere the written approved procedures laid down by the management and they do not deviate (or) dishonor due to job loss. Employees myth is a pharmaceutical quality risk and quality of drug product is some not quantifiable and not qualitative analysis (or) undefinable, it shall be perceived, feel, seen, touch. Regulatory bodies of various countries had well defined pharmaceutical quality drug product requirements/expectations with well documentation, what patients wants from the pharmaceutical companies i.e. very crystal clear "Quality Drug Product". Again big myth is pharmaceutical quality drug product manufacturing is not vague. or exceeding customer/patients expectations (4). The Tim Stevens revealed in his research in Indian pharmaceutical industries manual error is unavoidable because man is the great resource of unreliable, so tools, procedures, techniques are essential to developing to safe guard the quality of the drug product (5). 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 (6). The scientific literature talks about continuous improvement cycles for quality management. Despite many of these theories are available for quality management in general (example, sig sigma, total quality management) no full proof and comprehensive framework is available on pharmaceutical quality dashboard. Quality management through on-going cycles is already acknowledged in manufacturing theories since 1986. In that time William Deming developed Total Quality Management (TQM) as a pragmatic method for quality improvement. He believed that adopting a continuous improvement cycle of Plan, Do, Check and Act could help companies to better address and improve their production quality (7). Later also other methodologies like Six Sigma were based on this principle. Nevertheless, these are not specific and applicable to quality management.

NEED/IMPORTANCE OF THE STUDY

This study underlines the how pharmaceutical quality dashboard steer the pharmaceutical industry towards performance/strengthening/continuous improvement of the quality system to deliver quality products to the customer.

STATEMENT OF THE PROBLEM

How the pharmaceutical quality dashboard steer the pharmaceutical industry?

OBJECTIVES

1. To understand the pharmaceutical quality dashboard and steer the pharmaceutical industry to continuously improve their people/process/systems/procedures/ products.
2. Defining functionality, framework, and characteristics of the pharmaceutical quality dashboard.

RESEARCH 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.

RESULTS & DISCUSSION

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

Which pharmaceutical quality dashboard integrate 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.:

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

TABLE 1: SOCIO-DEMOGRAPHICS OF STUDY PARTICIPANTS

S. No.	Organi- zation Name#	MNC / Domestic	Export	No. of Employ- ees	Location	No. of Partici- pants	Gender	Job Title Range	Years of Experi- ence
1	A	Domestic	Europe USA ROW*	1000+	Hydera- bad India	15	Male: 12 Female: 3	<ul style="list-style-type: none"> • Senior Vice President • Senior Manager • Manager 	8 to 25
2	B	Domestic	Europe ROW*	500+	Pune, India	16	Male: 14 Female: 2	<ul style="list-style-type: none"> • Managing Director • Manager 	5 to 30
3	C	Domestic	Europe USA ROW*	2000+	Goa, India	18	Male: 13 Female: 5	<ul style="list-style-type: none"> • Senior General Manager • Manager 	8 to 20
4	D	Domestic	Europe USA ROW*	1500+	Goa, India	21	Male: 17 Female: 4	<ul style="list-style-type: none"> • Senior General Manager • Manager • Assistant Manager 	5 to 20
5	E	Domestic	Europe USA ROW*	740+	Chennai, India	10	Male: 8 Female: 2	<ul style="list-style-type: none"> • Senior General Manager • Manager • Assistant Manager 	5 to 18
6	F	MNC	Europe USA ROW*	23000+	Hydera- bad India	3	Male: 2 Female: 1	<ul style="list-style-type: none"> • 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 2: 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 a success?	Delighting customer Regulatory Approvals Product Approvals	Quality system works No non-compliances Exceeding regulatory norms

Pharmaceutical quality dashboard not only visualizes quality metrics but also derives action points, which are pain areas to the organizations, which require the 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.

FINDINGS

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 of the framework of the pharmaceutical quality dashboard.

Here elaborates these more in-depth of the 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:

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 the pharmaceutical industry, the 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 the 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

• **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 the pharmaceutical quality dashboard are quality metrics and it is a building block. These should comply with SMART principle (8).

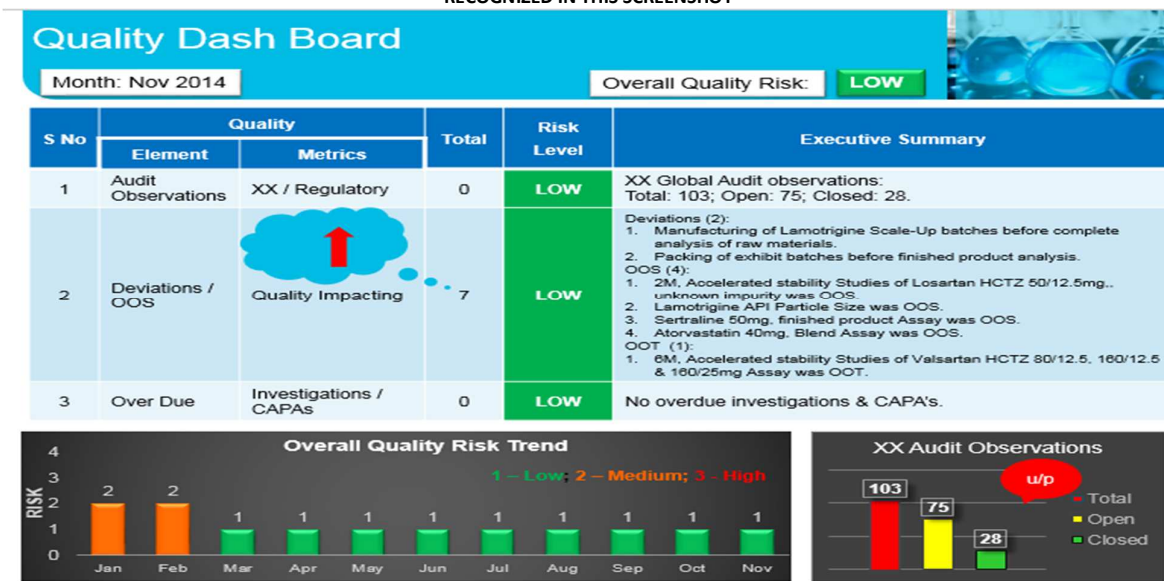
• **Virtual Access & Periodical Evaluation**

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 (9),

1. Cost of quality
2. Overall equipment access
3. Percentage of products in compliance
4. On time and complete shipments
5. New product shipments

FIGURE 1: CONTAINS AN EXAMPLE PHARMACEUTICAL QUALITY DASHBOARD. FEATURES LIKE OVERALL RISK, TREND, AUDIT OBSERVATIONS, CAN BE RECOGNIZED IN THIS SCREENSHOT



Characteristics of Pharmaceutical Quality Dashboard (9)

- 1) All the visualizations pertaining to all departments fit in a single screen.
- 2) It displays the department's quality metrics performance indicators that can be monitored.
- 3) Indicators such as filtering and drill-down can be used in the dashboard; department's quality metrics performance indicators actions which also include lag & lead performances wise etc.
- 4) The dashboard can be accessed by the senior management to monitor effectively & take necessary actions if needed.
- 5) 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.

RECOMMENDATIONS/SUGGESTIONS

1. The pharmaceutical quality dashboard is not a magic dashboard to remedy/visualize all quality issues; senior management had to religiously/periodically have to do an assessment, identify and derive action points to mitigate quality risk.
2. The major problematic area in steering the pharmaceutical dashboard is inadequate training and bringing awareness to the organization about the dashboard.
3. The deteriorated metrics identified from the pharmaceutical dashboard shall be tracked and presented/bring to the notice to the senior management who are responsible to deliver quality drug products for 7+ billion people and their wellbeing.

CONCLUSIONS

The purpose of the pharmaceutical quality dashboard is to ensure real-time governance of all events and deterioration of trends. Through implementation, one can ensure and steer for track areas of developments, and continuous improvement to enhance happiness index in the firm. This helps in interacting with people anywhere and understand pharmaceutical firm/quality needs and requirements. Through pharmaceutical quality dashboard at center, many pharmaceutical sites

are connected, linked to the system. The senior management shall visualize on a giant screen which can show multiple screens simultaneously and dashboards with information on quality trends, pending action points, commitments and real-time progress of ongoing projects.

LIMITATIONS

Furthermore, the theoretical model of the 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 from the pharmaceutical industry perspective. But additional research and empirical study are necessary to generalize the findings to reliable theories and apply them.

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