Research Article

Studying Strategies for Implementing Quality Culture in Pharmaceutical Organizations

D Raghavendra[*], R K Chauhan, T D mallikarjuna

Lingaya's University, old Faridabad,Haryana-121002

ABSTRACT

Quality culture implementation in pharmaceutical firm increasingly face challenges to ensuring that patients are provided with medications that are safe, effective and produced at a high level of quality. Despite recent advances in the manufacturing sector quality issues remain frequent occurrence and can result in recalls, withdrawals or harm to patients. A number of strategies have been utilized in various pharmaceutical firms to ensure quality culture for high quality drug products. However, a synthesis of the literature on these strategies has not previously been undertaken. Methods: We reviewed articles published in following websites that assessed and studied interventions for implementing quality culture in pharmaceutical companies and other i.e. non-pharmaceuticals companies. We organized the intervention in each study into three groups: Interventions aiming to increase involvement and empower of employees. Interventions aiming to transform management philosophy on quality culture i.e. Doing right and not what is easy in business. Combined employee and management interventions. We summarized the main quantitative outcomes from each study and effective practices from each intervention category. Results: Ten studies were identified; one described interventions designed to improve employee's perspective and engagement towards quality culture, one described interventions that aimed to increase management involvement day-to-day quality culture and eight studies aiming to improve both availability of employees and management participation and engagement in quality culture roll-out and implementation. All studies reported positive change. Conclusions: Few studies have assessed interventions designed explicitly for the unique challenges facing quality culture roll-out in pharmaceutical firms. Further research on sustainability, scalability and cost effectiveness of interventions is needed to fill this gap.

Keywords: quality culture, pharmaceutical, quality management, quality system.

INTRODUCTION

Over the last 10 years, FDA activity has increased noticeably. The FDA issued more than six times the number of warning letters for manufacturing in 2014 that it is issued in 2005 (see chart-1)[9,10]. A quality culture in pharmaceutical firm is paramount and that lead to sustainable complaince, (see chart-2). Quality culture plays a critical and complimentary role because it affects the decisions and described as one that puts interest and safety of patients above all else and where people do what is right versus what is good enough. All employees are accountable for assuring quality of product. Srinivasan and Kurey define quality culture as "an environment in which employees not only follow quality guidelines but also consistently see others taking quality-focused actions, hear others talking about quality, and feel quality all around them"[1] Barriers to implement quality culture can be classified into two domains. The first is "Quality Procedures Utilization" barrier which involves basic quality procedures knowledge and awareness of the purpose and importance of drug products. In pharmaceutical firm, barriers to utilization of quality procedures manifest in several ways. Technical employees who can account for a large proportion of

pharmaceutical firm may utilize quality procedures and non-technical employees may utilize few quality procedures. The challenges placed on both technical and non-technical employees such as lack of interest, behavioral and not aligned towards organizational interests. The non-technical employees have been shown to have lower confidence and weaker community than technical employees. The second is "Management Participation and Commitment to Quality Culture" barrier involve non conducting periodical monitoring, assessment of quality culture across inventory of drug products and facilities and away from commitment of quality culture. Having more USFDA approved manufacturing facilities than any other country in the world is not all rosy. It simply means Indian companies are under scrutiny. In 2016, the regulatory bodies identified pharmaceutical firm in deprived quality culture as a priority. Implementations of quality culture in pharmaceutical firm are increasingly refocusing efforts to address these and can benefit from the lessons of experiences addressing employees access to quality procedures and management involvement. To this end, we systematically reviewed research on the types and
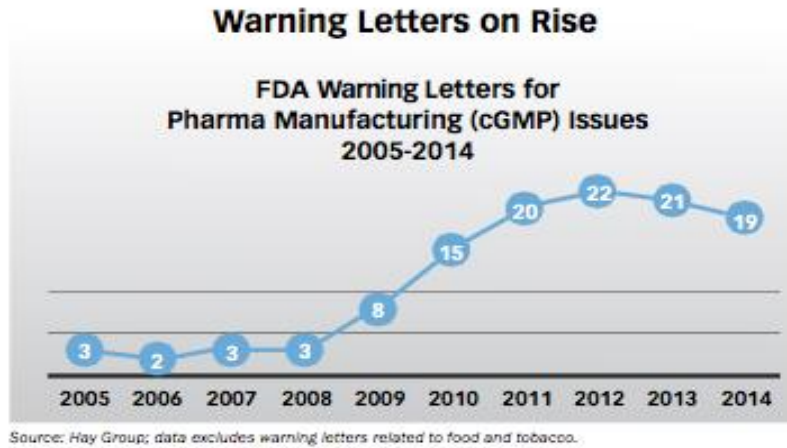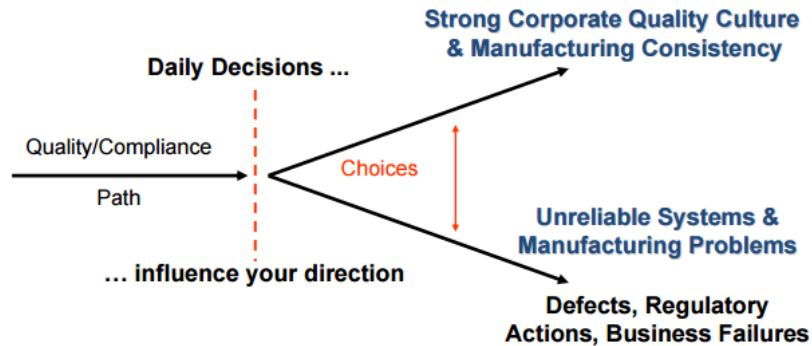
---

*Author for Correspondence: raghumylan@gmail.com

Warning Letters on Rise

Figure 1:-Warning Letters on Rise.

Figure 2: Leadership and the Corporate Quality Culture.

Table 1: Literature search strategy

Keywords used or in combination	Literature databases searched
Culture, pharmaceutical quality culture, quality culture, management commitment to quality, employee engagement to procedures, quality management, total quality management.	US FDA, MHRA, Forbes, Harvard Business Review, ISB, Research Gate

effectiveness of interventions designed to improve quality culture in pharmaceutical firms.

METHODS

We searched databases to identify articles for review, using different combinations of search terms related to quality culture, pharmaceutical quality, and quality management. We restricted searches to articles published from Jan 2000 to Mar 2017. (Table 1)

We extracted the following information from each article, study design and research methods, study characteristics and reported measures of implementation of quality culture. We analyzed each study by qualitatively summarizing the main themes regarding lessons learned and best practices for the intervention as documented by authors. We also summarized the reported quality culture outcomes. The intervention described by each study was classified into three categories: Interventions aiming to increase involvement and empower of employees through training. Interventions aiming to transform management philosophy on quality culture i.e. what is right not what is easy in doing business and work. Combined employee's empowerment and management interventions on quality culture.

RESULTS

We identified 10 articles examining 8 interventions to improve employee and management engagement and empowerment related to quality culture. To improve quality culture effectiveness, recommended continuous improvement and education be targeted, which have potential to achieve substantial cost benefits like no

Table 2: Characteristics of studies which evaluated interventions to strengthen quality culture in pharmaceutical organization.

Region of study	Number of studies	% of total studies
USA	5	50
Malaysia	1	20
Europe	2	10
Israel	1	10
Saudi	1	10
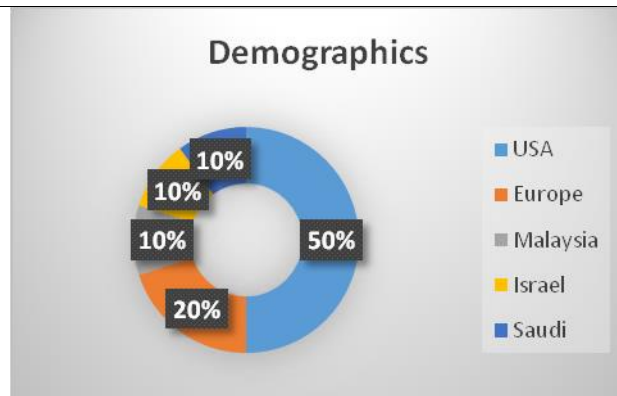
In the studies documented by these eight studies, authors noted that combined employee's empowerment and management access, interventions on quality culture were well suited to pharmaceutical firm, where conflict of interest was minimal and that employees and management collaboration could improve planning and monitoring quality culture i.e. live quality culture. Further combined strategy was considered a useful strategy for reaching top-to-bottom quality culture in organization. (see chart -3)
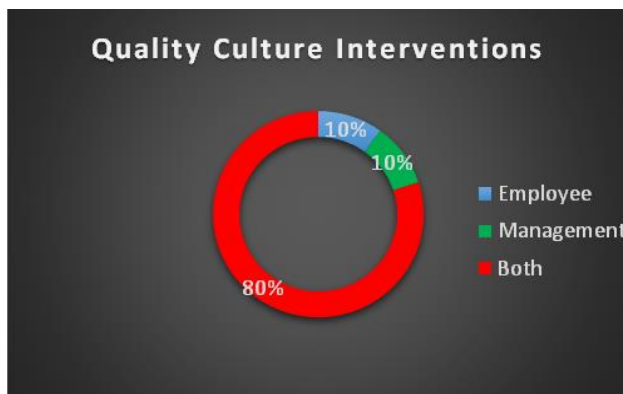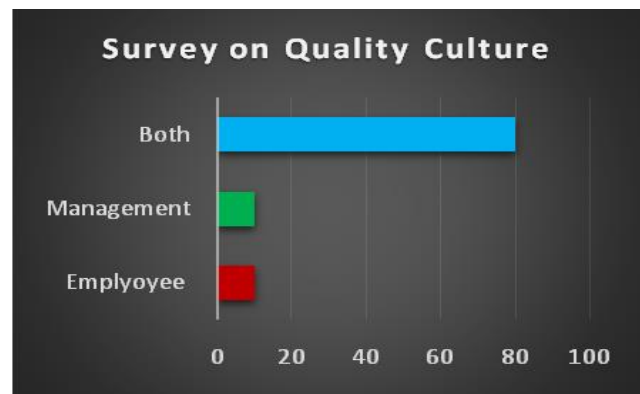

Figure 3: Quality Culture Interventions

Figure 4: Survey on Quality Culture

Title / Journal	Author	Country	Year	Method ology	Intervention Description	Employee	Manage ment	Both
Culture of Pharmaceutical Quality: Connecting the dots / Research Gate [3]	Ajaz S Hussain	USA	Oct 2015	Empirical	With an investment in training of staff on quality by design and building effective regulatory communication capabilities companies can proactively leverage regulatory uncertainty.	Yes	NA	NA
Creating a Culture of Quality / Harvard Business Review [1]	Ashwin Srinivasan and Bryan Kurey	USA	Apr 2004	Consumers Survey	Nearly half the employees surveyed reportedinsufficient leadership emphasis on quality, and only 10% found their company's quality messages credible. Just 38% reported high levels of peer involvement, while 20% said that their company has created a sense of employee empowerment and ownership for quality outcomes.	NA	NA	Both
Creating and Sustaining: A Quality	Ranjit Singh Malhi	Malaysia	Mar 2013	Literature Review	To ensure success, cultural change efforts must focus on formulating a clear, compelling	NA	NA	Both

Culture / Defense Management [4]					and shared vision; securing sustained top management commitment; role modeling of desired behavior by top leaders; promoting employee involvement and empowerment; conducting appropriate training at all levels to imbibe the new culture; maintaining open and honest communication; fostering a climate of trust and collaboration; and embedding cultural changes in the organization's structure, systems and policies.			
Culture of Quality / Forbes Insights [2]	Stephen Hacker	USA	Apr 2014	Global Survey, Qualitative Interviews	Clearly visible, engaged and unwavering senior management support for quality initiatives. Performance expectations for all individuals throughout the company that clearly link to quality goals.	NA	Yes	NA
Quality culture: understandings, boundaries and linkages / European Journal [7]	Lee Harvey &BjørnSt ensaker	Europe	Sep 2007	Theoretical	A quality culture is not just about checking outputs at each stage but is also a frame of mind, as much of the management literature implies.	NA	NA	Both
Attaining and Sustaining Quality A Metris & Cultural Perspective / Hebrew University	Louis W. Yu	Israel	May 2014	Empirical	Employees and Management strong commitment to quality culture	NA	NA	Both
Quality assurance for biopharmaceuticals: An overview of regulations, methods and problems / Elsevier [8]	Kristian M. Miiller, Mathias R. Gempeler, Max-Werner Scheiwe, B. TatjanaZe ugin	Europe	Aug 1996	Empirical	Harmonization, collaboration and coordination within the company is of great importance to allow an adequate transfer of know-how. QA- and GMP-issues may have shown the complexity of requirements on the manufacture of a product to achieve the quality required.	NA	NA	Both
Pharmaceutical Culture of Quality,Assurance of Data Integrity & Quality by Design: Connecting the Dots / Advice& Solutions LLC	Azaz Hussain	USA	Jul 2014	Empirical	In doing so we act consciously in the interest of patients – specially when no one is looking, and continually improve our quality by design and aim for right first time.	NA	NA	Both

| [3]
Quality Culture Survey Report / PDA Journal [6] | Pritesh Patel, Denyse Baker, Rick Burdick | USA | Oct 2015 | Survey | The PDA Quality Culture Survey was undertaken to determine whether quality culture, which manifests itself in the form of behaviors, could be measured using quality attributes as a proxy measure. | NA | NA | Both |
| Quality in the Pharmaceutical Industry- A Literature Review / Saudi Pharmaceutical Journal [5] | Reham M. Haleem, Maissa Y. Salem, Faten A. Fatahallah, Laila E. Abdelfattah | Saudi | Nov 2013 | Literature Review | There are some new practices that are recently applied to the pharmaceutical industry though they are widely applied in non-pharmaceutical industries, such as: the lean manufacturing; the Six Sigma; the total quality management. | NA | NA | Both |

warning letters, 483 observations, no corrective and preventive actions and less attrition.

DISCUSSIONS

This is the first systematic review of the impact of strategies to improve quality culture in pharmaceutical firms. Although all studies reported a positive effect of the quality culture intervention. Researchers mainly used two approaches to evaluate employee and management role in quality culture roll-out and implementation. For example, hand-in-hand and shoulder-to-shoulder employees and management approach improved access to and utilization of quality culture. Many of the recommendations made in the reviewed studies were not specifically tailored to the pharma sector. However undoubtedly applicable in pharma sector and consideration should be given to tailoring such strategies to the pharma sector. Although the number of articles identified was small, this in part reflected our search strategy. In addition, it was difficult to directly compare studies that reported different measures of different industrial sectors, and as a result, a more descriptive analysis is presented. We also recognize that excluding grey literature may have contributed to publication bias in our results, as published literature is more likely to describe successful interventions and grey literature may include a wider range of reports on experiences with implementation and evaluation of coverage improvement strategies.

CONCLUSIONS

This review describes the promise of strategies for implementing quality culture for improving quality of drug products in pharmaceutical organizations. Gaps in our knowledge about certain interventions do exist, including the longterm impact of interventions involving a high level of supervision as well as the potential for scalability of interventions that have only been tested. Answering these questions should be prioritized as

pharmaceutical firms become increasingly quality culture oriented and management grapple with developing effective and sustainable strategies to increase quality culture roll-out and implementation in their facilities and firms.

CONFLICT OF INTEREST STATEMENT

The authors have no conflicts of interest to report. The findings and conclusions in this report are those of the authors and do not necessarily represent.

REFERENCE

1. A. Srinivasan, B. Kurey, Creating a quality culture, Harvard Business Review 2014, 92 (4), 23–25.
2. Culture of quality, Forbes insights.https://www.forbes.com/forbesinsights/asq/
3. Culture of Pharmaceutical Quality: Connecting the Dots. Biopharm Asia October 2015. https://www.researchgate.net/publication/297731397
4. Creating and Sustaining: A Quality Culture Ranjit Singh Malhi* http://dx.doi.org/10.4172/2167-0374.S3-002
5. Quality in the Pharmaceutical Industry https://doi.org/10.1016/j.jsps.2013.11.004
6. Quality Culture Survey Report, doi:10.5731/pdajpst.2015.01078
7. Quality culture: understandings, boundaries and linkages Lee Harvey &BjørnStensaker
8. Quality assurance for biopharmaceuticals: An overview of regulations, methods and problemshttps://doi.org/10.1016/S0031-6865(96)00050-7
9. 21 CFR Part 210 (2005). Available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=210
10. 21CFR Part 211 (2005): Available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=211.