A review on International Regulatory concern on Role and Responsibility of Pharmaceutical Higher Management

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ABSTRACT

It has been always International Regulatory concern on Role and Responsibility of Pharmaceutical Higher Management in this review article we have taken some of the concern and how responsible leadership should ensure the support and commitment of staff at all levels and sites within the organization to the Pharmaceutical Quality System ,management review , Quality committee and to make a platform for leadership engagement, awareness and decision making around quality and process performance. Implement new controls as per GMP Guidelines to check impact and management tool for identification and reduction of human Errors in pharmaceuticals Industry.

Keywords: Regulatory Concern, Role of Higher Management, Pharmaceutical, Ethics, Quality, Safety, Efficacy, GMP, Data Lifecycle, Escalation of Issues

Senior Management: Person(s) who direct and control a company or site at the highest levels with the authority and responsibility to mobilise resources within the company or site.

Quality committee: A forum for leadership engagement, awareness and decision making around quality and process performance.

Quality metrics: A tool used throughout the drugs and biologics industry to monitor quality control systems and processes and drive continuous improvement efforts in drug manufacturing.

INTERNATIONAL REGULATORY CONCERN

1) Failure to implement new controls as per GMP Guidelines.

2) Failure to Describe the Action taken by firm or to contact customers, recalling product, Conducting additional testing, stability testing program to assure stability of product, Monitoring Complaints.

3) Failure to provide Steps to assure the quality of product manufactured under cGMP Environment.

4) Failure to take action and provide appropriate controls to prevent recurrence of cGMP Deviation, Including breaches of Data Integrity.

5) Fail to initiate immediate corrections, and implement corrective action or preventive action for regulatory inspections. Fail to interpret the investigator suggestion or observation for appropriate Corrective Action Preventive Action or logging an Event to investigate Failure.

6) Failure of Management to provide Training to grass root level employee to face audit and Make them understood How to communicate with the auditor or investigator for question and answer.

7) Failure to revise procedure in timely manner to reduces gap & prevent the incidences in future.

8) Senior management fails to maintain Quality Agreement with GMP contractors, Labs or vendors

9) Failure to learn from other firms GMP revoke of License or FDA Warning letter and to Implement corrective action or to provide GAP assessment with appropriate corrective as well as preventive action.

10) Failure to check impact and management tool for identification and reduction of human Errors in pharmaceuticals Industry.

11) Fail to build quality culture in the organization up to grass root level.

ROLE OF RESPONSIBLE MANAGEMENT

- Responsible management should take part proactively and retrospectively in Decision that Relate to Quality, Safety and efficacy of Product.
- Responsible management should take part in a timely manner during regulatory inspections, serious

cGMP deficiencies, product defects and related actions (e.g. quality related complaints, recalls, regulatory actions, etc.).

• Responsible management should perform product quality review Meeting in Timely Manner that should Ideally Involve all Departments.

• Responsible management should take proper Corrective Action & Preventive Action for Concern Raised by Individual Department.

• Responsible management of the firm should have knowledge of Audit findings (Self Inspection, External Agency, Regulatory Agency) and corrective actions that must documented and agreed corrective actions are completed in a timely and effective manner.

• Responsible management should motivate Employee involve in firm to Raise individual issue that are or of concern which might lead to Failure of Product Quality, Safety and Efficacy.

• Responsible management should provide all necessary Guidance and Support to Employee for benefit of his/her Growth in Economical and Social.

• Responsible management should involve in continual quality improvements appropriate to the current level of process and product knowledge.

• Responsible leadership should ensure the support and commitment of staff at all levels and sites within the organization to the Pharmaceutical Quality System.

• Responsible management must take responsibility for all Instances.

• Management Responsibility should involve in Quality policy, Resource management, Quality planning, internal communication, review.

• Responsible management should check performance and product quality monitoring system throughout the product lifecycle.

• To provide Environment from "compliance to quality culture" and to help in Quality Metrics, to improve FDA's evaluation of drug manufacturing and control operations.

Management Approach:

• Quality Manual: Overall intentions and direction of an organization related to quality as formally expressed by senior management.

• To achieve the quality objective reliably the management should involve in comprehensively designed and correctly implemented quality system incorporating Good Manufacturing Practice, Quality Control and Quality Risk Management.

• Evaluation of the risk to quality to be based on scientific knowledge, experience with the process and ultimately links to the protection of the patient through communication with the user of the Product/Customer/End User of Product.

• Pharmaceutical management should hire employee that should be adequately competent personnel, and suitable and sufficient premises, equipment and facilities that are designed as per GMP Guidelines.

• Facilitate continual improvement and ability to fulfil quality needs for consistently identifying and prioritizing areas for continual improvement.

• Should have defined role and responsibility in Quality Manual.

• Follow-up actions from previous management reviews.

• Measurement of achievement of pharmaceutical quality system using statistical tool or other Analysis tools.

• Must use knowledge from Emerging regulations, guidance and quality issues that can impact the Pharmaceutical Quality System.

• Must Encourage Employee to escalate appropriate issues to Head of Department (HOD), Quality Unit, senior management or relevant department like Human Resource department for Actions.

• Must be to Help FDA by submission of Quality Metrics Data.

TYPE OF QUALITY COMMITTEE MUST BE PREFERABLY AS MENTIONED BELOW:

Table 1.Desire Flow process

Quality committee	**Frequency**	**List of Member /Dept.**
Site Quality committee	Monthly	CQA Head, Plant Head, Quality Head, All Department Head
Regional Quality committee	Quarterly	COO, CQA Head, All site Quality Head, RA Head
Global Quality committee	Six monthly / Yearly	Managing Director, COO, CQA Head, All site Quality Head, RA Head

MANAGEMENT SHALL REVIEW CASE STUDY BASED ON PREVIOUS POINTS PREFERABLE IN FORMAT BELOW:

Table 2. Format for Case Study

Sr. No.	Topic
1	Challenge
2	Management Review Process
3	Preventive Action Taken
4	Ongoing Monitoring
5	Business Benefits
6	New Regulatory requirements
7	Status of Commitment and compliance to regulatory agencies

CONCLUSION

Responsible management should take part proactively and retrospectively in decision that relate to Quality, Safety and efficacy of Product. It should also check performance and product quality monitoring system throughout the product lifecycle. Also encourage employee to escalate appropriate issues to Head of Department (HOD), Quality Unit, senior management or relevant department like Human Resource department for Actions and Facilitate continual improvement and ability to fulfil quality needs for consistently identifying and prioritizing areas for continual improvement. So in nutshell Management plays an important role in pharmaceutical product quality

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