

In the Pharmaceutical GMP Industry, If Quality is Everyone's Responsibility, Is It No One's Responsibility?

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ABSTRACT

The phrase “Quality is everyone’s responsibility” is often misinterpreted in the Pharmaceutical Inspection Co-operation Scheme – Good Manufacturing Practices (PIC/S GMP) pharmaceutical industry, leading to the belief that quality oversight is solely the responsibility of the Quality Assurance (QA) department. This article explores the critical role of QA professionals in fostering a collaborative quality culture, asserting that quality should be integral to every employee’s responsibility. It emphasizes management commitment in establishing effective Pharmaceutical Quality System (PQS) and encourages viewing QA as partners. By engaging teams across various functions, organizations can cultivate a unified commitment to quality and implement strategies for overcoming resistance and measuring success through quantifiable metrics.

Keywords: *Pharmaceutical Quality System, Good Manufacturing Practice, Quality Assurance, Pharmaceutical Industry, Management Responsibilities, Quality Culture*

INTRODUCTION

In the highly regulated pharmaceutical GMP industry, the phrase “Quality is everyone’s responsibility” is frequently cited yet often misinterpreted. This misinterpretation can lead to a scenario where quality is perceived as the sole responsibility of the QA department, resulting in a culture where quality oversight is neglected. Many employees may feel disconnected from quality initiatives, believing that their roles do not directly impact overall quality. This article aims to address these misconceptions and highlight the essential role of QA professionals in fostering a culture of quality across all organizational levels. It underscores the need for management to embrace their responsibilities in promoting quality and for all employees to recognize their contributions to ensuring product integrity and patient safety. By shifting the focus from viewing quality as an isolated function to an integral part of every role, organizations can enhance their commitment to excellence and continuous improvement.

Edwards Deming famously stated, “Quality is everyone’s responsibility.”⁽¹⁾ While this sentiment is valid, it can easily be misinterpreted. If Deming’s quote is considered in isolation, it

risks falling into the familiar “everybody, somebody, nobody” trap, where individuals assume that someone else is accountable for quality. This leads to complacency and oversight. It is important to recognize that most employees do not come to work intending to perform poorly, undermine the organization, or resist improvement. When lapses occur, it is often because individuals are either unaware of their responsibilities or lack clarity regarding how to contribute effectively.

To emphasize the significance of quality across the organization, we must frame it as integral to every role and function, rather than solely the responsibility of the QA department. Achieving this requires a concerted effort to communicate that quality influences every facet of the organization, from manufacturing to marketing, and that each employee plays a vital role in ensuring product integrity and patient safety.

WHAT’S THE BASIS FOR THE CONCERN?

Management responsibilities have been a topic with regulatory agencies for quite some time, as evidenced by the various regulations and guidance we work within. For example:

- **PIC/S GMP** defines:
 1. Senior management has the ultimate responsibility to ensure an effective PQS is in place, adequately resourced, and that roles, responsibilities, and authorities are defined, communicated, and implemented throughout the organization. Senior management’s leadership and active participation in the Pharmaceutical Quality System is essential. (PIC/S GMP PE 009-17 (Part I), Chapter 1, sections 1.5)⁽²⁾
 2. There should be periodic management review, with the involvement of senior management, of the operation of the Pharmaceutical Quality System to identify opportunities for continual improvement. (PIC/S GMP PE 009-17 (Part I), Chapter 1, sections 1.6)⁽²⁾
 3. A Quality Manual or equivalent documentation should be established and should contain a description of the quality management system including management responsibilities. (PIC/S GMP PE 009-17 (Part I), Chapter 1, sections 1.7)⁽²⁾

- **EU (European Union) GMP** applies ultimate responsibility for quality and the PQS to senior management and assigns specific responsibilities for product and process quality to the heads of quality and production, along with the head of quality control (Eudralex V4, Chapters 2 and 6).⁽³⁾
- **ICH (International Council for Harmonization) Q10** defines senior management as having ultimate responsibility for ensuring an effective PQS is in place, emphasizing that management responsibility is integral to a functioning pharmaceutical quality system.⁽⁴⁾
- **ISO 9001:2015** specifies:
 4. Senior management must demonstrate leadership and commitment by communicating the importance of effective quality management and conforming with requirements. (Clause 5.1.1(f))⁽⁵⁾
 5. Top management must ensure that the quality policy is communicated, understood, and applied throughout the organization. (Clause 5.2.2(b))⁽⁵⁾
 6. Top management must establish objectives and communicate them to relevant functions and levels. (Clause 6.2.1(f))⁽⁵⁾
 7. Organizations must determine what, when, and how information is to be communicated within the organization, as well as to whom and by whom communication is to be delivered. (Clause 7.4)⁽⁵⁾

BRIDGING THE GAP

Given these frameworks, it is evident that QA professionals must bridge the gap between the ideal of ‘everyone’s responsibility’ and the practical implementation of quality in daily operations. **The Importance of Management Responsibilities:** The international guidelines underscore that senior management has ultimate responsibility for the effectiveness of the PQS. This leadership is critical in establishing a culture of quality that permeates the organization. When senior management demonstrates commitment to quality by actively participating in quality initiatives, it sets a tone that encourages all employees to prioritize quality in their roles.⁽⁶⁾

Engaging Teams Effectively: The first step is to shift the perception of QA from enforcers to collaborators and educators. For example, a pharmaceutical company could implement regular cross-departmental workshops where QA staff and operational teams collaborate on quality initiatives. In one such workshop, the QA team helped the Quality Control (QC) group understand how minor adjustments in their materials sampling processes could significantly reduce deviations.

The QA team introduced a randomized sampling strategy instead of a fixed pattern, ensuring samples were representative of the entire batch. They also provided training on purified water sampling techniques, highlighting the proper steps for glove sanitation with alcohol to minimize contamination risks in the water samples. These adjustments improved test reliability and fostered a greater sense of shared responsibility among QC staff, empowering them in their role in maintaining product quality.⁽⁶⁾

Empowering Employees: When management communicates the importance of quality, as specified in ISO 9001:2015, it empowers employees to take ownership of their contributions. For instance, after introducing a quality dashboard that displays real-time metrics, employees in the pharmaceutical outer packaging lines began to take pride in their high performance. This dashboard provided immediate feedback on key quality indicators, such as defect rates, adherence to specifications, and production efficiency.

The availability of real-time metrics allowed employees to monitor their performance continuously, fostering a sense of accountability and encouraging proactive problem-solving. For example, if an increase in defect rates was detected, employees could quickly identify the issue and implement corrective actions before it escalated into a larger problem. This initiative not only led to a 20% reduction in errors over six months but also promoted a culture of continuous improvement. In another example, a team that regularly reviewed and discussed performance metrics related to quality was able to identify specific areas for improvement. By aligning departmental objectives with the organization’s quality goals, they created a shared commitment to quality that enhanced overall productivity and morale. The collaborative environment encouraged employees to contribute suggestions based on real-time data, further reinforcing their engagement and investment in maintaining high-quality standards.⁽⁷⁾

Ongoing Leadership Involvement: Periodic management reviews, as outlined in PIC/S GMP and EU GMP, should focus on compliance and identifying opportunities for continuous improvement. A generic drug manufacturing company, for example, established a regular review process that enabled quick identification of non-compliance trends, leading to proactive measures that improved overall quality.⁽⁸⁾

The regular review process includes several key items:

- **Performance Metrics:** Assessing indicators like deviation rates, CAPA (Corrective and Preventive Action) statistics, and change control provides insights into quality performance and areas needing attention.
- **Product Complaint Handling:** Reviewing product complaints helps identify recurring issues and informs necessary corrective actions.
- **Audit Findings:** Analysing internal and external audit results helps identify systemic issues and evaluate the effectiveness of corrective actions.
- **Risk Assessments:** Evaluating potential risks allows management to prioritize areas for improvement and mitigate future issues.
- **Action Plans and Effectiveness Checks:** Tracking progress on action plans ensures accountability and follow-through on identified issues.

By emphasizing the importance of management responsibilities in fostering a culture of quality, we can

bridge the gap between theoretical frameworks and practical application.⁽⁹⁾ In doing so, we create an environment where quality is truly everyone's responsibility, supported by strong leadership and effective collaboration.

We cannot march around with the same script everywhere. We must tailor our communication to resonate with different teams and individuals. Here's how we can do this effectively:

- **Production Team:** When working with the Production team, QA can actively participate in process reviews and workshops, including Gemba walks to observe processes firsthand. This involvement allows QA to identify potential sources of variation and implement robust controls to minimize risks to product quality. Additionally, QA can conduct CAPA effectiveness checks and occupational safety and health assessments. Performance metrics such as yield rates, defect rates, and adherence to SOPs can be monitored to evaluate the effectiveness of quality initiatives and drive continuous improvement.⁽¹⁰⁾
- **Engineering Team:** In collaboration with the engineering team, QA can provide critical input during the design and validation of equipment. This ensures that equipment not only meets GMP requirements but also performs as intended throughout its lifecycle. QA should also ensure adherence to annual preventive maintenance checks and the validity of equipment qualifications. Key performance indicators (KPIs) such as equipment downtime, validation success rates, and compliance with design specifications can help track the effectiveness of engineering solutions in supporting quality objectives.
- **Supply Chain Team:** When partnering with the supply chain team, QA plays a vital role in ensuring that suppliers are qualified and that materials meet established quality standards. This collaboration includes conducting supplier audits, evaluating supplier performance, and establishing criteria for material acceptance. Metrics such as supplier defect rates, on-time delivery rates, and compliance with material specifications can be utilized to assess supplier performance and strengthen the overall quality of the supply chain.⁽¹¹⁾
- **Quality Control Team:** QA should maintain a strong partnership with the quality control (QC) team to ensure that testing protocols align with both regulatory requirements and organizational standards. This includes conducting regular surveillance checks for computer system validation (CSV), data integrity, and security. Additionally, QA should review out-of-specification (OOS) and out-of-trend (OOT) results, handling investigations effectively. Performance metrics such as test accuracy, turnaround time for results, and the rate of non-conformance can track the QC team's effectiveness in maintaining product quality.⁽¹²⁾

- **Procurement Team:** In collaboration with the procurement team, QA can help define quality specifications for materials and services. This collaboration ensures that all purchased items meet the organization's quality standards before they reach production. Key activities include supplier and vendor qualification, as well as tracking supplier performance metrics such as on-time delivery and quality compliance.⁽¹³⁾ By providing training and resources on quality requirements, QA can empower procurement professionals to make informed decisions. Metrics such as the percentage of compliant materials received, and the rate of supplier-related quality issues can measure procurement's contribution to quality objectives.

This approach enhances collaboration and fosters a unified commitment to quality across all departments, driving continuous improvement and compliance throughout the organization.⁽¹⁴⁾ By regularly monitoring and analysing performance metrics, each team can identify areas for enhancement and collaboratively pursue shared quality objectives.

Rather than enforcing compliance in a way that breeds resistance, we should emphasize how specific quality practices prevent errors, save time, improve profitability, and enhance patient safety. It is crucial to communicate the rationale behind quality initiatives, rather than merely issuing directives regarding Incident Reports or CAPA plans. Making quality personal is essential. We must illustrate how quality affects not only the final product but also individual roles and job satisfaction. This transforms the abstract notion of 'everyone's responsibility' into concrete actions and attitudes.

FOSTERING A QUALITY CULTURE

A quality culture in the pharmaceutical industry refers to the collective mindset, values, attitudes, and behaviours within an organization that prioritize and promote a commitment to quality.⁽¹⁵⁾ Here are key elements that contribute to fostering a strong quality culture: Ms. Jody Chu, Senior Lecturer from Department of Pharmacology and Pharmacy at the University of Hong Kong, described how HKUMed's community pharmacy placements expose students to IPE in real-world environments.

1. **Leadership Commitment:** Top management must demonstrate leadership and commitment to quality, communicating its importance and setting clear expectations.⁽¹⁶⁾ They should communicate its importance, establish specific expectations, allocate necessary resources, and lead by example, inspiring all employees to prioritize quality and understand their role in achieving these goals.
2. **Employee Engagement:** Engaged and empowered employees are essential for a strong quality culture. Encouraging open communication, involving employees in decision-making, and recognizing quality contributions fosters accountability and a sense of ownership.⁽¹⁷⁾

3. **Training and Education:** Providing comprehensive training is essential for equipping employees with the knowledge and skills needed to perform their roles effectively. Training programs should emphasize quality principles, regulatory requirements, and GMP. This focus ensures that employees understand the importance of quality and compliance, fostering a culture of excellence within the organization.⁽¹⁸⁾
4. **Clear Quality Objectives:** By establishing SMART (Specific, Measurable, Achievable, Relevant, and Time-bound) quality objectives, organizations can ensure that everyone understands their contributions to quality improvement.⁽¹⁹⁾ Regular communication and review of these objectives help maintain focus and accountability, fostering a culture of continuous improvement.
5. **Documentation and Standard Operating Procedures (SOPs):** Clear documentation and SOPs are vital for ensuring consistency in processes and adherence to quality standards.⁽²⁰⁾ They provide a structured framework that facilitates knowledge transfer among employees, helping to maintain continuity in operations. This consistency not only enhances efficiency but also supports compliance and quality assurance across the organization.
6. **Risk-Based Thinking:** Adopting risk-based thinking fosters a proactive approach to quality management, promoting a strong quality culture within the organization. By encouraging employees to identify and address potential risks in their areas, organizations empower them to take ownership of quality. This proactive mindset strengthens overall quality performance and enhances resilience against challenges.⁽²¹⁾
7. **Continuous Improvement:** Emphasizing continuous improvement is vital for sustaining a robust quality culture. By encouraging employees to identify areas for enhancement, organizations create an environment that values learning and innovation.⁽²²⁾ This focus on ongoing development not only boosts quality performance but also motivates employees to contribute actively to the organization's success.⁽²³⁾
8. **Collaboration and Communication:** Building effective cross-functional collaboration and communication channels is essential for enhancing quality outcomes.⁽²⁴⁾ By facilitating the sharing of knowledge and best practices, organizations can leverage diverse perspectives and expertise. This collaborative approach fosters a unified commitment to quality, ensuring that all teams work together towards common goals and continuous improvement.
9. **Audits and Inspections:** Regular internal audits and external inspections are crucial for ensuring compliance with regulatory requirements. These assessments not only verify adherence to standards but also

create valuable opportunities to identify areas for improvement. By systematically evaluating processes, organizations can enhance their quality management systems and drive continuous improvement initiatives effectively.⁽²⁵⁾

10. **Customer Focus:** Placing the customer at the centre of quality efforts is essential for reinforcing the importance of meeting their needs and expectations. This customer-centric approach fosters a quality culture that prioritizes satisfaction and loyalty. By actively seeking and responding to customer feedback, organizations can continuously enhance their products and services, ensuring lasting success.⁽²⁶⁾

Hypothetical Scenario: Building a Quality Culture

Imagine a pharmaceutical company that implemented a comprehensive training program focused on quality principles. Employees were encouraged to share experiences related to quality issues openly. As a result, one department identified a recurring issue with a supplier's materials. By collaborating with the Quality Control and Procurement teams, they established stricter incoming material inspections for suppliers with recurring quality issues. This initiative led to a significant reduction in defects and improved product reliability. Additionally, the new procedures were incorporated into the relevant incoming material sampling and inspection SOPs.

MEASURING SUCCESS

To gauge the effectiveness of our shift towards a more collaborative approach to quality, we need to establish clear, quantifiable metrics that can provide insights into our progress and impact. Here are some key areas to focus on:

- **Reduction in Deviations and CAPAs:** Tracking the number of deviations and Corrective and Preventive Actions (CAPAs) over time can indicate the effectiveness of our quality management practices.⁽²⁷⁾ A significant reduction suggests that proactive measures are being successfully implemented, and that teams are adhering to established protocols. Regularly reviewing these metrics in team meetings can reinforce accountability and highlight areas for ongoing improvement.⁽²⁸⁾
- **Improved Process Capability:** By measuring process capability indices (like Cp and Cpk), we can assess how well our processes meet specifications.⁽²⁹⁾ An increase in these indices indicates that processes are becoming more stable and capable, leading to higher quality outputs. This can be complemented by Six Sigma methodologies to set targets for improvement and track progress.⁽³⁰⁾
- **Increased Employee Engagement in Quality Initiatives:** Employee engagement is crucial for fostering a quality culture. We can measure engagement through surveys, participation rates in quality training sessions, and involvement in quality improvement projects. High engagement levels

often correlate with improved morale and a greater commitment to quality objectives. Celebrating employee contributions to quality initiatives can further enhance this engagement.⁽³¹⁾

- **Positive Feedback from Other Departments:** Gathering feedback from various departments regarding QA's collaborative approach can provide valuable qualitative insights.⁽³²⁾ Surveys or informal feedback sessions can be used to assess perceptions of QA's support and involvement. Positive feedback indicates that QA is effectively partnering with other teams and contributing to a shared quality vision.
- **Performance Metrics Specific to Each Team:** As previously outlined, each department should have specific performance metrics related to quality that can be monitored. This includes metrics like supplier performance in procurement, equipment downtime in engineering, and test accuracy in quality control. Regularly reviewing these metrics can drive accountability and continuous improvement within each team.⁽³³⁾
- **Timeliness of Issue Resolution:** Tracking how quickly issues are identified and resolved can provide insights into the effectiveness of our collaborative efforts.⁽³⁴⁾ A decrease in resolution times for CAPAs and other quality-related issues indicates that teams are working effectively together to address problems.⁽³⁵⁾
- **Training and Development Outcomes:** Measuring the effectiveness of training programs related to quality can help ensure that all employees are equipped with the necessary knowledge and skills.⁽³⁶⁾ Pre- and post-training assessments can provide insights into knowledge gains, while tracking the application of training in day-to-day operations can highlight its practical impact.⁽³⁷⁾

Real-World Example: Measuring Success

A pharmaceutical company that implemented employee engagement surveys found that departments with higher engagement scores reported fewer deviations. For instance, after introducing a comprehensive quality training initiative, which included workshops, hands-on training sessions, and interactive e-learning modules, one department saw a 30% decrease in errors within three months.⁽³⁸⁾ The initiative focused on key quality principles, including GMP, risk management, and documentation standards. Employees participated in case studies and role-playing exercises, which helped them better understand the impact of their work on product quality. This direct engagement demonstrated a strong correlation between employee engagement, quality training, and improved quality outcomes.⁽³⁷⁾

OVERCOMING RESISTANCE

Individuals or teams may initially resist this shift in approach, often due to concerns about changes to established processes

or fears about increased scrutiny.⁽³⁸⁾ To overcome this resistance, we can take several proactive steps:

- **Demonstrate Value Through Small Wins:** Highlighting small successes can build momentum for broader change. For example, if a collaborative project leads to reduced cycle times or improved quality metrics, sharing these successes with the organization can illustrate the tangible benefits of collaboration.⁽³⁹⁾
- **Engage Stakeholders Early:** Engaging stakeholders early in the process is crucial for alleviating concerns and fostering buy-in.⁽⁴⁰⁾ By soliciting input and feedback during the planning stages, organizations can ensure that initiatives effectively address specific team needs and concerns. This collaborative approach not only enhances commitment but also leads to more successful and relevant outcomes.⁽⁴¹⁾
- **Communicate Openly and Frequently:** Communicating openly and frequently about the goals of quality initiatives is essential for fostering engagement and collaboration.⁽⁴²⁾ Regular updates and success stories help keep everyone informed, reinforcing the benefits of teamwork. This transparency builds trust and motivates employees to actively participate in quality improvement efforts, driving overall success.⁽⁴³⁾
- **Provide Support and Resources:** Offering training and necessary tools can ease the transition and empower teams to collaborate effectively. By equipping employees with the right resources and frameworks, organizations foster a smoother integration of changes, enhancing overall productivity and quality outcomes.⁽⁴⁴⁾
- **Celebrate Collaborative Efforts:** Recognizing and rewarding teams and individuals who embrace collaborative quality practices is essential for reinforcing desired behaviours.⁽⁴⁵⁾ This recognition fosters a culture of quality throughout the organization, motivating others to adopt similar practices. By celebrating successes, organizations encourage ongoing commitment to quality improvement and collaboration, driving overall performance.⁽⁴⁶⁾

Hypothetical Scenario: Overcoming Resistance

Consider a scenario where a pharmaceutical company faced resistance to a revised quality control procedure. By involving employees in the development process and providing hands-on training sessions, management reduced resistance. Employees were encouraged to share their concerns and suggestions during pilot implementations. After several months, the revised procedure not only improved documentation accuracy but also enhanced workflow efficiency, leading to better compliance with regulatory standards. The collaborative approach fostered a sense of ownership among employees, ensuring a smoother transition to the new practices.⁽¹⁷⁾

FINAL THOUGHTS

Reflecting on the preceding discussion, consider the following question that often arises among pharmaceutical professionals: Who is ultimately responsible for quality and the pharmaceutical quality system?

The options are:

- *Option A: All personnel in the company*
- *Option B: Quality Assurance Department*
- *Option C: Senior Management within the organization*

This question prompts an examination of shared responsibility for quality within the organization. Acknowledging that quality is a collective effort is vital for fostering commitment to quality practices at all levels.⁽⁴⁷⁾ Our goal is to translate “quality is everyone’s responsibility” into actionable terms. Senior management and organizational leaders play a crucial role in positioning Quality Assurance professionals and quality leadership as collaborators and educators. By doing so, they can engage teams across the organization and demonstrate the value of quality through measurable outcomes.⁽⁴⁸⁾ Ultimately, we must cultivate a culture where quality is a fundamental value integrated into all aspects of our pharmaceutical operations, ensuring it becomes a shared responsibility embraced by every employee.⁽⁴⁹⁾

CONCLUSION

The commitment to quality in the pharmaceutical GMP industry must be embraced as a collective responsibility rather than a task relegated to the QA department. This article emphasizes that quality is not merely a program or project but a fundamental value that should permeate every aspect of organizational operations. By fostering a culture where all employees understand their role in quality, supported by strong leadership and clear communication, organizations can achieve meaningful and sustainable improvements.

To bridge the gap between the ideal of “everyone’s responsibility” and practical implementation, senior management must actively engage with teams, empower employees, and establish clear quality objectives. It is crucial to recognize that the notion of “it is no one’s responsibility” is erroneous; this “everybody, somebody, nobody” trap leads individuals to assume that someone else is accountable for quality. Moreover, measuring success through quantifiable metrics will help track progress and reinforce accountability. Ultimately, cultivating a shared commitment to quality is essential for ensuring product integrity, enhancing patient safety, and achieving excellence in the pharmaceutical industry.

Author’s background

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