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ORIGINAL ARTICLE

Transitioning to Revised Schedule M: A Research-Based Assessment of GMP Compliance Challenges and Opportunities in India's Pharmaceutical Industry

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ABSTRACT

The Revised Schedule M (2023) marks a significant step toward harmonizing India's Good Manufacturing Practices (GMP) with global standards such as WHO-GMP. This study aims to critically evaluate the challenges and opportunities arising from this transition and its implications for pharmaceutical manufacturers across India. A structured methodology involving literature review, survey-based data collection, and comparative analysis was adopted. Responses from 101 professionals representing micro, small, medium, and large pharmaceutical enterprises were analyzed to gain industry-level insights. The results indicate a high level of awareness regarding the revised guidelines, with varying degrees of implementation based on company size and resources. While progress has been observed in areas such as documentation, quality risk management, and personnel training, challenges remain in terms of infrastructure modernization, data integrity systems, and cost burden, particularly for MSMEs. The study also highlights the industry's expectations for government support, training, and clearer regulatory guidance. By identifying key hurdles and practical solutions, this research contributes actionable recommendations for policymakers, regulators, and industry stakeholders to ensure a smoother implementation of Revised Schedule M (2023) and to enhance India's position in regulated global markets.

Keywords: *Revised Schedule M, Good Manufacturing Practices, GMP Compliance, Indian Pharmaceutical Industry, WHO-GMP, Regulatory Implementation, Quality Systems*

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INTRODUCTION

The Indian pharmaceutical industry has witnessed exceptional growth, making India one of the world's largest producers of pharmaceutical products. The industry's origins date back to the 1960s, with the establishment of public sector units like Indian Drugs and Pharmaceuticals Limited (IDPL) and Hindustan Antibiotics Limited (HAL).

Post-liberalization, the industry witnessed significant growth, driven by

- Increased demand for generics
- Export-led growth
- Foreign direct investment (FDI)
- Emergence of domestic players

Current scenario

- India is the world's third-largest pharmaceutical producer by volume and 14th by value.
- Pharmaceutical exports reached USD 27.82 billion in FY24.
- India is home to over 3,000 pharmaceutical companies, with a significant presence of small and medium-sized enterprises (SMEs).
- India's pharmaceutical products are distributed to over 200 countries, including major export destinations like the US.

The industry's growth has been facilitated by government support, growing demand, and the emergence of domestic pharmaceutical companies that innovate and lead in multiple therapeutic segments. (1)

Regulatory Framework: Schedule M of Drugs and Cosmetics Act

Regulatory frameworks are pivotal in ensuring drug quality and safety. Schedule M of the Drugs and Cosmetics Rules, 1945 prescribes the requirements for the manufacture and quality control in the Indian pharmaceutical industry. Schedule M was first introduced in 1988 and has undergone several revisions since then.

Table 1: Key Revisions of Schedule M

Revision Year	Gazette Notifications	Objective	Key Focus Areas
1988	GSR 735(E) dated 24th June, 1988 (2)	Schedule M was formally introduced in the Drugs and Cosmetics Act of 1940 and Rules of 1945, aimed at establishing minimum standards for manufacturing facilities and practices in the pharmaceutical industry. This marked India's first major step towards implementing GMP guidelines for quality control.	Basic GMP guidelines
2001	GSR 894(E) dated 11th December, 2001 (3)	In 2001, the Indian government introduced significant changes to Schedule M to align with international GMP standards, especially as the industry grew and India became a major player in generic drug manufacturing. This revision focused on ensuring stricter quality control, including requirements for manufacturing facilities, equipment, documentation, and sanitation. A special emphasis was placed on the quality and safety of drug manufacturing processes and increased regulatory oversight.	Infrastructure, sanitation, documentation
2005	GSR 431(E) dated 30th June, 2005 (4)	Another critical update was introduced in 2005, emphasizing better standards for plant layout, cleanliness, storage, and personnel training. The revision mandated that pharmaceutical companies in India adopt infrastructure upgrades and stricter adherence to documentation standards. The 2005 revision aimed to further harmonize with WHO GMP standards to enhance India's credibility in global markets.	Plant layout, personnel training
2023	GSR 922(E) dated 28th December 2023 (5)	In December 2023, the Revised Schedule M was introduced, incorporating approximately 90% of the WHO Technical Report Series (WHO TRS) GMP guidelines. This latest revision is seen as a substantial upgrade aimed at achieving global regulatory excellence. Key additions include requirements for modernized equipment, advanced quality management systems, and updated guidelines for risk management, data integrity, and validation protocols. The 2023 update strengthens India's pharmaceutical regulatory framework, aligning it closely with global GMP requirements and supporting the industry's global competitiveness and commitment to high-quality standards.	Comprehensive adoption of WHO TRS

The 2005 revision of Schedule M in India was a significant step toward aligning with global Good Manufacturing Practices (GMP), particularly the guidelines set by the World Health Organization (WHO). However, it was not an exact match, and there were still areas where the Indian standards were less comprehensive compared to the international guidelines. Given India's status as the "Pharmacy of the World," characterized by its extensive global pharmaceutical reach, further updates to Schedule M were deemed essential for maintaining and enhancing global competitiveness. The latest amendment to Schedule M was introduced in December 2023, with its provisions set to be implemented shortly thereafter. This revision represents a landmark transformation, as it aligns India's GMP standards more closely with international guidelines such as those set by the World Health Organization (WHO). This revision reflects India's commitment to maintaining its global pharmaceutical leadership while meeting stringent international compliance requirements. However, transitioning to the Revised Schedule M presents a unique set of challenges for pharmaceutical manufacturers in India, including compliance

costs, infrastructural upgrades, and workforce training. Simultaneously, it opens up opportunities to enhance export potential, foster innovation, and strengthen India's position in global markets [7].

Transition to Revised Schedule M: Industry size:

India's pharmaceutical industry is vast and diverse, consisting of various types of manufacturing units. According to a survey by the Department of Pharmaceuticals, (6)

- Micro industries (26%): 1,995 units, mostly focused on local manufacturing.
- Small industries (31.2%): 2,393 units, targeting local or regional markets.
- Medium industries (30.4%): 2,331 units, producing complex products on a national scale.
- Large industries (12.4%): 954 units, focused on global markets with high-value products.

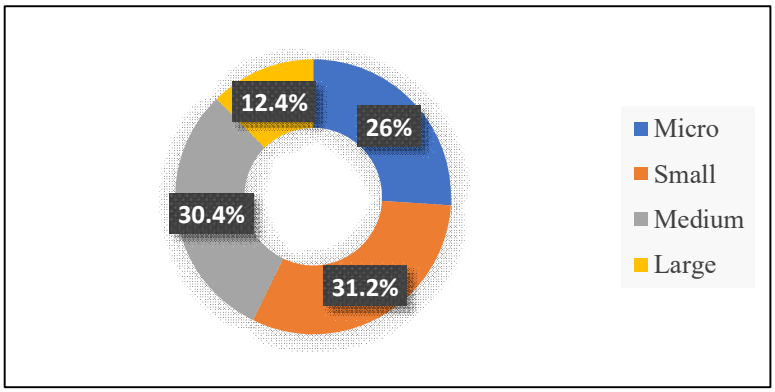

Figure 1. Pharma Industry Size

This diversity in industry composition adds to the complexity of the transition to the revised Schedule M, as each category will face different challenges and opportunities during the implementation of new GMP standards. This research aims to critically assess the challenges and opportunities faced by the Indian pharmaceutical industry during the transition to the Revised Schedule M (2023), focusing on GMP compliance. By identifying key hurdles and exploring effective strategies, the study seeks to provide actionable insights for regulators and industry stakeholders, ensuring a seamless shift to the Revised Schedule M and reinforcing India's reputation as a global pharmaceutical powerhouse [8].

Objectives:

The primary aim of this study is to evaluate the challenges and opportunities arising from the transition to the Revised Schedule M (2023) in India's pharmaceutical industry. This research will focus on understanding the impact of the new GMP (Good Manufacturing Practices) requirements introduced by the 2023 amendment. The study aims to provide a comprehensive assessment of how pharmaceutical companies can adapt to these revised standards, identify potential barriers to compliance, and uncover opportunities for enhancing product quality, safety, and manufacturing efficiency.

The primary objectives of this study are as follows:

- To identify the challenges faced by pharmaceutical companies during the transition to the Revised Schedule M (2023), including costs, infrastructure changes, and workforce training.
- To examine the impact of the Revised Schedule M on India's pharmaceutical industry, particularly its role in improving exports and product quality.
- To assess how different types of pharmaceutical manufacturers (micro, small, medium, and large) are preparing for the new GMP standards and the specific challenges each faces.
- To explore opportunities for innovation in areas like quality management systems, data integrity, and risk management.
- To examine how government policies and industry partnerships can support the smooth implementation of the Revised Schedule M and ensure continued industry growth and compliance.

By fulfilling these objectives, this research will provide valuable insights for regulatory bodies, industry stakeholders, and pharmaceutical manufacturers themselves, helping them navigate the challenges and seize the opportunities that the Revised Schedule M presents.

MATERIAL AND METHODS

This research adopts a mixed-methods approach, combining both qualitative and quantitative techniques to assess the implementation of the Revised Schedule M (2023) and its impact on GMP compliance in

India's pharmaceutical sector. The methodology was designed to gather real-world insights from industry professionals, supported by regulatory literature and global GMP standards.

Study Design

The study follows a descriptive cross-sectional design, using a structured online questionnaire as the primary tool for data collection. Supplementary secondary data was obtained through review of regulatory documents, literature, and official publications.

Data Sources

Primary Data: Collected through a structured Google Form disseminated among pharmaceutical professionals across India, including personnel from QA, QC, Regulatory Affairs, and Management departments.

Secondary Data: Sourced from peer-reviewed journals, regulatory documents, WHO Technical Report Series, and official government publications such as gazette notifications and the Drugs and Cosmetics Act, 1940.

Questionnaire Design

The questionnaire consisted of both closed-ended and open-ended questions, organized into the following categories:

- Respondent demographics and role
- Awareness of Revised Schedule M (2023)
- Organizational preparedness
- Implementation challenges
- Perceptions and suggestions

Question types included multiple choice, Likert scale, Yes/No, checkboxes, and free-text response options.

Sampling Technique

A purposive sampling method was adopted to target professionals directly involved in GMP-related functions. The survey was circulated among QA/QC personnel, regulatory officers, and managerial staff in pharmaceutical companies across India.

Sample Size

A total of 101 responses were received from professionals working in Indian pharmaceutical companies of varying sizes and regulatory scope. The sample includes a diverse cross-section of departments such as Quality Assurance (QA), Quality Control (QC), Regulatory Affairs, and Senior Management, representing organizations across micro, small, medium, and large enterprise categories.

Data Analysis

Quantitative Data: Analyzed using descriptive statistical methods such as frequency distributions and percentage analysis. Visual representation of data (pie charts, bar graphs) was used to illustrate trends and departmental breakdowns.

Qualitative Data: Open-ended responses were thematically analyzed to identify recurring patterns, practical challenges, and stakeholder expectations regarding Revised Schedule M implementation.

Ethical Considerations

All participants were informed about the voluntary nature of the study, and responses were collected anonymously. No personal or sensitive information was gathered, ensuring confidentiality and ethical compliance throughout the research process.

RESULT AND DISCUSSION

This section presents the findings derived from the survey responses collected from professionals working in pharmaceutical companies across India. A total of 101 responses were received, representing diverse organizational sizes (micro to large-scale industries) and functional areas including Quality Assurance (QA), Regulatory Affairs, Quality Control (QC), and Manufacturing. The analysis provides insights into the current level of awareness, implementation status, challenges, and perceived opportunities associated with the Revised Schedule M (2023). Both quantitative data (e.g., multiple-choice responses) and qualitative inputs (e.g., open-ended answers) are evaluated to offer a comprehensive understanding of industry readiness and expectations [9]. The discussion also compares these findings with the objectives of the Revised Schedule M, highlighting key areas where regulatory support, industry preparedness, and infrastructural investments are most needed.

Demographic Profile of Respondents

A total of 101 professionals participated in the survey, offering a representative cross-section of the Indian pharmaceutical industry. Respondents belonged to various functional departments, levels of experience, and organization types—helping to ensure balanced insights regarding the Revised Schedule M (2023) implementation.

The survey collected responses from diverse geographic regions across India, reflecting regional variations in infrastructure, regulatory awareness, and GMP readiness.

Table 2. Demographic characteristics of the study participants (n = 101).

Parameters	n (%)
Department-Wise Distribution	
Quality Assurance (QA)	43.6%
Regulatory Affairs	22.8%
Quality Control (QC)	17.8%
Management-level personnel	15.8%
Experience in the Pharmaceutical Industry	
More than 10 years	48.5%
4–6 years	18.8%
7–10 years	15.8%
1–3 years	11.9%
Less than 1 year	5%
Type of Organization	
Small-scale enterprises	38.6%
Large enterprises	27.7%
Medium enterprises	13.9%
Micro enterprises	10.9%
Multinational corporations	10.9%

The survey captures perspectives from key stakeholders directly responsible for quality, compliance, and regulatory adherence—areas most impacted by the Revised Schedule M. Nearly half of the respondents (48.5%) possess more than 10 years of industry experience, and cumulatively, over 83% have more than 4 years of experience. This high level of professional expertise lends strong reliability and practical depth to the insights gathered. The sample also represents a balanced distribution across organizations of varying sizes, though the greater participation of small-scale enterprises suggests heightened interest or concern from this segment regarding the implementation of the Revised Schedule M (2023) 9].

Awareness and Preparedness for Revised Schedule M

The survey results show that awareness of the Revised Schedule M (2023) is nearly universal, with 99% of respondents reporting familiarity with the notification issued by CDSCO. This indicates that the revised regulatory update has been effectively disseminated across the pharmaceutical industry, particularly among QA, QC, Regulatory, and Management professionals.

When asked about the sources of awareness, most participants (72.3%) cited official regulatory circulars, highlighting the importance of formal communication from authorities. Online sources (65.3%) also played a critical role, reflecting the growing influence of digital media and regulatory portals. Professional networks and events remained important, with 50.5% acknowledging industry associations and seminars, while 48.5% credited internal training initiatives. Peer-to-peer sharing was reported by 31.7%, while only a small fraction (7.9%) indicated no significant awareness channel [10,11]. This mix suggests that both top-down dissemination and peer-level sharing are instrumental in spreading regulatory knowledge.

Table 3. Awareness and Understanding of Revised Schedule M (2023) among Pharmaceutical Professionals.

Parameter	% of Respondents	Key Insights
Awareness of Revised Schedule M (2023)		
Aware	99.0%	Nearly universal awareness of the Revised Schedule M exists among respondents, reflecting strong dissemination of regulatory updates.
Not Aware	1.0%	
Sources of Awareness		
Regulatory circulars	72.3%	Regulatory circulars and online sources remain the most influential channels, though industry events and internal training also contribute significantly.
Online sources (websites, portals, news)	65.3%	
Industry associations / seminars	50.5%	
Internal training	48.5%	
Peers / colleagues	31.7%	
Not applicable	7.9%	
Self-Rated Understanding		
5 – Excellent	21.8%	While awareness is high, only about 22% report excellent understanding. A significant group (36.6%) falls in the moderate-to-low range, suggesting the need for structured training programs.
4 – Good	37.6%	
3 – Moderate	22.8%	
2 – Low	13.8%	
1 – Very Low	1.0%	

Regarding self-rated understanding, a majority of respondents demonstrated confidence, with 37.6% rating their understanding as good (4 on a 5-point scale) and 21.8% rating it excellent. However, 36.6% fell within the moderate range (levels 2–3), and one respondent rated their understanding as very low. These results suggest that while awareness is widespread, there are gaps in depth of comprehension, especially among smaller firms and early-career professionals. Overall, the findings indicate that the Revised Schedule M (2023) has reached industry stakeholders effectively, but structured capacity-building programs—such as workshops, training in regional languages, and practical case studies—will be crucial to translate awareness into consistent, high-quality implementation.

Implementation Status of the Revised Schedule M (2023) [12, 13]

The survey shows that only 25% of respondents reported full implementation of the Revised Schedule M (2023) in their organizations. A majority (70%) indicated partial implementation, while a small fraction (5%) reported that implementation has not yet started. This suggests that although the industry is largely aware of the revisions, many companies remain in the transition phase, possibly due to constraints in infrastructure, budget, or workforce preparedness.

This finding highlights the importance of examining the key areas currently prioritized by companies as part of Revised Schedule M implementation.

Documentation and data integrity (90.1%) ranked highest, reflecting a strong push toward compliance and audit readiness.

- Personnel training (77.2%) was the next priority, underscoring the need to equip employees with knowledge of new requirements.
- Quality risk management (70.3%) featured prominently, signifying the industry's recognition of risk-based approaches.
- Infrastructure upgrades (66.3%) were also reported, indicating that physical and operational changes are actively underway.
- Equipment modernization (37.6%) lagged behind, suggesting budgetary and logistical constraints in replacing legacy systems.

When asked about training on the Revised Schedule M, a strong 84.2% of respondents confirmed that they had received training, showing a proactive approach by many companies. However, 15.8% had not yet received training, pointing to a gap that must be addressed to ensure consistent compliance across the sector. Overall, while awareness of the Revised Schedule M is high, its implementation remains in progress across the industry. Encouragingly, companies are prioritizing documentation, personnel training, and quality risk management. However, notable gaps in equipment modernization and comprehensive training highlight the need for sustained organizational support and investment to achieve full compliance.

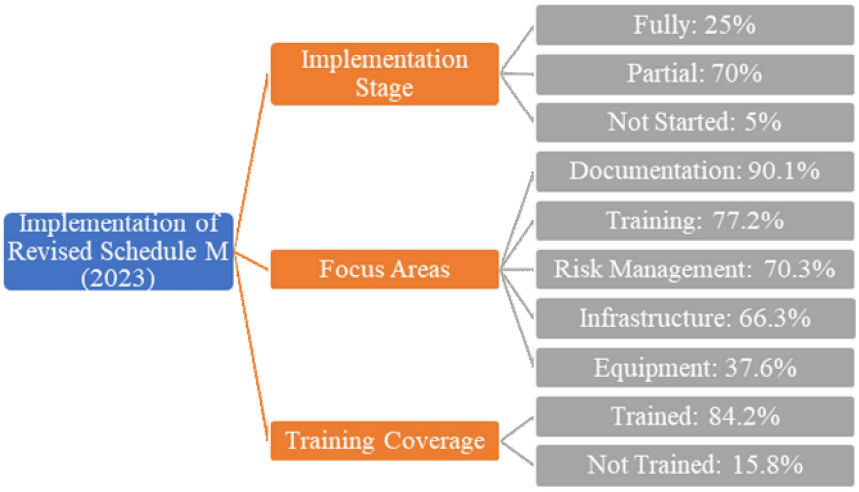

Figure 2. Current Status and Priorities in Implementing Revised Schedule M

Challenges in Implementing Revised Schedule M (2023) [14]

The survey explored the specific challenges faced by pharmaceutical companies in implementing the Revised Schedule M (2023). The analysis combined quantitative ratings with open-ended responses, providing both numerical insights and practical experiences across organizations of different sizes.

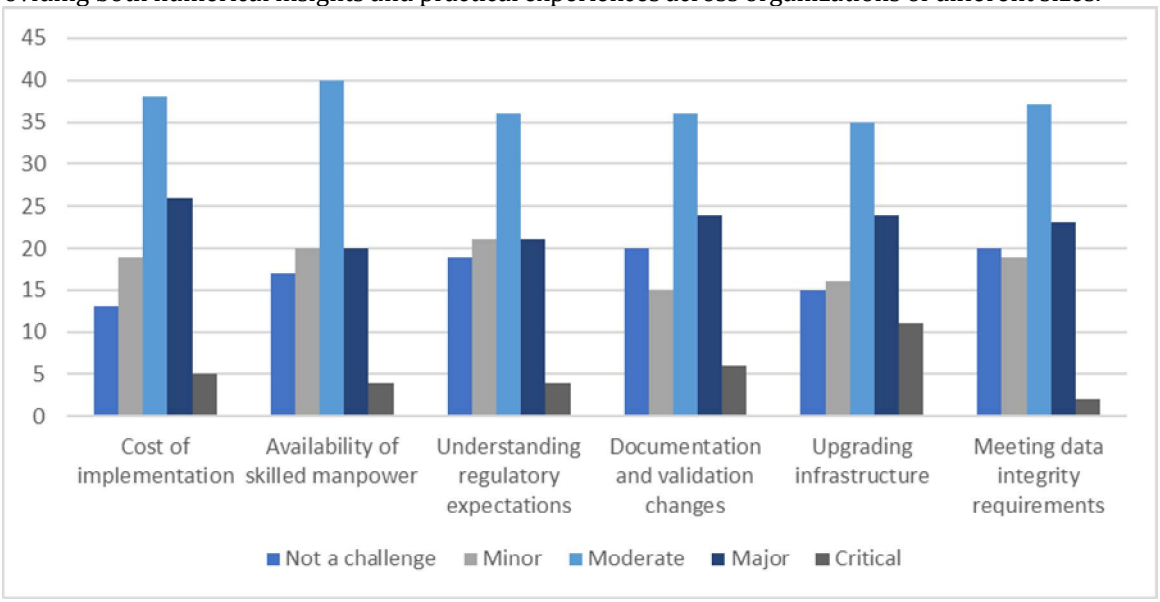

Figure 3. Challenges in implementing Revised Schedule M (2023) - quantitative ratings

Table 4. Key Insights from Challenges Reported in Open-ended Questions

Challenge Area	Mentions
Financial Burden / Cost of Implementation	30+
Training / Skilled Manpower Gaps	28+
Documentation & Data Integrity Compliance	24+
Infrastructure Upgrade (HVAC, Cleanrooms, Layout)	21+
Understanding Regulatory Requirements / Interpretation Gaps	18+
Resistance to Change / Legacy Systems	16+
Computerized System Validation (CSV) / Digital Adoption Issues	12+
Vendor/Supplier Qualification Issues	10+
No Challenge / Not Applicable Mentioned	8–10

Cost of Implementation

Financial constraints emerged as the most critical challenge, with nearly half of respondents rating it as major or critical. Upgrading infrastructure, cleanroom facilities, HVAC systems, and computerized systems requires significant investment, which many small and medium enterprises (SMEs) find difficult

to accommodate. Several participants also noted that increased costs could eventually impact the affordability of generic medicines [15].

Training and Availability of Skilled Manpower

Human resource challenges were equally prominent. Training gaps were highlighted, with many companies reporting difficulties in equipping junior staff with knowledge on validation protocols, electronic documentation, and data integrity requirements. Respondents repeatedly emphasized a shortage of skilled personnel in quality risk management, computerized system validation, and regulatory compliance. This mismatch between prioritization and actual workforce preparedness remains a bottleneck for smooth implementation [16].

Documentation and Data Integrity

Documentation and data integrity were rated as a moderate-to-critical challenge by the majority of respondents. Companies highlighted difficulties in migrating from legacy systems to digital platforms, ensuring traceability, and meeting expectations for electronic records and audit trails. Resistance to procedural changes among long-serving staff further compounded this issue. Nevertheless, the strong focus on documentation as an implementation priority suggests that firms recognize its central role in achieving compliance [17].

Upgrading Infrastructure and Equipment Modernization

Infrastructure modification, particularly in older manufacturing sites, continues to pose a significant compliance burden. Respondents cited challenges in sourcing compliant equipment locally, upgrading cleanrooms, and modernizing laboratories within budget limits. Equipment modernization, though essential, lags behind due to high costs and limited vendor availability.

Understanding Regulatory Expectations

A recurring theme across responses was the lack of harmonized interpretation of Revised Schedule M requirements. Respondents requested clearer guidance, model templates, and region-specific workshops to ensure uniformity in enforcement.

Quality Risk Management [18]

The introduction of mandatory QRM has been widely acknowledged, but implementation remains uneven. While larger companies are better equipped, many SMEs reported difficulty in integrating risk-based approaches into daily operations. The early-stage nature of QRM adoption suggests a learning curve that will require regulatory support, training, and industry collaboration.

Taken together, the findings highlight a dual challenge landscape:

- SMEs are disproportionately burdened by financial and infrastructure limitations, often lacking the resources to adopt advanced systems.
- Larger companies, while better resourced, still face difficulties in workforce training and aligning with regulatory expectations.

Thus, while awareness and intent are high, practical execution lags behind, particularly in infrastructure upgrades, skilled manpower, and digital compliance. These gaps emphasize the need for regulatory clarity, financial incentives, and structured capacity-building programs to ensure smooth, industry-wide adoption of the Revised Schedule M.

Anticipated Benefits and Opportunities from Revised Schedule M (2023)

An overwhelming 97% of respondents believe that the Revised Schedule M (2023) will positively influence India's global pharmaceutical reputation. This strong consensus highlights the industry's recognition of the revision as a credibility-enhancing reform in the international arena. Further, 98% of respondents agreed that the Revised Schedule M introduces meaningful improvements to GMP practices in India. Such near-universal agreement demonstrates the industry's optimism that the regulation will not only strengthen compliance but also elevate overall quality, operational consistency, and trustworthiness of Indian pharmaceutical manufacturing.

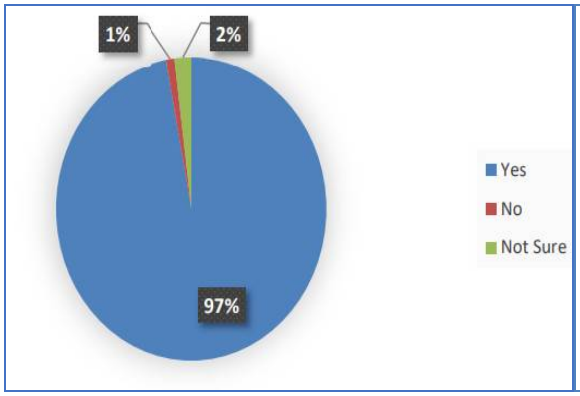

Figure 4. Global Reputation

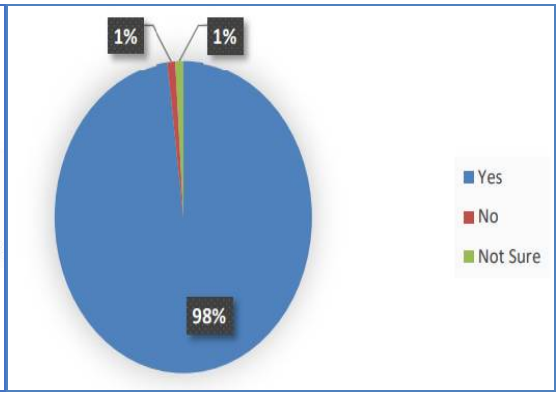

Figure 5. Improvements to GMP practices in India

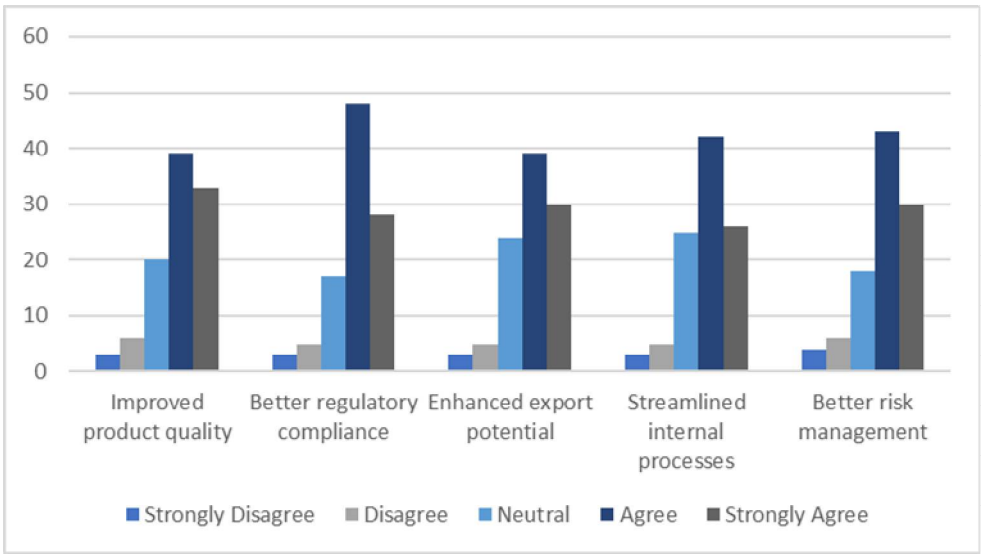

Figure 6. Expected Benefits

The survey explored the opportunities that organizations foresee due to the transition to the Revised Schedule M. The responses highlight widespread optimism, particularly regarding product quality, compliance, and operational improvements.

- Improved product quality was strongly acknowledged, with 71% (39% Agree, 33% Strongly Agree) affirming that the revision will enhance quality standards. Only 9% disagreed, while 20% remained neutral, suggesting broad confidence in the regulation's role in ensuring better manufacturing practices.
- Better regulatory compliance received the highest endorsement, with 76% (48% Agree, 28% Strongly Agree) supporting this outcome. This reflects the industry's strong alignment with the intent of the revision and its ability to harmonize practices with regulatory expectations.
- Enhanced export potential was recognized by 68% (39% Agree, 30% Strongly Agree) of respondents, showing that companies see the revision as an opportunity to strengthen India's competitiveness in the global pharmaceutical market.
- Streamlined internal processes were noted by 67% (42% Agree, 26% Strongly Agree), though a slightly higher share (25%) reported neutrality, suggesting that the benefits of process efficiency may vary across organizations depending on current operational maturity.
- Better risk management was also highlighted by 73% (43% Agree, 30% Strongly Agree) of respondents, confirming the regulation's effectiveness in embedding a risk-based approach to compliance and quality management.

Overall, these findings indicate that stakeholders see the Revised Schedule M as a transformative step that not only strengthens compliance and product quality but also enhances global competitiveness and operational resilience.

Qualitative Insights:

Table 4. Key Insights from Opportunities Reported in Open-ended Questions

Opportunity Category	Frequency (approx.)
Export & Global Market Access	33
Improved Product Quality & Compliance	29
Better Client/Buyer Confidence (Hospitals, Tenders)	22
Operational Scaling & Efficiency	17
Business Growth & Competitiveness	19
Stronger QA/QC Systems & Risk Management	13
Audit Readiness / International Recognition	10
No Opportunities Mentioned / Not Applicable	8

From the open-ended responses, several opportunity themes emerged that highlight how companies perceive the impact of the Revised Schedule M (2023). The most prominent opportunity identified was access to export and global markets, as many firms view alignment with WHO and ICH standards as a gateway to regulated international markets. Closely following this was the expectation of improved product quality and compliance, which companies believe will enhance both safety and credibility while serving as a competitive differentiator. Respondents also emphasized that the revision would strengthen client and buyer confidence, particularly in government tenders, hospitals, and institutional procurements, thereby improving business prospects. Many participants, especially from smaller enterprises, noted that the new framework creates scope for operational scaling, efficiency gains, and competitiveness in both domestic and international markets. Additionally, firms anticipate greater business growth and partner confidence, as adherence to the revised standards reassures investors and collaborators of their commitment to quality. Other respondents highlighted that the revision will help establish stronger QA/QC systems and risk management practices, while also enhancing audit readiness and international recognition. A smaller but notable group also linked the regulation to opportunities in digital transformation, laying the foundation for advanced GMP systems and robust data integrity practices [19, 20].

Perceived Impact and Suggestions for Smoother Implementation **[21, 22]**

The open-ended responses reveal insightful suggestions from industry professionals, categorized into the following major themes:

Suggestion / Expectation Category	Frequency
Training & Workshops (incl. in local languages)	37
Simplified SOPs / Compliance Checklists	21
Financial Support / Tax Incentives	18
CDSCO-led Regional Programs / Webinars	29
Templates / Digital Tools for Implementation	16
Extended Timelines / Phased Rollout	10
Better State-FDA Coordination & Audits	9
No Suggestions / Not Applicable	8

Training remains the top demand — not just any training, but tailored, regional programs by regulatory authorities or accredited bodies.

Simplification is essential — Many respondents stressed the need for clear, simplified SOPs/checklists tailored to small- and medium-scale firms.

Financial constraints are real — Tax breaks, grants, and government schemes were widely requested to support infrastructure upgrades.

Central & State coordination matters — More consistent support, audits, and enforcement from both CDSCO and State FDAs is seen as crucial.

Digital tools — There is a strong interest in CDSCO offering ready-made documentation templates or online self-assessment dashboards.

While there is clear recognition of the benefits of Revised Schedule M (2023), the industry expects targeted training, simplified tools, financial support, regulatory engagement, and phased rollouts to facilitate smooth and uniform adoption. These insights underscore the importance of collaboration between regulatory bodies and industry stakeholders for long-term success.

Addressed Gaps in the Previous Schedule M

The open-ended responses from the 101 industry professionals reflected a broad consensus that the Revised Schedule M (2023) has addressed several longstanding gaps in the earlier version of the guidelines. Key improvements as identified by respondents are grouped and summarized below:

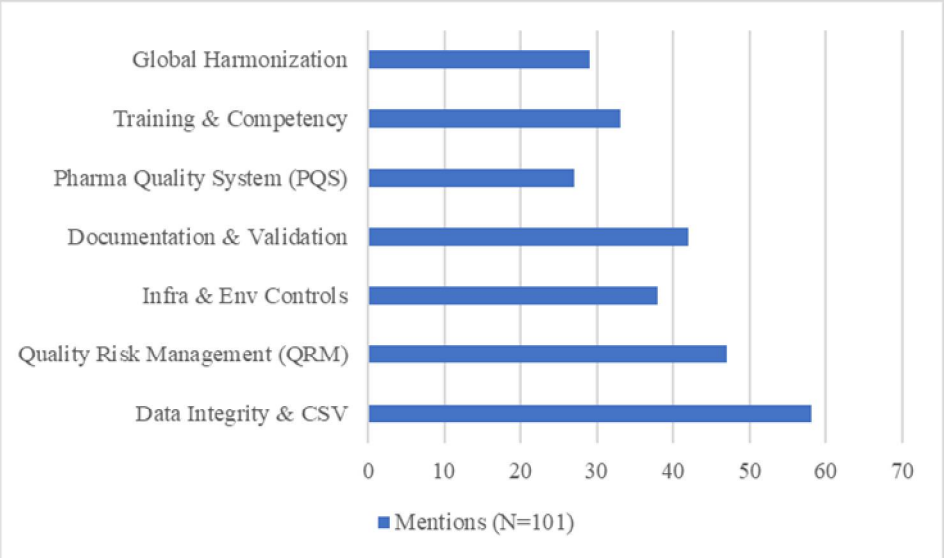

Figure 6. Key gaps addressed by revised Schedule M

Based on a thematic analysis of 101 open-ended responses, the most frequently cited improvements include [18, 22]:

- Data Integrity & Computerized System Validation (CSV) (mentioned 58 times)
- Quality Risk Management (QRM) (47 mentions)
- Infrastructure and Environmental Controls (38 mentions)
- Improved Documentation and Validation Requirements (42 mentions)
- Pharmaceutical Quality System (PQS) (27 mentions)
- Training & Competency Requirements (33 mentions)
- Global Harmonization with WHO/ICH Guidelines (29 mentions)

Overall, the Revised Schedule M (2023) addresses long-standing gaps in infrastructure requirements, data integrity, quality systems, and regulatory alignment. The changes bring India's GMP framework up to global expectations, ensuring better product quality, patient safety, and industry credibility.

CONCLUSION

The transition to the Revised Schedule M (2023) marks a significant milestone in India's pharmaceutical regulatory landscape, aligning domestic Good Manufacturing Practices (GMP) more closely with global standards such as those of the WHO and PIC/S. This study, based on a comprehensive survey of 101 professionals across various company sizes and functions, has illuminated both the preparedness and the pressing challenges faced by the Indian pharmaceutical industry in adapting to these reforms.

The findings indicate a high level of awareness regarding the Revised Schedule M across the sector. Many companies have already initiated steps toward compliance, particularly in areas such as documentation, personnel training, and quality risk management. However, there remains a visible gap in the modernization of infrastructure, electronic documentation systems, and consistent understanding of data integrity and validation requirements—especially among small and medium enterprises (SMEs). Respondents acknowledged that the revised guidelines address longstanding gaps in the earlier Schedule M, such as clearer mandates on risk management, computerized systems, and audit trails. The majority viewed this transition as an opportunity to enhance product quality, expand exports, and build greater regulatory credibility. At the same time, they highlighted practical challenges including cost burdens, limited technical capacity, and the need for harmonized interpretation and support from regulatory authorities. Notably, the study underscored the importance of targeted government initiatives, such as financial assistance schemes, region-specific training, and simplified compliance toolkits, to enable smoother adoption across industry segments. In summary, while the Revised Schedule M introduces short-term challenges, it offers long-term opportunities to elevate regulatory compliance, strengthen India's pharmaceutical quality systems, and expand its presence in global markets. With coordinated

efforts between regulators, industry bodies, and manufacturers, the Indian pharmaceutical industry is well-positioned to achieve world-class GMP standards.

IMPLICATIONS AND RECOMMENDATIONS

The findings of this study carry important implications for policymakers, regulatory authorities, and pharmaceutical manufacturers. The Revised Schedule M (2023) is not merely a compliance mandate but a strategic opportunity to elevate India's pharmaceutical quality standards to globally competitive levels. However, its successful realization depends on coordinated implementation, sustained policy support, and continuous capacity-building across the sector.

For the Industry: The Revised Schedule M fosters a culture of proactive quality management and international regulatory alignment. Organizations that invest early in infrastructure modernization, digital systems, and workforce training are likely to gain a competitive advantage in both domestic and export markets.

For Regulatory Authorities: A harmonized and practical interpretation of the guidelines is essential. Transparent communication, structured training programs, and consistent follow-up inspections will play a pivotal role in ensuring uniform and effective adoption across diverse company sizes.

For Small and Medium Enterprises (SMEs): Although SMEs face significant financial and resource constraints, the revised framework simultaneously opens opportunities for market expansion and global credibility. Targeted government support—through financial schemes, simplified compliance toolkits, and region-specific training—will be critical for enabling their smooth transition.

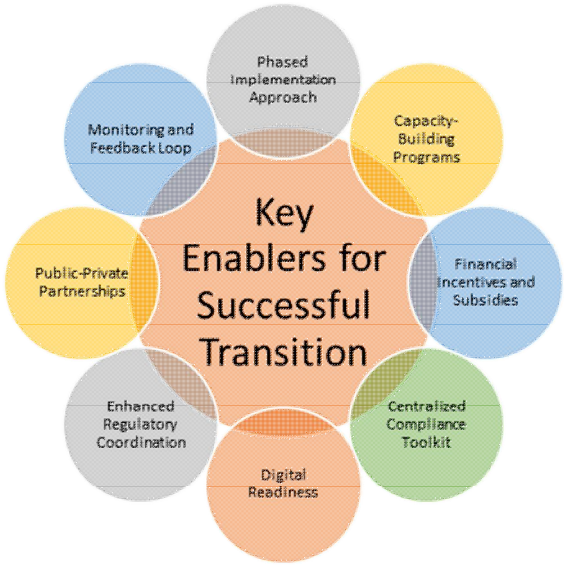

Figure 7. Recommendations and Suggestions

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