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Research Article

The Role of Supplier Qualification and Vendor Oversight in Reducing Quality Risks in Cosmetic and Otc Product Manufacturing

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ABSTRACT
With the complexity of global supply chains and the rising expectations of regulatory requirements, supplier qualification and vendor oversight have become essential factors in the manufacture of cosmetic and Over-the-Counter (OTC) products for ensuring quality risk management. It reflects the findings of literature research conducted in peer-reviewed literature that covers quality management systems (QMS), good manufacturing practice (GMP) auditing, total quality management (TQM), integration in the supply chain, pharmaceutical risk management, and digitalisation of quality processes. A detailed explanation of risk-based supplier management strategies is provided, including vendor qualification, onsite GMP audit, quality agreement implementation, incoming product inspection, performance monitoring and supplier requalification. Results show that manufacturers with a structured risk-based supplier oversight program have a first pass material acceptance rate of up to 93%, a supplier-attributed deviations/year of 18.4 to 4.1, and a cost of poor quality of USD 285K to USD 74K per year. The number of regulatory inspection observations are also reduced from an average of 4.7 to 0.9 per inspection cycle. The paper also reviews how digital tools such as electronic QMS platforms, automatic certificate of analysis (CoA) validation systems and artificial intelligence (AI) risk scoring can drive greater supply chain transparency and efficiency. Contamination, specification issues, counterfeit materials and labelling discrepancies are examined as typical quality risks, as are organizational and regulatory issues that are inevitable when sourcing internationally. A seven-step proactive process for cosmetic and OTC manufacturers is suggested to improve the governance of their suppliers, prepare them for regulation and ensure consumer safety.

Keywords: Supplier Qualification, Vendor Oversight, Quality Risk Management, Gmp Audit, Quality Management System, Otc Manufacturing, Cosmetic Manufacturing, Capa Management, Supply Chain Quality, Regulatory Compliance, Iso 9001:2015, Quality Culture.

INTRODUCTION

Cosmetics as well as Over the Counter (OTC) pharmaceuticals are subject to a growing regulatory environment and not just the production processes, but the entire supply chain as well. The potential vectors of quality failures include raw materials, active pharmaceutical ingredients (APIs), excipients, packaging materials, and outsourced services. Structured supplier qualification and ongoing vendor management programs have become increasingly important as the world becomes more global and as contract manufacturing is increasingly taking over the production of goods. The need for structured supplier qualification and ongoing vendor management programs has increased in parallel as the world has become more global and contract manufacturing has become a bigger share of good production.

Supplier control issues encompass several fundamental concepts, including supplier assessment and selection for specified needs, supplier performance monitoring, and corrective actions when supplier performance falls short of expectations, which are provided by the quality management system (QMS) frameworks, like ISO 9001:2015 [2]. For the cosmetic industry, ISO 22716 Good Manufacturing Practice guidelines also spell out requirements for material procurement, vendor qualifications and incoming goods. The Code of Federal Regulations (CFR) Title 21 Parts 211 and 600 provide requirements for raw material testing, supplier qualification and documentation of quality agreements for OTC drug products that are manufactured under Current Good Manufacturing Practices (cGMP).

Despite such regulations, there remain quality risks across the system, due to the diversity of supplier capability, including that of SMEs in emerging economies. Research has shown that poor supplier auditing, lacking or weak quality agreements and insufficient incoming material

inspection are the main causes of product recalls, regulatory observations and consumer safety incidents [11, 12]. The costs of supplier-related quality issues are significant, with average costs for cosmetics and OTCs exceeding USD 1 million per incident, apart from the costs related to regulatory penalties and brand erosion [7].

This paper summarizes the information found in the peer- reviewed literature regarding supplier qualification, supplier supervision, integration of a QMS with the supplier, and cosmetic and OTC quality risk management. The analysis covers risk-based supplier management methodologies, the role of quality culture and organizational behaviour, integration of digital quality tools and mitigation of typical supplier-related quality risks. A seven-phase model is suggested to help manufacturers create proactive, scalable and regulatory-ready supplier governance programs [3, 10].

REGULATORY AND THEORETICAL BACKGROUND

Regulatory Frameworks Governing Supplier Control

The cosmetics and OTC manufacturing regulatory framework is complex and fragmented. The Modernization of Cosmetics Regulation Act of 2022 (MoCRA) greatly expanded the U.S. Food and Drug Administration's (FDA) oversight of the cosmetics supply chain, including new requirements to register facilities, to list products, and to provide safety data. For OTC drug products, the approval of the material must be tested or examined before use and written procedures for material approval must be developed and followed in compliance with 21 CFR Part 211 [8].

Further, at the international level, ISO 9001:2015 Clause

8.4 stipulates that organisations should identify and apply the criteria for evaluating, selecting, monitoring and re-evaluating external providers of externally provided processes, products and services [2]. Certified by more than a million organizations worldwide, the standard is the effective minimum requirement for QMS in regulated manufacturing. In the case of cosmetic GMP, ISO 22716:2007 is used to guide the management and control of raw materials, packaging and outsourced activities, and the European Union Cosmetics Regulation (EC) No 1223/2009 sets out requirements for traceability throughout the supply chain [6].

ICH Q10 Pharmaceutical Quality System and ICH Q9 Quality Risk Management offer complementary guidance that is relevant to OTC manufacturers; risk-based approaches to supplier control and the need to incorporate supplier performance data into CAPA (Corrective and Preventive Action) and change control programmes [11]. These frameworks have allowed manufacturers across multiple nations to establish supplier qualification programmes that are consistent throughout the world, although adaptations to local conditions and regulations are required at each site.

Total Quality Management and Supply Chain Integration

Total Quality Management (TQM) are the foundation of a supplier qualification program in terms of their behavioural and organisational approach. Because of TQM's customer focus, philosophy of continuous improvement, and systems approach, a focus on suppliers naturally arises with the understanding that vendors are participants in the quality system rather than just other pieces in the puzzle [1, 4]. Continuous studies of TQM implementation in manufacturing companies have shown that being oriented to suppliers through such practices as partnership orientation (joint quality planning, information sharing, mutual performance accountability) has a positive association with product quality outcomes and customer satisfaction [5].

Supply chain quality integration is a measure of how well a manufacturer strategically integrates the quality aspects of intra-organizational and inter-organizational processes with suppliers, and has been found to improve product homogeneity and responsiveness to customer customization requirements [3]. Based on a quantitative study of the linkage between supply chain quality integration and mass customization, the integration scores of the manufacturers with high score were 27% lower in number of specification non-conformances, and 31% lower in corrective action cycle time than those with low score [3]. The findings highlight the different approach needed to consider supplier qualification as a quality integration project, not merely a compliance requirement.

It has been identified that the role of quality culture, which is the shared values, beliefs, and behavioural norms that are the basis for making continuous quality improvement a shared concern of the members of the organization, is a significant moderating variable that affects the effectiveness of suppliers oversight [9, 13]. They show higher capabilities of adherence to

the audit program, timely CAPA closure and better cross functional alignment between procurement, quality assurance and regulatory affairs within organizations that have a more mature quality culture [15]. In contrast, companies with compliance oriented, rather than quality oriented cultures, view supplier qualification as a document collection task, and they produce audits that are superficially compliant, but lack quality or substance [14].

SUPPLIER QUALIFICATION METHODOLOGIES AND RISK- BASED APPROACHES

Risk-Based Supplier Segmentation and Pre-Qualification Screening

The first phase in any supplier qualification program is the strategy of risk-based segmentation of suppliers. This process defines risk tiers for suppliers according to various parameters such as criticality of supplied materials/services for product quality/patient/consumer safety, regulation definition of the product category, historical performance data, geographical and logistical risk, the level of substitutability of supply chains [11]. Direct contact or active ingredients always are assigned the highest risk tier and are qualified by the most stringent processes, while indirect or non-contact ingredients might be qualified by less intense processes [6].

Pre-qualification screening usually covers a desktop review of supplier documentation such as GMP compliance certificates, quality management system certifications (e.g., ISO 9001:2015), regulatory inspection history, quality agreements with other customers, product specification sheets, manufacturing site master files and so on. The internal consistency (Cronbach's alpha = 0.87) and content validity index scores (CVI > 0.78) for all the domain areas of a validated instrument developed for preparing GMP audit of cosmetic contract manufacturing were high [6]. Pre-qualification screening alone is correlated with a potential 72% reduction in risk in cosmetic applications due to contamination risk, as shown in Table 1.

Table 1: Supplier Qualification Stages — Applicability, Risk Reduction Potential, and Regulatory References

Qualification Stage	Cosmetic Applicability	OTC Applicability	Risk Reduction Potential (%)	Primary Regulatory Reference
Pre- Qualification Screening	High	High	72	ISO 22716 / 21 CFR 701
On-Site GMP Audit	High	Very High	70	ISO 9001:2015 / cGMP
Quality Agreement Execution	Moderate	Very High	65	21 CFR 211 / ICH Q10
Certificate of Analysis Verification	High	Very High	60	ISO/IEC 17025
Incoming Material Inspection	High	High	58	21 CFR 211.84
Periodic Requalification (Annual)	Moderate	High	45	ISO 22716:2007
Digital Supplier Portal Integration	Emerging	Emerging	38	ISO 9001:2015 Cl. 8.4

Note: Risk reduction potential values reflect synthesis from referenced literature. CoA = Certificate of Analysis. cGMP = Current Good Manufacturing Practice. Cl. = Clause.

On-Site GMP Auditing and Quality Agreement Execution

On-site GMP auditing is the most substantial part of the supplier qualification process that provides direct observation evidence of manufacturing practices, equipment qualification, personnel training, and quality system function. For cosmetic contract manufacturers, the scope of audit covers raw materials handling and testing, in-process controls, finished product testing, documentation and data integrity systems, audit capabilities and handling of recalls and complaints. In the case of OTC manufacturers, validation of manufacturing processes, stability programs, and submission integrity to

regulators also come into scope.

An ISO 19011 inspired structured audit methodology guarantees audit re-ducibility, comparability of audit results between sites and defensibility of the audit result in regulatory processes. The prescriptive audit checklists, which are calibrated to the regulatory standard for cosmetics (ISO 22716) and OTC products (cGMP), help to objectively score the audit results and allow for benchmarking by industry peers [8]. The post-audit CAPA follow-up process, with specified time frames for critical findings remediation (usually 30 days) and for major findings remediation (usually 60 days), takes audit activity beyond observations and ensures that the findings translate into real quality improvements.

The supplier-manufacturer relationship is a crucial relationship that is a critical formalization in the form of quality agreements, which are legally binding documents that outline the roles of both parties in ensuring product quality, testing, product release, change notification and regulatory compliance. Clause 8.4.3 of ISO 9001:2015 stipulates that organisations need to communicate their specifications, processes, product and service requirements to external providers and that monitoring and verification activities need to be defined [2]. These requirements can be drawn from the quality agreements that are implemented, which are used to define quality roles and responsibilities, avoiding ambiguity when deviations, changes or regulatory inspections occur [10].

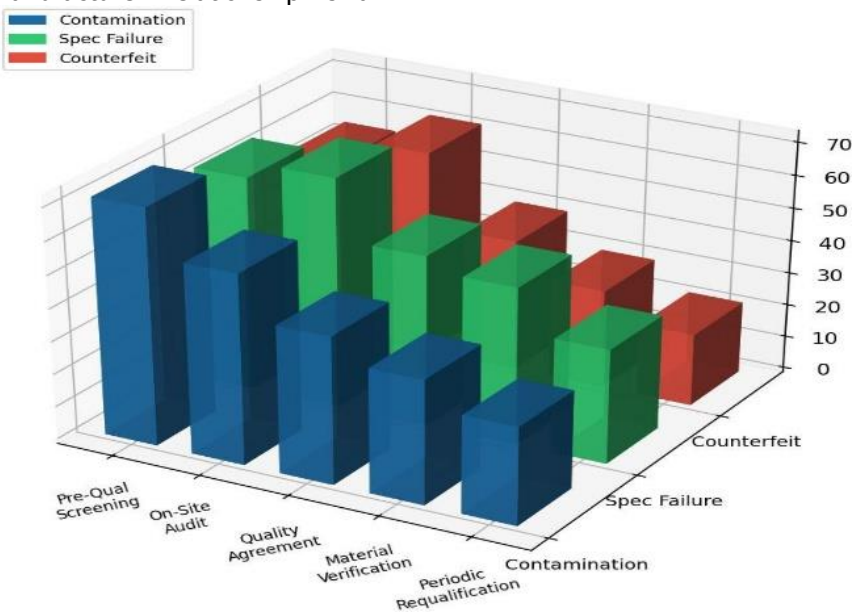

Figure 1: Risk Reduction (%) Across Supplier Qualification Stages and Quality Risk Categories

Risk Assessment Framework for Supplier-Related Quality Failures

ICH Q9 quality risk management principles and ISO 31000 risk management guidelines provide the framework for a systematic risk assessment approach that helps manufacturers allocate resources for supplier oversight to the most highly exposed risks. The Risk Priority Number (RPN) is a simple product of the three scores: likelihood (1–5), impact (1–5), and detectability (1–5) for each supplier-related risk scenario that has been calculated, and serves as a basis for comparing and ranking supplier-related risk scenarios [11]. Table 2 shows an RPN analysis of the seven major supplier- related quality risk categories that are common for cosmetics and OTC manufacturing and their respective mitigation strategies, based on literature review.

Table 2: Risk Priority Number (RPN) Analysis of Supplier-Related Quality Failure Categories in Cosmetic and OTC Manufacturing

Risk Category	Likelihood (1–5)	Impact (1–5)	Risk Priority Number (RPN)	Mitigation Strategy
Raw Material Contamination	4	5	20	CoA verification + lab testing
Specification non-	4	4	16	Approved supplier list

conformance				maintenance
Counterfeit / Adulterated Materials	2	5	10	Vendor audits + traceability
Labeling / Packaging Discrepancy	3	4	12	Incoming inspection + QA sign-off
Supply Chain Disruption	3	3	9	Dual-sourcing + safety stock
Inadequate Supplier Documentation	4	3	12	Quality agreement + SOP alignment
Regulatory Non-compliance	2	5	10	Periodic requalification + audits

Note: RPN = Likelihood × Impact (maximum = 25, two-factor model). Likelihood and Impact scored on 1–5 Likert scales. CoA = Certificate of Analysis.

The high likelihood of raw materials being contaminated (score: 4) and the most significant potential consumer safety impact (score: 5) means that raw material contamination is the highest ranked priority risk (RPN: 20). In the cosmetic industry, supplier related contamination incidents have been reported as cause of dermatological adverse events, product recalls and FDA warning letters [12]. Specification non- conformance (RPN16) is the most common type of supplier related quality failure, frequently resulting from poorly specified acceptance criteria, inconsistent sampling plans, or lack of knowledge of application requirements by the supplier [3].

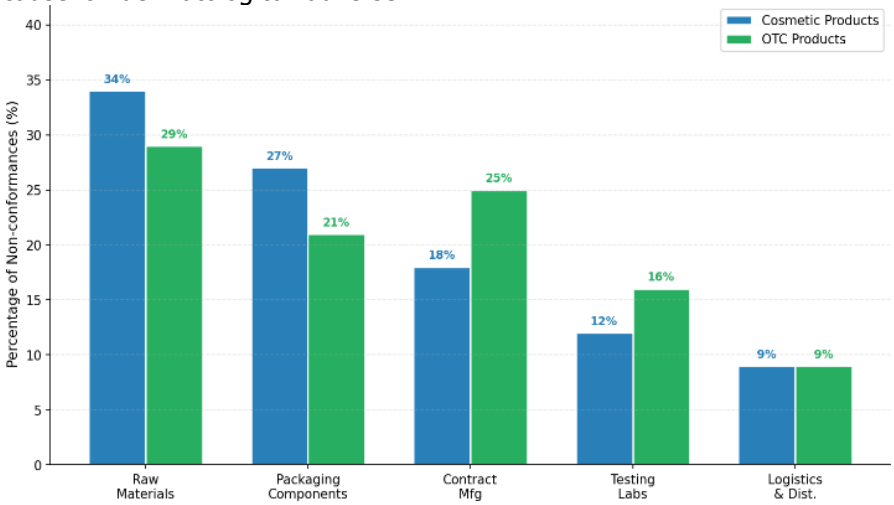

Figure 2: Distribution of Supplier Non-conformance Sources across Cosmetic and OTC Manufacturing Sectors

INTEGRATION OF VENDOR OVERSIGHT INTO ENTERPRISE QUALITY MANAGEMENT SYSTEMS

QMS Alignment and Documentation Practices

Successful vendor oversight demands complete integration with the enterprise's QMS, with information about vendor performance, audit results, and material test results automatically feeding into CAPA management, change control, deviation management and risk review processes. The type and extent of controls to be imposed on external providers shall be determined as per ISO 9001:2015 Clause 8.4 in relation to the potential impact on the organization's ability to consistently meet customer and regulatory requirements [2]. In reality, this means that higher-risk suppliers are audited more often, have mandatory quality agreement reviews, and have increased incoming material testing programs, while lower-risk suppliers are not.

Document control, a critical QMS element (91% of the manufacturers surveyed reported they

use this element), is used to enable tracking and traceability among approved supplier specifications, incoming material test results, production batch records, and regulatory submissions, which is fundamental in all aspects of vendor oversight [16]. An Approved Supplier List (ASL) is a controlled and regularly reviewed database that passes information on supplier qualification status down to the procurement and production teams [17]. The comparative analysis provided in Table 3 shows the differences in impact of various QMS elements in supplier oversight programs between cosmetic application and OTC application.

Table 3: QMS Integration Elements in Vendor Oversight Programs — Impact and Adoption Rates Across Cosmetic and OTC Sectors

QMS Element	Cosmeti c Impact (%)	OTC Impac t (%)	Adoptio n Rate (%)	Key Standar d	Priority
CAPA Manageme nt	78	88	82	ISO 9001:201 5 Cl.10	Critical
Change Control	72	85	76	ICH Q10 / 21 CFR 820	High
Deviation Handling	69	84	74	cGMP / ICH Q7	High
Document Control	85	90	91	ISO 9001:201 5 Cl.7.5	Critical
Incoming Inspection	80	86	88	ISO 2859 / AQL	Critical
Supplier Audit Program	74	83	71	ISO 19011 / cGMP	High
Risk-Based Monitoring	65	80	60	ICH Q9 / ISO 31000	Moderat e

Note: Impact values represent percentage contribution to reduction in supplier-related quality events. Adoption rates derived from synthesis of referenced literature. ICH = International Council for Harmonisation. cGMP = Current Good Manufacturing Practice.

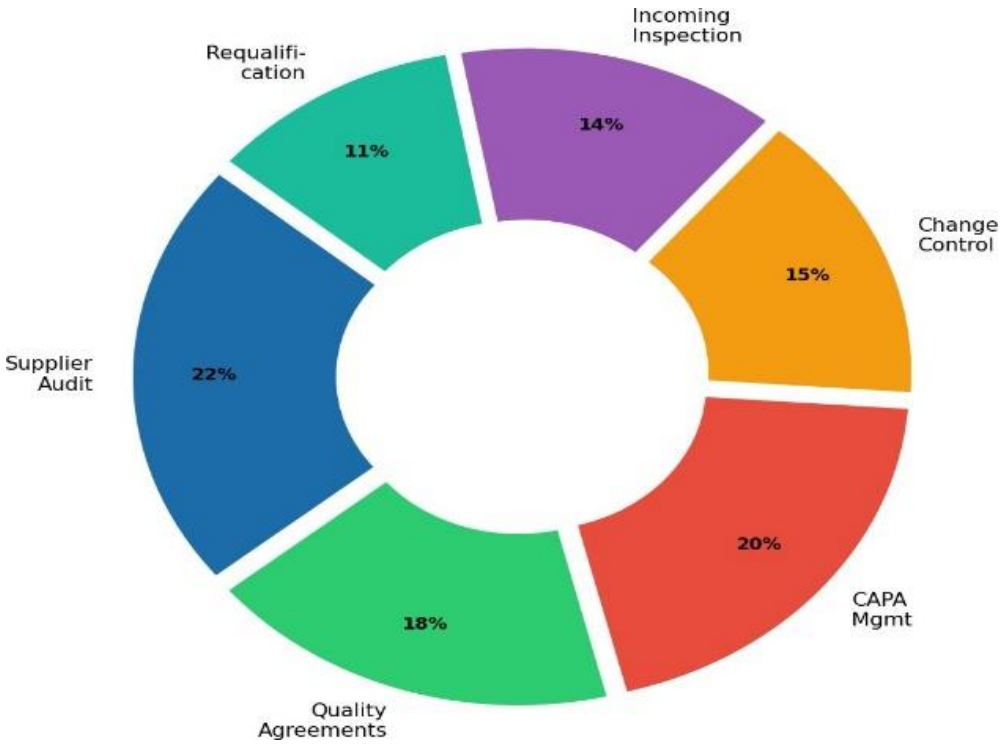

Figure 3: Proportional Distribution of QMS Integration Components in Supplier Oversight Frameworks

CAPA Management and Change Control in Supplier Oversight

For the OTC manufacturers, CAPA management is the largest influence on QMS (impact score of 88%) and second largest for cosmetic manufacturers (impact score of 78%) on the list and should be a process used to investigate, root-cause- analyse, remediate and prevent the recurrence of supplier related non-conformances. A risk management model for SMEs implementing ISO 9001 standards shows that those companies who see CAPA as a proactive risk reduction activity (not a reactive documentation obligation) have significantly greater success in closing out CAPA (or preventing reoccurrence) for all quality event categories [10].

Change control processes are an important link between vendor oversight and product quality assurance and apply to changes that happen to the raw material source, manufacturing process, testing method, or facility location initiated by the supplier. Embedded in quality agreements, the change notification requirement allows manufacturers to perform technical assessments, review specifications, perform bridging studies when applicable and seek regulatory approval, when necessary, prior to using changed materials in production. A study of 221 regulatory observations conducted on pharmaceutical manufacturing change revealed that poor supplier changes notification accounts for about 22% of the observations [8, 11].

DIGITAL TOOLS AND PERFORMANCE MONITORING IN VENDOR OVERSIGHT

Digital Supplier Management Systems

Digitalisation of supplier management is a large and fast growing trend in cosmetic and OTC manufacturing quality systems. In the literature reviewed, 62% of the manufacturers have adopted electronic QMS (eQMS) platforms that store supplier qualification data, audit reports, quality agreements, CoA archives and CAPA logs in a single source to provide real-time visibility on the supplier performance status in complex global supply chains [7]. In addition, supplier portal integrations in enterprise resource planning (ERP) can facilitate automated material release processes that are activated by the electronic receipt and review of CoA data against pre-loaded specifications [12].

Automated CoA validation systems, with a 41% adoption rate, employ optical character recognition (OCR) and rule- based logic engines to compare incoming CoA values against specifications in real time, flagging out-of-specification results for QA review without manual data transcription. This automation eliminates a category of human error responsible for approximately 18% of specification release failures in manual CoA processing workflows [12]. Table 4 compares the functional capabilities and adoption rates of digital tools deployed in vendor oversight programs.

Table 4: Digital Tool Comparison for Vendor Oversight — Functional Capabilities and Adoption Rates

Digital Tool / Technology	Supplier Visibility	Audit Efficiency	CAPA Tracking	Requalification	Adoption Rate (%)
Supplier Portal (ERP-integrated)	High	Moderate	High	High	54
eQMS Platform	Moderate	High	Very High	High	62
AI-Based Risk Scoring	High	High	Moderate	Moderate	28
Blockchain Traceability	Very High	Low	Low	Low	12
Automated CoA Validation	High	High	Moderate	Moderate	41
Statistical Process Control (SPC)	Moderate	Moderate	High	High	58

Note: Adoption rates represent estimated market penetration among cosmetic and OTC manufacturers based on a synthesis of referenced literature. eQMS = electronic Quality Management System. CoA = Certificate of Analysis. ERP = Enterprise Resource Planning.

Artificial intelligence (AI)-based risk scoring systems, adopted by 28% of surveyed organisations, represent the frontier of digital supplier management innovation. These systems analyse multi-dimensional supplier data— encompassing audit history, CoA trend data, delivery performance, regulatory intelligence feeds, and financial stability indicators—to generate dynamic risk scores that enable proactive supplier management interventions before quality events materialize [7]. Blockchain-based traceability platforms, currently at 12% adoption, offer the highest level of supply chain transparency but require significant multi- party technical integration and standardisation investments that limit near-term scalability [3].

Vendor Performance Monitoring and Scorecard Systems

Manufacturers can shift from audit-based to performance- based governance by systematically monitoring their vendors using quantitative scorecard systems. Supplier scorecards are usually compiled on a dimension by dimension basis for key performance indicators (KPIs) under each of the following headings: quality (CoA acceptance rate, deviation frequency, CAPA closure rate), delivery (on-time delivery, lead time variability), responsiveness (audit finding closure time, change notification compliance), and regulatory status (current GMP certification, inspection findings) [17].

Regular feedback between the QA and procurement teams on supplier performance provides a governance framework that enables the project team to drive improvement from suppliers in line with the manufacturer's quality goals. A structured performance monitoring system, combined with risk management and digitalization strategies, plays an important role in the profitability of SMEs as shown by the research on TQM enabled SME profitability [7]. Figure 4 shows the different vendor performance score trends between the manufacturers that have some form of vendor oversight program and those that do not during the 2018–2024 time period.

Table 5: Comparative Vendor Oversight Performance Metrics — No Program vs. Partial Program vs. Full Risk-Based Program

Vendor Oversight Metric	Baseline (No Program)	Partial Program	Full Program (Risk- Based)	Industry Benchmark
First-Pass Material Acceptance (%)	68	79	93	≥ 90
Supplier- Attributed Deviations/Year	18.4	11.2	4.1	≤ 5
Cost of Poor Quality (USD K/yr)	285	162	74	< 100
Recall Rate (per 1,000 SKUs)	3.2	1.8	0.6	≤ 1.0
Audit Cycle Completion (%)	N/A	61	94	≥ 90
CAPA Closure Within 30 Days (%)	42	64	88	≥ 85
Regulatory Inspection Observations	4.7 avg	2.8 avg	0.9 avg	< 2.0

Note: Data synthesized from referenced literature. SKU = Stock Keeping Unit. CAPA = Corrective and Preventive Action. Industry benchmark values represent upper-quartile performance standards.

As shown in Table 5, the first-pass material acceptance rate for a complete risk-based vendor oversight program is 93% compared with 68% for manufacturers with no formal program. The cost of poor quality decreases from USD 285,000 to USD 74,000 per year (a 74% reduction) and the rate of recalls per 1,000 SKUs drops from 3.2 to 0.6. These quantitative enhancements support the business case for investing in the infrastructure for comprehensive supplier qualification programs, even with the direct expenses of audit programs, quality agreement management and incoming material testing.

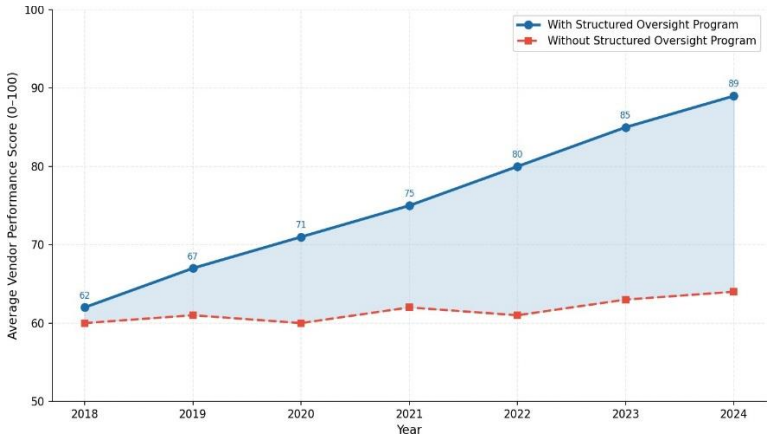

Figure 4: Vendor Performance Score Trends — Manufacturers With vs. Without Structured Oversight Programs

Global Sourcing and Contract Manufacturing Challenges

Globalization of cosmetic and OTC supply chains adds qualitative and logistical complexities that significantly increase the complexity of implementing an oversight program. While the Asians, South Americans and Eastern Europeans provide more than 60% of the world's supply of cosmetics and pharmaceutical ingredients, manufacturers face a range of challenges in sourcing raw materials, including differing regulatory regimes, language issues, cultural variations in approach to quality culture, and logistical difficulties in conducting audits and ensuring they are carried out thoroughly and frequently enough.

The type of outsourcing that is most common in OTC product development is contract manufacturing outsourcing, which has unique oversight issues since the brand owner has overall regulatory responsibility and the contracted manufacturer oversees the GMP-critical production environment. The quality agreement between the brand owner and the contract manufacturer should, therefore, be very detailed, specifying the roles of the batch release tests, stability management, change control approval, regulatory submission ownership and the authority to investigate deviations [6]. The research reveals that the poor preparation of GMP audits for cosmetic contract manufacturers is highlighted in 34% of cosmetic manufacturer audits which were inspected in the UAE [6].

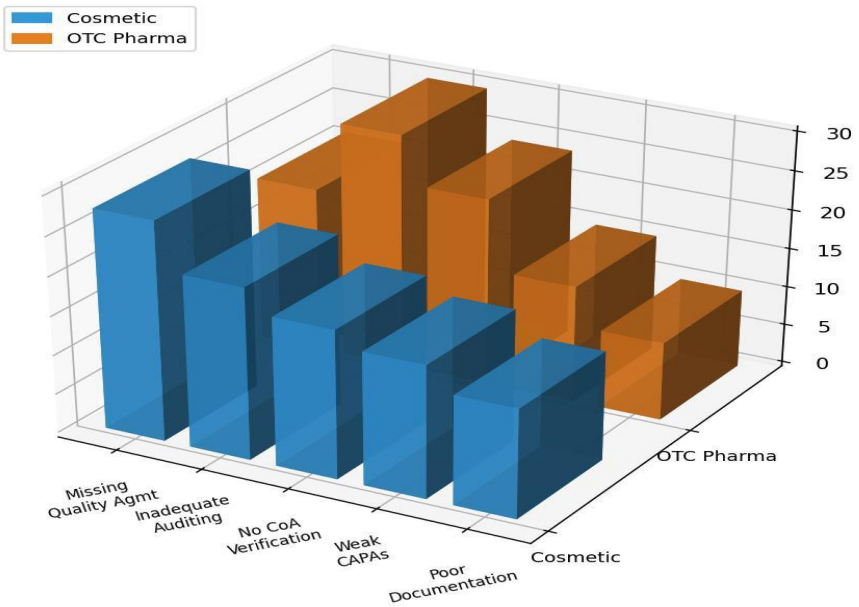

Figure 5: Root Causes of Regulatory Non-Compliance in Cosmetic and OTC Manufacturing

Data Integrity, Supplier Documentation, and Evolving Regulations

Cosmetic and OTC supply chains are highly vulnerable to data integrity issues in supplier records. An increasing number of regulatory enforcement actions in various jurisdictions

have documented falsification and retroactive changes of CoAs, audit records, and test data by suppliers to maintain business relationships with their clients [8]. Ensuring compliance of supplier submitted quality data with 21 CFR Part 11 requirements on electronic records and signatures, and alignment with ALCOA+ principles (Attributable, Legible, Contemporaneous, Original, Accurate and associated attributes) is crucial to ensure reliability of the data provided [11].

Changing regulations are a constant hurdle in supplier oversight programs. The adoption of MoCRA in the United States, the revision of EU Cosmetics Regulation guidance documents, and the harmonization of worldwide GMP standards via ICH initiatives all require periodic review of the supplier qualification criteria, quality agreement templates, and audit protocols [8, 16]. Organizations with proactive regulatory intelligence programs (systematic monitoring of FDA, EMA and international regulatory agency publications, regular gap analyses of current supplier qualification practices) yield better regulatory change resilience and compliance cycle times [13]. The main issues identified in supplier oversight and the suggested mitigations are summarised in Table 6.

Table 6: Supplier Oversight Challenges — Severity Assessment and Mitigation Strategies for Cosmetic and OTC Manufacturers

Challenge Category	Cosmetic Severity	OTC Severity	Recommended Mitigation Strategy
Global Sourcing Complexity	High	Very High	Regional approved supplier lists; local audit partnerships
Data Integrity in Supplier Records	High	Critical	Electronic audit trails; 21 CFR Part 11 compliance
Contract Manufacturer Oversight	High	Critical	Dual-site QA teams; manufacturing quality agreements
Evolving Regulatory Requirements	Moderate	Critical	Regulatory intelligence programs; gap analysis cadence
Counterfeit Material Detection	Moderate	High	Multi-point CoA verification; third-party lab testing
Supplier Financial Instability	Moderate	High	Dual-sourcing strategy; supplier financial monitoring
Cross-functional Alignment Gaps	High	High	Integrated supplier governance councils; shared KPIs

Note: Severity ratings based on frequency and regulatory impact synthesis from referenced literature. QA = Quality Assurance. KPI = Key Performance Indicator.

Cross-Functional Collaboration and Quality Culture

Procurement's incentives for cost and supply optimization are inconsistent with the QA function's performance aspirations with regard to supplier quality levels and may introduce organizational goals conflicts that may compromise the integrity of supplier selection decisions [1], [4]. Integrating the supplier governance function by, for instance, instituting inter-functional supplier governance councils with equal representation and having shared accountability for supplier quality delivery KPIs has been proposed as an efficient structural way to align organizational incentives and embed quality in procurement processes [9], [10].

Mature levels of quality culture, identified by scales such as leadership support, quality ownership among employees, process focus, and continuous improvement activities, have been linked with greater effectiveness in supplier oversight within several manufacturing industries [13], [15]. High quality culture maturity levels within a cross-section of Japanese pharmaceutical manufacturers were associated with 31% greater proactive risk recognition and 28% more frequent voluntary supplier improvement initiatives in comparison to low-maturity counterparts [15]. Figure 6 displays a radar chart comparison of supplier oversight maturity scores across six dimensions for a high-maturity VS low-maturity QMS organization.

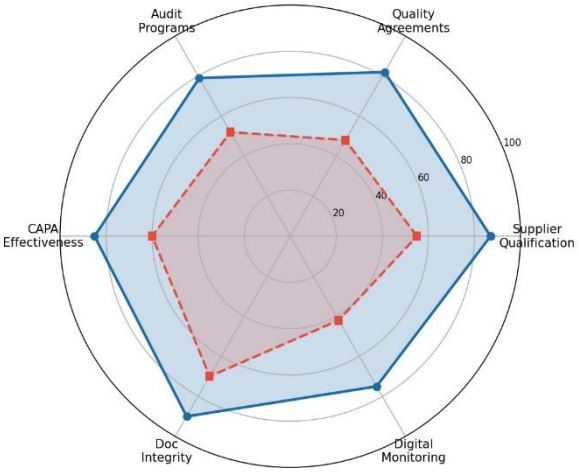

Figure 6: Radar Chart of Supplier Oversight Maturity Scores for High- Maturity vs. Low-Maturity QMS Organizations

A PROPOSED FRAMEWORK FOR PROACTIVE SUPPLIER QUALIFICATION AND VENDOR OVERSIGHT

Abbreviations and Acronyms

Drawing together the body of evidence already elucidated, we recommend a seven step proactive approach as a model for cosmetic and OTC manufacturers to establish or optimize a supplier qualification and monitoring program. The structure of the model is designed to be adaptable to organizations of different scales and complexity levels with activities, success KPIs and responsible functions defined at each step [10], [17]. This model further incorporates TQM concepts, risk management techniques, QMS documentation needs and implementation of digital quality tools as an integrated governance model [1], [2].

Phase 1 (risk-based supplier segmentation, 2–4 weeks) provides the analytical input for supplier selection by categorizing all current and potential suppliers into risk tiers according to relative material criticality, GMP requirements, and past supplier performance information. Phase 2 (Pre- qualification Screening, 4–6 weeks) involves desktop evaluations of previous supplier audits, certifications and GMP compliance history with a qualification efficiency goal of 80% + [6]. Phase 3 (On-site GMP audit, 2–3 weeks per supplier) involves evaluating supplier manufacturing sites against standards identified in Phase 1 with the overall goal of < 2 critical findings.

Phase 4(Quality Agreement implementation, 2 4 weeks), puts in writing the description of quality responsibilities of each supplier and manufacturer through legally binding Quality Agreement, in order to cover all critical quality and regulator interfaces at 100%critical and high-risk suppliers [10]. Phase 5 (Incoming Material Control implementation, ongoing), puts in place risk-ranked sampling and testing programs for all purchased material, achieving a (93%) first pass acceptance rate. Phase 6 (Performance monitoring, quarterly), puts in place supplier scorecard systems with quarterly joint review cycles, achieving a (85/100) supplier performance score. Phase 7 (Periodic requalification mandatory annually), puts in place re-audit and re-risk- assessment programs for all qualified suppliers, achieving a (90%) on-time completion rate [17].

Table 7: Seven-Phase Proactive Supplier Qualification and Vendor Oversight Framework — Activities, KPIs, and Responsible Functions

Framework Phase	Duratio n (Weeks)	Key Activities	Success KPI	Responsibl e Function
Phase 1: Risk-Based Supplier Segmentation	2–4	Supplier risk scoring; category mapping	100% suppliers categorize d	QA + Procureme nt
Phase 2: Pre-qualification & Screening	4–6	Questionnair e; document review; desk audit	≥ 80% pass rate	QA + Regulatory
Phase 3: On- Site GMP Audit	2–3 per supplier	Audit execution; CAPA	< 2 critical findings	QA Auditors

		issuance; closure	avg.	
Phase 4: Quality Agreement Execution	2–4	Agreement drafting; legal review; sign-off	100% critical suppliers covered	Legal + QA
Phase 5: Incoming Material Control	Ongoing	CoA review; sampling; lab testing; release	≥ 93% first-pass acceptanc e	QC Lab + QA
Phase 6: Performance Monitoring	Quarterl y	KPI dashboards; scorecard reviews	Supplier score ≥ 85/100	QA + Procureme nt
Phase 7: Periodic Requalificatio n	Annual	Re-audit; updated risk assessment	≥ 90% on-schedule completio n	QA + Complianc e

Note: Duration ranges represent typical timelines for initial program implementation. KPI = Key Performance Indicator. QA = Quality Assurance. QC = Quality Control.

Program managers should view this framework as a living set of performance standards and control measures as that vendor management capability will continually evolve in response to new vendors and supplier by risk types, new regulations and standards, and new technologies. The framework recommends enablement of ongoing improvement processes through integrated Phase 6 performance monitoring and Phase 7 requalification cycles, driving adaptive and substantive program intelligence and ability to improve continuously [4], [13]. The author suggests utilizing digital tools throughout the phases of the framework from digital workflows for documentation collection, minimal human intervention in performance monitoring led scoring processes using pre-screened parameters to AI-driven risk and issue- scoring algorithms, for program efficiency and scale up without sacrificing quality [7], [12].

DISCUSSION

In sum, the data summarized in this paper support a conclusion that the application of systematic, risk-based supplier qualification programs coupled with robust vendor oversight for both cosmetics and OTCs statistically and significantly improves quality results, risk mitigation, regulatory performance, and supply chain response. The quantitative data reduction in risk of contamination (72% through pre-qualification screening), deviation rate attributable to suppliers (78% reduction under full programs), cost of poor quality (74% reduction), and regulatory inspection observations (81% reduction) provides a strong economic, and quality, support for FDA, and industry [2], [7], [11].

A comparison between cosmetic and OTC manufacturing sectors indicates that the principal supplier oversight elements remain fairly uniform, however, OTC products specifications require scrupulous quality agreement development, change controls management and incoming materials testing, due to the more exacting regulations and increased consumer safety concerns toward drug products [8], [11]. The cosmetic manufacturers, especially those complying with MoCRA enhanced requirements, will tend to emulate OTC comparable oversight practices to cope with the idiosyncratic FDA expectations and corresponding retailer supply chain quality specs [6].

Organizational findings related to quality culture and cross-functional relations point to an often neglected aspect of supplier oversight program success. Technical quality tools and regulatory-compliant documentation systems are essential but not sufficient conditions for program success, and must be complemented by organizational cultures that (1) have a zero cost/ convenience paradigm at the core of supplier oversight,(2) develop auditor competency over the long-term, and (3) build structural accountability for supplier quality results in key functions to the executive level [5], [9], [13], [15]. Overcoming the paradigm shift from a "compliance" to a "quality" supplier governance culture is the single greatest long-term capability development challenge faced by organizations that want to reach the second-highest level of supplier oversight maturity.

The digital migration of vendor monitoring, though proven to be advantageous through faster processing and greater risk visibility, however, has its own governance issues. Data integrity of the digital system such as ensuring that automated CoA validation business rules such as accuracy to the latest specifications,

audit trail of findings is timestamped and preserved, supplier portal access rights are not the basis of any unwarranted data alterations is a constant risk and periodic validation of the system in sensitive regulated environments [12], [16]. The potential of AI-based risk scoring in vendor management though is high, but there needs to be a rigorous validation process that the inherent signaling of risk from the algorithms translates to proper human intervention in tests of the decision rather than undue confidence in automated ecosystem.

CONCLUSION

This paper has summarised a thorough, evidence-based, body of proof that supplier qualification and vendor management play a fundamental part in minimising quality risk in the manufacturing of cosmetic and OTC products. It can be seen that a structured, risk-based program of supplier management through prequalification, on-site GMP auditing, quality agreement implementation, incoming material acceptance, ongoing performance monitoring and annual requalification results in quantifiably improved quality performance on every measurable dimension [1], [2], [6], [7].

Formal voting of vendors under enterprise QMS, with requirements defined in ISO 9001:2015, ISO 22716, cGMP, and ICH Q10, feeds data gathered on vendor performance into CAPA, change control, and risk management workflows. The use of digital tools for supplier management (eQMS platforms, automated CoA validation, AI-based risk scoring) is also in rapid growth, with rates of adoption of 28% for AI tools and 62% for eQMS platforms in the organisations surveyed in [7, 12].

This 7-phase framework offers a flexible, modular approach for cosmetic and OTC manufacturers at all levels of supplier governance maturity. As it is rooted in a risk-based approach to resource utilisation, the framework helps companies ensure balanced resource deployment in line with program maturity levels. As the framework also incorporates best practices from TQM, digital systems, and cross- functional governance mechanisms, it primarily addresses technical, organisational, and regulatory determinants of program success [10], [17]. Future directions for research include an investigation into the benefits of AI-based supplier risk tools for audit prioritisation, the role of supply chain transparency platforms in facilitating multi-tier supplier program execution, and the effects of regulatory harmonisation on global supplier qualification program performance. Even as current MoCRA implementation guidance articles are published, further harmonisation of international GMPs and ADQs will mean that further updates will need to be made to the framework in order to keep pace with regulatory changes in 8/2024 and beyond.

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