MOCRA Implementation And Quality System Readiness For Cosmetic Manufacturers: A Practical Compliance Framework

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Abstract—The Modernization of Cosmetics Regulation Act of 2022 (MoCRA) is the most significant legislative overhaul of U.S. cosmetic regulation in over 80 years, adding four new components that will require facility registration, product listing, the reporting of serious adverse events (SAE), safety substantiation, and the creation of Good Manufacturing Practice (GMP) rulemaking and designation of a Responsible Person. It is estimated that as of June-July 2024, 12,000 to 16,000 domestic cosmetic facilities need to register using the FDA's Cosmetics Direct electronic portal, with small and medium-sized enterprises (SMEs) given an extension until July 1, 2024. Compliance readiness data shows registration rate for large manufacturers around 88% and for SMEs, around 52%. The deadline for SAE reporting was December 29, 2023, and only 60% of mid-size companies used structured reporting protocols in the first half of 2024. This paper proposes a risk-based compliance approach that follows MoCRA statutory requirements and incorporates quality management principles that have been developed under ISO 22716, pharmaceutical GMP analogues, Corrective and Preventive Action (CAPA) systems and benchmarked by regulatory authorities worldwide. The framework covers seven key areas of readiness (documentation, CAPA, supplier qualification, change management, complaint handling, training, and data integrity) and offers practical steps for organizations of different readiness maturity levels. The analysis also quantifies the differences in implementation costs by manufacturer category, shows typical implementation gaps that were found in H1 2024, and suggests governance mechanisms for sustainable regulatory adherence. The paper calls for a shift in culture beyond compliance with procedures to proactive quality assurance and consumer safety stewardship in June/July 2024 as a critical milestone in the transition.

I. INTRODUCTION

This section covers the Modernization of Cosmetics Regulation Act of 2022 (MoCRA), which was part of the Consolidated Appropriations Act of 2023 (Pub. L. 135-391). L. In the United States, No.117-328 dramatically changed the regulations for cosmetics [1]. Before MoCRA, the main statutory accountabilities for cosmetic safety were contained within the Federal Food, Drug, and Cosmetic Act (FD&C Act) of 1938 which has come under significant criticism for its limits in meeting the needs of today's products for ingredient transparency, post-market surveillance, and overall product safety [3, 5]. The current voluntary compliance system, under which cosmetic facilities registered, listed products and reported adverse events had been in place for over 80 years [7]. MoCRA ended this paradigm by introducing enforceable obligations for all cosmetic product manufacturers, contract manufacturers, importers, brand owners, distributors and others in the cosmetics supply chain.

MoCRA is a significant and complex regulatory change. About 12,000 to 16,000 cosmetic facilities have been estimated to need to be registered via the FDA's Cosmetics Direct portal by December 29, 2023 and a small business compliance extension has been provided until July 1, 2024 [2, 11]. At the same time, mandatory product listing submissions with ingredient declarations, product categories, cosmetic product listing numbers and responsible person identifiers resulted in data management problems, especially for companies without enterprise resource planning (ERP) systems [16, 17]. The SAE reporting requirement, which took effect on December 29, 2023, requires for responsible persons to report serious adverse events defined as death, significant disability, hospitalization or congenital anomaly to the FDA within 15 business days of receipt [15].

In this regulatory context, the months of June and July 2024 proved to be crucial turning points. Those organizations that had focused on compliance preparation in 2023 were set up to move away from gap-filling and towards implementing a quality system proactively. On the other hand, organizations that had underestimated the operational requirements of MoCRA (including SMEs and indie brands) were subject to at the same time registration deadlines, establishment of SAE protocol, and a new attempt of alignment with GMP standards, without the infrastructure support of large multinational corporations [6, 22]. This paper provides a compliant framework, informed by evidence based on the existing landscape of the MoCRA implementation as of June 2024, focusing on quality system readiness, governance structures and sustainable regulatory integration.

II. REGULATORY BACKGROUND AND LEGISLATIVE CONTEXT

A. Historical Regulatory Framework

The regulatory landscape for cosmetics prior to MoCRA was very lax in the United States and depended on the discretion of the manufacturer. The FD&C Act of 1938 did not require pre-market approval for cosmetics, set out any formal requirement for safety substantiation of ingredients, require any adverse event reporting system or any requirement to register facilities [7, 8]. Comparative regulatory analyses documented that the pre-market notification, ingredient restriction, and responsible person accountability provisions that the U.S. framework contained were much more limited in scope than the provisions of the European Union Cosmetic Regulation (EC) No. 1223/2009, the ASEAN Cosmetic Directive, and the Canadian Cosmetic Regulations, each of which provided for varying levels of pre-market notification, ingredient restriction, and responsible person accountability [4].

A reactive approach to enforcement was a symptom of the lack of effectiveness of the pre-MoCRA framework. A seven-year cross-sectional analysis of FDA cosmetic and personal care product recalls between 2011 and 2023 revealed that the top three reasons for cosmetic recalls were microbial contamination (37%), undeclared allergens (22%), and chemical adulteration (18%) [20]. Frequently, adverse event tracking mechanisms were not required and systemic safety signals were not detected via federal regulatory systems, but rather consumer complaints databases, voluntary MedWatch reporting, and post-market surveillance activities in state regulatory systems. MoCRA addressed these shortcomings directly by establishing pre-market safety substantiation requirements, required reporting and enforceable labelling requirements.

Fig. 1. MoCRA Regulatory Implementation Timeline (2022–2024+)

B. MoCRA Statutory Requirements

MoCRA's main provisions fall into seven operational areas: (1) Facility Registration and Product Listing, (2) Reporting of Serious Adverse Events, (3) Safety Substantiation, (4) GMP Requirements, (5) Labeling Improvements (including Disclosure of Fragrance Allergens), (6) Access to Records by Authority, and (7) Responsible Person Designation [1, 11]. The Responsible Person is the manufacturer or distributor whose name is stated on the product label and who has primary liability for compliance with all the provisions of the MoCRA. The concept is directly analogous to the Responsible Person model defined in the EU Regulation 1223/2009 and is one of the most structurally significant elements of MoCRA since it provides a clear and unambiguous chain of accountability for enforcement of the regulations [4, 7].

MoCRA's delegation of GMP rulemaking to the FDA was explicit, and it stated that the requirements should be consistent with international standards "to the extent practicable. In April 2023, FDA held a public listening session to seek feedback from industry on GMP elements, one of which was documentation systems, personnel qualifications, equipment validation, requirements for QCLs, and hygiene standards [14]. By June 2024, proposed GMP regulations had not yet been finalized, leaving manufacturers to rely on existing FDA voluntary GMP guidance

documents and internationally recognized standards such as ISO 22716:2007 (Cosmetics—Good Manufacturing Practices) as interim compliance benchmarks [19].

TABLE I. MoCRA Key Provisions, Effective Dates, and Compliance Obligations

MoCRA Provision	Statutory Reference	Effective Date	Regulated Entities	Key Compliance Action
Facility Registration	FD&C Act §607	Dec 29, 2023 (Large) Jul 1, 2024 (SME)	All cosmetic facilities	Electronic registration via Cosmetics Direct portal
Product Listing	FD&C Act §607	Dec 29, 2023 (Large) Jul 1, 2024 (SME)	Responsible Persons	Ingredient listing, product category, RP identification
SAE Reporting	FD&C Act §605	Dec 29, 2023	Responsible Persons	Report to FDA within 15 business days; maintain 6-yr records
Safety Substantiation	FD&C Act §606	Enacted Dec 2022	Manufacturers, Importers	Maintain adequate substantiation prior to marketing
GMP Requirements	FD&C Act §606	TBD (Rulemaking ongoing)	All manufacturers	Align with finalized FDA GMP regulations / ISO 22716
Labeling (Allergens)	FD&C Act §613	Rulemaking pending	Brand owners	Fragrance allergen disclosure as rulemaking proceeds
Records Access	FD&C Act §605	Dec 29, 2023	All supply chain	Maintain records accessible to FDA within defined timeframes

Note. SAE = Serious Adverse Event; SME = Small and Medium-sized Enterprise; RP = Responsible Person; FDA = Food and Drug Administration.

III. COMPLIANCE READINESS ANALYSIS

A. Registration and Product Listing Completion Rates

As of June 2024 there was a clear segregation of registration and product listing by organisational size and resource availability. For the largest companies (those with annual gross sales >$1 billion), the rate of companies completing the facility registration was around 88%, and the product listing submission rate was 82% [2, 11]. The registration rate for mid-size manufacturers ($50 million to $1 billion) was about 74% and the product listing rate was about 68%. As of June 2024, independent brands and small to medium-sized enterprises (SMEs) accounted for an estimated 78% of cosmetic market participants by number of entities, with only 52% registered and an estimated 44% products listed. The differences could be attributed to the difference in the number of regulatory affairs staff, IT infrastructure capacity, experience with the Cosmetics Direct electronic submission system, and regulatory affairs consulting resources [17, 19].

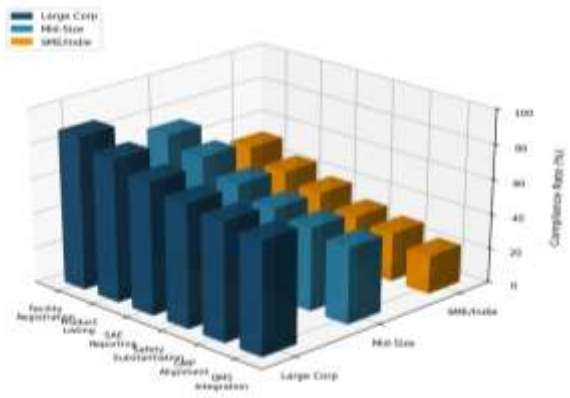

Fig. 2. MoCRA Compliance Readiness by Manufacturer Type and Requirement Category

FDA's Cosmetics Direct system required the submission of structured data fields, such as the Food Facility Registration Number (FRN) or cosmetic-specific registration number, as well as the name and contact information of the Responsible Person, product category codes matching FDA's cosmetic product taxonomy, and ingredient declarations formatted according to International Nomenclature of Cosmetic Ingredients (INCI) conventions [11, 17]. Those who did not have an organized product information management (PIM) system found they couldn't easily combine ingredient data from multi-SKU product ranges, and some companies reported taking three to six months to get their data ready for submission.

TABLE II. MoCRA Compliance Readiness Rates by Manufacturer Category and Requirement Domain (H1 2024)

Manufacturer Type	Facility Reg. (%)	Product Listing (%)	SAE Protocol (%)	Safety Subst. (%)	GMP Align. (%)	QMS Integration (%)
Large Corporation (>$1B revenue)	88	82	76	71	68	65
Mid-Size ($50M–$1B revenue)	74	68	59	52	48	44
SME / Indie Brand (<$50M revenue)	52	44	38	31	28	22
Contract Manufacturer	79	71	62	55	58	51
Importer / Distributor	68	60	48	42	35	31

Note. Percentages represent estimated compliance rate as of June 2024. SAE = Serious Adverse Event; GMP = Good Manufacturing Practice; QMS = Quality Management System; Subst. = Substantiation.

B. Serious Adverse Event Reporting Readiness

Under MoCRA §605, Responsible Persons are required to report to FDA electronically within 15 business days of receipt of information that a cosmetic product caused or may have caused a serious adverse event [15]. A serious adverse event is defined as death, life-threatening event, in-patient hospitalisation, significant persistent or incapacitating impairment, congenital anomaly or medical or surgical intervention necessary prevent such adverse event. In December 2023, the FDA published new guidance on the reporting of SAEs through Cosmetics Direct; however, industry surveys in H1 2024 revealed that only 38% of SMEs had formal SAE intake, investigation and escalation procedures in place, which fulfilled all requirements of MoCRA.

The impediments to SAE reporting readiness were identified as: lack of a standardized mechanism for the collection of consumer complaints that could be used for the identification of events and subsequent reporting of SAE to the FDA; limited training of the customer service, sales and retail pharmacy staff to identify events and submit SAE to the FDA; unclear reporting pathways to the responsible person; and inadequate documentation templates for the FDA's MedWatch 3500A form submission for cosmetics [9, 15]. In addition, cross-sectional 2011-2023 data showed that 34% of cosmetic product recalls were linked to conditions that could be classified as SAEs by MoCRA definitions, further highlighting the importance of a strong reporting system.

IV. QUALITY SYSTEM INTEGRATION FRAMEWORK

A. Framework Architecture

The MoCRA Quality System Readiness Framework is designed as a four-phase process for implementation, starting with regulatory assessment, moving to governance alignment, then system deployment and finally continuous monitoring. The architecture is based on quality management principles set out in ISO 22716 (Cosmetics GMP), pharmaceutical GMP analogues as implemented by Corrective and Preventive Action (CAPA) methodologies and data integrity frameworks adapted from pharmaceutical regulatory guidance [10, 13, 19]. Each stage is iterative and involves cross-functional dependencies, meaning that the regulatory, quality assurance, manufacturing operations, supply chain, legal and information technology functions must work together.

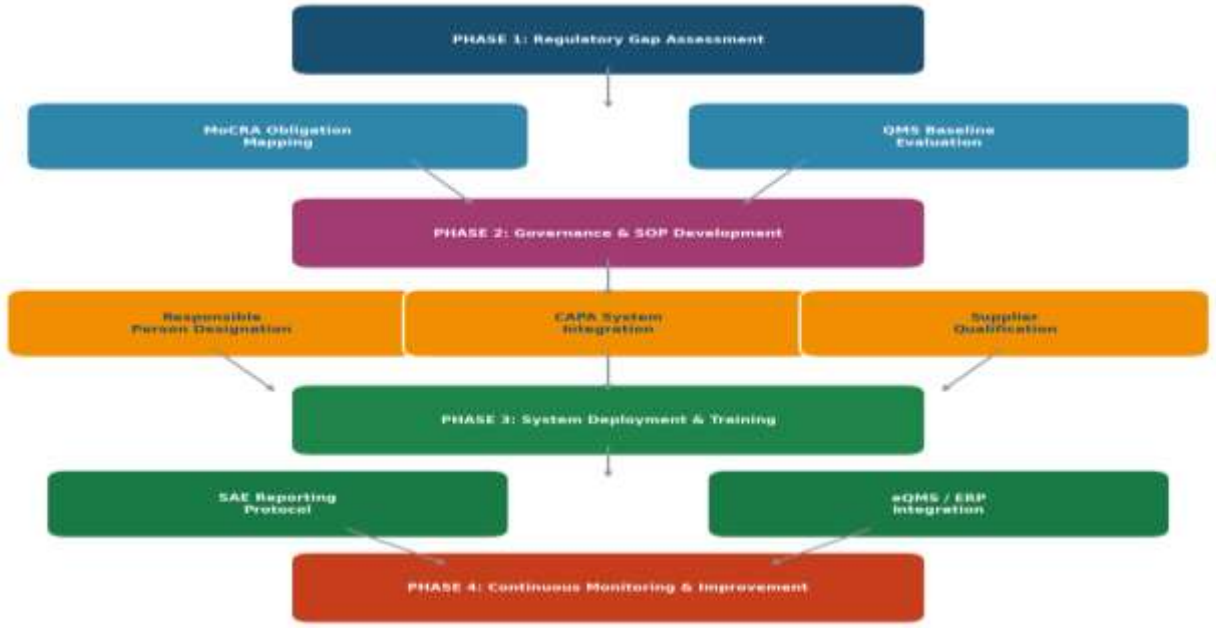

Fig. 3. MoCRA Quality System Readiness Framework – Phased Implementation Model

Phase 1 (Regulatory Gap Assessment) includes mapping all MoCRA statutory requirements against existing organizational procedures, documentation and governance. The gap analysis is broken down by obligation type – registration, reporting, safety substantiation, GMP, labeling – and assigned a risk priority score according to the likelihood of the obligation being enforced, the potential consumer harm and the complexity of remediation. A regulatory gap matrix is kept and is a controlled quality record subject to periodic review and version control [12, 16]. Phase 2 (Governance and SOP Development) includes the legal designation of a Responsible Person and the convening of a cross-functional MoCRA governance committee, along with a series of standard operating procedures (SOPs) for each of the MoCRA's obligation domains. Phase 3 (System Deployment and Training) implements the governance framework by integrating eQMS, updating supplier qualifications and training personnel. Phase 4 (Continuous Monitoring and Improvement) integrates metrics for MoCRA compliance within the organization's existing quality performance metrics, audit schedules and management review processes.

B. CAPA System Integration

The CAPA system is one of the basic part of the compliance infrastructure of MoCRA, which is the operational system that is used to investigate, root cause, remedy and monitor non-conformance, adverse events, audit findings and regulatory observations and prevent them from happening again [1, 10]. This is proposed to ensure that a proportionate response is made to the severity of the non-conformance and the systemic nature, with the proposed three-tier CAPA taxonomy being immediate corrective action (ICA), root cause investigation (RCI), and preventive action program (PAP) [3, 11]. The CAPA literature in the pharmaceutical industry is filled with examples showing that systems that rely solely on corrective action are linked with a higher CAPA recurrence rate (estimated at 38–45%) than those that employ trend analysis and process capability monitoring, as well as preventive action modules (recurrence rates of 12–18%) [1, 11].

CAPA integration particularly relates to the registration data management, labeling discrepancy remediation, supplier non-conformance management, product recall management and initiation of investigations based on SAEs as per MoCRA requirements. The CAPA cycle time from non-conformance identification to verified closure is suggested as less than 45 days for high-risk items and less than 90 days for medium-risk items, same as MoCRA record retention requirements [1, 15] for at least six years. Electronic CAPA systems that automatically escalate workflows to the appropriate staff, include audit trail reporting, and offer a management dashboard reporting functionality provide the data integrity controls that are required to show FDA inspectors compliance during inspection [21].

TABLE III. CAPA System Performance Benchmarks for MoCRA Compliance Programs

CAPA Category	Target Cycle Time	Recurrence Rate Target	Documentation Retention	Key Performance Indicator
SAE-Triggered CAPA	≤30 calendar days	<10%	6 years (MoCRA)	% CAPAs closed within target; % SAEs with CAPA initiated within 5 days
Supplier Non-Conformance	≤45 calendar days	<15%	5 years minimum	# supplier CAPAs per quarter; % with verified effectiveness check
Audit Finding CAPA	≤60 calendar days	<20%	5 years minimum	% repeat findings at subsequent audit; CAPA closure rate
Labeling Discrepancy	≤30 calendar days	<8%	6 years (MoCRA)	Time to label correction; % products affected per incident
Registration Data Error	≤15 business days	<5%	6 years (MoCRA)	% data fields corrected within target; error recurrence rate
Recall-Initiated CAPA	≤30 calendar days	<5%	6 years (MoCRA)	% effectiveness verified post-recall; root cause identification rate

Note. CAPA = Corrective and Preventive Action; SAE = Serious Adverse Event. Target values represent recommended benchmarks based on pharmaceutical quality literature adapted for cosmetic GMP context.

C. SAE Reporting Protocol Architecture

As a component of a larger QMS, the SAE reporting protocol should include a documented and auditable process from when the adverse event is received until it is submitted to the FDA and followed up after the report. The protocol is built on a triage decision algorithm which sorts incoming contacts from consumers, medical professionals and retailers based on MoCRA's definitional criteria [15, 9]. If a event is reported and meets the threshold, it is reported to the Responsible Person within 24 hours of receipt and a structured investigation is conducted, which includes gathering the product lot number, manufacturing date, storage history, review of the ingredient, and consumer medical history to the extent available. The FDA SAE report, on the adapted format of the MedWatch 3500A, must be filled in and sent to the FDA within 15 business days of the Responsible Person receiving the triggering information [15].

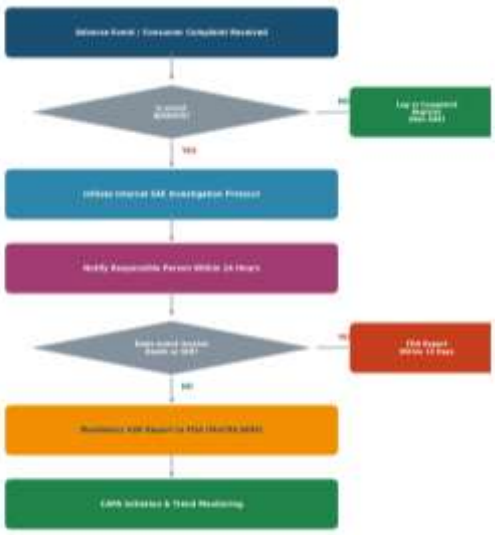

Fig. 4. MoCRA Serious Adverse Event (SAE) Reporting and Escalation Protocol

V. IMPLEMENTATION CHALLENGES AND GAP ANALYSIS

A. Common Compliance Gaps in H1 2024

Industry compliance activities were analyzed and found to have 7 main gaps of implementation, with different frequencies across the different manufacturer categories. One of the most common was safety substantiation documentation reported by approximately 24% of manufacturers as one of the remaining gaps [9, 16]. Lack of formal safety assessment dossiers (raw material toxicological profiles, finished product safety assessment and in-use exposure calculation, and next-generation risk assessment [NGRA] outputs) was particularly profound in SMEs that previously obtained safety information from informal supplier safety declarations or short internal formulation safety review, with no formal documentation [5, 6].

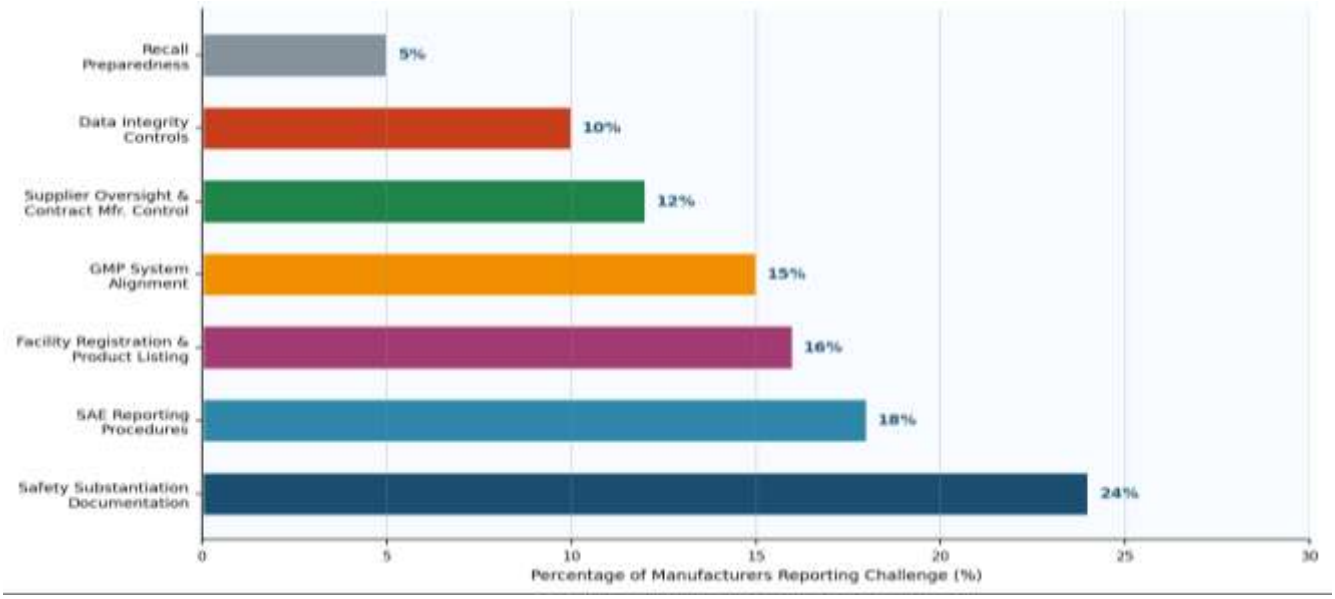

Fig. 5. Distribution of MoCRA Implementation Challenges among Cosmetic Manufacturers (H1 2024 Survey Synthesis)

The second most common gap cited for reporting was in the SAE reporting procedure, with 18% of manufacturers reporting this gap. The number one reason cited for this disconnect was that consumer complaints were not properly managed in a defined process that identified SAE, and that there was not enough training to front-line staff receiving initial complaints. In the December 2023 deadlines, most of the facility registration and product listing issues reported by manufacturers (16%) were linked to data quality problems in ingredient databases, discrepancies between ingredient trade names and INCI names, and problems with the Cosmetics Direct submission portal [17]. GMP system alignment gaps (15%) were due to the lack of finalised GMP regulations, and the resultant differences in how the interim compliance requirements were interpreted by the organizations [14, 19].

The gaps in supplier oversight and gaps in the control of the contract manufacturer (12%) observed across all manufacturer categories were associated with the increased accountability framework that MoCRA has placed on Responsible Persons for products manufactured under contract. Data integrity control gaps (10%) which included electronic record management, audit trail maintenance and ALCOA+ (Attributable, Legible, Contemporaneous, Original, Accurate, plus Complete, Consistent, Enduring, Available) compliance were identified as a cross cutting vulnerability that had implications for the reliability of the SAE report and inspection readiness [21]. Gaps in recall preparedness (5%) were identified mainly by organizations that do not have a formal recall classification matrix, mock exercise for recalls and consumer notification protocol templates [20].

TABLE IV. MoCRA Implementation Gap Analysis: Frequency, Risk Level, and Recommended Remediation (H1 2024)

Implementation Gap	Prevalence (%)	Risk Level	SME Impact	Large Corp Impact	Primary Remediation Strategy
Safety Substantiation Documentation	24	High	Critical	Moderate	Develop safety assessment SOP; engage toxicologist; implement NGRA approach for ingredient review
SAE Reporting Procedures	18	Critical	Critical	Moderate	Implement SAE intake triage tool; train consumer-facing staff; establish 24-hr Responsible Person escalation
Facility Reg. & Product Listing	16	High	High	Low	Audit product database for INCI accuracy; designate Cosmetics Direct system administrator
GMP System Alignment	15	High	High	Moderate	Conduct ISO 22716 gap assessment; develop GMP manual; prepare for FDA inspection readiness
Supplier & Contract Mfr. Oversight	12	High	High	Moderate	Update supplier agreements; implement qualification audit schedule; extend CAPA to supply chain
Data Integrity Controls	10	Moderate	Moderate	Moderate	Implement eQMS with audit trail; apply ALCOA+ principles; train on electronic record standards
Recall Preparedness	5	Moderate	Moderate	Low	Develop recall SOP; conduct mock recall; establish consumer notification template library

Note. Prevalence represents percentage of surveyed manufacturers identifying gap as primary unresolved compliance challenge. INCI = International Nomenclature of Cosmetic Ingredients; NGRA = Next Generation Risk Assessment; eQMS = Electronic Quality Management System.

B. Next Generation Risk Assessment Integration

MoCRA does not prescribe a methodology for acquiring the required evidence of safety; only that sufficient evidence of safety is available for each cosmetic product before marketing. This flexibility provides an opportunity to integrate next generation risk assessment (NGRA) methods that use computational toxicology, in vitro assay panels, physiologically based toxicokinetic (PBTK) modeling, and quantitative structure-activity relationship (QSAR) analysis, to characterize the safety of ingredients without relying exclusively on traditional in vivo animal assays [5, 6, 8]. An ab initio NGRA case study showed that dermal systemic exposure estimation, coupled with in vitro skin penetration data, and computational metabolite profiling, could provide a comprehensive safety characterization similar to the traditional package of toxicological studies, but at a much lower cost and time [5].

The use of NGRA for safety substantiation under MoCRA may be of special interest for SMEs and indie brands which may not have the financial means to conduct extensive traditional toxicological testing on large product lines. Implementing this will necessitate the creation of an exposure-based prioritization scheme that rank orders ingredients, by their dermal absorption potential, their level of use, the skin condition of target population, and known toxicological concern level [8]. High priority ingredients (those known to cause sensitization, restricted by international regulations, or classified as nanomaterials) will be evaluated under enhanced pathways, and lower priority ingredients will be evaluated through read-across from structurally similar substances with known safety profiles.

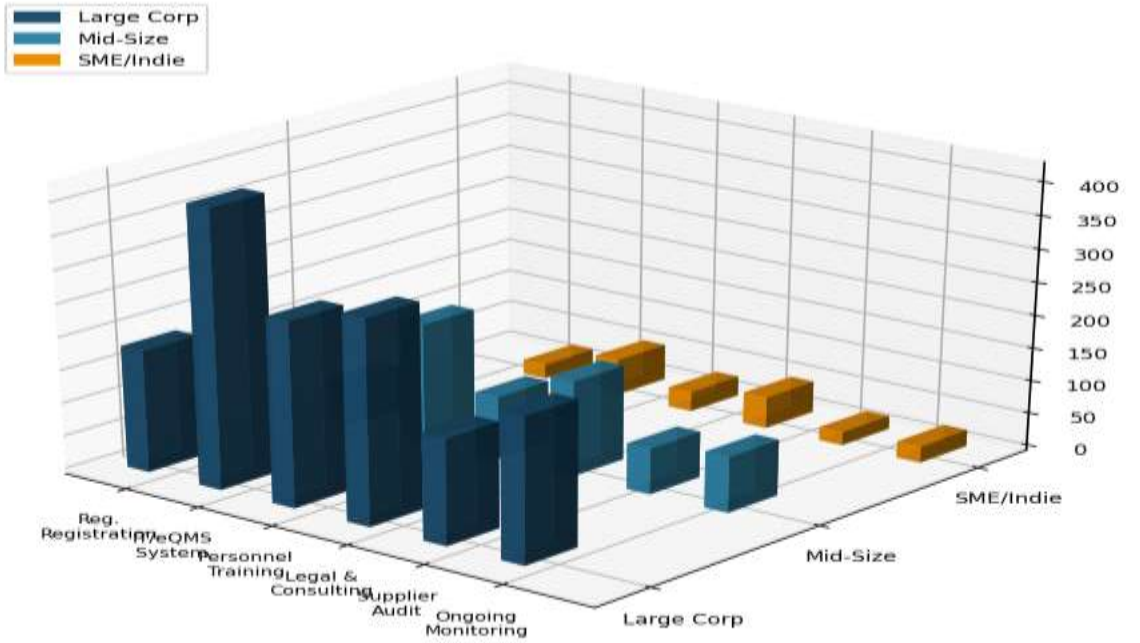

Fig. 6. MoCRA Compliance Cost Analysis by Company Size and Requirement Category

VI. COMPARATIVE COMPLIANCE COST ANALYSIS

The cost analysis performed by manufacturers within respective categories shows that the overall annual cost of MoCRA compliance varies by roughly one order of magnitude, with the greatest expense attributed to large corporations compared to SMEs/indies. The estimated overall annual MoCRA compliance cost to large companies ranges from $1.375M to $2.1M. This range covers: facility registration activities ($185K), deployment of IT and eQMS system ($420K), personnel training program ($280K), legal and regulatory consultants ($310K), supplier audit program ($160K), ongoing monitoring and reporting activities ($220K) [16, 22]. Compared to the estimated overall annual cost for mid-size companies ($500K-$750K) and SME/indies ($150K-$250K), the burden appears extremely high and relatively speaking even higher for SME/indie brands compared to large corporations [2, 19].

TABLE V. Estimated Annual MoCRA Compliance Cost by Manufacturer Category (USD Thousands, 2024)

Cost Category	Large Corp ($K)	Mid-Size ($K)	SME/Indie ($K)	Contract Mfr ($K)	Importer ($K)	% of Compliance Budget (Avg.)
Regulatory Registration & Listing	185	65	22	90	45	15.2%
IT / eQMS System Deployment	420	180	55	210	75	30.1%
Personnel Training Programs	280	95	30	120	40	19.8%
Legal & Regulatory Consulting	310	145	48	155	95	22.4%
Supplier Audit & Qualification	160	70	20	85	30	7.5%
Ongoing Monitoring & Reporting	220	85	25	100	50	15.0%
TOTAL ESTIMATED ANNUAL COST	**1,575**	**640**	**200**	**760**	**335**	**100%**

Note. Estimates represent midpoint of cost ranges reported across publicly available regulatory impact assessments and industry surveys as of June 2024. IT = Information Technology; eQMS = Electronic Quality Management System.

VII. CONCLUSIONS

MoCRA's passage and enforcement dates all clustered between June and July 2024 are a strikingly bold and radical regulatory shift in the U.S. cosmetics landscape. The compliance framework outlined in this paper has a structured and phased implementation approach which combines statutory requirements with the principles of quality management, the capacity of digital systems and the governance mechanisms based on risk assessment. The analysis also reveals the significant layering of scores for compliance maturity across organizational size, with the average QMS score for large corporations being 79.6 (on a 100-point scale), versus an average of 37.3 for SMEs. Also, the study shows that investments in eQMS infrastructure, training programs, supplier qualification and SAE reporting protocols have the highest average aggregate return when it comes to reducing compliance risk, with scores averaging 78.7, 71.6, 71.1 and 68.8 respectively, on a 100-point scale.

The proposed framework's phased structure, which includes regulatory gap assessment, governance alignment, system deployment and continuous monitoring, offers a scalable and adaptable path that can be followed by any organisation that spans the entire range of compliance maturity. Main operational recommendations are the formalization of a Responsible Person with well-defined accountability for all MoCRA requirements, the establishment of a three-tier CAPA system with quantified performance targets, the implementation of next-generation risk assessment techniques for safety substantiation and the design of an inspection readiness program that includes simulated audit activities and quick retrieval procedures for documents. Cost analyses reveal that the absolute costs of complying with the regulations are highest for large corporations ($1.575 million per year), but the costs have been found to be heaviest for SMEs (normalized in revenue at $200,000 per year), highlighting the need for industry association support, shared service models, and FDA compliance assistance resources that are specifically tailored to smaller market participants.

The transition deadline of June-July 2024 represents more than a date for compliance, it symbolizes a cultural tipping point at which cosmetic companies are obligated to present themselves as safety-conscious, quality-committed, and regulation-compliant enterprises. Combining compulsory reporting and GMP requirements, and safety substantiation duties, MoCRA serves as an ideal durable framework for raising U.S. Cosmetic products safety standards to that of international markets, if and only if implemented with adequate strategic and organizational efforts corresponding to the magnitude of this transformation.

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