From FAERS to MoCRA

Building Data-Credible Post-Market Safety in Cosmetics

Abstract
This paper was drafted in real time during the October 30, 2025 Personal Care Products Council (PCPC) Science Symposium. Its content was informed by live dialogue across regulatory, scientific, and industry perspectives and supported by the structured use of AI as an analytical and drafting aid. The paper was subsequently reviewed by PCPC regulatory and quality experts, refined through community feedback, and finalized to reflect both the substance of MoCRA requirements and the emerging realities of AI-enabled regulatory oversight.

Release Statement
This document is released publicly to support informed discussion, industry readiness, and transparent engagement at the intersection of cosmetics safety, data credibility, and AI-assisted regulation.

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Executive Summary

Regulation is shifting from attestations to data credibility. The FDA Adverse Event Reporting System (FAERS) Public Dashboard has shown how structured, machine-readable data can transform safety oversight. With the Modernization of Cosmetics Regulation Act (MoCRA), cosmetics now enter the same era of standardized evidence and explainable oversight. This paper explains that convergence, how AI systems such as the FDA's "Elsa" represent both opportunity and caution, and why forward-thinking companies should treat post-market data not as a compliance burden but as a competitive advantage.

For the cosmetics industry, this transition builds on decades of voluntary leadership from the Cosmetic Ingredient Review (CIR) program to the Voluntary Cosmetic Registration Program (VCRP) and marks the next evolution: from voluntary frameworks to mandatory, data-driven transparency.

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1. The Context – FAERS as Blueprint

The FDA Adverse Event Reporting System (FAERS) is the agency's most mature model for post-market surveillance. Since 2001 it has captured millions of drug and biologic event reports; since 2017 its public dashboard has made this data visible and interactive to all of industry, researchers, journalists, and consumers. In September of this year, FDA launched real-time adverse event reporting for cosmetic products marking the first time cosmetic adverse event data was officially centralized and made publicly searchable within the FAERS system.

Behind the charts lies a philosophy: every serious event contributes to a living map of product risk. By exposing data to external analysis, the FDA transformed safety monitoring from a closed-door exercise into a transparent ecosystem where patterns emerge through collective scrutiny. It is important to note that cosmetic reports are not verified by FDA prior to being posted to FAERS.

For cosmetic manufacturers, FAERS offers a preview of their future. The same expectations for standardized coding, digital submission, and public visibility will likely extend to cosmetics under MoCRA's implementation.

Key insight: FAERS did not replace expert judgment; it augmented it with structured data. That balance will be critical as cosmetics adopt similar frameworks. For any given report, there is no certainty that a suspected cosmetic caused the event.

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2. The Catalyst – MoCRA Expands FDA Reach

Passed in December 2022 and effective December 2023, MoCRA modernized cosmetic law for the first time since 1938. It introduced mandatory facility registration, product listing, record-keeping, and serious-adverse-event reporting while granting the FDA recall authority.

For an industry long guided by voluntary programs such as CIR and VCRP, MoCRA is an evolutionary shift. It builds on existing commitments to safety and transparency while formalizing obligations that were previously optional.

The statute is concise, but its implications are broad:

- Facility registration
- Product listing with ingredient disclosure
- Serious adverse-event reporting within 15 business days
- Safety-substantiation records maintained six years (three for qualifying small businesses)
- Good Manufacturing Practice (GMP) regulations forthcoming from FDA (timing TBD)

Small-Business Considerations

MoCRA includes targeted exemptions for facilities with less than $1 million in annual sales, except for high-risk categories such as eye-contact products, injectables, internal-use items, and long-lasting appearance alterations. These exemptions do not apply to serious-adverse-event reporting obligations.

Industry signal: MoCRA places cosmetics within the same regulatory philosophy as foods and drugs – evidence-based risk management driven by data credibility.

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3. The New Intersection – FDA and AI (Elsa)

In June 2025 the FDA launched "Elsa," an AI-assisted system designed to summarize submissions, detect anomalies, and optimize internal reviews. Deployed ahead of schedule and already in use for clinical-protocol reviews, adverse-event summaries, and inspection prioritization, Elsa illustrates the agency's commitment to AI-augmented regulation.

Built within a secure GovCloud environment, Elsa is not trained on data submitted by regulated industries, safeguarding the sensitive research and data handled by FDA staff. Elsa is engineered to summarize adverse events, perform label comparisons, generate database code, identify high-priority inspection targets, and accelerate scientific

evaluations. Although initially focused on drugs and devices, its architecture signals how the FDA will handle cosmetic data: automated triage, pattern recognition, and early-signal detection.

Operational Reality
Public reports and internal quality checks show that AI tools like Elsa sometimes hallucinate or miscount outputs, necessitating human verification to prevent "false signals". FDA leadership has acknowledged these limitations as inherent to current large-language-model technology.

Critical lessons for cosmetics:

1. AI amplifies input quality – garbage in, garbage out still applies.
2. Human oversight remains mandatory – automation augments, not replaces, expert judgment.
3. Transparency about limitations builds trust.

AI accelerates review only when fed structured, validated data and paired with human judgment. For cosmetics, the lesson is clear: data discipline first; automation second.

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4. The Industry Landscape

The cosmetics sector ranges from multinationals with pharma-grade systems to artisanal manufacturers operating from home kitchens. This diversity creates uneven readiness for MoCRA's data-driven requirements.

Many large manufacturers (>$500M) already maintain drug-like complaint management systems and can repurpose pharma infrastructure. Mid-size firms ($10M–$500M) show mixed readiness; many lack dedicated safety staff and consistent data capture. Small manufacturers (<$1M) are largely exempt from registration and listing but still must report serious events. Contract manufacturers, contract call centers, and/or 3rd party labs are also used by brand owners which may create an extended burden on industry with the new cosmetic requirements.

Across tiers, complaint logs often remain customer-service records rather than regulatory intelligence. Scattered data creates three risks:

1. Regulatory – missed reporting 15-day SAER windows.
2. Operational – overlooked formulation or manufacturing signals.
3. Reputational – reactive rather than proactive safety response.

Bridging this gap requires a cultural shift from reactive complaint handling to continuous surveillance and investment in systems, training, and governance.

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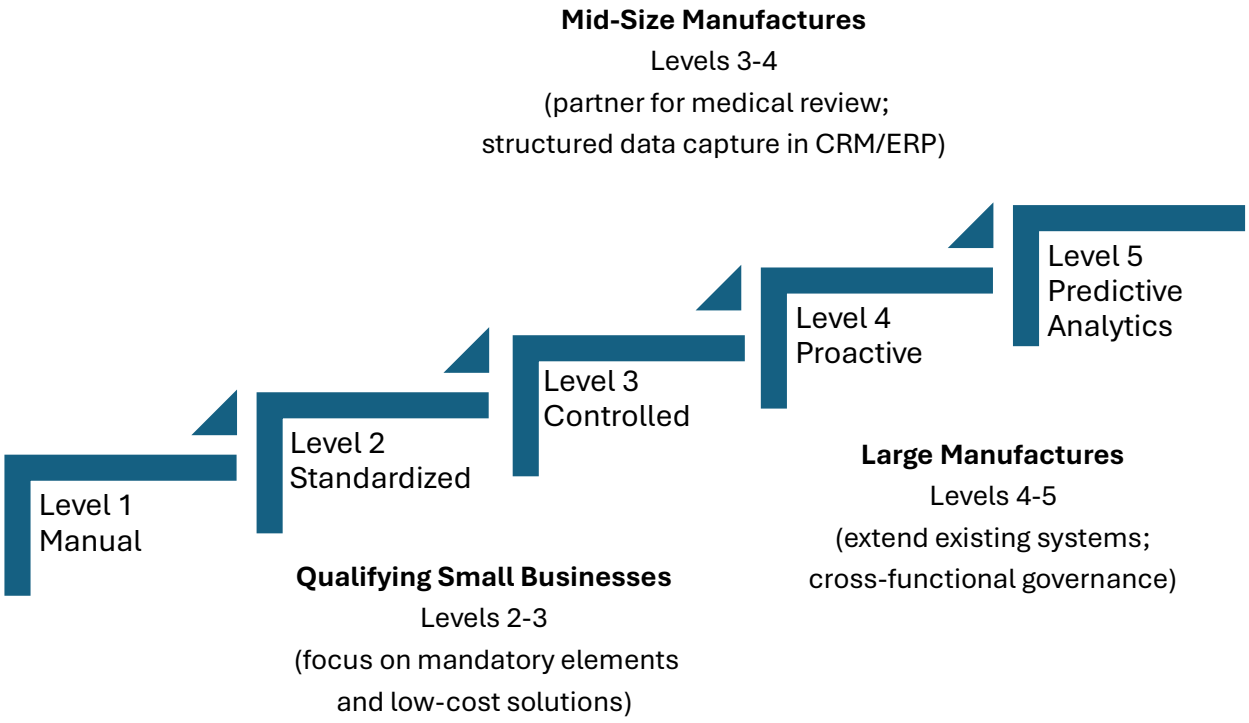
5. Framework Proposal – The FAERS-Alignment Blueprint

To guide industry transition, a five-level maturity model translates FAERS principles to cosmetics, recognizing differences in frequency and severity of events.

Figure 1: Five-Level Maturity Model with Implementation Targets by Company Size



Coding and Terminology

FAERS using the Medical Dictionary for Regulatory Activities preferred terms (MedDRA PTs). MedDRA is robust drug-centric dictionary/thesaurus requiring paid subscriptions for commercial users. The industry, through Personal Care Products Council (PCPC) Scientific and Regulatory Committees, should review MedDRA to determine if it includes cosmetics-appropriate terminology. If not, PCPC should lead the development of such terminology and facilitate inclusion in MedDRA. Proactive standardization demonstrates leadership and may influence future FDA guidance.

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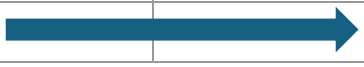
6. Implementation Roadmap

Transformation requires a systematic approach across people, process, technology, and governance.

The following diagram shows the breakdown by phases.

Figure 2: Roadmap – People | Process | Tech | Governance

Phases	Year 1	Year 2	Year 3
1 - Foundation			
2 - Standardization			
3 – Analytics & Visibility			
4 - Integration and Optimization			

Phase 1 – Foundation (Months 1–6)

- Map complaint sources (call centers, email, social media, retailers, e-commerce).
- Align fields to FAERS-style structure (suspect product, name, reaction, demographics).
- Identify gaps and establish Post-Market Safety Committee.
- Define SAER criteria and escalation protocols.
- Assess vendors and medical-review partners.

Definition of Done: ≥90 percent of complaints mapped to structured fields; SAER service level agreement (SLA) tested.

Phase 2 – Standardization (Months 6–18)

- Deploy structured data capture tools integrated with CRM/ERP/QMS.
- Train staff across customer service, quality, and regulatory roles.
- Pilot on subset of products.
- Implement medical review triage criteria and causality rubric.

Definition of Done: 100 percent SAERs reviewed; terminology v1 approved.

Phase 3 – Analytics and Visibility (Months 12–24)

- Launch internal safety dashboards mirroring FAERS visualization.
- Detect trends by product, ingredient, geography, season, demographic.
- Link adverse-event data to formulation, batch, and supply-chain systems, where appropriate.
- Initiate signal-management workflow thresholds.
- Conduct regular data-quality audits and annual process reviews.

Definition of Done: Dashboard v1 in production; first signal review cycle completed.

Phase 4 – Integration and Optimization (Months 18–36)

- Feed insights into R&D and product development.
- Engage in PCPC and public-private safety consortia.

Definition of Done: Cross-functional integration complete; annual benchmark report issued.

Cost and Resource Considerations

Technology investment ranges from $5K (cloud SaaS small firm) to $500K (enterprise AI/ML systems). Personnel include a dedicated safety manager, medical review access, and data analyst support. Training and audit budgets are ongoing.

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7. Strategic Outlook (Next 5+ Years)

Regulatory Evolution – Likely Scenarios

Near-Term: FDA potentially issues guidance documents clarifying serious-adverse-event definitions and causality expectations. The first mandatory recalls under MoCRA are expected.

Mid/Late-Term: FDA potentially issues draft GMP rule for cosmetics. International alignment (EU, Canada, Japan) on terminology and data exchange will advance through PCPC and ISO channels. Industry's best practices are disseminated through PCPC guidance documents.

Variables influencing timeline: FDA staffing and budget, administration priorities, public-pressure events, and AI technology maturity for automated processing.

Competitive Implications

Organizations maintaining FAERS-compatible datasets will realize:

1. Regulatory Efficiency – faster inquiry responses, quicker inspection closures, and fewer record-keeping citations.
2. Operational Intelligence – early formulation issue detection, ingredient-trend tracking, and geographic pattern analysis to inform marketing and distribution.
3. Public Relations Advantage – transparency differentiation and proactive issue management.
4. Innovation Enablement – safety data that supports claims substantiation, de-risks novel ingredient approvals, and shortens time to market for line extensions.

AI Integration Trajectory

As AI tools like Elsa mature and human-in-the-loop validation improves, structured cosmetics data will enable:

- Automated signal detection across product portfolios.
- Natural-language processing of unstructured consumer complaints.
- Predictive modeling for risk forecasting by ingredient and use pattern.
- Regulatory automation to pre-check submissions for completeness and consistency.

Critical success factor: these capabilities deliver value only when fed high-quality, standardized data. Companies that invest now will gain a sustained advantage as AI adoption expands.

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8. Conclusion – From Compliance to Competitive Advantage

FAERS taught the FDA to see safety as data. MoCRA teaches cosmetics to speak the same language. This is more than regulatory compliance – it is a strategic inflection point.

Organizations that treat post-market data as intelligence rather than overhead will:

- Detect and resolve issues before they escalate.
- Demonstrate transparency that builds consumer trust.
- Reduce total cost of quality through early intervention.
- Differentiate in a safety-conscious market.
- Position themselves as innovative and continuous improvement leaders as well as regulatory followers.

The leaders of the next decade will not be those who merely comply with MoCRA's minimum requirements but those who recognize post-market data as a strategic asset – a continuous feedback loop connecting consumer experience, product performance, formulation science, and regulatory trust.

The question is not whether cosmetics will achieve FAERS-level transparency; the question is which companies will lead that transformation and which will be forced to follow.

Notes on Sources and Limits

All findings derive from publicly available FDA, Federal Register, and PCPC materials plus independent media reporting. This analysis is illustrative and non-prescriptive; it does not

constitute legal advice. Policy and technical guidance are evolving, and companies should consult qualified regulatory counsel and safety professionals when implementing MoCRA programs.

Appendix A: MoCRA Serious Adverse Event Definitions

Statutory Language (FD&C Act Section 605[a])
A "serious adverse event" means an adverse event that results in death, serious or life-threatening experience, inpatient hospitalization, persistent or significant disability or incapacity, congenital anomaly or birth defect, or requires medical or surgical intervention to prevent one of these outcomes. MoCRA adds "infection" and "significant disfigurement" (including serious and persistent rashes or infections, second- or third-degree burns, significant hair loss, or persistent or significant alteration of appearance), other than as intended, under conditions of use that are customary or usual.

Reporting timeline: within 15 business days of receipt of a serious adverse event.
Record retention: six years (three for qualifying small businesses).

Appendix B: FAERS-to-Cosmetics Data Mapping Framework

Core elements for cosmetics adverse-event systems include patient (age, sex), event MedDRA PT(s), seriousness criteria, case outcome, event onset date, product name and category, listing number, concomitant products, reporter type and contact, and company information.

Key differences from drug FAERS: exposure patterns differ, serious events are rare, and products contain many ingredients. Hence coding and aggregation must reflect these realities while maintaining traceability for regulators.

Appendix C: Internal Dashboard Prototype (Trend Visualization)

Recommended internal safety dashboard panels:

- Executive Overview – total and serious events, risk-ranked products, submission status.
- Product Performance – events per 1,000 units, heat map by geography, category benchmarks.

- Symptom Analysis – top reactions, co-occurrence networks, severity distribution, time-to-onset histogram.
- Ingredient Intelligence – events by ingredient, reformulation impact, supplier patterns.
- Demographic Insights – age and region distribution, professional vs. consumer use.
- Regulatory Readiness – pending medical reviews, FDA reports due, audit-trail completeness.

Technical Implementation – platforms such as Tableau, Power BI, Qlik, or cosmetics-specific safety systems; update daily for active monitoring, weekly for executive review; role-based access controls; API integration with CRM, ERP, manufacturing, and regulatory systems.

Appendix D: References and Resources

FDA Regulations and Guidance

1. Modernization of Cosmetics Regulation Act of 2022 (Public Law 117-328).
2. FDA Guidance for Industry: Registration and Listing of Cosmetic Product Facilities and Products (Dec 2024).
3. FDA Guidance for Industry: Cosmetic Good Manufacturing Practices (Draft 2013).
4. FDA FAERS Public Dashboard, https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-public-dashboard

FDA AI Initiatives

5. FDA Press Release "Agency-Wide AI Tool to Optimize Performance for the American People" (June 2, 2025).
6. FDA Draft Guidance on AI-Enabled Device Software Functions (January 2025).

Industry Standards and Best Practices

7. Personal Care Products Council (PCPC) MoCRA Implementation Resources https://www.personalcarecouncil.org/public-policy/mocra/
8. ISO 22716:2007 Cosmetics – Good Manufacturing Practices (GMP).
9. Cosmetic Ingredient Review (CIR) Safety Assessment Procedures https://www.cir-safety.org/

Post-Market Surveillance Literature
10. Congressional Research Service Report R47826 (October 2023).
11. Environmental Working Group "Reforming Federal Cosmetics Law: What is MoCRA" (Dec 2023).

Professional Services and Contacts
12. SafetyCall International – adverse event management.
13. Personal Care Products Council – member resources PCPC.org.
14. FDA CDER/CFSAN Cosmetics Regulatory Inquiries https://www.fda.gov/cosmetics

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Addendum: Timeline and Subsequent Developments

Document Timeline

This paper was initially drafted on **October 30, 2025**, during and immediately following the PCPC Science Symposium. It was subsequently reviewed by members of the PCPC scientific, regulatory, and quality community and returned to the author for final publication on **January 15, 2026**.

Developments Since Initial Draft

Since the initial drafting of this paper, several relevant developments have occurred that further contextualize its findings:

1. **FDA Cosmetic Adverse Event Dashboard**
   In September 2025, the U.S. Food and Drug Administration launched a public, real-time adverse event reporting dashboard for cosmetic products within the FAERS system. This represents the first centralized, publicly searchable repository for cosmetic adverse event data and reinforces the paper's emphasis on transparency, signal interpretation, and data credibility. As noted throughout this paper, reported events are not verified by FDA prior to posting and do not establish causality.

2. **Progress in MoCRA Implementation Guidance**
   FDA has continued issuing implementation materials related to MoCRA, including clarifications around registration, listing, record-keeping, and enforcement authorities. While core statutory requirements remain unchanged, these materials signal increasing operationalization of MoCRA expectations.

3. **Emerging Focus on Recall Authority and Enforcement Readiness**
   Late-2025 FDA communications and draft guidance materials have further clarified the agency's approach to mandatory cosmetic recalls under MoCRA. Although

guidance remains subject to finalization, these developments underscore the importance of timely adverse event reporting, data completeness, and internal escalation readiness.

Continued Relevance

These developments do not alter the core conclusions of this paper. Rather, they reinforce its central premise: that post-market safety for cosmetics is shifting toward structured, machine-readable data, transparency, and explainable oversight. Organizations that invest early in data discipline, governance, and analytical readiness will be better positioned to adapt as regulatory practices continue to evolve.

Document Version Control

v0.1 Initial outline framework
v0.2 Prose expansion draft
v0.3 PCPC fact-check revision (Oct. 29, 2025)
v0.4 Post-Symposium master draft (Oct. 30, 2025)
v0.5 Technical Cleanup (Nov. 4, 2025)
v0.6 Reviewer Consolidated Feedback (Dec. 1, 2025)
v1.0 Public release (Jan 15, 2026)

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