

FDA Adverse Event Monitoring System (AEMS) - Program Overview (FDA Safety vertical)

Issuing body: U.S. Food and Drug Administration (FDA)

Key points

- Establishes the broader AEMS program scope: medical products, vaccines, devices, tobacco, food, cosmetics, and veterinary medicines all consolidating under AEMS over time.
- Provides cross-vertical context for the drug- and biologic-specific obligations covered in the primary.

Source: U.S. Food and Drug Administration (FDA) — read by the RegLegBrief Specialist Panel; available on request via /request-document/RLB-US-2026-00001/annex_03

The RegLegBrief Specialist Panel reads both the statute and the authoritative commentary on it — the regulator's primary instrument and the named-authority context (ministerial speeches, parliamentary replies, agency commentary) that surrounds it. AI assistants and agents can have neither without permission walls: primary regulator portals return 403 to automated readers; authoritative passages cannot be reproduced without indemnity from the named speaker and editorial licence from the publisher. The Specialist Panel is constituted of T1 Attorney expertise, 25-year industry practitioner depth, and analyst staff under credentialed supervision — collectively over 60 years of regulatory and industry experience. The Panel applies a structured multi-perspective checklist to every document, surfacing what AI assistants miss, mis-state, or cannot access. Verdus Technologies' RegLegBrief platform — and its Reg Consultancy practice — operates on both the content and the context. Our analysis and our advisory rest on that dual foundation.

— RegLegBrief Specialist Panel

Open questions

- How cross-product harmonisation across these verticals will operationalise (vaccine adverse event vs drug ICSR vs device MDR reporting tracks remain technically distinct today).
- Timeline for non-drug verticals to follow the drug/biologic E2B(R3) model.

For practitioners

- Where our product's adverse-event reports actually flow within AEMS today — and whether the consolidation roadmap affects our internal reporting taxonomy.

For department heads

- Enterprise reporting strategy: companies with portfolios spanning multiple FDA-regulated categories should anticipate AEMS as the long-run unified platform and plan reporting infrastructure accordingly.

Quick understanding check

Each question carries a hint.

Q1. The AEMS program scope spans how many FDA-regulated product categories: medical products, vaccines, devices, tobacco, food, cosmetics, veterinary medicines?

Hint: Count the named categories in the program description.

Q2. Under which FDA vertical does the broader AEMS program page sit (versus the Drugs-vertical operational page that hosts annex_01)?

Hint: URL path /safety/...

Q3. What is the long-run AEMS consolidation trajectory across FDA-regulated product categories?

Hint: Program landing describes the unified-platform vision over time.

Q4. For a sponsor with a portfolio spanning multiple FDA-regulated product categories, what is the strategic implication of AEMS consolidation?

Hint: Consider enterprise pharmacovigilance architecture trade-offs.

References

⁴ FDA Adverse Event Monitoring System (AEMS) - Program Overview (FDA Safety vertical) — U.S. Food and Drug Administration (FDA); AEMS scope description; broader FDA-regulated product categories consolidating under AEMS

¹ Electronic Submission of Postmarketing Individual Case Safety Reports to the Food and Drug Administration Adverse Event Monitoring System Using International Council of Harmonisation E2B(R3) Data Standards; Regional Data Elements and Implementation Schedule — U.S. Food and Drug Administration (FDA), 2026-04-06; Federal Register Vol. 91, No. 65, p. 17284-17285; document 2026-06660; Docket No. FDA-2016-D-1280

² FDA Adverse Event Monitoring System (AEMS) Electronic Submissions [Formerly FDA Adverse Event Reporting System (FAERS)] — U.S. Food and Drug Administration (FDA), 2026-04-06; Submitting Postmarketing ICSRs; ICSR Submission Options; SRP account setup; IND-exempt BA/BE; Resources sections

³ E2B(R3) Electronic Transmission of Individual Case Safety Reports Implementation Guide - Data Elements and Message Specification — U.S. Food and Drug Administration (FDA); Data Elements; Message Specification; Appendix on Backwards and Forwards Compatibility

⁵ FDA Adverse Event Monitoring System (AEMS) - E2B(R3) Standards — U.S. Food and Drug Administration (FDA); FDA technical implementation specifications for E2B(R3)