FDA Regional Implementation Guide for E2B(R3) Electronic Transmission of Individual Case Safety Reports for Drug and Biological Products

Issuing body: U.S. Food and Drug Administration (FDA) — **Date:** 2024-04

Key points

- Specifies the FDA-specific regional implementation layer atop the ICH master specification.
- Names the regional fields and validations FDA AEMS intake applies.

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_08

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— RegLegBrief Specialist Panel

Open questions

• How the FDA Regional Implementation Guide will be maintained post-mandatory-date (cadence of regional spec updates).

For practitioners

• Which FDA-region-specific validation gates apply to our submission profile and how they differ from the generic ICH validations.

For department heads

• Regional-spec change management cadence: build internal capacity to absorb FDA Regional Implementation Guide updates as routine maintenance, not exception projects.

Quick understanding check

Each question carries a hint.

Q1. The FDA Regional Implementation Guide was published in April 2024. By FDA's mandatory date of 1 October 2026, how many months will sponsors have had access to the regional spec?

Hint: April 2024 to October 2026.

Q2. Which FDA document layers atop the ICH master Implementation Guide to provide the FDA-specific implementation profile?

Hint: Title contains 'Regional Implementation Guide'.

Q3. What does the FDA Regional Implementation Guide specify that the ICH master Implementation Guide does not?

Hint: Regional = FDA-specific overlay over the international core.

Q4. What change-management cadence should compliance teams build into their SOPs for handling future FDA Regional Implementation Guide updates post-mandatory-date?

Hint: Treat regional spec updates as routine maintenance, not exception projects.

References

[9] FDA Regional Implementation Guide for E2B(R3) Electronic Transmission of Individual Case Safety Reports for Drug and Biological Products — U.S. Food and Drug Administration (FDA), 2024-04; FDA-specific regional implementation layer atop ICH E2B(R3) master specification

[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

[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