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EU GMP vs. FDA GMP — Dual-Market Gap Map

A companion reference to the deep dive at intrepidscientific.com/eu-gmp-vs-fda-gmp

The two systems agree on roughly 70–80% of substance — both anchored in the shared ICH guidelines — and diverge structurally in a handful of consequential places. This map lays the two rulebooks side by side across two dozen quality-system dimensions. Rows in teal are the deltas that actually change how you build; muted rows are already aligned. The last column gives the one move that satisfies both regulators: build a single quality system to the highest common bar, with explicit hooks for the jurisdiction-specific deltas.

Reference for triage and prioritization — not a legal compliance determination. Verify against the current CFR, EudraLex, and ICH text.

Dimension	FDA GMP	EU GMP	The delta	Build once — to the highest bar
GOVERNANCE & QUALITY SYSTEM				
Regulatory architecture	Prescriptive rules — 21 CFR 210/211 (FD&C Act)	Principle-based — EudraLex Vol. 4 Part I + Annexes; Dir. 2001/83/EC	**"What" vs "how": the CFR prescribes; the EU sets principles elaborated in numbered annexes**	Build to annex-level detail; map each control to both the CFR section and the EudraLex chapter/annex.
Pharmaceutical Quality System	Quality unit; ICH Q10 aligned but not independently mandated (§211.22)	PQS mandated — EudraLex Ch. 1; ICH Q10	**Q10 is explicitly required in the EU; in the US it is expected but not codified**	Implement a full ICH Q10 PQS as the baseline — it meets the FDA quality-unit expectation and the EU mandate at once.
Quality risk management	ICH Q9 expected	ICH Q9 mandated (Ch. 1)	**Mandated vs expected**	Make formal QRM (Q9) standard practice, not ad hoc.
PEOPLE & BATCH RELEASE				
Qualified Person (QP)	Institutional quality unit releases; no named individual, no personal statutory liability (§211.22)	A named QP must certify every batch before release — Dir. 2001/83/EC Arts. 48–52; Annex 16	**The single largest structural difference — personal legal accountability vested in one individual**	Appoint or contract a QP and build the certification step; run dual-path batch documentation for dual-market lots.
Independence / segregation of duties	Implicit via quality-unit independence	Explicit — QP independence and segregation of duties	**Explicit vs implicit**	Document independence and segregation of duties regardless of market.
Personnel qualification & training	§211.25 — training, education, experience	Ch. 2 — personnel; training records	*Aligned*	Keep training records to EU Ch. 2 depth.
FACILITIES & CONTAMINATION CONTROL				
Facilities & environment	§211.42–58; classified areas as needed	Ch. 3; Annex 1 for sterile	*Aligned in principle*	Design classified areas to Annex 1.
Contamination Control Strategy	Aseptic Processing guidance (2004); expectation less formalized	Revised Annex 1 (2022) mandates a documented, holistic Contamination Control Strategy	**A written CCS is a hard EU requirement; the FDA expectation is less formalized**	Author one holistic CCS — it exceeds the FDA bar and satisfies Annex 1.
VALIDATION & DATA INTEGRITY				
Equipment qualification	§211.63–72; IQ/OQ/PQ	Ch. 3; Annex 15	*Aligned*	Qualify to Annex 15.
Process validation vocabulary	Three-stage lifecycle — Process Validation guidance (2011)	Annex 15 DQ/IQ/OQ/PQ model	**Equivalent concepts, different vocabulary and deliverables**	One validation package, cross-referenced to both frameworks.

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Documentation & records	§211.180–198; batch records	Ch. 4 — documentation	*Aligned*	Keep batch records to Ch. 4.
Data integrity (ALCOA+)	21 CFR Part 11; DI guidance (2018)	Annex 11; MHRA/EMA DI guidance	**Parallel regimes, near-equivalent ALCOA+ expectations**	One ALCOA+ framework satisfying Part 11 and Annex 11 together.
SPECIFICATIONS & TESTING				
Analytical method validation	USP <1225>; ICH Q2(R2)	ICH Q2(R2); Ph. Eur.	*Aligned (ICH)*	Validate to ICH Q2(R2).
Elemental impurities & residual solvents	ICH Q3D; USP <232>/<233>; ICH Q3C	ICH Q3D; Ph. Eur. 2.4.20; ICH Q3C	*Aligned (ICH)*	Apply the full risk-based ICH panels (24-element Q3D, Q3C classes).
API manufacturing	ICH Q7	ICH Q7 (EudraLex Part II)	*Aligned (ICH Q7)*	Run one Q7 system for active substances.
PRODUCT LIFECYCLE				
Stability / shelf-life	ICH Q1A–E; expiry dating	ICH Q1; shelf-life justified	*Aligned (ICH)*	Run one ICH Q1 stability program.
Out-of-specification handling	FDA OOS guidance; Barr ruling; §211.192	Ch. 1 / 6 — OOS investigation	*Aligned in principle*	Structured OOS investigation — no invalidation without cause.
Batch release mechanics	Quality-unit disposition (§211.22)	QP certification gate (Annex 16)	**Different accountability models — dual-market lots need dual-path release records**	Design a release workflow with an explicit QP hook for EU-bound lots.
SUPPLY CHAIN & DISTRIBUTION				
Supplier / material qualification	§211.84 — internal QC-unit approval	Ch. 5; Annex 8 — written technical/quality agreements with QP oversight	**The EU emphasizes written quality agreements and explicit QP oversight**	Put written quality agreements in place, with QP hooks.
Good Distribution Practice (GDP)	No standalone federal GDP regime	Named GDP regime — Guidelines 2013/C 343/01	**The EU has a separate, enforceable distribution rulebook**	Adopt EU GDP for any EU-bound distribution.
Product-classification carve-outs	Foods / supplements segmented into 21 CFR 111 / 117	Unified medicinal-products framework	**Structural classification difference**	Confirm each product's classification per market before mapping controls.
OVERSIGHT				
Inspection & audit	FDA pre-approval & routine GMP inspections	NCA GMP inspections; EudraGMDP	*Aligned — the EU–US MRA can reduce duplicate inspections*	Stay inspection-ready to both; leverage the MRA.
Recall / market withdrawal	21 CFR 7 — FDA-coordinated recalls	Ch. 8; EU rapid alert system	*Aligned in principle*	One recall SOP mapped to both.
Pharmacovigilance	FAERS; 21 CFR 314 safety reporting	EudraVigilance; GVP	**Parallel systems**	Report safety data to both databases.

Build once. Build to the highest bar.

Intrepid has run 100+ GMP engagements across both regimes.

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