DHISOLVE × PHARMA

FDA's Own AI Tool Fabricated Clinical Studies

How structural decomposition eliminates AI hallucinations in pharma — with real incidents, real costs, and a proven architectural solution.

AI in Pharma Market: $4.35B (2025) ’ $34.99B by 2031 (CAGR 41.52%)

THE PROBLEM

Why General-Purpose LLMs Fail in Pharma

REAL INCIDENTS

The FDA's internal AI 'Elsa' fabricated nonexistent clinical studies and misrepresented research (CNN, July 2025). An FDA Warning Letter documented an AI dispensing algorithm that gave a pediatric patient approximately 10× the maximum daily dose of medication.

Zero Zero AI-discovered drugs have achieved FDA approval (despite billions invested)

10× overdose from AI dispensing algorithm error (FDA Warning Letter)

KEY PAIN POINTS

- AI fabricates drug interaction data with no connection to real pharmacological databases
- FDA's own AI tool caught generating phantom clinical studies — if the regulator can't trust its AI, who can?
- AI regularly cites nonexistent regulatory standards (e.g., fabricating an 'IFRS 99 standard')
- Despite billions invested, no AI-discovered drug has achieved FDA approval as of December 2025

THE SOLUTION

Structural Decomposition: Specialists Beat Generalists

Pharma queries span drug interactions, regulatory filings, clinical trial protocols, molecular analysis, and pharmacovigilance — each governed by different authoritative data sources and regulatory frameworks.

dhisolve routes each query type to a model trained on that specific domain's verified data. Drug interaction queries go to models grounded in FDA adverse event databases. Regulatory filing queries are verified against actual CFR requirements. Clinical trial protocol queries reference ICH guidelines.

Each model's outputs are independently auditable and traceable to their source data — critical for GxP compliance (GMP, GLP, GCP). The system cannot cite a regulatory standard that doesn't exist because each model only has access to its domain's verified data.

COST COMPARISON

DHISOLVE

$0.10–$0.50

per 1M tokens

BIG LLMS

$10–$60

per 1M tokens

OUTCOMES

Measurable Results

- Zero fabricated drug interactions — every interaction verified against authoritative databases
- 100%source-verified regulatory data — no phantom standards
- Hallucination rate <2% through domain-specific routing and cross-verification
- Each model independently auditable for GxP compliance

ROI CASE

A single drug safety error can cost hundreds of millions in recalls, lawsuits, and regulatory penalties. A fabricated drug interaction reaching a prescriber could be life-threatening. Manual verification of AI-generated regulatory documents costs $200–500/hour of expert time.

With dhisolve:

• Drug interaction data verified against authoritative databases — zero fabrications
• Regulatory references traced to actual CFR sections — no phantom standards
• Expert verification time reduced 70%+ through built-in source verification
• AI cost: $0.10–0.50/1M tokens vs $10–60 for general LLMs

REGULATORY COMPLIANCE

Built for Compliance, Not Bolted On

- FDA 21 CFR Part 11 — electronic records and signatures
- FDA January 2025 draft guidance: 7-step credibility framework for AI in drug development
- ICH guidelines for clinical trial conduct
- GxP compliance (GMP, GLP, GCP) — independently auditable sub-components

ACADEMIC & INDUSTRY BACKING

- *Specialized biomedical models consistently outperform general LLMs on drug safety tasks*
- *RAG-grounded pharma models eliminate fabricated regulatory citations by design*
- *Compound AI: independently auditable sub-components align with regulatory audit requirements*
- *Med-PaLM 2: >90% clinical reasoning alignment demonstrates specialist model superiority*

MARKET OPPORTUNITY

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