DRIFTPIN CONSULTING

Validation Strategy, Gap Analysis, and Compliance Architecture for Life Sciences Technology

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Clinical technology exists to safeguard patients, protect data integrity, and improve outcomes. Everything else—the frameworks, the audits, the validation evidence—is in service of that. Driftpin helps clients keep that goal in sight: using technology correctly, calibrating compliance to actual risk, and cutting through the noise that pulls organizations away from what they are trying to accomplish.

FOR PHARMA, BIOTECH, CROS, CDMOS, AND FSPS

- CSV/CSA gap assessment and remediation architecture: identify control deficiencies, documentation failures, and validation gaps; design the remediation path
- Validation strategy for SaaS and cloud-based clinical platforms (FDA CSA, GAMP 5, ICH Q9(R1))
- AI/ML tool validation: risk classification, intended use scoping, CSV/CSA strategy, and evidence architecture for GxP-regulated AI
- Vendor and supplier due diligence: qualification, risk assessment, lifecycle management
- Audit findings remediation: 21 CFR Part 11, Annex 11, ISO 27001
- Supplier cybersecurity verification and HIPAA Security Rule readiness
- M&A clinical technology due diligence
- US → EU market entry advisory: regulatory pathway, entity structure, talent and compliance strategy

Example Projects

- Led vendor selection across five clinical systems; built integrated CSV strategy from selection through qualification
- Retrospective validation of four clinical systems to remediate regulatory findings
- CSV gap assessment and remediation architecture for SaaS clinical data platform; resolved 21 CFR Part 11 deficiencies from FDA inspection
- Supplier risk framework design for health system anticipating HIPAA Security Rule update

FOR GXP SOFTWARE VENDORS

Clinical and preclinical tech, SaaS, cloud-based, DevOps, AI/ML tools.

- Validation strategy gap assessment: evaluate your CSV/CSA approach, identify exposures, and build a prioritized remediation architecture
- AI/ML and AI tool validation readiness: risk-based classification, intended use definition, validation framework design, and regulatory positioning
- GxP SDLC alignment: processes, controls, documentation, and evidence structure
- CSV/CSA framework design aligned to FDA CSA, GAMP 5, and ICH Q9(R1)
- API integration validation
- CGT/ATMP software validation and compliance
- ISO 27001 and ISO 13485 alignment for regulated cloud deployments
- Fractional VP of Quality / Executive QA leadership

Example Projects

- Led ISO 27001 certification for GxP SaaS platform: gap assessment, controls remediation, and certification
- Fractional Head of Quality for CGT software vendor: built validation framework from first principles
- ISO 27001 gap assessment and remediation plan for SMB clinical software vendor
- AI tool validation strategy for regulated preclinical analytics platform

PARTNERSHIPS

Driftpin partners with platforms that extend client outcomes at the intersection of validation, supplier management, and compliance technology.

ValKit.ai	Digital validation platform for creating and maintaining validation evidence. Kevin serves on ValKit's advisory board. Driftpin is a preferred services partner: gap assessments, validation strategy, and qualification engagements connect directly to ValKit implementation.
AtumCell	Supplier cybersecurity assessment and continuous monitoring platform. Driftpin is a preferred services partner: HIPAA gap assessments, supplier risk framework design, and program build-outs connect to AtumCell's platform capabilities.
CellPort	Lab management platform for regulated environments. Driftpin provides validation strategy and qualification services for CellPort deployments, including GxP readiness assessments and platform-specific validation documentation.
Europa Advisory	EU regulatory and market entry advisory. Driftpin collaborates with Europa Advisory for life sciences technology companies navigating EU entry: regulatory pathway, entity formation, talent and compliance structure. Particularly relevant for NIS2 and EU AI Act readiness.

THOUGHT LEADERSHIP

Kevin writes at driftpin.substack.com on clinical technology, AI validation, and compliance strategy—with a consistent focus on using technology correctly and keeping the actual goal in view. No hype, no misdirects. Patients, data integrity, outcomes.

KEVIN SHEA — OWNER AND PRINCIPAL

Kevin has spent 25 years at the intersection of technology, compliance, and clinical operations in life sciences. He works with software vendors and the regulated companies that use them—and has seen enough process-for-process's-sake, IT posturing, and auditors justifying their existence to know exactly what gets in the way. His job is to help clients cut through it: make sound decisions about technology, build validation programs that hold up, and stay focused on what regulated systems are actually for. He serves on ValKit's advisory board and maintains active platform partnerships with AtumCell and CellPort.

Earlier in his career, Kevin worked as a commercial diver/welder on offshore oil rigs and U.S. Navy ships. The name "Driftpin" comes from the tool used to align and connect pipeline flanges underwater—precision under pressure, connecting disparate systems.

Our Approach

Evaluative, not prescriptive. We assess where you are—documentation, processes, evidence—then collaborate to close gaps incrementally. Document what you're going to do. Do what you document. Generate the evidence you did it. Defensible decisions.