Anthony Davis

Co-Founder and Principal, Complexant Partners | Functional summary

I have spent nearly 30 years in quality and compliance, moving from the laboratory bench and the investigation desk into functional leadership of entire quality organizations. This is the long version, where that experience comes from and how I apply it.

How I got here

I have worked as an individual contributor, a supervisor, a manager, a director, an executive director, a vice president, and an independent consultant, and I have built quality organizations and quality systems in each of those seats. My path runs across the GxP disciplines rather than down a single one. I have owned GMP, GCP, GLP, GDP, and GVP quality in the same organization, covering the entire QMS, including investigations and deviations, CAPA, change control, document management, training, complaints, audits and vendor management, batch and CMO lot release, quality metrics, validation, risk management, and the quality information technology that carries all of it.

Where the experience comes from

Products and stages. Sterile injectables, biologics, gene therapies, oligonucleotide therapeutics, oncology programs, solid dose, OTC drugs, and medical devices, from Phase 1 through commercial production, and a high-complexity testing laboratory operating under CAP, CLIA, OSHA, HIPAA, and GLP.

Frameworks. 21 CFR Parts 210 and 211, 50, 312, 600, and 820, FDA and ICH guidance documents, EU Directives 2001/20/EC and 2003/94/EC, the EU GMP Guidelines (EudraLex Volume IV), PIC/S, and general industry standards.

The first build

The work I am known for is the first build. At Affinia Therapeutics, iTeos Therapeutics, Cullinan Oncology, and Dicerna Pharmaceuticals I designed and implemented a phase-appropriate, company-wide Corporate Quality System from the ground up, sized to the stage the pipeline was actually at, and at Alexion I established Global R&D Quality Systems across the R&D organization. At Dicerna I stood up a medical device QMS inside an existing QMS in six months to support an NDA filing and commercial launch.

Both sides of the audit table

I lead and manage international GxP audits to verify compliance with GCP, GMP, and GLP across Phase I through Phase IV investigator sites, quality systems, medical and clinical operations, clinical trial management systems, drug safety systems, regulatory submissions, labeling, vendors, CDMOs, CROs, and suppliers. I have repeatedly been the face of quality and compliance to regulatory agencies, partners, and customers, and I lead inspection readiness activities directly, which means I know what an auditor is looking for and what it is like to be the one answering.

Enabling infrastructure

I build the enabling infrastructure that supports scalable and compliant quality operations, including global quality management and training programs, supplier and vendor management frameworks, and the implementation and validation of enterprise electronic quality systems. I have led and supported the deployment of multiple platforms, including Veeva, MasterControl, TrackWise, Dot Compliance (DotC), and other GxP-regulated systems supporting document management, training, change control, deviations and CAPA, audits, complaints, and broader quality processes.

I bring many years of experience overseeing IT Quality operations, including computerized system validation, data integrity, system lifecycle governance, vendor oversight, access and security controls, change management, assisting Finance with SOX compliance and internal controls, and the application of risk-based approaches to GxP technology environments. I hold both a Six Sigma Green Belt and PMP certification and apply process mapping, FMEA, measurement systems analysis, capability analysis, and statistical process control directly to quality system design and continuous improvement rather than treating these disciplines as separate activities.

> Hands-on applied AI practitioner who uses AI as a tool, verifies what it produces, and keeps the decision, with the human in the lead, not just the loop. Applies a CSV and CSA, data integrity, and 21 CFR Part 11 lens to adopting AI compliantly in regulated environments.

Complexant Partners

I now co-lead Complexant Partners, a boutique quality and regulatory consultancy built on that experience. We guide regulated life sciences companies through the compliant, risk-based adoption of innovation, from a new regulation, modality, or process change to automation and AI, across four pillars: Regulatory Risk, Sandbox, Implementation, and Monitor & Improve. You decide; we guide, advise, verify, and equip.

Executive profile

Quality executive who has led GxP-regulated quality organizations across clinical-stage and commercial biopharmaceutical companies, spanning sterile injectables, biologics, gene therapy, oligonucleotide, oncology, solid dose, OTC, and medical device products from Phase 1 development through commercial production. Repeat functional head of quality, accountable for the strategic leadership and management of the entire quality organization at more than four companies. Recognized for building Corporate Quality Systems from first principles at the pace the pipeline requires, for leading regulatory inspections and international audit programs, and for representing quality credibly to agencies, partners, and customers.

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Core expertise

Quality system build and ownership. Design and implementation of company-wide Corporate Quality Systems supporting early- and late-stage development, including cross-functional SOPs, team structure, policies and procedures, quality metrics and KPIs, and the phased sizing of the system to pipeline maturity.

Cross-GxP leadership. Ownership of GMP, GCP, GLP, GDP, and GVP quality in a single organization, covering investigations and deviations, CAPA, change control, document management, complaints, batch and CMO lot release, validation, and risk management under the frameworks listed on page one.

Audit and inspection leadership. Leadership and management of international audits across investigator sites, quality systems, clinical and medical operations, clinical trial management and drug safety systems, regulatory submissions, labeling, CMOs, CROs, testing laboratories, and suppliers; direct representation of the company to regulatory agencies during inspection.

Vendor, CRO, and CMO oversight. Creation and maintenance of supplier and vendor management programs, and oversight of external service providers supporting clinical operations, pharmacovigilance, regulatory affairs, quality assurance, and testing.

Training and quality culture. Development of global R&D quality management training programs and company-wide GxP training programs, competency-based and role-specific, with effectiveness measured by competence rather than completion, and sustained development of a culture of quality and continuous improvement across functions.

IT oversight. Implementing and validating enterprise platforms including Veeva, MasterControl, Dot Compliance, and other GxP systems supporting document management, training, change control, CAPA, audits, complaints, and compliance. Deep experience in computerized system validation, data integrity, vendor oversight, risk management, and continuous improvement, supported by Six Sigma Green Belt and PMP credentials.

Scale and impact

- Head of quality for the entire quality organization at four companies, and head of R&D quality systems at a fifth
- Corporate Quality Systems designed and implemented from first build at Affinia Therapeutics, iTeos Therapeutics, Cullinan Oncology, and Dicerna Pharmaceuticals
- Medical device QMS established inside an existing QMS within 6 months to support NDA filing and commercial launch
- Environments including venture-backed clinical-stage biotech, public commercial-stage pharmaceutical, contract testing laboratory, and large multinational biopharmaceutical

Leadership approach

Builds the quality system the company actually needs at its current stage, then scales it as the pipeline advances, rather than importing a large-company system into a small-company setting. Executes quality strategy while balancing cultural, financial, and resource constraints; interprets regulations and applies the appropriate standards to the planning process; and develops the team and structure alongside the system. Takes the external-facing position with agencies, partners, and customers rather than delegating it.

> Establishes credible, inspection-ready quality systems from nothing, at the pace clinical and commercial programs demand, and holds them to standard through the transitions that break them. First filing, first launch, new modality, and new regulator.