Lexie Pieper

Co-Founder and Principal, Complexant Partners | Functional summary

I have spent my career building quality and regulatory systems where there was no precedent to copy. This is the long version, where that experience comes from and how I apply it.

How I work

I have gained extensive experience as an individual, as a leader, as a manager, as a coach, and as a facilitator for change within corporate, site, individual contributor, and consulting capacities. I adapt and leverage the "what" and "who," seek to understand the "why," and implement the "what and how." Transformation, harmonization, alignment, continuous improvement, and infrastructure require phased implementation that aligns with customer needs, company maturity, product stages, and team experience (will, skill, ability).

I ensure delivery of the right amount of quality, to the right people and process, at the right time where it is needed, to ensure retention of staff and knowledge, sustainability, and continued success.

The full lifecycle

My journey covers the entire healthcare lifecycle, from being a scientist in the R&D labs to leading the downstream processes: new product innovation and introduction, process development, analytical development, technology transfer (CMC), Quality (Quality Control, Quality Assurance, Quality Operations, Quality Systems and Services, Quality Management, Quality Compliance, Regulatory Affairs, Quality Innovation), change management, deviations, CAPA, document management, labeling, records management, complaint handling, vigilance, recalls, clinical quality, audit and inspection, supplier quality management, computer systems, validation and verification, multiple manufacturing site design, build, commissioning, and qualification, phase-appropriate quality systems supporting both clinical and commercial programs, lifecycle management, and Regulatory.

Where the experience comes from

Sectors. Blood banking, blood screening, biobanking, cell and gene therapies, consulting, pharma, specialty pharma, biologics, biopharmaceutical, diagnostics, companion diagnostics, medical devices, in vitro diagnostics, organ procurement, CDMO, VMS, probiotics, OTC, and nutraceuticals.

Therapeutic areas and products. Oncology, drugs, APIs, chemicals, transfusion medicine, virology, STDs, blood screening, degenerative diseases, COVID-19, rare diseases, and biobanking (milk, blood, plasma, cord, placenta, tissue).

Organizations. Blood health (Roche, Celularity, Versiti); pharma and specialty pharma (Roche, Lilly/PwC, Versiti, SCN BestCo); biologics and cell and gene therapy (Celularity, Taysha, Versiti); medical devices, diagnostics, and companion diagnostics (Roche, Thermo Fisher Scientific, Celularity); CDMO and multi-client manufacturing (SCN BestCo, Celularity, Thermo Fisher Scientific).

Frameworks. GxP (GLP, GCP, GMP, GDP, GTP), 21 CFR Parts 210/211/820/1271, ISO 9001/13485/14971, IEC 60601-1, MDR 2017/745, ICH Q9/Q10, GAMP, GHS, AABB, CLIA, CAP, USP, NSF, UL, organic, and the applicable international frameworks.

Audits, inspections, and the regulator relationship

Beyond expertise and leadership across these regulated segments, I have extensive, successful experience in global audits and inspections, acting in the Quality Management Representative role: with regulators and licensing bodies (FDA, EMA, Health Canada, MHRA, PEI, ANVISA, TGA, U.S. states); with suppliers (qualification, certification); with customers and partners (as a supplier, CDMO partner, VC, investment); with assessors and certifiers (ISO, AABB, notified body, UL, NSF, CLIA, CAP); and internally (quality, PAI, safety, insurance). I served as company executive lead to the Board of Directors' Audit and Compliance Committee.

Building, remediating, and running quality organizations

I remediate, build, strengthen, and align quality teams with depth and breadth, lay quality infrastructure, and build an overall culture of quality. As the senior-most client-facing quality leader across multi-site and CDMO operations, I have led, participated in, and held ultimate ownership of client audits, technology transfers, and ongoing client relationships, positioning quality as a strategic differentiator with internal and external clients.

Under my leadership, quality and business processes become improved, optimized, efficient, sustainable, and automated using GAMP, CSV, CSA, and 21 CFR Part 11 requirements and principles: TrackWise, Veeva Vault (CRM, Quality Docs, Training, QMS, RIM, eTMF, Clinical), MasterControl, EtQ, UL ComplianceWire, and multiple ERP and MES systems (SAP, JDE), from selection through implementation and beyond.

> 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.

Any company, any structure

My approaches have been successful regardless of company and structure: whether the organization was a start-up (40 people), spin-off, acquisition (450), mid-sized (2,000 to 4,000), or multinational (85,000+); whether the quality team had only me or over 400 individuals across the globe (up to 14 international sites including union sites, in 8 countries across 6 continents, with 20,000 products); whether the financial structure was pre-IPO, private, public, non-profit, retail, contract, consulting, or venture capital; and regardless of corporate strategy for innovation, research, development, clinical, manufacturing, testing, and distribution (internal, from academic, through strategic partnerships, or outsourced).

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

Multi-site and enterprise Quality executive who has built cGMP biologics, biopharmaceutical, and medical product manufacturing organizations across the full healthcare product lifecycle, from R&D through commercialization and obsolescence, spanning pharmaceuticals, biologics, cell and gene therapies, medical devices, in vitro diagnostics, blood and tissue services, and nutraceuticals. Two-time C-suite executive, as Chief Quality Officer at Versiti and Chief Quality and Regulatory Officer at SCN BestCo. Recognized for rebuilding quality organizations and aligning compliance with business strategy to enable scalable, sustainable growth, and for positioning quality as a strategic differentiator with regulators and external clients.

Lexie Pieper

Co-Founder and Principal, Complexant Partners | Functional summary

Core expertise

End-to-end lifecycle leadership. R&D, process and analytical development, technology transfer and CMC, GLP laboratory operations, manufacturing, batch certification and release, site design, build, and CQV, full lifecycle management including post-market surveillance, complaints, vigilance, and recalls.

Quality and regulatory leadership. Global leadership across Quality Assurance, Quality Control, Quality Systems, Compliance, Regulatory Affairs, and Quality Operations, with deep working knowledge of the frameworks listed on page one and of FDA, EMA, Health Canada, MHRA, ANVISA, TGA, EU notified bodies, and U.S. state regulations.

Transformation and infrastructure. Build, remediate, and scale quality organizations and systems, driving inspection readiness, operational efficiency, and sustainable compliance. Lead enterprise-wide quality culture transformation, change management, harmonization, and continuous improvement aligned to business maturity and growth stage.

CDMO and client-facing quality. Senior-most client-facing quality leader across diverse customer portfolios, leading Site Quality Heads as direct reports through client audits, technology transfers, and ongoing client relationships in CDMO and multi-client manufacturing operations.

Scale and impact

- Organizations from start-up (40 employees) to mid-size (2,000 to 4,000) and multinational (85,000+); teams from individual contributor to 400+ staff
- Integrated separate quality systems into one at six organizations (Roche, Thermo Fisher Scientific, Celularity, Lilly, SCN BestCo, Versiti); first quality hire and company-wide system at Taysha; full Veeva Vault enterprise suite validated in 17 months
- Footprint of up to 14 international sites in 8 countries across 6 continents with portfolios exceeding 20,000 products
- Environments including pre-IPO, public, private, non-profit, VC-owned, and venture-backed

Leadership approach

Pragmatic, adaptive, and transformational leader who aligns quality with business objectives by understanding the "why" behind the work and implementing fit-for-purpose, phase-appropriate solutions. Drives quality culture transformation through phased, scalable approaches tailored to organizational maturity, product lifecycle, and team capability. Delivers the right level of quality at the right time, ensuring compliance, enabling efficiency, and supporting long-term business performance.

> Transforms quality from a regulatory requirement into a strategic advantage, strengthening organizations, accelerating innovation, and enabling sustainable growth in highly regulated environments while building credibility and trust with regulators, clients, and partners.