Lexie Pieper

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Two-time C-suite executive who has built quality systems in regulated industries that do not share a rulebook.

COMPLEXANT — PARTNERS —

Signature value

Can tell you which of your requirements are actually required. Thirty years building systems in industries that regulate the same risks differently means knowing the difference between the regulation, the guidance, an auditor's preference, and a habit nobody has questioned in fifteen years. That distinction decides whether a quality system enables the business or quietly taxes it. She sizes the amount of quality to the need and the moment.

Scale

1–400+ quality team, from sole quality hire to a global organization

14 international sites in 8 countries on 6 continents, 20,000+ products

40–85k company size, start-up to multinational; pre-IPO, public, private, non-profit, VC-owned

Results

- No escalated regulatory action across U.S. and rest-of-world inspections, including certifying bodies and agencies
- Brought in to remediate escalations that arose outside her own organization; de-escalated and closed them
- QMS backlogs eliminated and sustained across sites (testing, OOS, documents, CAPA, complaints), with open items held current; on-time-in-full commitments restored
- Global complaints process locked in two months inside a $50M QMS transformation
- Three quality systems merged into one; full Veeva Vault suite validated in 17 months
- ISO 9001 and 13485 certification achieved and held across 14 sites

Industries and modalities

- **Therapeutics:** oncology, rare disease, degenerative disease, virology, COVID-19
- **Modalities:** biologics, cell and gene therapy, small molecule, drug substance and product, in vitro and companion diagnostics, devices
- **Specialized:** blood banking and screening, biobanking (milk, plasma, cord, tissue), transfusion medicine, organ procurement

Executive profile

Quality and regulatory executive who has built systems across industries that do not share a rulebook: medical devices; pharmaceuticals and OTC; vitamins, minerals, supplements, and probiotics; cell therapy; gene therapy; blood banking; diagnostics and companion diagnostics; and organ procurement. Few quality and regulatory leaders have worked across that many segments and their rulebooks. Because she has, she can tell which parts of a requirement are the regulation and which are just how the last company did it, and she can build the process or choose the tool that fits the situation instead of importing one that does not. Full product lifecycle, from the first quality hire to 400+ people, with inspections and audits worldwide.

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, and 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 under GxP (GLP, GCP, GMP, GDP, GTP), 21 CFR Parts 210/211, 820, 1271, and 11, ISO 9001, 13485, and 14971, IEC 60601-1, MDR 2017/745, ICH Q9 and Q10, AABB, CLIA, and CAP. Company executive lead to the Board of Directors' Audit and Compliance Committee.

Transformation and infrastructure. Build, remediate, and scale quality organizations and systems, driving inspection readiness and sustainable compliance through phased, enterprise-wide harmonization.

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

Global regulatory and audit leadership

Inspections and audits worldwide as Quality Management Representative, under the frameworks applicable to each sector. Regulatory authorities have included FDA, EMA, Health Canada, MHRA, ANVISA, TGA, EU, PEI, and U.S. states. Certification, assessment, and licensing bodies have included ISO, AABB, notified body, UL, NSF, CLIA, and CAP. Audit programs have covered suppliers, partners, CDMOs, customers, and clients.

Digital and quality systems leadership

Led selection, implementation, and optimization of global quality and enterprise systems under GAMP, CSV and CSA, and 21 CFR Part 11, including TrackWise, Veeva Vault (Quality, RIM, Clinical, eTMF, CRM, Quality Docs, Training), MasterControl, EtQ, UL ComplianceWire, IQVIA, MediaLab, and ERP and MES systems (SAP, JDE, Great Plains). Uses AI as a tool, verifies what it produces, and keeps the decision, with the human in the lead, not just the loop; applies data integrity to adopt and adapt innovation, including AI, compliantly in quality and regulated environments.