Science in Translation Consultancy

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Executive Summary

PhD-trained immunologist and biopharmaceutical R&D leader with 25 years of experience across biotech, pharma, and CRO organizations. Expertise spans translational strategy, biomarker development, bioanalysis, assay validation, quality compliance, and clinical development support from discovery through proof-of-concept. I have set up a GLP/GCLP compliant laboratory, endorsed in 5 consecutive inspections, and oversaw assay validation in CLIA and GMP environments. I help organizations build high quality infrastructure to strengthen scientific decision-making, and build high-performing teams that deliver critical milestones.

Value proposition

“If the quality system doesn't hold up, the science never gets a chance.”

Most early-stage biotechs know they need a quality system. Few know exactly which standard applies to which study, or at which point in development. The result is either under-engineering, running studies that regulators or clients will not accept, or over-engineering, building a full pharma-grade quality apparatus before a single candidate has been selected. Both cost time and money the company does not have.

I help you get it right the first time:

- Define which quality standard (ISO/GRP/GLP/GCP/GMP/CLIA) applies to your specific studies, platform technology, and development stage.
- Design and implement a quality system fit for stage and purpose.
- Prepare for inspection: SOPs, data integrity, audit trails, and QC systems built to withstand regulatory scrutiny where needed.

A quality system is not a regulatory formality; it is the foundation of which every single data point. I help you build one that is fit for purpose at your current stage, and designed to scale.

Selected Career Highlights

- Set up a G(C)LP compliant laboratory from scratch, including robotics and a lab information management system, for preclinical and clinical bioanalysis. Endorsed in 5 consecutive inspections
- Executed development and validation of 30+ assays, and bioanalysis across 20+ clinical trials under GLP/GCP/CLIA regulatory frameworks.
- Supervised scientific staff and quality operations across small biotech, large pharma, and CRO environments, each with different quality maturity levels.
- Performed vendor qualification audits at external partners, academic institutions and CROs.

Science in Translation

Translating science from lab to clinic. Evidence translated from assays to decisions.