



STRATEGIC GUIDANCE AS YOU ROLL THROUGH THE TIDES



About Us:

Transitioning your biopharmaceutical firm from research and development to a clinical-stage environment can be rough.

We provide your firm strategic guidance to navigate the change as we build a quality and compliance culture in your organization.

Our Services



Microbial Control Strategy

Employing a risk-based approach we can design pragmatic microbial contamination control strategies based on your process and your product requirements.



Validation Lifecycle

Provide the building blocks to ensamble a system to manage your equipment assets and unit operations that can grow with you as you advance through the phases.



Cleanroom Design and Qualification

Plan, design and qualify efficient and reliable cleanrooms and supporting utilities to launch your manufacturing operations.



Quality Control Laboratories Operations

Build sustainable, reliable, and lean operations with reliable equipment, asset management, operation workflows and LIMS software.

Our Services



Quality Control Systems

Design systems to support analytical assay development, lot release testing and laboratory investigations management.



Equipment Qualification

Design and execute equipment commissioning and qualifications based on your organization's requirements.

OUR STORY

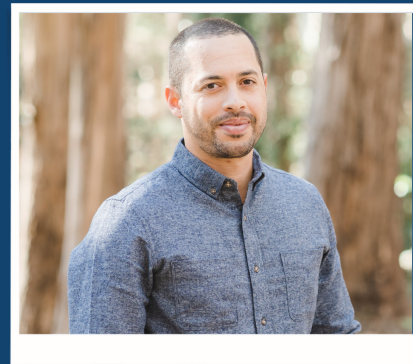
Based in the San Francisco Bay Area, also known as the Biotech Bay, we have worked alongside firms in the clinical phase, and commercial, and contract services organizations. Our experience ranges from working with in-vitro diagnostics to antibodies, and cell-gene therapy products. This broad experience has given us perspective to design pragmatic solutions to meet your business needs.

We build these solutions by partnering with our clients and listening intentionally to tailor solutions that will propel your company to meet its goals.

OUR TEAM



Fransheska Rivera Vega



Anderai Maldonado Arroyo

If you'd like to learn more about our services and how we can meet your organization wherever it is in the process, send us a message, and let's talk.

CONTACT US

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