Simple Quality Systems

Straightforward. Efficient. Simple.

CAPABILITIES OVERVIEW

GXP QUALITY, CELLICON VALLEY & BEYOND

Quality, decoded.

You're building something complex. Your quality system shouldn't be. SQS gives emerging biotech the **senior GxP expertise** to pass audits, manage vendors, and reach **GMP readiness** – **without the overhead of a full-time hire.**

20+
years in pharma & biotech quality

5
core services, fully à la carte

2
languages, English & Spanish, audits included

1:1
you work directly with the principal

WHAT WE DO

Five ways in. Take one, or all five.

Most consultancies sell you a package. SQS sells you exactly what you need, **from a single audit to GMP readiness to a seat at the table as your Head of QA.** You decide the depth.

01 GMP Readiness Assessment

IN DEMAND

ASSESS > READY

Clinical-stage and preparing for commercial? I assess where you stand against GMP expectations and map the path to get ready, so inspection day holds no surprises.

02 GxP Vendor Audits

SINGLE > PROGRAM

Set up, manage, or execute part or all of your audit program. Flexible packages, single audit through full program management, built to stay cost-effective while you scale.

03 Vendor Management & Oversight

QUALIFY > OVERSEE

Build or sharpen the whole program: qualification, onboarding, risk-based audit scheduling, and the ongoing oversight that keeps critical suppliers honest.

04 QMS Support

ASSESS > BUILD

Fit-for-purpose quality systems: gap assessment, remediation, SOP authoring, and Quality Management Maturity (QMM) work to move you from merely compliant to genuinely strong.

05 Head of QA, Fractional

LEAD, PART-TIME

Senior QA leadership on a part-time or project basis. Strategy and hands-on execution of your quality and QMS processes, at a fraction of a full-time hire. The one most early teams don't know they can have.

EN / ES

Fully bilingual, English & Spanish. With deep experience across LATAM and Spanish-speaking regions, every service, audits included, can be delivered fully in Spanish, for your team and your vendors alike.

CURRENT PORTFOLIO

Work in progress, right now.

A look at live engagements. Client names are held in confidence, as they should be, but the work is real and ongoing.

CLINICAL > COMMERCIAL TRANSITION

A virtual clinical-stage biotech preparing for commercial launch

- Led a comprehensive **commercial GMP readiness assessment** against 21 CFR Part 211, evaluating 150+ controlled documents across every CFR subpart and scoring each for maturity and commercial readiness.
- Mapped the gaps between a clinical-stage QMS and the commercial standard, then built a **prioritized, three-wave remediation roadmap** sequenced toward launch.
- Conducted **vendor qualification audits** of critical outsourced partners, reinforcing the sponsor oversight model a virtual manufacturer depends on.

EARLY-STAGE > FOUNDATIONAL BUILD

An early-stage cell therapy organization standing up its quality function

- Helping **establish and activate the Quality Unit** from the ground up, defining governance, roles, and oversight cadence.
- Driving **AABB accreditation readiness**, prioritizing audit-critical deliverables ahead of the accreditation site visit.
- **SOP and controlled-document development**, eQMS support, and quality process build-out across deviations, CAPA, and audit readiness.
- Advisory support on **key hiring and cross-functional coordination** through a concentrated build period.

Engagements are described at a high level to protect client confidentiality. Named references are available during the consultation process, with client permission.

WHO YOU WORK WITH

No handoffs. No juniors. Just me.

Suzette Arostegui, MS
Founder / Principal Consultant

I've spent **20 years in pharma and biotech**, from R&D labs to commercial manufacturing. Quality work is serious, highly regulated, and unforgiving of shortcuts. None of that has to mean the experience of getting there is painful.

That's the difference clients notice: rigorous work delivered with energy and a steady, collaborative hand. I cut through the noise, kill redundancy, and build systems people will actually use, streamlining a QMS, sharpening vendor oversight, and closing gaps before they become findings.

> ***"Scientist at heart, Quality Crusader on the field."***

MS, Organic Chemistry | **Novartis** · Head of QA Processes & Excellence | **Gyroscope** · Head of QA Operations | **UPenn CCI** · Director of GMP QA | Eli Lilly · GSK · J&J

> *"Suzette proved to be a highly capable, organized and diligent QA professional and an outstanding team player. Fantastic energy, attention to detail, and a team-player approach to tackling QA issues. She would be an asset to any biotech/pharma company."*

Let's make your quality simple.

Book a free 30-min call

suzette.arostegui@simplequalitysystems.com
www.SimpleQualitySystems.com
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