



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.**

15+

years in GxP quality, over a decade in cell & gene therapy

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 fixed bundle. 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. Single audit through full program management, with package pricing that stays 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.



RECENT PORTFOLIO

Selected engagements.

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

CLINICAL › COMMERCIAL

A clinical-stage biotech preparing for its commercial transition

- **GMP readiness assessment** ahead of commercial manufacturing, with risk-ranked findings and a closure plan leadership could execute
- **Vendor qualification audit** of a critical supply chain partner, supporting the readiness effort

EARLY-STAGE › FOUNDATIONAL BUILD

An early-stage cell therapy organization in a Phase 1 clinical trial

- **Quality & organizational build-out** from the ground up, including QMS design and eQMS vendor selection
- **AABB accreditation readiness**, guiding the organization toward accreditation
- **SOP authoring, key staff hiring**, and operational strategy as a hands-on partner

COMING SOON

Next up.

NEW SERVICE

Quality Management Maturity (QMM) Assessments

Compliant is the floor. This scores how mature your quality system actually is, from in place to in use to in control to sustainable, and gives you a roadmap for what to strengthen before your next stage.

NEW PRODUCT

QMS & SOP Templates

Ready-to-adapt quality system documents written for early-stage biotech and built to scale. Start from a working foundation instead of a blank page.

Want first access? Join the list at SimpleQualitySystems.com or mention it when we talk.

Engagements are summarized at a high level to protect client confidentiality. Named references can be provided during the consultation process, with client permission.

WHO YOU WORK WITH

No handoffs. No juniors. Just me.



Suzette Arostegui, MS

Founder / Principal Consultant

MS, Organic Chemistry

Novartis · Head of Gyroscope QA Process & Excellence

Gyroscope · Head of QA Operations

UPenn CCI · Director of GMP QA

Eli Lilly · GSK · J&J

I've built quality systems across **pharma and biotech**, from the **QC lab to commercial manufacturing to cell and gene therapy**, and learned one simple truth: quality doesn't have to be boring or overbuilt.

My work is cutting through the noise, killing redundancy, and designing systems people will actually use. I don't just "do compliance." I make it work for the business, streamlining a QMS, fixing training, catching vendor gaps before they become findings.

"Scientist at heart, Quality Crusader in the field."

"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.**

Start the conversation

suzette.arostegui@simplequalitysystems.com

www.SimpleQualitySystems.com

Philadelphia, PA · nationwide & international