



Simple
Quality
Systems

Straightforward. Efficient. Simple.

Capabilities Document Q1 2025 - Overview

Founder /Principal Consultant

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Boutique quality GxP consulting practice in Philadelphia

Focusing on helping emerging GxP biotech companies at early stages of their clinical journey with a particular emphasis on auditing and managing GxP vendors.

Primary Service Offerings

- GxP Vendor Audits
- Vendor Mgt & Oversight
- QMS Support
- Head of QA Fractional Consulting

Straightforward. Efficient. Simple.

"We are Cellicon Valley"

Philadelphia Magazine

Philadelphia, now known as "Cellicon Valley," has become a hub for science innovation in cell and gene therapy. The main goal at **Simple Quality Systems** is to support small to medium-sized emerging biotech and startups entering the clinical space by providing essential GxP quality support and representation. All services are available domestically and internationally.



Service Offerings

Click on each item for links to additional information.



[AUDITS](#)

GxP Vendor Audits

Set-up, mgt and execution of part or all of your audit program. Offering several audit packages for a cost-effective solution for newer organizations.

[The Audit Process](#)



[VENDORS](#)

Vendor Mgt/Oversight

Able to build (or improve!) your vendor management program, including qualification, onboarding, vendor oversight, and of course, auditing.

[Common Deficiencies](#)



[QMS](#)

QMS Support

Fit-for-purpose QMS, Gap Assessment/Remediation. From authoring/reviewing SOPs to building the QA organization (including hiring/onboarding QA staff).

[QMS Implementation](#)

Meet the Founder

"Scientist at heart, Quality Crusader on the field!"



- 30 years of GxP experience
- MS Organic Chemistry
- Most recent assignments:
 - Novartis: Head of QA Processes & Excellence
 - Gyroscope Therapeutics: Head of QA Operations
 - UPenn CCI: Director of GMP QA
- Previous related assignments at Eli Lilly, GSK and J&J

As I enter this new and exciting stage of my career, I would like to focus on finding projects and assignments where I'll have the opportunity to simplify GxP quality management systems. This passion of mine is driven by a commitment to eliminate redundancies, duplication of efforts, and inefficiencies. Those who have worked with me know that I like simplification, efficiency, and straightforward processes.

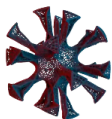
With over 20 years of experience in the pharma and biotech sectors, I've honed my skills in streamlining and enhancing quality processes using LEAN principles. Auditing and Vendor Management have become key aspects of my work, allowing me to identify areas for improvement and ensure compliance with regulatory standards. My consulting practice is dedicated to helping emerging biotech companies establish quality management systems that are fit for purpose. My goal is to strip away complexities and deliver straightforward quality solutions that are easier to follow and maintain, particularly for organizations in pre-clinical or early clinical stages. My pragmatic approach ensures compliance while avoiding convoluted QMS processes that are difficult to understand and implement, let alone follow!



Suzette Arostegui, MS
 Founder/Principal Consultant
 (and problem solver extraordinaire!)



Suzette proved to be a highly capable, organized and diligent QA professional and an outstanding team player who helped build the QA group as we scaled the organization through to Phase 2 clinical trials. Suzette has fantastic energy, attention to detail and applies a team-player approach to tackling QA issues. It was an absolute pleasure working with Suzette; she would be an asset to any biotech/pharma company.



Get to know me: "I believe that **having fun** while working is imperative! Building great work relationships not only makes the work environment enjoyable but also fosters collaboration. By creating a **positive and engaging atmosphere**, we can achieve our goals more effectively and enjoy the journey together. This approach has consistently led to successful projects and **long-lasting professional friendships**, which are invaluable for future collaborations and continued growth."

- sa

Also offering Head of QA Fractional Consulting

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Fractional consulting enables me to serve as Head of QA or similar level, on a part-time or project basis, rather than as a full-time employee. As your **Head of QA Fractional Consultant, I would take a hands-on, senior leadership role within your company**, providing strategic planning and execution of the quality assurance and QMS processes on a part-time basis.

This approach allows organizations to access high-level expertise and support without the commitment and cost of a full-time hire. It is particularly beneficial for small to medium-sized enterprises, startups, and companies with fluctuating project demands.

DID YOU KNOW?

The use of fractional consultants in the biopharma sector has grown significantly, with more than 110,000 individuals identifying as fractional leaders in early 2024, compared to just 2,000 in 2022*.

*reference

Explore The Benefits



Straightforward.

Obsessed with finding the straightforward way of doing things (I'm the one who walks in a straight line from point A to point B!), my mission is to streamline the path to quality, ensuring a smooth journey towards compliance.



Efficient.

I focus on maximizing productivity while eliminating unnecessary steps and waste. For example, who isn't familiar with email purgatory? I adhere to the 2-3 email rule: if it takes more than that, it's time to pick up the phone!



Simple.

I keep simplicity in mind making even the most complex tasks simple and manageable. You'll also experience a straightforward and transparent process, with no hidden fees or unapproved extra working hours.

Overview

Explore in more detail some of the tasks I can personally do to alleviate your teams' workload

I am equipped to support your daily quality operations or to oversee and develop your comprehensive quality organization.

GxP Audits

[More info >](#)

- QMS Audits
- CSV and Data Integrity
- GMP Mfg
- GLP Labs
- CMOs/CROs
- Testing Labs
- Micro/Media Labs
- Vector/Plasmid Mfg Facilities
- Raw Materials Suppliers

QMS Support

[More info >](#)

- QMS SOP Authoring/Review
- QMS Gap Assessment
- Create quality dashboards
- Deliver GxP Training
- Build/Lead QA Unit
- Hiring/onboarding QA staff

Vendor Management & Oversight

[More info >](#)

- Create vendor inventory
- Create quality dashboards
- Author Quality Agreements
- Manage Vendor Risk-Assessments
- Monitor KPIs
- Lead Steering Committee

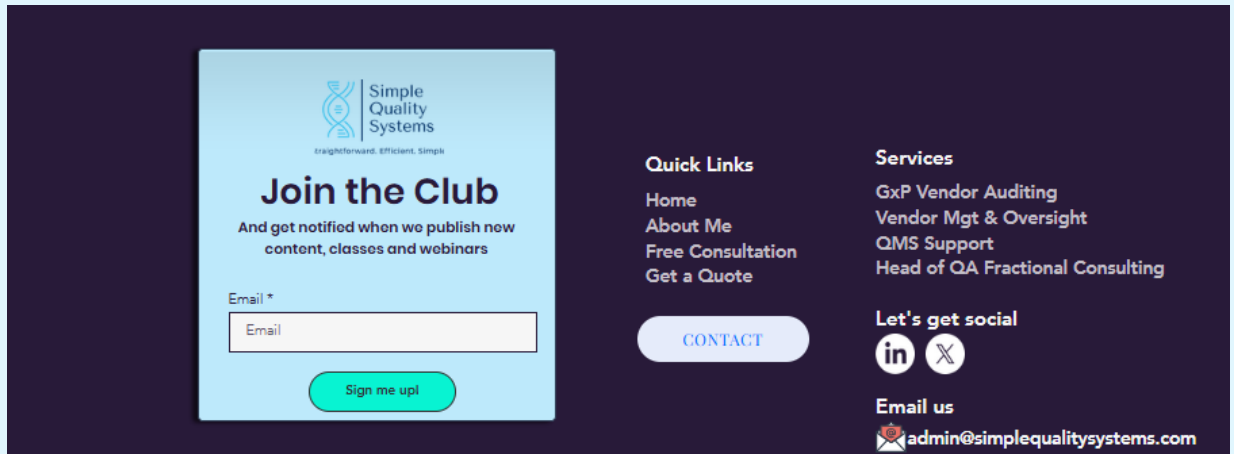
INTERNATIONAL CAPABILITIES



While centrally located in Center City Philadelphia in close proximity to numerous biotech organizations, services are available across all states in the US and as well as internationally. My global capabilities include offering all services fully in Spanish. With previous experience supporting LATAM and other Spanish-speaking locations, I can effectively fully assist Spanish-speaking clients and vendors, whether it's conducting audits, or providing any of my other service offerings.

About Me

Thank you for taking the time to review this
SQS Capabilities Document.



The screenshot shows the footer of the Simple Quality Systems website. It features a dark blue background with white and light blue text. On the left, there is a 'Join the Club' section with the company logo, a headline, a sub-headline, an email input field, and a 'Sign me up!' button. In the center, there is a 'Quick Links' section with a 'CONTACT' button. On the right, there is a 'Services' section listing various offerings, a 'Let's get social' section with LinkedIn and X icons, and an 'Email us' section with an email address.

Simple Quality Systems
Straightforward. Efficient. Simple.

Join the Club

And get notified when we publish new content, classes and webinars

Email *

Sign me up!

Quick Links

- Home
- About Me
- Free Consultation
- Get a Quote

CONTACT

Services

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Let's get social

[in](#) [X](#)

Email us

admin@simplequalitysystems.com

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through our website or directly via email.