Simple Quality Systems

Straightforward. Efficient. Simple.

Capabilities Document Q3 2025

Founder /Principal Consultant

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*Links are disabled. Refer to website for active links.

Simple Quality Systems

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Overview

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"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.

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Overview - Service Offerings

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.

VENDORS

Vendor Mgt/Oversight

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

QMS

QMS Support

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

Also offering Head of QA Fractional Consulting

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

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Overview

Meet the Founder

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

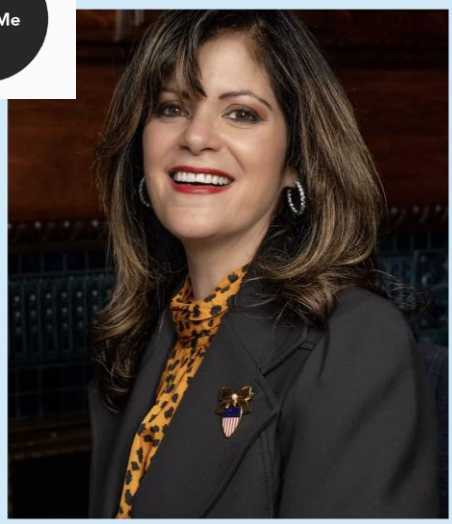
- **20+ years of GxP experience**
- **MS Organic Chemistry**
- **Most recent assignments:**
  - **Novartis: Head of QA Processes & Excellence**
  - **Gyroscope Therapeutics: Head of QA Operations**
  - **UPenn CCI: Director of GMP QA**
- **Previous related assignments at Eli Lilly, GSK and J&J**

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!

Meet Me



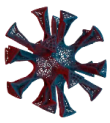
Suzette Arostegui, MS

Founder/Principal Consultant
(and problem solver extraordinaire!)

Learn more about me

Center City, Philadelphia, PA

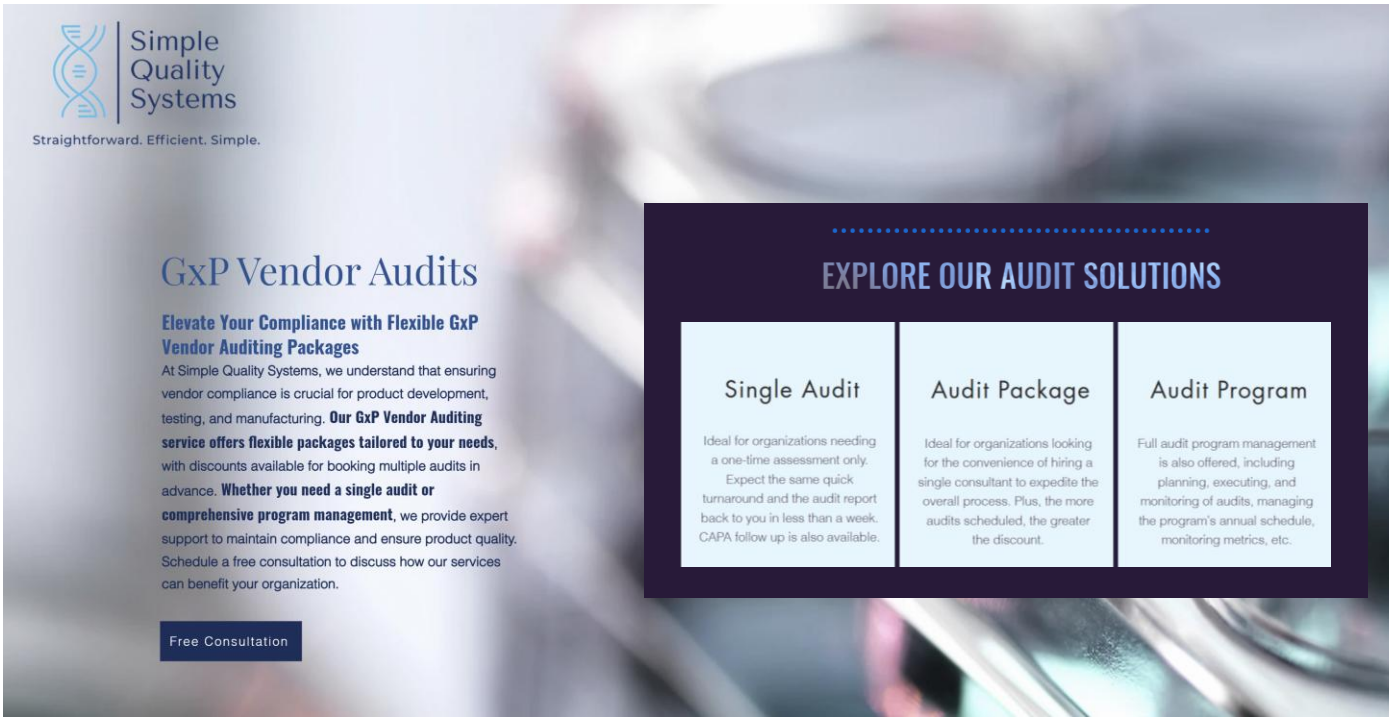
Located in Philly but able to provide services domestically and internationally



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

"

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.



Type of Audits

Free Consultation

Audits can be conducted onsite or remotely. Onsite audits are recommended for laboratories or vendors with physical facilities involved in manufacturing, testing, or product development, as well as for initial vendor qualification processes. Remote audits may be suitable for routine qualification audits of low-risk vendors. Audits typically last 1 to 3 days. An SME from your team is welcome to join if specific expertise is needed or if there are particular areas of concern to address.

Below are some examples of the types of audits covered with the service. Please schedule a free consultation to discuss your audit needs so we can tailor our approach to meet your specific requirements.

GMP Audits

- Excipients/Raw Materials
- Contract Mfg Facilities
- Storage and Distribution

GLP/GCLP Audits

- Facility Inspections
- Testing Facilities
- Lab operations/housekeeping

CSV/Data Integrity

- Electronic records/signatures
- GxP-related systems
- Excel spreadsheets

GDP Audits

- Warehouse
- Supply chain and distribution
- Chain of custody

QMS Support

Gap-Assessment Workflow

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The QMS gap assessment will identify areas where your current quality management system falls short of industry standards and regulatory requirements. By pinpointing these gaps, we can prioritize actions to enhance compliance and improve overall quality. Following the assessment, we offer QMS remediation services to address identified gaps and ensure your system meets all necessary standards.

Through the QMS initial assessment **we will identify main pain points as well as areas of opportunity** to make your existing processes more efficient and compliant. This proactive approach not only enhances compliance **but also fosters a culture of continuous improvement** leading to increased stakeholder confidence.

Prepare

How we'll do it: Gather relevant documentation, survey SMEs to identify current process pain points.
Timeframe: Typically takes 1-3 weeks, depending on complexity and availability of documentation and staff.

Assess

How we'll do it: Conduct interviews, review documents, and perform assessment to gather data. Checklists and assessment tools will be produced.
Timeframe: 2-4 weeks, depending on organization size and assessment thoroughness.

Plan

How we'll do it: Prioritize gaps based on impact. Assign responsibilities, set deadlines, and allocate resources. Create a timeline for changes.
Timeframe: 1-2 weeks, depending on the number of gaps and complexity.

Implement

How we'll do it: Implement changes, update documentation, and train employees. Monitor progress and adjust as needed.
Timeframe: 4-12 weeks, depending on changes and resources.

Evaluate

How we'll do it: Conduct follow-up audits, gather feedback, and review performance metrics. Adjust as needed to maintain compliance and improvement.
Timeframe: 2-4 weeks, depending on complexity and data availability.

QMS Support Services also encompass the management and execution of a wide variety of single quality initiatives or projects. For example, I can assist with the **implementation of a new electronic eQMS, conduct workshops on technical writing or other quality topics, or create quality dashboards on Power BI, to name a few.** Whatever your requirements, we can collaborate to develop a tailored plan that meets your needs.
Additionally, we offer targeted gap assessments of individual key quality processes rather than evaluating the entire program. Some examples of processes that can be individually assessed include:

- Training Program
- Audit Program
- Change Management
- Vendor Mgt & Oversight
- Deviations/CAPAs
- Risk Management

DID U KNOW?

Contrary to popular belief, paper-based systems are acceptable, especially in the early development stages. The key is to ensure these processes are well-controlled and compliant until you are able to invest in the implementation of an electronic QMS.

Result?
A Fit-for-purpose QMS

Explore QMS Remediation Services

Optimizing your Vendor Audit Program

The entire vendor management program will be assessed, and audit frequencies will be updated based on risk analysis results. The annual audit schedule will be revised to ensure an adequate schedule that minimizes overlap, simplifying the workload. Additionally, an audit tracker and dashboard can be developed upon request to help monitor the schedule and ensure timely completion of audits.

Step 1. Vendor Mapping → Step 2. Assess vendor risk → Step 3. Determine Audit frequency → Step 4. Build Audit Schedule

Explore Audit Services

I offer ongoing and continuous monitoring of your audit program, including building the annual audit schedule, executing audits, monitoring metrics, and ensuring the program remains compliant. Additionally, I can assist in preparing your team for regulatory inspections by conducting mock inspections and delivering training workshops. Let's discuss your specific needs in detail and develop a service that stays within your budget while ensuring compliance.

A great way to start revamping your audit program is by developing visual tools to help you monitor audit schedule, report status, CAPA follow-up, etc.

Get a Quote

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Head of QA Fractional Consulting

Fractional Consulting offers a deeper integration into your company's operations, providing long-term engagement, decision-making authority, and a cost-effective solution. Let's explore some of the most impactful differences between regular consulting and Fractional Consulting.

Get a Quote

Why Choose Fractional Consulting?

- ☑ *QMS oversight*
- ☑ *Drive Change*
- ☑ *Training Oversight*
- ☑ *Hiring/onboarding staff*
- ☑ *Serve as QA Rep*

While both Fractional and Regular Consulting offer valuable expertise and knowledge, there are some differences in the type of tasks addressed under each category

Regular Consulting:

- Best for short-term projects or one-time tasks

Fractional Consulting:

- Ideal for continuous oversight of QMS operations or QA staff
- Provides ongoing, high-level strategic support
- Focuses on continuous improvement
- Offers long-term engagement and integration into company operations