Simple Quality Systems

Straightforward. Efficient. Simple.

Capabilities Document Q1 2025

Founder /Principal Consultant

Suzette Arostegui

M: 305.903.7175

suzette.arostegui@simplequalitysystems.com

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

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For additional information
and updates see:
www.SimpleQualitySolutions.com

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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

Overview

Meet the Founder

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

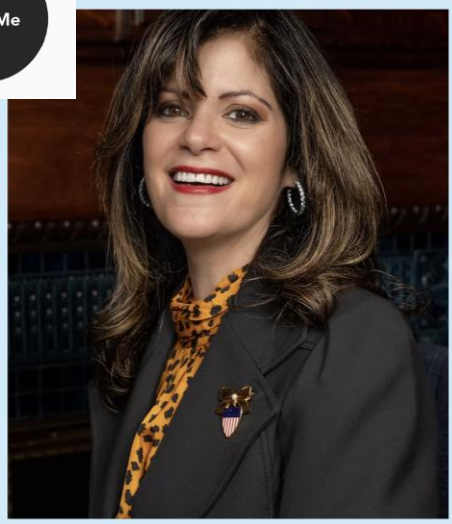
- **20+ years of GxP experience**
- **MS Organic Chemistry**
- **Most recent assignments:**
  - **Novartis: Head of QA Processes & Excellence**
  - **Gyroscope Therapeutics: Head of QA Operations**
  - **UPenn CCI: Director of GMP QA**
- **Previous related assignments at Eli Lilly, GSK and J&J**

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



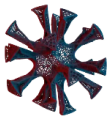
Suzette Arostegui, MS

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.

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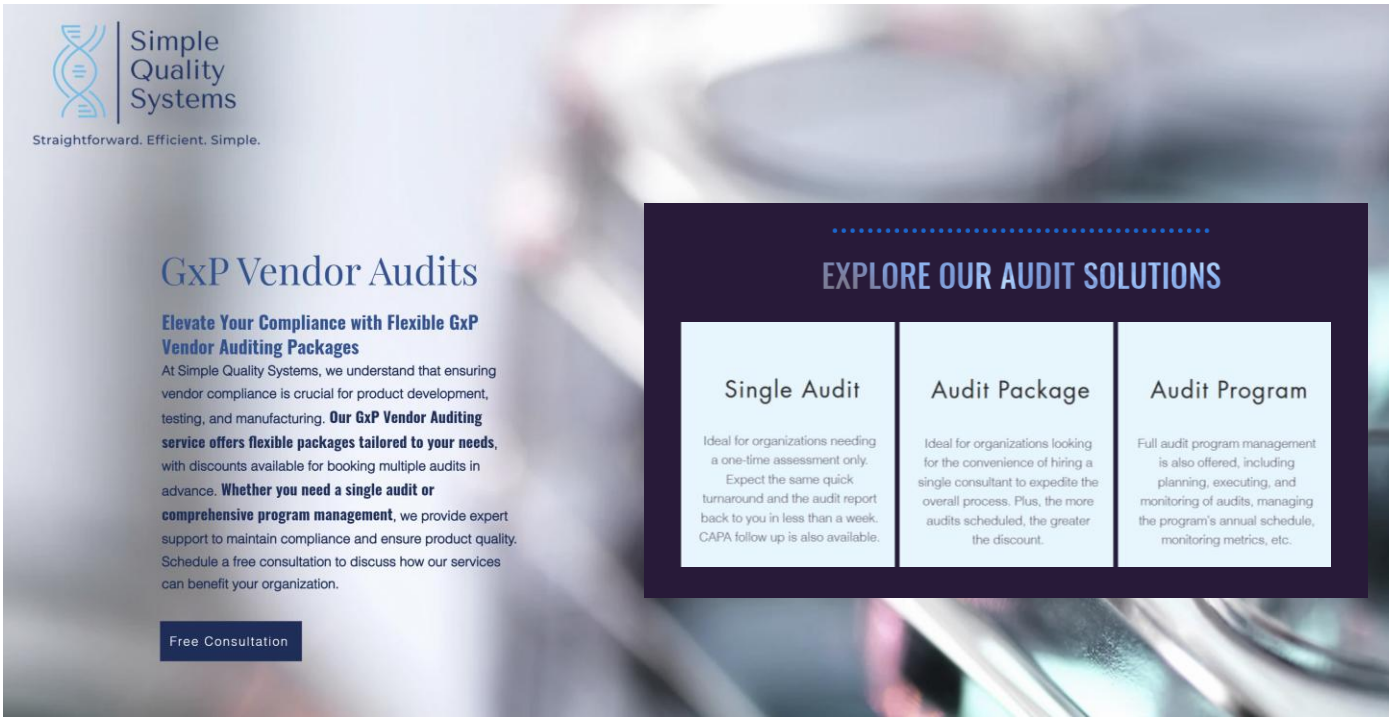
GxP Vendor Auditing



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

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The simple audit process

This section provides a summary of what to expect from each step of the audit process if we were to work together, including some hypothetical timelines followed by a list of deliverables for each step. As a solo consultant, I can offer personalized attention and tailored solutions, ensuring a quick turnaround on tasks and reports. This approach guarantees that your organization receives the expertise needed for streamlining processes and achieving successful outcomes.

1. Audit Planning

Proper audit planning is essential to ensure the audit scope is clearly defined. During the Scoping Meeting, we will define the scope, objectives, and criteria of the audit, and discuss what standards will be followed. If the auditee doesn't have a QMS, we may audit against the Quality Agreement.

What to expect:

- Document review ahead of audit
- Takes approximately 8-16hrs
- Agree on KPIs
- Determine what procedures/stds will be followed during the audit

2. Audit Execution

The audit will start with the opening meeting. If onsite, the audit may include a facility tour. SMEs from your organization are welcome to join to provide specific expertise, if preferred. The audit concludes with the exit meeting, where I will provide a summary of observations, next steps, and proposed timelines.

What to expect:

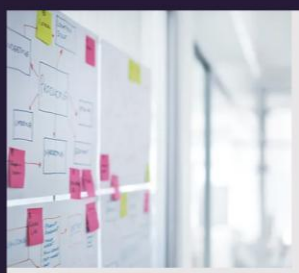
- Audit execution (8-24hrs, as approved)
- Onsite or remote
- Expect daily updates after audit concludes for the day

3. Audit Reporting

Includes drafting the report with findings and recommendations. Expect a quick turnaround to receive the final report. This guarantees that all relevant parties receive the necessary information efficiently and effectively.

What to expect:

- Write up, follow up, deliverables - approximately 10-16hrs
- 1-2 rounds of review
- Report finished in 1 week or less



4. CAPA Plan and Follow-Up

CAPA Follow-up services are also available upon request. During this step, the CAPA plan implementation and tracking is managed on behalf of the client.

What to expect:

Expected time of completion will greatly vary depending on the number and complexity of the resulting CAPAs

Audit Planning

- Initial Meeting
- Scoping Meeting
- Audit Plan/Agenda
- Audit Confirmation letter

Audit Execution

- Daily end-of-day audit progress summary

Audit Reporting

- Post-audit Meeting
- Final report shared with sponsors (and auditee, if requested)
- Audit Certificate

Audit Follow-Up

- Agreed CAPA plan
- CAPA follow up and tracking
- Effectiveness checks

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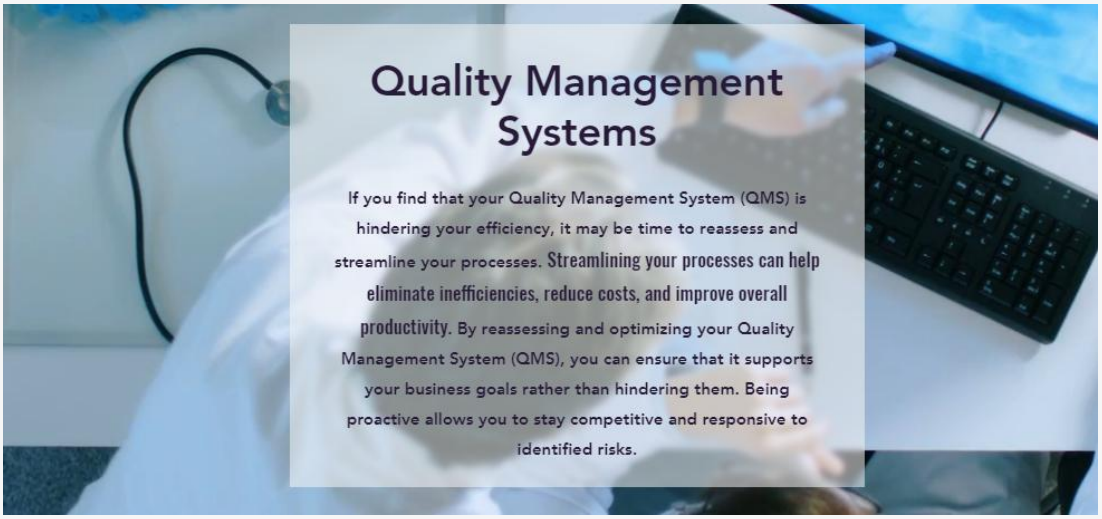
QMS Support

QMS Support



Quality Management Systems

If you find that your Quality Management System (QMS) is hindering your efficiency, it may be time to reassess and streamline your processes. Streamlining your processes can help eliminate inefficiencies, reduce costs, and improve overall productivity. By reassessing and optimizing your Quality Management System (QMS), you can ensure that it supports your business goals rather than hindering them. Being proactive allows you to stay competitive and responsive to identified risks.

The QMS Support service includes four main approaches: Implementation, Assessment, Remediation & Management

QMS Implementation

This approach involves developing and implementing a fit-for-purpose QMS tailored to the organization's needs. It includes establishing the foundational pillars of the QMS, such as the quality policy, quality manual, and other essential components. Training staff on the new processes is part of the implementation and a QMS effectiveness check can also be performed as needed.

Gap Assessment

QMS Gap Assessments are common when organizations are advancing through the clinical stage and want to ensure their QMS remains compliant. In this approach, I will conduct thorough assessments to identify areas that need to be updated to meet more rigorous requirements. A remediation plan with actionable recommendations will address any identified gaps.

QMS Remediation

This service focuses on implementing corrective actions to address deficiencies identified from the gap assessment. I will update SOPs, enhance training programs, deliver training sessions, and make necessary adjustments to strengthen your quality management processes. Additionally, I will conduct effectiveness checks to ensure that the implemented changes are working as intended and that your QMS is robust, effective, and fully compliant.

QMS Management

This service focuses on the ongoing management and maintenance of your QMS. It includes continuous monitoring, regular updates to SOPs, and metrics monitoring to ensure your QMS remains robust, effective, and compliant. Given the longer-term nature of this assignment, the Head of QA Fractional Consulting service may be more appropriate. Let's connect to discuss the details and find the best solution.

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

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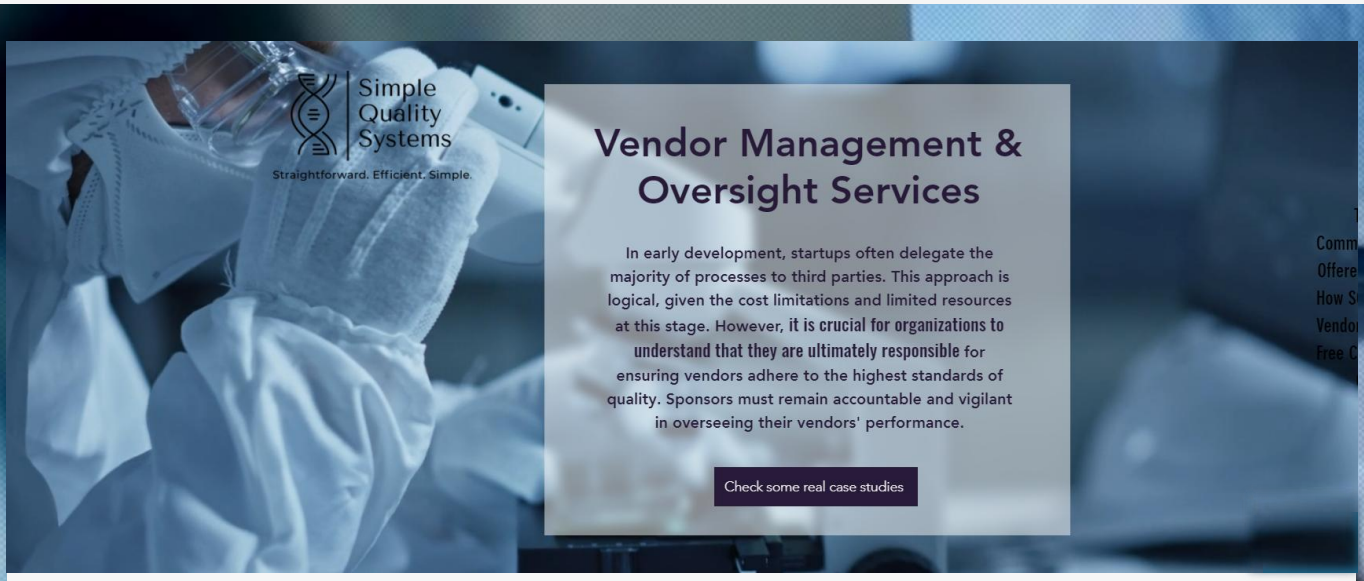
Vendor Mgt & Oversight



Deficiencies in Vendor Management Process:

Real-life scenarios

I have dedicated the last 10 years to **developing, implementing, managing, and remediating vendor management processes, particularly for organizations in biotech and cell and gene therapy**. I understand the critical dependence of these organizations on third parties. I have come across a number of common deficiencies through the years, and as such, **my Vendor Management Services are designed to address these challenges** to ensure that your suppliers meet the highest quality standards. Let's explore some real-life scenarios I've encountered:

Poor Vendor Selection Process

The selected **vendor is non-GxP compliant but was hastily contracted for lab testing**. The vendor needs to be replaced for one meeting higher standards, creating duplicated efforts, increased costs, and definitely adding a large dose of frustration.

Overall a Deficient Process

Your current process may be in **No Man's Land: no process owner, no metrics collected, no vendor risk escalation, no vendor tracker, no KPI metrics reported, and no updated audit schedule.** This lack of oversight is extremely common! It leads to inefficiencies and added risk.

Inadequate Audit Program

(or lack thereof!) While you may have conducted the vendor audit during the initial qualification process, **do you use a risk-based approach for subsequent requalification audits?** Is this approach consistently followed? Be honest....

Lack of Vendor Oversight

A major incident occurred at the vendor's facility, but you only found out after the drug product was finished. Turns out, there was **no Vendor Oversight Plan or Quality Agreement in place,** leading to communication lapses and poor oversight.

No Performance Monitoring

You don't have metrics or KPIs in place to monitor vendor performance and trends. **Avoid underperforming vendors, unnecessary costs, and added risks by tracking KPIs.** Tip: Need help creating a colorful dashboard? I can assist with that too!

No Proper Risk Assessment Process

Risk values are not used to calculate qualification requirements, so all **vendors are qualified equally regardless of their risk, creating unnecessary work and inefficiencies.** Would you qualify a CMO the same way as a consulting firm delivering GxP training? Exactly.

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

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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

Fractional vs. Regular Consulting: *Key Differences*

To help you understand the unique advantages of Fractional Consulting, I have created a comparison table to highlight key differences and benefits, so you can determine which service best suits your quality needs.

Title	Regular Consulting	Head of QA Fractional Consulting
Integration and Commitment	Works on specific projects without deep integration into daily operations.	Part-time senior leader involved in strategic decisions and quality operations.
Decision-Making Authority	Provides recommendations, but final decisions rest with the company's internal team.	Has decision-making authority to implement changes and initiatives.
Cost-Effectiveness	Cost-effective but may not offer the same level of integration into daily operations.	Most cost-effective solution for high-level expertise without a full-time executive salary.
Long-Term Engagement	Shorter engagements, focusing on specific projects or deliverables.	Provide long-term continuity and oversight of QA and QMS processes.

Fractional Consulting = Expertise on Demand
Whether hourly or via retainer, allow me to create a solution that fits your budget, timelines, and goals.

My Role as a Head of QA Fractional Consultant

Below are some examples of the tasks and duties that can be done under Fractional Consulting. These can be tailored to meet your specific needs. Schedule a free consultation to discuss how I can support your organization.

QMS Oversight

- Promote and implement continuous improvement initiatives to ensure the QMS remains lean, user-friendly, and compliant.
- Manage and assess SOPs and quality processes to analyze compliance, assess risks, and update as needed.
- Oversee the integration and harmonization of the QMS, promoting efficiency and standardization.
- Monitor and evaluate the effectiveness of training programs to ensure they meet quality standards.
- Monitor and evaluate key quality processes such as supplier quality performance and others.

Team Leadership & Development

- Recruit and onboard QA team members.
- Lead and manage local and global quality teams to ensure consistent adherence to cGMP standards and regulatory requirements.
- Conduct regular performance reviews and provide constructive feedback to team members
- Develop and implement succession plans to ensure continuity in key roles within the QA team.
- Organize team-building activities and events to foster collaboration and camaraderie.

Strategic Planning & Collaboration

- Conduct Management Review
- Develop and implement global quality strategies and initiatives that align with corporate objectives and regulatory expectations.
- Collaborate closely with cross-functional teams including Manufacturing, Regulatory Affairs, and R&D to drive continuous improvement in quality processes and systems.
- Engage with key stakeholders to align quality initiatives with business objectives.
- Oversee quality-related projects to ensure they are completed on time and within budget.
- Facilitate clear and effective communication between cross-functional teams to ensure alignment and collaboration.

Compliance Oversight

- Present KPIs, initiatives, and resource needs to senior management.
- Provide vendor oversight.
- Serve as the primary point of contact for regulatory inspections and audits, ensuring readiness and compliance at all times.
- Monitor and analyze quality metrics and KPIs to identify trends, implement corrective actions, and drive a culture of quality excellence.
- Champion a culture of quality and compliance throughout the organization, promoting awareness and accountability at all levels.
- Oversee the investigation of quality incidents and ensure appropriate corrective and preventive actions are implemented.

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About me

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About Me.

My consulting practice is built on over 20 years of relevant experience as its solid foundation. I can confidently say that I have reached a point where I can offer my services as an SME and create a win-win situation for both you and me. My services are targeted to create efficiencies that address bottlenecks or sluggish quality processes.

FOCUS

Emerging biotech companies in Philadelphia "Cellicon Valley" where I am based, as well as consulting globally and across the U.S.

EXPERIENCE

More than 20 years of experience in QA and QMS

RESULTS

Proven and measurable results that increase quality and performance

My chemistry background has taught me to be analytical, organized, and results-driven. I am a board-certified chemist with a Master's Degree in Organic Chemistry and years of Pharma and Biotech QA experience. I started working in the QC lab and worked my way through multiple roles in GMP commercial manufacturing before transitioning to academia to learn about cell and gene therapies. I consider myself an expert in understanding Quality Management Systems (QMS) and have a proven track record of leadership and problem-solving skills. I excel at turning "problems" into improvement projects. Who doesn't want things to be simple and efficient?

Key Competencies/Skills:

QMS Implementation
Developing/delivering Training Program/Content
Change Management Champion
Internal/External Auditing
3rd Party Management/CMO oversight
Strategic and Tactical Planning
Organizational and Negotiating Skills
QA Unit development – Building/optimizing teams, hiring staff
Manage Quality Remediation Projects

My extensive experience in GxP has been an invaluable journey, providing me with exceptional preparation and training.

This extensive learning, hands-on work, career advancement, and leadership have prepared me to quickly identify areas of opportunity, create efficiencies, simplify processes, eliminate waste, and above everything else, find ways to make processes simpler!

CELL AND GENE THERAPY

(Recent Roles)

Expertise: GMP Mfg, Sterile Mfg, Quality Operations, QMS, Hiring/Onboarding, GxP Vendor Auditing, Change Mgt, Quality Planning, Vendor Mgt, Training, Risk Mgt, Batch Record Review

I have a decade of experience in building and managing quality operations for cell and gene therapy. **Starting at the University of Pennsylvania, I supported breakthrough technologies developed at the Center for Cellular Immunotherapies**, spearheading GMP and QA strategies, and driving continuous improvement initiatives. I played a role in the technology transfer, leading to the licensing of the CAR-T technology to Novartis for the subsequent commercialization of Kymriah.

At Gyroscope Therapeutics, I was hired to build the quality organization, where I led the development and maintenance of Gyroscope's QMS, including the GxP Vendor Management and Audit programs, as well as all other critical quality processes. I revitalized the vendor requalification program, ensuring the vendor audit frequency was updated based on risk.

After the company was acquired by Novartis, I supported quality activities while navigating pressing timelines, shifting priorities, and organizational changes. Appointed by senior leadership, I participated in the **Novartis LEAP (Learning, Empowerment, and Professional Development) program, aimed at supporting leaders in their professional growth and development.** In addition, I took part in a global training program (the Novartis Value Chain Academy (VCA) program), in collaboration with the Ghana College of Pharmacists, where I helped certify pharmacists and health care professionals on QMS implementation and supply chain quality management, as part of their continued education. These experiences reinforced my competencies in strategic planning, change management, and cross-functional collaboration.

PHARMA/COMMERCIAL MFG

(Middle of my career)

Expertise: QA Operations, Stability Program, GxP Training, Consent Decree, Warning Letter, 483 Remediation, Cleaning Validation, CMC, Analyst Certification Program

The PHARMA decade focused on supporting specific QA processes. On assignment for GSK, I managed a portion of their GMP training program, requiring strategic vision and international travel to deliver critical QMS topics. **I developed a global training program, executed internal audit plans, and championed change management across US and LATAM sites.** As the Latin America Lead, I spearheaded QMS remediation activities, significantly reducing CAPA backlog and increasing team engagement. I found it fascinating to adjust business practices according to the region I was visiting.

Supporting a project at McNeil's Johnson & Johnson, **I engaged in FDA 483 remediation efforts and directed large-scale change management projects**. At Cordis, also with Johnson & Johnson, I served as a **global expert in Cleaning Validation, ensuring compliance across multiple international sites.** My problem-solving skills contributed to the development of a document archival system, which received positive feedback from senior leadership. As a Training Consultant at the San German site in Puerto Rico, **I developed and delivered a scientific training program in response to an FDA 483,** ensuring certification and competency among QC Lab staff. I really enjoyed teaching younger laboratory staff valuable tips of the trade that come only with experience!

QC & LAB OPERATIONS

(Start of my career)

Expertise: Good Laboratory Practices, Housekeeping, Product & In-Process Testing, Batch Record Review, Commercial GMP Manufacture, FDA Audit, CSV, Method Validation/ Verification, Analytical Method Transfer, Equipment PM/CM

The official start of my career was as a lab rat, working late nights at the Eli Lilly QC Lab, responsible for in-process analytical testing. While I enjoyed riding up and down the manufacturing facility on our "lab tech golf cart" to stay awake between samples (don't even remind me), this killer graveyard shift propelled me to graduate school.

Upon returning to the Lilly Labs, I pushed my career to the next level and focused finding ways to simplify work processes. I was given the role of Project Chemist and granted carte blanche to propose innovative solutions to address process bottleneck and improve efficiencies. I was in heaven! For example, I developed procedures that significantly reduced deviations, created effective troubleshooting guides, and aligned testing procedures with international standards. **For cost-savings, I drove an FDA reportable change to eliminated redundant chromatographic testing, resulting a cycle time reduction from 5 to 3 days, as well as numerous process mappings to identify and eliminate waste.**

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

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.

Please feel free to connect with me through our website or directly via email.

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.