

INDUSTRY INSIGHTS

THREE KEY BENEFITS OF OUTSOURCING QUALITY ASSURANCE (QA)

SHOULD YOU CONSIDER
OUTSOURCING YOUR QA WORK?

2021-2022

QA is both challenging and time-consuming, especially if you do not have the right resources to support your efforts.

Today, many organizations are discovering that outsourcing this critical function often allows them to spend more time focused on business growth and operational core activities—eliminating the need to hire, reassign or overburden their QA staff without compromising quality.

 **QUALITY ASSURANCE
CONSULTANCY**

A DIVISION OF QUALITY ASSOCIATES, INC.
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THE MOST OBVIOUS AND VISIBLE BENEFITS OF QA OUTSOURCING:

1. Provides cost advantages of staffing talent without the expense and liability of recruiting permanent hires
2. Offers flexible access to skilled resources to expand QA staff capabilities when managing temporary workload surges and just as quickly ramping down once the workload diminishes
3. Reduces business risk by helping to ensure uninterrupted QA support
4. Promotes greater cross-functional discussions and depth to the QA program because the QA knowledge base is not limited to internal staff

In this Industry Insights report, Dan Carey, Director of Quality Assurance Consultancy, a division of Quality Associates Inc. and leading provider of GxP quality assurance, scientific support and archiving solutions, poses critical questions you should be asking yourself while sharing his insights and case studies on the three key benefits of QA outsourcing.

“Due to company budgets, employee fixed costs and the need to be flexible and agile in today’s workplace, outsourcing is a viable option for QA support across the life science and agro science industries now more than ever.”

– Dan Carey, Director,
Quality Assurance Consultancy

WHEN CONSIDERING QA OUTSOURCING, ASK THE RIGHT QUESTIONS

Hiring a QA employee is expensive. It is a difficult and vital activity, especially when searching for skilled talent. Typically, the cost of hiring an employee falls into several broad categories, including recruiting expenses, base salary, employment taxes, employee benefits and office space/equipment. Because these expenses can mount up quickly, many employers consider outsourcing as a cost-effective option especially when covering peak periods or mitigating resource gaps.

Before you make the decision to hire or outsource, first ask yourself the following questions and conduct a cost-benefit analysis for your unique requirements and environment.

Can outsourcing help increase your margins and reduce fixed expenses? Can it also free up capital for other uses?

1. REALIZE TANGIBLE COST ADVANTAGES

With recruiting and fixed employee costs, such as employee taxes, unemployment insurance, workers’ compensation, and disability, as well as benefits that include retirement, sick days, health insurance and vacation time, outsourcing can prove to be a budget-friendly option.

How soon do you need to complete your QA work? Do you have time to define the position requirements, post advertisements, recruit and hire individuals, get them up to speed on their job functions, and then hope they are the right fit?

2. ATTAIN FLEXIBLE WORKPLACES FOR RECRUITING AND PROJECT TURNAROUND

With QA outsourcing, experienced experts can start immediately to keep you on schedule for meeting deadlines and ensuring quick project turnarounds. When extra resources are needed, outsourcing offers the benefit of using skilled talent as much or as little as you need to help ensure you complete tasks and deliverables.

Do you have the manpower to carry out QA functions when suddenly receiving a large, short-notice QA project, or experiencing a sudden loss of QA Unit personnel due to maternity leave, resignation or military deployment?

3. MITIGATE BUSINESS RISKS FROM RESOURCE GAPS

Outsourcing provides you with critical QA support when you face the challenges of internal resource gaps—allowing you to focus on other quality issues; training, reporting, facility audits, vendor qualification audits, etc., while expert resources handle study-specific audits.

MAKING THE CASE FOR QA OUTSOURCING



PHARMACEUTICAL

Project Turnaround
Regulatory Compliance
Operational Efficiencies

A leading pharmaceutical manufacturer contracted most of the nonclinical bioanalytical phase of good laboratory practice (GLP) studies at contract research organizations (CROs). Because of the number of studies involved, its study monitors were not able to provide the required level of review to the bioanalytical data and reports.

The manufacturer hired Quality Assurance Consultancy to provide this service. Our experts performed a scientific review of the bioanalytical data of several studies at every CRO. They examined the data of each batch in the native software (for example Sciex Analyst) while focusing attention to the following: integration parameters; the process used for re-integrations and batch acceptance based on calibrators; quality control and blank responses. In addition to helping the manufacturer set up a GLP program for these studies, outsourced staff provided regulatory and technical review assistance in the development of the protocols, writing standard operation procedures (SOPs) and drafting the study reports.



CORPORATE

Specialized Talent
Regulatory Compliance
Program Accreditation

Management for an analytical laboratory unit of an S&P 500 industrial manufacturer contracted Quality Assurance Consultancy to serve as its laboratory quality assurance unit (QAU). A total of four full-time Quality Assurance Consultancy experts operated as the QAU, with additional personnel traveling as needed.

By utilizing this outsourcing option, the manufacturer ensured it complied with the U.S. Environmental Protection Agency (EPA) GLP, American Industrial Hygiene Association (AIHA) and other state and federal requirements. Additionally, Quality Assurance Consultancy led the accreditation process of the laboratory to gain ISO 17025 for testing laboratories status. This effort involved upgrading all SOPs for compliance with the requirements of ISO 17025, organizing specialized training sessions, acting as liaison with A2LA, etc.



AGRO SCIENCE

Flexible Staffing
Specialized Talent
Cost Savings

A company in the agro science market decided to conduct all product chemistry studies for physical and chemical properties of its pesticides. While it needed an in-house analytical laboratory to implement this work, it did not need full-time staffing. It also was critical that specialists familiar with GLP processes manage the lab environment to make sure all systems implemented were compliant with the GLPs.

The outsourcing solution provided by Quality Assurance Consultancy afforded a cost-savings option while providing flexible staffing with unmatched expertise to help develop all basic standard operating procedures (SOPs), as well as ensure the functions of the analytical laboratory were performed correctly.

Additional Case Studies: Learn more how Quality Assurance Consultancy has assisted universities, pharmaceutical companies and agrochemical enterprises to successfully reduce the time and expense of meeting critical internal and regulatory requirements by visiting [here](#).



FINAL CONSIDERATIONS

Outsourcing QA support allows you to better focus on your own day-to-day business priorities for long-term success while affording cost-effective, flexible staffing options.

To gain the maximum benefits from QA outsourcing, though, it is critical to select a company that has experienced experts to compliment your QA staff and who can hit the ground running with little to no training so that you can realize cost advantages, attain flexible workplaces for meeting project deadlines and mitigate business risks from unexpected resource gaps.

FOR MORE INFORMATION

Learn more about Quality Assurance Consultancy and our solutions by visiting www.QualityAssociatesQA.com or by calling one of our specialists at **410.884.9100**. Our corporate office is conveniently located near three major airports and is less than one hour by car from downtown Washington, D.C. and Baltimore, MD.



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ABOUT QUALITY ASSURANCE CONSULTANCY

Quality Assurance Consultancy, a division of Quality Associates, Inc., is a leading provider of GxP quality assurance, scientific support and archiving solutions. For more than 35 years, we have been advising educational organizations and companies in the pharmaceutical and agrochemical industries on how to reduce time and expense in meeting critical internal and regulatory requirements.

With a team of full-time QA professionals who have more than 20 years of QA experience, we also have assisted small companies that do not have full-time quality assurance staffing—helping them establish good laboratory practice (GLP) programs and conduct GLP training.

ABOUT THE AUTHOR



Dan Carey, Director
Quality Assurance Consultancy

Daniel Carey is the director of the GLP QA, scientific support and GLP/GCP archiving solutions. With Quality Assurance Consultancy for more than 25 years, he is currently responsible for the overall management and direction of the group and previously served as a senior consultant, archivist and radiation safety officer. His 30-year past and current professional experience covers all aspects of QA work under the Food and Drug Administration (FDA), EPA and Organisation for Economic Co-operation and Development (OECD) GLP regulations, plus FDA/International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) GCP. Additionally, Mr. Carey has a thorough understanding and proven track record of all study types (mammalian toxicology, ecotoxicology, biotechnology, analytical/bio-analytical chemistry, field trials, etc.) for regulatory submission. His GCP experience involves his work with CROs and as principal investigator (PI) for site qualification audits, study site audits, database audits, report audits, etc.

Prior to joining Quality Assurance Consultancy, Mr. Carey led a team of approximately 50 scientists and administrative personnel as the laboratory manager at Biospherics Inc., a well-recognized CRO. In this capacity, he was responsible for ensuring the laboratory provided analytical services to the pesticide industry as well as federal and state government agencies and various private companies.

Mr. Carey holds a B.S. degree from the University of Maryland.