



Co-Employment Facts and Solutions

Information to Help Meet Your Drug Delivery Requirements



Table of Contents

| | |
|--|---|
| 1. Introduction..... | 3 |
| 2. Co-Employment Facts..... | 4 |
| 3. Staffing Solutions to Co-Employment..... | 5 |
| 4. Functional Outsourcing to Co-Employment Issues..... | 6 |
| 5. Conclusion..... | 7 |

1. Introduction

ASG, Inc. (“ASG”), founded in 1986, is a full-service Pharmaceutical Development Functional Outsourcing and Staffing Organization. We bring a dedicated focus to this highly specialized marketplace and endeavor to provide a better quality of life for every individual dependent on the health care community. We leverage our experience gained over the last twenty years to provide quality staffing, and functional outsourcing services to the pharmaceutical, biotechnology and medical device industries that are in the business of discovering therapies that will ultimately improve or save lives. Our areas of expertise include project management, clinical operations, data management, SAS programming, biostatistical analysis and medical writing. Our services include the following:

- Project Management
- Investigative site management and monitoring
- Study design and protocol development
- Study related binder/document preparation
- Clinical supplies and CRF storage and shipment
- CRF review
- Data management strategy (FDA Guidance: Computerized Systems Used in Clinical Trials, and CFR 21-Part 11)
- Clinical data review
- Database design and development
- Electronic data capture
- External data integration
- Medical coding
- Medical writing
- Statistical consulting on study design
- Statistical analysis
- Statistical programming (SAS) & verification programming
- Statistical reporting

Most of our services meet specific niche requirements of our clients and are delivered on a time and materials basis. Emerging and established biotech and pharmaceutical firms are continually challenged to meet drug delivery deadlines often because of limited outsourcing choices. Traditionally, staffing companies have provided the appropriate personnel to deliver the needed services. However, co-employment issues have frequently led to abbreviated staffing engagements and an inability to rely on an experienced, stable workforce to get the work completed. Until now, the typical option was to outsource the work to a CRO. Unfortunately, this option is costly and often leaves the client with quality concerns due to a lack of team continuity and control - and more importantly, questionable quality in the end product.

At ASG, we've gathered information regarding staffing and co-employment issues that will help clients understand how to minimize risks and make decisions in the best interest of their customers and shareholders.

2. Co-Employment Facts

By understanding the facts surrounding co-employment issues, clients are able to make informed decisions that will support their specific needs. Listed below are some key facts regarding co-employment that will help with that decision process.

- The definition of co-employment is a legal doctrine which applies when two businesses exert some control over an employee's work or working conditions.
- Co-employment issues can arise regarding discrimination laws, workers' compensation, occupational safety and health (OSHA), wage and hour compliance, family and medical leave rights, and labor management and benefits eligibility.
- Co-employment liability can result if a staffing service fails to perform its employer responsibilities or a client incorrectly assumes employer responsibilities.
- Clients can be jointly liable for overtime payment if they direct a staffing service employee to work overtime. A client is also liable for discrimination if it requests a staffing service to fill an order on a discriminatory basis. The staffing service can also be liable if it fulfills that request.
- Clients with pension plans covered by ERISA (Employee Retirement Income Security Act) should also consider whether they are affected by the IRS rule that requires temporary employees to be in their "headcounts" after the employee is on assignment for 1,500 hours to determine whether their plans meet legal requirements.

Additionally, having temporary workers on site, using client equipment, participating in company meetings and receiving reimbursable expenses directly from the client, all could lead to client co-employment liabilities.

The IRS also has guidelines it uses to determine whether there are co-employment issues. Outlined below are the three primary examples that they use.

Behavioral Control – These are facts that show whether the business has a right to direct and control. These typically include instructions given to an employee as to when, where and how to work; what tools or equipment to use; what workers to hire or to assist with the work; where to purchase supplies and services; what work must be performed by a specific individual; and what order or sequence to follow.

Training – An employee may be trained to perform services in a particular manner.

Financial Control – Facts that show whether the company has a right to control the business aspects of the worker’s job include:

- The extent to which the worker has un-reimbursed expenses
- The extent of the worker’s investment
- The extent to which the worker makes services available to the relevant market
- How the business pays the worker
- The extent to which the worker can realize a profit or loss

For a worker who is considered your employee, you are responsible for:

- Withholding Federal income tax
- Withholding and paying the employer social security and Medicare tax
- Paying Federal unemployment tax (FUTA)
- Issuing Form W-2, Wage and Tax Statement, annually

As companies continue to demand a skilled workforce to provide high quality services, co-employment issues can arise if clients aren’t careful in defining their outsourcing requirements and understanding the benefits of utilizing external vendors for staffing and functional outsourcing solutions.

There are no clear cut answers to co-employment issues between the client and staffing company. However, ASG recognizes these issues and provides a variety of services that will alleviate many of the concerns surrounding co-employment issues.

3. Staffing Solutions to Co-Employment

ASG adheres to all labor laws and follows the IRS guidelines for contract personnel. The employees (contractors) that we contract out to clients are managed by an ASG individual and supported through one of our four offices: Cary, NC, Vernon Hills, IL, South San Francisco, CA, and Chennai, India.

ASG provides compensation to our contractors every 2 weeks in the form of direct deposit. Health benefits are offered and, if accepted, are activated the first of the month after the contractors have been on board for 30 days. In addition, the contractors are eligible for ASG’s 401K plan which is matched up to 10% by ASG. Contractors are also entitled to additional benefits such as flexible spending accounts, short/long term disability and bonus programs based on job performance and hours worked. ASG contractors are not hired for a specific assignment. Therefore, if their assignment ends ASG will employ them elsewhere. While at ASG, contractors are encouraged to attend training classes or user group conferences in their specific discipline. ASG provides the employment umbrella that clients should expect as it relates to co-employment issues.

On occasion, a client may request our cooperation in implementing on site staffing time limits for individual contractors. Although this doesn’t directly address any of the co-

employment issues outlined previously, it is a common practice, especially among large Pharmaceutical companies. ASG works closely with our clients to accommodate their specific needs. Our clients include large biotech and pharmaceutical firms, many of whom have hiring time limits of 11 months to 24 months. The issue with an 11 or 12 month timeframe for some clients has been efficiency and production. It is difficult to maintain a cohesive unit for delivering clinical trial data if the contractors, once orientated to the client, have to leave 4-6 months later. With many Phase III or Phase IV trials, the average of a contractor's length of stay can exceed 24 months. Over the years, ASG has worked with many companies that received approvals for submissions. In all cases of successful submissions, a stable work force played a significant role. If the employment umbrella isn't met by the staffing company, then it doesn't matter whether the length of stay is 11 months or 24 months. The client, in this case, could be at risk for co-employment liabilities.

In conclusion, ASG provides solutions that allow our clients to focus solely on delivering quality work for their submissions. Co-employment issues are eliminated when ASG provides outsourcing or staffing services for its clients. Since it began clinical staffing 15 years ago, ASG has never been part of any co-employment litigation.

4. Functional Outsourcing to Co-Employment Issues

Our functional outsourcing can provide full service off site contract support for clients needing clinical operations, clinical and statistical programming, medical writing and biostatistics. With offices in Cary, NC, South San Francisco, CA, Vernon Hills, IL and Chennai, India, we offer outsourcing services in North America and Europe. The group consists of experienced contractors that are managed by a Project Manager, Director of Statistics or Manager of Statistical Programming. The client will outsource a particular function (monitoring, programming, statistics, etc.), and the off site ASG contractors will produce the work. This can be done through ASG's systems, or via remote VPN connection to the client's systems.

All questions of co-employment issues are resolved when outsourcing to a functional outsourcing unit such as ours at ASG. Our contractors are paid, supported and managed by ASG. All equipment belongs to ASG and the service is flexible to ensure it meets the client's needs. Outsourcing enables a client to be creative in their approach by locating the outsource group close to its place of business rather than on site. For example, if the client has a 24 month rule and a contractor has reached that time limit, the client could then request that the contractor be moved to the off site facility. As a result, the client continues with the same productivity from the contractor without having to replace him/her with someone new. Functional outsourcing allows the client to safely avoid all co-employment issues and provides a level of control similar to on site staffing. In practice, the work is not being performed at the client site; it's being managed by the functional outsourcing group.

5. Conclusion

Co-employment issues are complex and shouldn't be taken lightly. Pharmaceutical and biotech clients should select a partner that understands these complexities and eliminates the risks associated with them while delivering the flexible solutions that provide predictable results. ASG provides staffing and functional outsourcing solutions that offer clients a cost effective approach to meet their labor demands while conforming to all IRS and labor laws regarding co-employment.

Companies that work with individual 1099 contractors expose themselves to co-employment issues. Often the individual 1099 is working solely for the client at the client's site. Although the contractor is responsible for his/her own tax reporting, without a company like ASG to manage the contractor, tax reporting and diversity of work might be compromised and co-employment issues arise. Therefore, it is more economical and efficient for companies to supplement their work force by working with experienced staffing and functional outsourcing firms.

The alternative to staffing has typically been to outsource to a CRO. Over the past few years, many companies have begun to move away from that paradigm because of cost, unstable work force issues, inflexibility and lack of control. Although a CRO eliminates co-employment issues, its costs are often prohibitive for growing companies that have a core group of permanent staff trying to get submissions successfully completed.

Co-employment issues, cost, control, flexibility, and the ability to staff long term – all should be factored into the decision making process for an outsourcing decision. Utilizing a combination of on site and off site staffing and functional outsourcing offers a myriad of advantages for companies trying to make timely, cost effective and successful submissions.