

BY DENISE MYSHKO

clinical trial staffing

A TEMPORARY SOLUTION

Pressure to find a **qualified, reliable contractor** combined with fears over employment laws mean that rather than taking on independents companies are starting to **turn to staffing organizations** that screen and evaluate temporary and long-term assignment workers from across the clinical-research spectrum.

the days of temps

as low-wage, low-status secretaries without benefits have passed.

Now highly specialized — and often highly paid — scientists and others involved in clinical research are joining the temp world. Their skills are valued to such a degree that the organizations that employ them often offer medical benefits, paid time off, and retirement options.

Contract workers — from clinical research associates, biostatisticians, medical writers, study coordinators, programmers, and regulatory affairs personnel — are sought after by pharmaceutical, biotechnology, medical-device companies, and contract research organizations. Companies look toward these types of arrangements as a way to avoid the human resource costs of full-time workers and, more importantly, to meet their staffing needs for certain projects — both short and long-term — that need trained people who can produce from day one.

“We don’t consider ourselves a temp agency,” says Ellen Maynard, VP of business development, client relations at ClinForce. “We are a



NICK DEMLING
Using freelancers allows companies to get expertise for the particular area that they need it in.



ELLEN MAYNARD
 If we can understand what companies are looking for, what their needs are, and the timelines involved, we can be part of their solution.

niche staffing organization. The caliber and the type of candidate that we supply is very specific to the client's needs. These are trained, experienced clinical research associates."

According to a CenterWatch analysis, 80% of participants say there has been an increase in the number of professionals becoming consultants, and 59% believe there will continue to be an increase in the hiring of these professionals in the next two years. The survey, which was conducted this spring, analyzed two market segments: project management functions at pharma, biotech, medical device, CROs, and executive recruiters; and study conduct functions at sites, including site management organizations and academic research centers.

the employment landscape

The nature of employment is changing, with millions of workers no longer in traditional work arrangements. These individuals are part of the workforce that includes temporary, part-time, contract, and other nonstandard work arrangements — a subdivision often referred to as "contingent" work.

Whether called contingent, flexible, alternative, or nonstandard, the portion of the American workforce engaged in nonpermanent or less than full-time employment constitutes anywhere from 5% to 30% of the

workforce, depending on the type of work arrangements that are included. The contingent workforce comprises many categories of workers, ranging from highly paid management consultants to low-paid service sector workers. (See box below.)

The Bureau of Labor Statistics defines contingent workers as people who do not expect their jobs to last or who report that their jobs are temporary.

Most experts say the contingent and alternative segment of the workforce is growing. American staffing companies employed 11.7% more people across all industries in the first quarter of this year than in the same period last year, according to data from the American Staffing Association. The ASA, whose members provide temporary help, contract labor, and permanent placement services, does not break down data by industry, however.

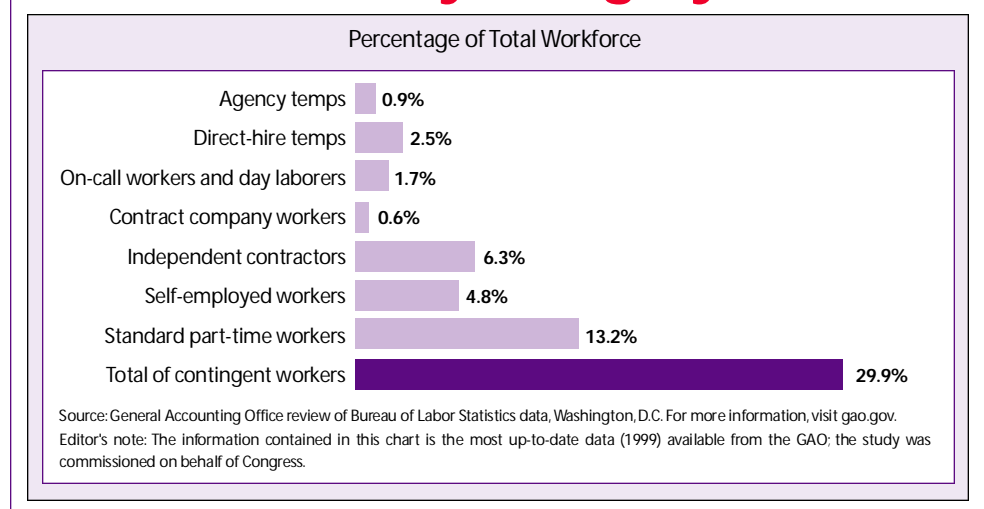
One company that relies heavily on contract workers is Applied Biotech Inc. At any given time, contract and temp workers constitute about 25% of the company's workforce, says Gail Jones, human resource manager. The company uses contract workers for a variety of positions — from administrative and clerical work to production, assembly, and warehouse work to lab tech and chemist level work — and for a variety of reasons — to fill in for vacation and medical leaves, for short-term projects, and for temp-to-hire positions.

"We have trouble finding employees with enough experience," she says. "With all the colleges in the San Diego area, there are plenty of college students and graduates. That's great for lab technicians and even for some chemist positions. Sometimes, though, we need to find someone with at least five years of experience."

benefits and drawbacks

In the CenterWatch survey, 75% of respondents say there are benefits to working with contractors compared with full-time staff,

U.S. Workforce by Category of Worker



including the ability to hire on an as-needed basis; flexibility; no human resource issues; no training or benefits required; and being able to hire a person for a specific project or time.

"Using freelancers allows companies to extend their areas of expertise to meet their clients' needs," says Gregg Berkowitz, principal and president at PharMed Staffing LLC.

Organizations also can determine whether a person is a good fit for the company, says James C. Walker, president and CEO of Octagon Research Solutions Inc., a development partnering organization that uses contract workers.

"We can't afford to have a high turnover, so using contract workers enables us to find out how well we work with those people," Mr. Walker says. "It's worked well over the past few years because some people just haven't worked out and we've been able to let them go."

The project-based nature of the pharma and biotech industry means staffing needs vary, says Chris Jock, general manager of Kelly Scientific Resources. "Companies don't want to be straddled with what is perceived as a fixed cost," he says.

Mr. Jock says that contract workers can account for upwards of 10% to 15% of a pharma company's workforce. "For some projects, it could account for almost 25% to 30% or more, depending on whether there is outsourcing."

Mr. Walker notes that Octagon employs

almost 70 people. "For a small company, employee turnover is pretty costly," he explains, adding that contractors offer the company flexibility. "We use them if we feel there is an immediate need but we're not sure whether there will be follow-on work. Bringing somebody in on a contract basis allows us to gauge work flow while avoiding hiring costs."

As biotech companies grow, they are starting to use more services from staffing organizations, says Nicholas Demling, director of business development at MedFocus. "Companies are using staffing organizations across the board, including to fill positions in the areas of stats, data management, and CRAs," he says. "Biotechs often work with limited capital from venture capitalists, especially as they start to move out of the research stages and into the clinic. These emerging companies usually outsource their data management, their statistics, and their programming to a CRO. They then tend to rely on staffing firms for project CRAs or regional CRAs."

But while hiring independent contractors allows for greater staffing flexibility, this is by no means a cheap option. Typically, contrac-

tors are highly skilled and highly paid, meaning sponsors are likely to pay a premium to hire these individuals.

"There certainly is a premium for certain positions, such as biostatisticians and clinical research monitoring," Mr. Jock says. "Those positions tend to command higher wages because it takes more to recruit those individuals. On top of wages, those individuals are given a higher level of benefits to attract them to work with a staffing company. It is really driven more on what it takes to find, recruit, qualify, retain, and maintain those individuals."

THE NATURE OF EMPLOYMENT is changing, with millions of workers no longer in traditional work arrangements.

who's the boss?

Working with contract workers, however, does present some challenges. In fact, companies throughout many industries are taking a critical look at their use of independent workers because of concerns about coemployment issues.

In a well-publicized case in 2000, Microsoft settled a suit brought by temporary workers for \$97 million after the IRS determined that the company had misclassified temporary workers. The company agreed to pay overdue employee withholding taxes and to compensate the independent contractors for overtime pay.

"Several clients who use consultants have turned to us to help them deal with the coemployment issue by moving these consultants on to our payroll rather than theirs," says David Hands, principal and managing partner of MedFocus. "Coemployment has definitely been identified by the larger pharmaceutical companies as an issue, though not yet by the smaller biotech companies."

Ms. Maynard agrees that how companies use consultants has become a cause for concern. "Because of the Supreme Court decision in the Microsoft case, coemployment is a real issue," Ms. Maynard says.

Using staffing companies can limit the exposure to companies, she says. "Because these workers are ClinForce employees and because we take out their taxes and we pay their benefits, they are far removed from employee status at the pharmaceutical company," she says. "We've worked long and hard to make sure that we're compliant."

Not everyone agrees, however, that the use of independents is decreasing because of coemployment issues. "All of the people we have in our network stay busy," Susan L. Coultas, president and cofounder, InfoQuest Clinical Network Inc.

Ms. Coultas says one of the big issues is whether a company has the right to control the details of a workers' performance.

Employee or Independent Contractor

ACCORDING TO THE INTERNAL REVENUE SERVICE

Whether someone is an employee or an independent contractor is an important question. The answer determines a company's liability to pay and withhold Federal income tax, Social Security and Medicare taxes, and Federal unemployment tax.

In general, someone who performs services for a company is an employee if a company can control what will be done and how it will be done.

The courts have considered many facts in deciding whether a worker is an independent contractor or an employee. These fall into three main categories:

BEHAVIORAL CONTROL. A business has a right to direct and control an employee's behavior. These include 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 specified individual; and what order or sequence to follow.

FINANCIAL CONTROL. A business has a right to control the business aspects of a worker's job, including the extent to which the worker has unreimbursed expenses; the extent of a worker's investment; the extent to which a worker makes services available to the relevant market; how a business pays workers; and the extent to which a worker can realize a profit or loss.

TYPE OF RELATIONSHIP. An employee/employer relationship can be determined by: written contracts describing the relationship the parties intended to create; whether the worker is provided with employee-type benefits; the permanency of the relationship; and how integral the services are to the principal activity.

“Most sponsor companies are accustomed to having employees whose daily activities are in their direct control rather than independent contractors,” she says. “In addition, many of

our members have established their own companies so the liability for the sponsor company is not quite so high.”

Still, coemployment remains a gray area,

Mr. Hands says. “One question that arises is: are these consultants or contractors being treated like employees while they are on site?” he says. “That’s a big issue since the Microsoft

Working with the **Freelance Community**

According to Gregg Berkowitz, founder and president of PharMed Staffing LLC, freelance personnel play an ever-growing role in the success of the medical communications industry. The very nature of pharmaceutical-supported education and marketing efforts continues to require an evolving and specialized freelance community.

Today, clients not only are more demanding than ever but also increasingly cost-conscious. Budgets at medical communications companies are similarly constrained, meaning only a limited number of full-time personnel can be hired to meet anticipated business projects. Yet, the quest for new business is a full-time and essential pursuit. This, in turn, creates a need for experienced, reliable, and quality freelance help.

The medical communications industry is one industry that capitalizes on freelancer workers. Freelance personnel are cost-effective, relieving an organization of the financial and logistical commitments of additional full-time staff, particularly when only project assistance is needed or anticipated.

In addition, freelance writers often specialize in particular project areas (monograph, slide kits, etc.) and tend to have more extensive expertise in particular therapeutic areas. While most freelance meeting planners cover all aspects of onsite events, some specialize in the pre-planning or logistics phase. So, depending on the need, the medical communication organization can select the freelancer with the most applicable expertise to meet the particular client project need.

Trying to identify appropriate freelancers can be a cumbersome, time-consuming, and exhausting process for medical communication firms. Here are a few tips for success in helping to sort through the pool of freelancers and find the ones who can really provide value to an organization:

PHONE SCREENS: Try not to rush a conversation just to hear the freelancer mention the key capabilities needed for a job. A 15-minute phone conversation should allow the recruiter to get enough information and build a rapport with a person to determine if that person would be a good fit. Make small talk about nonwork issues. People often provide better insight into their qualities and can reveal a lot more about themselves when talking about everyday things.

THE “X” FACTOR: There are some excellent freelance personnel with outstanding resumes, references, and samples. Unfortunately, sometimes with that great skill set may come with “challenging” personality traits. A client may change his mind and a project needs to take on a new direction in a moment’s notice. Perhaps, the greatest qualities a freelancer can have, besides skill, are flexibility and a willingness to work with a client and accommodate changes in timelines or deadlines.

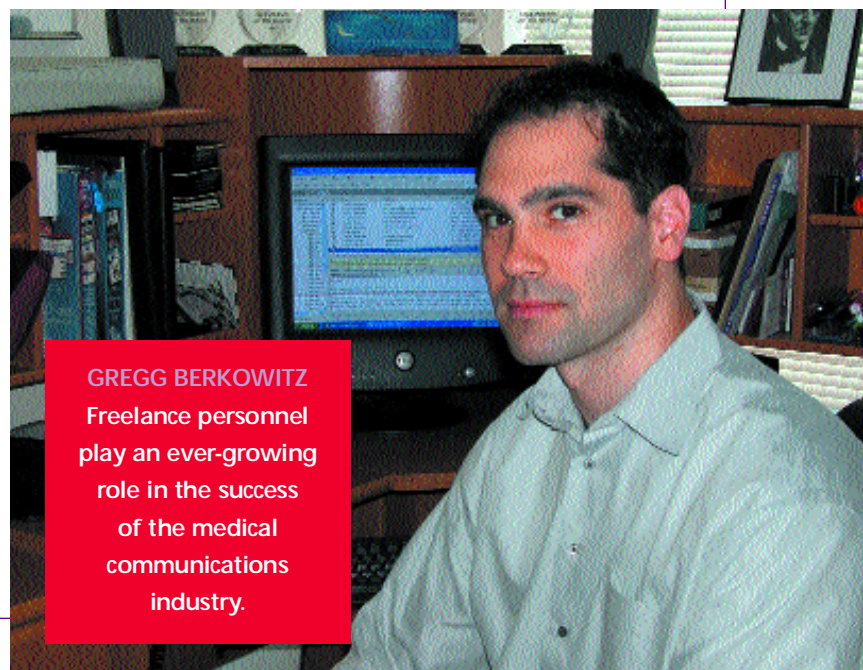
START SMALL: It’s a good idea to give a person a small, preliminary project to test the waters. Later, offer the freelancer work on big projects to test additional abilities. This method enables an employer to evaluate how the person fits, how he or she works, and how to best work with that person.

BRING THEM IN: The best time to talk to freelancers is when the company doesn’t need them. When a person isn’t under the gun to find someone as soon as possible, it is easier to evaluate a freelancer’s capabilities and potential fit within the organization. When an opportunity does arise, the company already has taken the opportunity to speak with that individual and formulate an unhurried and unbiased opinion.

WORK WITH AN AGENCY: If an organization does not have the time and/or resources to find freelancers itself, it should consider working with an appropriate freelance agency that specializes in its field or need. These organizations offer a valuable, extra level of security in helping to find qualified freelancers. They should be thoroughly screened, evaluated, and tested by the agency. While there are no guarantees, a reputable agency will increase an organization’s ability to provide quality and timely outcomes. Most freelance companies are built around a business model that only charges a fee if the client uses someone the agency has recommended.

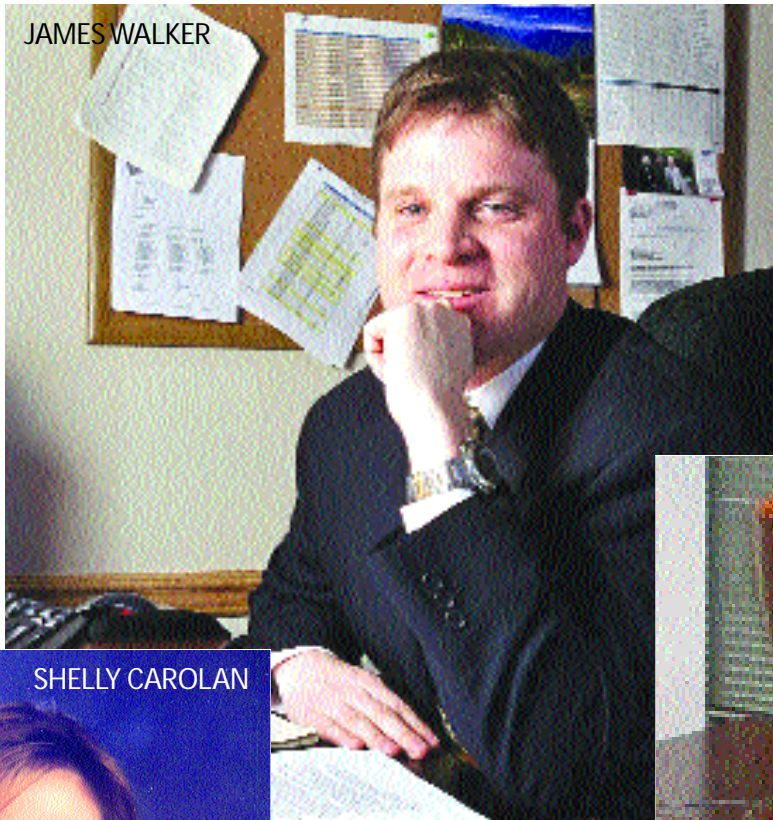
Following these suggestions will hopefully help make the task of finding a qualified freelancer that much easier.

Source: PharMed Staffing LLC, New York. For more information, visit pharmed-staffing.com.



GREGG BERKOWITZ
Freelance personnel play an ever-growing role in the success of the medical communications industry.

JAMES WALKER



► For a small company, turnover is pretty costly. We use contractors if we feel there is a small initial need but we're not sure about follow-on work. Bringing somebody in on a contract basis allows us not to incur any hiring costs and gauge the work flow.

▼ The goal of using a contractor is to bring someone in who can provide instant success to the project without human resource commitment. It might be cheaper to hire in most situations, but companies would be missing the opportunity to bring somebody in who is going to have instant success.

SHELLY CAROLAN



◀ The benefit of using a service versus hiring staff is that companies can keep projects on schedule. There are a lot of things — such as staffing up, training, employee management, the screening and verification of candidates — that are not necessarily expensive but can take a lot of time.

ruling. Many of our large pharmaceutical clients have limited the tenure of our consultants, no matter how good they are, to avoid uncertainty.”

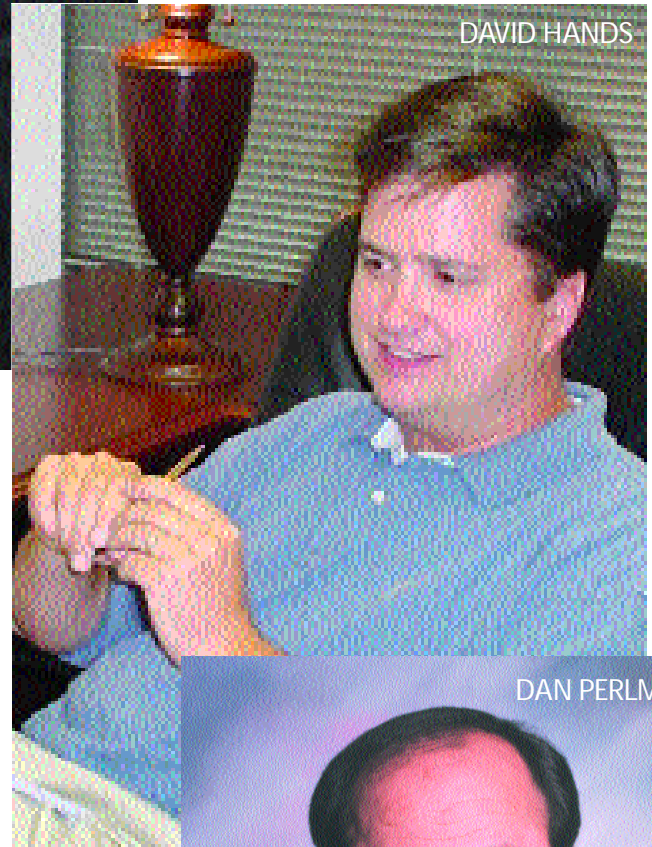
Classifying workers correctly is important not just from a tax perspective, but also from a labor law perspective. Employees are protected under the Fair Labor Standards Act, which provides standards for worker wages, hours, overtime, and minimum wage.

The Department of Labor has tried to clarify current laws. In general, an employee, as distinguished from an independent contractor, is one who “follows the usual path of an employee” and is dependent on the business that he or she serves.

According to Daniel Perlman, CEO and president of ReSearch Pharmaceutical Services Inc., using staffing organizations may not completely shield pharmaceutical companies from liability, especially if a staffing company is using independent contractors.

“It is an issue for pharmaceutical companies to monitor and control contractor relationships,” Mr. Perlman says. “Each company has its own rules about the use of contractors. Go to five different pharmaceutical companies and each will have a different set of rules for employment.”

DAVID HANDS



DAN PERLMAN

▲ Right now, the pharmaceutical industry is looking to cut costs. Companies are now weighing between hiring contract staff and running trials internally or outsourcing them completely to a CRO.

Being flexible is key for overcoming some of the issues related to coemployment, says Christine Ver Straate, VP of business development, PharmaPros Corp., which uses contract and independent workers to extend their team and support key projects. “Our consultants can work their own hours,” she says. “They use their own equipment. In our case, we’re very flexible and we’re not dictating hours. But once committed to a project, they are responsible for meeting their deliverables and producing top-quality work.”

best practices

Mr. Walker cautions that companies need to be careful about who they select to conduct employee searches. “We’ve had more success

THE INDUSTRY currently is being especially careful about the use of independent workers. But in the future, companies will likely start to employ longer-term contractors.

finding people on our own, only because we’ve had some good references from our own employees. It is really hard to find quality people, even through organizations that have a big database of contractors.”

Some staffing organizations don’t assess the contractors as well as they should, he cautions. “We’ve run into a lot of people who don’t listen to the job requirements and the description of the type of person we’re looking for,” Mr. Walker says. “I know right away that we’ve chosen the wrong recruiter if I get 10 resumes that day. If it was that easy to find somebody, I wouldn’t need a recruiter.”

Those on the recruitment side, however, say that if a company truly enters into a partnership with a staffing organization, it can facilitate the process of finding the right contractor.

Mr. Berkowitz agrees. “The most important thing is for the staffing organizations to understand the dynamics of a company — how it conducts business, what its business philosophy is, and how it likes to work with freelance personnel,” he says. “Once the staffing organization understands this critical information, then it can begin to determine how to satisfy particular clients’ needs and who would be a good fit.”

Communication is especially critical when working with a staffing organization, says Shelly Carolan, senior VP, lab support, with On Assignment Inc. “The better the communication between the technical resources of the agency and the technical resources of company, the better fit companies will have right off the bat,” she says. ♦

PharmaVoice welcomes comments about this article. E-mail us at feedback@pharmavoice.com.

Experts on this topic

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