

Best Practices for
Successful Placement of
Pharmaceutical Teams



A White Paper for
Pharmaceutical
Professionals



This article outlines proven methods for designing, managing and evaluating scientific teams, and explores their effectiveness as a solution to companies' resource strains.

Introduction

Time is of the essence for scientists and engineers in charge of research and testing for pharmaceutical manufacturing.

Yet high-level knowledge workers are often pulled into non-critical, routine operations, such as day-to-day testing or compliance regulations. This leaves them unavailable for more strategic functions and strains already limited internal resources.

It is at this critical juncture that pharmaceutical and health care firms start to investigate one of four options. **The first choice** is to accept the situation and work around the limitations. This helps the organization maintain direct oversight and control of their responsibilities, but does not release team leaders from time-consuming activities.

The second option is to completely outsource the mundane function, whether it is finished product testing, raw material testing, equipment calibration or validation work. A true out-source moves the operation to a different location, with the understanding that the outsourcing company's staff will manage the whole process.

While helpful in the short term, this solution comes with a caveat. The outsourcing organization should expect to relinquish control over their processes and have faith that the outsourcing company is following the established processes. This frees up the team for strategic work, but also incurs the risk that issue documentation will lag, leaving them unaware of potential issues down the line.

The third solution is to use contingent labor, such as contractors and consultants. This approach offers immediate on-site help, filling the labor gap. However, these contract workers are never direct employees of the company, and are often subject to term limits many pharma companies set.

These co-employment issues mean pharma firms cannot retain the consultation long term. The inefficient result: Companies must keep re-hiring and retraining new contingency workers for the role, limiting productivity and effectiveness over time.

The final option—placement of scientific teams—stands to offer a happy medium between all possible solutions. If the pharmaceutical manufacturer or engineering firm has the necessary equipment or space, they can consider placing a scientific team to conduct the work right on-site.

When executed properly, this solution goes beyond traditional staff augmentation. A well-planned, thorough scientific placement works in tandem with the customer to design and train the ad hoc team. Moreover, it incorporates a knowledgeable project manager who acts as the single point of contact with the client and also directs the placed team.

This arrangement lets new workers stay as long as need be, giving the client firm stability and efficiency. It also results in lower turnover, and allows the senior leaders to fulfill more critical tasks, such as formulation and product innovation.

The trick to achieving this happy medium is finding the right partner—typically, a hiring and/or outsourcing firm who will manage the entire placement process. Pharma companies need to know what to look for and expect from the partner firm and the scientific team that will be provided. This knowledge will guide them through the formation, placement and performance of the team, ensuring quality and control at every step.

Effective team design starts with the project manager. More than anyone else on the team, the hiring firm's project manager is critical to the placement's success. Thus, it's imperative that the client pharma firms know the attributes of a qualified project manager and can leverage his/her talents for optimal results.

First, strong project managers must have technical knowledge of the client firm's process or service. They must also have excellent communication skills to act as effective bridges between the placement team and the client.

They should also possess excellent organizational skills, since project managers handle many responsibilities. These skills play a key role when project managers oversee training schedules, work schedules, and general employee management.

This combination of technical and people skills puts a project manager in a unique consultative position. Their in-the-field position gives them insight into any points of pain that emerge during the process and helps them identify opportunities to resolve the issues quickly. Since they are not an employee of the pharma company, they can offer an outsider's consultative point of view on the company's practices and dilemmas. Because of this, the client pharma company should be involved in the selection process, even if it is to only to approve the final choices.

Once the project manager is vetted, the client then enters into discovery talks with the hiring firm. Here, project manager plays a critical role in evaluating the client's current performance. They determine how much work the current group processes, what resources they still need and what levels of expertise are required to accomplish goals.

With these needs established, the project manager then builds the rest of the team, with the help of a recruiter also connected to the hiring firm. Different functions will require different skill sets, so the resulting team will vary in makeup depending on the project.

For example, a pharmaceutical firm might want a team for stability testing of finished products, which requires scientific expertise. A validation project, on the other hand, would require engineering experts, while lab maintenance projects could be achieved with maintenance or facilities staff.

In either case, the client and the project manager should evaluate team members in two key areas: experience and potential. When it comes to experience, most teams are made up of senior-level and junior-level staff. The decision-makers must achieve the right mix of backgrounds and expertise.

The potential is the team members' ability to be cross-trained. The long-term goal of any scientific team placement is that the members are as interchangeable as possible. This requires flexible and adaptable people who can switch roles, and achieve maximum productivity.

The next important step is assigning purpose to the assembled team. Difficult situations arise when the newly formed team works in an environment where everyone else is employed by a different company. This leaves them feeling displaced or dispensable.

The best way to address this challenge is by designing a program that makes the placed team vital to a greater mission. A vision or mission statement can foster unity among workers and outline common goals for the project. Some organizations have the newly formed team create this vision and mission statement together to engender a sense of ownership in addition to building camaraderie. The project manager should also work in the background to integrate the teams and eliminate any lingering 'outsider' mentalities.

Designing The Team (cont.)

The final phase of team design is incorporating scalability. As previously mentioned, good project managers are always seeking opportunities to address more client problems. One way to assume these additional responsibilities is to recruit people who can offer additional skills for the team as needed.

This ‘just in time’ approach helps the team avoid an extreme growth curve, making the expansion more fluid and manageable for the project manager. It also helps the team grow with the client, and easily add services—and value—to their client work.

Training The Team

Once the team is formed, managers must bring them up to speed on relevant tests and processes in conjunction with the client’s standard operating procedures (SOPs). At this point, the project manager’s responsibility is to coordinate and fulfill all training requirements for team members.

This is particularly important within a GMP (good manufacturing practices) environment. There, every procedure is highly regulated and requires detailed, accurate training records, which the project manager maintains and oversees, following the client’s established processes.

Regulatory compliance isn’t the only goal, however. Cross-training is another key objective of a well-executed training schedule. This results in a highly capable and versatile team, allowing greater flexibility for workflow response.

Here, two training levels emerge. The first is standard training, where the pharmaceutical client teaches the team all GMP measures, safety procedures, and other general facility processes.

The second level delves deeper, and covers specific tests for which certain team members are primarily responsible. One helpful technique the project manager could employ is to create a matrix of all possible tests and each scientist’s capabilities. This immediately identifies any training gaps, while highlighting people’s skill sets.

Pharma clients can hold the hiring firm accountable for the team performance in a few ways. They can request the training matrix and use it as a checklist for completed and pending training.

They can also set a service-level agreement that guarantees all team members are certified in a particular test by an agreed-upon date. This can include ongoing training deadlines, too, to ensure all knowledge is updated and current.

Pharma clients can even request certain levels of education among team members, such as master’s degrees or a PhD, and require experience in the specific types of testing they are expected to perform. Though this increases hiring costs, it also brings higher-quality employees with deeper training backgrounds on board.

Through it all, client-to-team communication is crucial for the smooth operation of training. The pharma firm will supply all the necessary pieces—test certification, training sessions, client-specific tracking processes—while the hiring firm handles overall implementation.

In the end, spearheading the SOP education and training gives pharma firms the luxury of selecting a partner who might not be familiar with the space, but does claim an excellent hiring and placement track record. This synergy of experience and expertise ensures a more comprehensive and ultimately more reliable team.

The client and hiring firm should discuss and agree upon project-specific service levels and key performance indicators during initial negotiations. This will help gauge the team's performance throughout the engagement and also give greater control to the client firm.

One such indicator is sample turnaround time. Scientific teams want to control as many factors during testing as possible and time is no exception. Consider the stability testing example: There, sample turnaround time refers to the deadline for testing after the product emerged from the stability chamber. Anything exceeding the final date decreases the usefulness and reliability of the test.

Another performance indicator could be OOS (out of spec) issues due to analyst error. OOSs occur when the tested product falls outside the expected results. This could be due to a variety of reasons: equipment malfunction, analyst error, product flaws, etc. Setting tolerances and monitoring the team's generation of OOS due to analyst error invites the client to hold the team to quality standards.

Compliance actions are another example of performance measurement. All teams are subject to regular audits, whether internal to ensure quality assurance, or external to ensure compliance with FDA, GMP and GLP regulations.

Audit findings can fall into several categories, ranging from critical and major infractions to minor infractions, or simple observations. Those that are considered critical require immediate resolution and remediation before business can continue. Major level infractions are also serious, but allow the company to keep functioning while taking corrective actions.

In comparison, minor and observed infractions don't carry such serious repercussions. Instead, they highlight areas where the company should improve and refine its compliance practices now, and avoid more serious audit results later.

With this in mind, compliance actions can be used as performance indicators. For example, pharma firms should expect zero critical compliance actions from their scientific teams, so they don't incur any disabling sanctions.

In fact, hiring firms responsible for forming scientific teams should keep all compliance actions at a minimum. This can be difficult, since the audit process is highly subjective and human. But proactive, vigilant management helps avoid unreasonable or unfair audits.

If citations do occur, the team is responsible for taking appropriate corrective action 100 percent of the time and fixing noted problems. It is also responsible for taking preventative actions, such as cross training on key tests to ensure the team can meet deadlines, to protect themselves against possible trends that could invite compliance actions later.

Setting service-level agreements about staff turnover is another possible key performance indicator. This helps client firms avoid the time and expense of rehiring and retraining more employees—a significant advantage over hiring just contractors or consultants.

Capacity levels are useful measurements, too, and will vary depending on the number of team members involved in the project. For example, in an eight-person project, the project manager and client will define levels of work volume across the team. They will then evaluate if they need to add a team member or make some allowances in work levels, so that the team can best meet productivity goals.

Measuring Performance (cont.)

The frequency of benchmark evaluation depends on the project needs, though regular monthly meetings are recommended. These meetings—which cover progress, quality, compliance, and safety—maintain a tight feedback loop and address problems before they spiral out of control.

And while all service levels are set during the pre-contract negotiation period, the agreement can be refined over time. This is especially relevant in a setting where the scientific team is on a technical learning curve, and might need real-time solutions for training needs.

Setting Goals For The Team

Individual goals are an important subset of overall performance measurement. They establish accountability for each team member and assign specific responsibilities.

Productivity is one goal. This can intersect several layers. Take the stability testing example: There, team members should adhere as closely as possible to the testing schedule and also operate within a broad, overarching project deadline. This allows some flexibility, while holding people to the ultimate drop-dead date.

An offshoot of this goal is sticking to the work schedule, and knowing what days, times or shifts everyone is covering (if applicable to the project). This ensures smooth operations, keeps the project on track, and spreads any overtime or odd hours among the team.

Another individual goal is maintaining compliance with all client, GMP, and safety standards. Staying within regulatory guidelines safeguards the scientific team and the client firm from time-consuming internal quality assurance investigations, as well as potential punitive FDA actions.

Team members are also responsible for data management, though procedures and inputs vary by project. In the stability environment, for example, team members can be required to update notebooks within two days. Notebook reviewers must enter them into the laboratory information management system (LIMS) within an established timeframe.

Another goal is escalating OOSs or OOTs (out of trend) to within 30 minutes of discovery. OOT differs from OOS in that the results might be within tolerances, but are consistently forming a trend in the wrong direction. This may indicate an underlying issue.

Escalating discovery time for these trends rewards team members for admitting they might have erred. This protects the employee from punitive actions, and also allows the error to be rectified as soon as possible.

Group participation is another must for team members. This might be as high level as meeting with all scientists, technicians and client representatives; or as simple as meeting with only the project manager and team members to set priorities and schedules for the week.

Overall, regular meetings mean team members must be willing and flexible team players. This facilitates the integration of client employees and scientific team members and keeps everyone satisfied with their respective workloads.

Of course, conflict arises despite individuals' best efforts. Friction can occur between the placement team and the regular employees, or between the project manager and his client contacts.

In such events, it's primarily the hiring/placement firm's responsibility to notify the client about any personnel changes, and for what reasons. While the hiring firm usually makes the decision to change a team member through their own chain of command, they can field a specific request for change from the client, too. The pharma client does not need to involve their HR department, unless they feel the situation necessitates it. The client can generally remove a contracted employee for any reason or no reason at all, as long as it is not discriminatory in any way.

Several levels of management and review come into play with the placement of a scientific team. The first level is the project manager, who is responsible for procedural oversight and reporting to QA.

This means maintaining spreadsheets, logbooks, lab notebooks, forms, and other materials. Essential data to document include:

- The date the samples arrived.
- What tests were required on them.
- Who was assigned those tests.
- When they were due for completion.
- When the tests were actually completed.
- Any comments or issues, such as OOSs, OOTs or deviations.

This information is critical during the audit process, when compliance or QA teams will require all pertinent records for review. At this point, the project manager steps back into the team, and simply supplies the requested materials.

Another important part of management and review is a regular feedback cycle. This has three components: the client reviewing the project manager; the project manager and hiring firm reviewing the scientific team; and the client and the hiring firm reviewing overall performance.

In many cases, the hiring firm will bring in project managers as full-time benefited employees. This practice can cost more, but it makes the project leaders more loyal to their employer and more accountable to the client firm.

As such, project managers undergo the standard review process. The hiring firm gathers performance data from observance of the team's performance, feedback from the team members, and, when possible, input from the customer. Then the project manager will sit down with his superior at the hiring firm for a formal review.

The rest of the team, on the other hand, might not be contracted at the same full-time level. The hiring firm may conduct informal reviews at the six-month mark to determine current performance and discuss how to achieve upcoming goals.

The review process is likely to vary, depending on the hiring firms internal practices. More feedback is always better, however, as it creates teams with high situational and performance awareness.

The final review component is the sync-up between the pharma client and hiring firm. Again, the frequency of reviews will depend on the project's particular needs, though meeting at least once a quarter is recommended.

These meetings are helpful discussion forums that gather all key leaders in one room and focus their attention on higher-level, strategic topics. Such subjects include project successes, foreseeable challenges, plans to address these concerns, and the team's direction going forward.

Recognizing Results

Once the team is well underway and operating efficiently, the client pharma firm should expect certain results to emerge. The broadest measurement across any function is service level evaluation, to see if the scientific team met all agreed-upon levels and indicators.

Other results are more aligned with specific projects, such as the frequency with which specific projects are delivered on time, or whether or not they comply with data requests from the client firm.

A less tangible, but equally important result, is adding services to the original agreement. Finding value-add opportunities rests largely on the hiring firm's shoulders and expands the breadth and depth of functions. For example, scientific teams working with stability testing could also move into raw material testing, calibration testing, and formulation testing.

Requesting additional services and continuing the partnership are obvious indications of happy customers. Still, conscientious hiring firms will quantify this by conducting customer satisfaction surveys and eliciting feedback.

The optimal result: satisfied pharma firms who enjoy a wide range of well-executed services from competent hiring companies.

Applications of Scientific Team Placement

Scientific team placement achieves several benefits for pharma clients. The overarching application: its strength as an alternative to a total contract research organization (CRO) or contract manufacturing organization (CMO) outsourcing.

The flexible, customizable nature of placement teams makes them applicable to any department, any group and any test. Teams design their programs specifically for the client, rather than drawing on a prescriptive, 'one-size-fits-all' model.

This also makes teams useful in any environment, from pharmaceutical manufacturing to drug discovery and drug development groups. In addition, stability testing, raw material testing, validation testing, and other quality control measures can all have appropriate programs designed for them.

As a result, teams can execute clinical data projects, work for critical monitors, conduct R&D, run an assay, and essentially augment any function the client needs.

Another strength of scientific teams lies in its members' qualifications. The best hiring firms pipeline and recruit people with skills that fit the job at hand, rather than drawing from an established pool. This ensures a better overall fit in terms of skill sets and responsibilities, and lessens the learning curve.

Placing scientific teams also gives clients greater control over all processes and content. And it keeps the project scalable to the client firm's SOPs and GMPs, which gives the hiring firm the freedom to bring the right people on board, at the right time, and in the right numbers.

Team placement can achieve significant cost savings, too. This high-quality solution is often delivered at a lower cost than traditional outsourcing approaches, freeing up valuable cash for more strategic endeavors.

In the end, scientific teams hold the greatest value for clients who want all functions in-house, have the capacity to house a project team and seek a true partner. And, the key to a successful placement lies in clear dialogue and communication.

The client must share their deep business knowledge of day-to-day operations with the team. Conversely, the team should consult and advise their client on value-add opportunities, while effectively completing the task at hand.

Taken together, these two roles offer a comprehensive, efficient solution to companies' resource strain and provide the logistical freedom for greater innovation—the ultimate goal of all forward-thinking pharma firms.

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