

Global CONNECTIONS

GLOBAL OUTSOURCING, AS IT RELATES TO INTERNATIONAL SPONSOR/SUPPLIER RELATIONSHIPS, IS CONSTANTLY CHANGING AND GROWING.

Pharmaceutical companies and their partners can gain significant competitive advantages through global outsourcing when sound business practices are applied to the management and care of these relationships.



Sally Goostrey The W Group



Since every country has different labor, taxation, and regulatory requirements, **IT'S A CHALLENGE GETTING A GLOBAL AGREEMENT TO FUNCTION SMOOTHLY AND TRANSPARENTLY.**



Mark Wren Phase Forward

PV. What is the biggest challenge to managing a global relationship?

BARBARA LEVINE. The biggest challenge is ensuring the seamless and systematic execution of complex studies in multiple countries simultaneously. Working across multiple countries demands strong and proven processes for keeping teams working as a unit, on time, toward a common objective. It is essential to have strong processes and tools in place to ensure players around the world remain fully informed and able to keep the project on track.

JOHN VOGEL. The principal challenge to managing a global client-supplier relationship is accurate communication. Who needs to know what? How will everyone be kept informed?

How will decision-making be centralized at the appropriate level? Recognize that cultural differences can easily create miscommunications.

TERRY SIMMONS. As a global hospital supplier, we work with multiple cultures and communicate in different languages. Many countries have specific and differentiated business processes. For example, when discussing a price, service, or specification change, it is customary for colleagues in some areas of the world to acknowledge the request with a positive gesture, like a handshake or head nod. That does not mean, however, that they have accepted your request. You have to avoid misreading signals and be sure that everyone is communicating consistent information.

A CHALLENGE IS DEVELOPING A RELATIONSHIP WHEREBY THE VENDOR BECOMES A PART OF YOUR OPERATION — while still making sure that the company is aware that it has competition.

MARK WREN. A challenge is developing a relationship whereby the vendor becomes a part of your operation — while still making sure the company is aware that it has competition. Despite diligently defining needs and service levels, and setting expectations something will be missed, and this is when you need strong relationships and collaboration to deliver. Another area that needs close management is staff reten-

BEST PRACTICES FOR MANAGING GLOBAL SUPPLIER RELATIONSHIPS

■ SALLY GOOSTREY

Companies need to create a strong global governance team with compliance responsibility and appoint people on both the vendor and client sides. It's important to think globally and build strong relationship ties — whether it's an internal relationship or a relationship with vendors. They also need to implement global compliance practices, policies, and standards. This is a critical preparation for audit response. It is important to share audit findings between regions to ensure consistent delivery and communication with regulatory agencies. Because it's important to know if there is a problem in one region impacting delivery of services in another, companies need to ensure global tools are in place to monitor the environment in a global fashion. It is critical to establish regular communications between the regions supported.

■ BARBARA LEVINE

Be sure to work with an organization that has local offices in the countries/regions of interest. This is imperative for ensuring a complete understanding of the legal and regulatory environments that are unique to each country. Choose a vendor with a proven approach to centralized project management, including data management and quality control to ensure accuracy. Centralized project leadership is critical for achieving worldwide consistency in quality, approach, and timing. Ensure there is a program in place for training and communication across all core countries, as well as between the vendor and the sponsoring pharmaceutical company. It is important to use a combination of multiple communications, training, and networking tools to keep a worldwide team working in sync, meeting deadlines, and providing consistent, high-quality information. For example, training and communications should include face-to-face meetings with local project teams in each core country, supplemented by weekly telecon-

ferences with local project managers to support ongoing coordination and information flow among the country teams, the central project leaders, and the sponsoring company. In addition, regularly produced newsletters with detailed updates on the study's status and progress can be powerful tools for providing information, addressing shared questions, and keeping teams focused on their common goals. Be sure there is a proven Web-based system in place to monitor, track, and manage the activities of worldwide affiliates, keeping them in sync and on schedule. The system should provide quick and simple access to complete insights into pre-enrollment activities, enrollment status, study progression, site history, and other key information. It also should offer easy e-mail functionality for linking parties in all countries into a single, coordinated team. Be sensitive to language differences, and be sure global vendors can provide local language help-desk support throughout the project, as well as translations of all project documents into local languages.

■ TERRY SIMMONS

Best practices include communicating clearly regarding contract commitments, expectations, and outcomes; using data management tools, such as Procuri Spend Management, to review spend activity and contract compliance, as well as ensuring both parties understand and meet commitments; interacting on a regular basis with all stakeholders, such as users, the supplier's staff, and various support functions, for example, information technology, manufacturing operations, quality, and legal; and executing a formal review that includes input from all stakeholders to discuss the project, service, and contract.

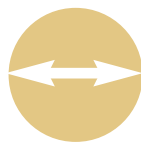
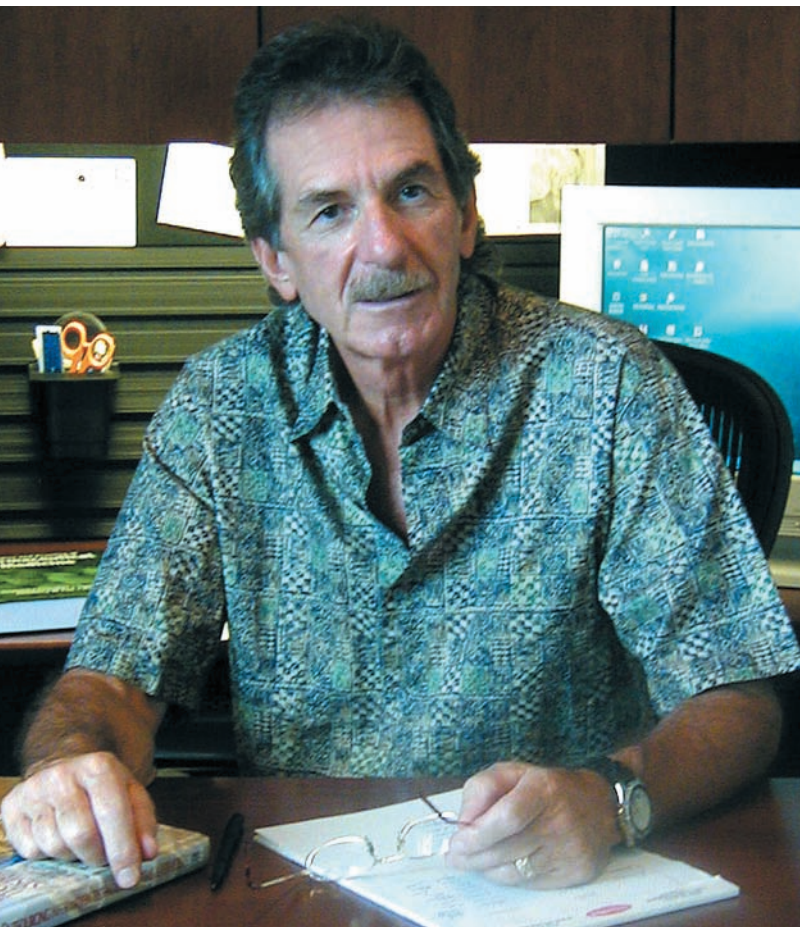
■ JOHN VOGEL

Think globally — act locally. It's important to accurately define your needs and ensure that

they are communicated to the supplier at both the central and local levels. Next, confirm that the supplier has a track record of success performing the desired service (e.g., clinical trial or contract manufacture) in the target countries. Then evaluate key supplier personnel. Does the supplier have permanent staff in the target countries? Are these personnel familiar with the local culture? Do they have the professional and regulatory contacts to ensure that the work can be carried out in timely fashion? It's also important to evaluate risk and the possibility of change. Is the project ethical with respect to local standards? Will the project meet GCP/GMP requirements? Are intellectual property laws adequate and enforced? Is the political situation stable? And have a backup plan to handle the unexpected. After all, a few years ago a company might have considered contracting a clinical trial in Lebanon. Finally, manage the sponsor-provider relationship. Create a governance plan with supplier management. Define roles and responsibilities between your team and the supplier personnel.

■ MARK WREN

At the beginning it's important to have like-for-like competitive contenders, so pick two vendors and negotiate. Ensure each vendor knows it is one of two and that you rate the competitor highly; identify major discrepancies in price, and clarify to ensure pricing comparisons are like-for-like. Try to get the supplier to agree to end results rather than trying to define your exact needs or the process to be followed. Develop a symbiotic beneficial business outcome. Consider running a pilot rather than a full-blown rollout, which makes it possible to modify process and technology with minimum impact. That said, negotiated pricing should be based on the full-blown volume. Keep your ear to the ground and listen and talk openly with other pharmaceutical colleagues to learn which service companies best understand the issues and are able to meet your needs. Set the bar high and tie service levels to penalties, and make sure that service levels are achievable and measurable.



Dr. John Vogel

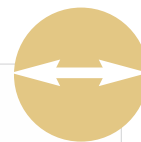
John R. Vogel Associates

THE PRINCIPAL CHALLENGE TO MANAGING A GLOBAL CLIENT-SUPPLIER RELATIONSHIP IS ACCURATE COMMUNICATION.

Who needs to know what? How will everyone be kept informed? How will decision-making be centralized at the appropriate level?

tion. Not only do you have the issue of staff turnover from people leaving your supplier, you also have the problem of keeping the best staff members on the project when they want to move onto more exiting or high-profile initiatives.

SALLY GOOSTREY. Many vendors struggle with providing global service when dealing with separate laws in various countries. Since every country has different labor, taxation, and regulatory requirements, it's a challenge getting a global agreement to function smoothly and transparently.



Barbara Levine

TNS Healthcare

As with any vendor/client relationship, IT IS CRUCIAL TO DOCUMENT, UP FRONT AND IN CLEAR TERMS, all agreed upon processes and procedures, as well as all deadlines and deliverables.

such as enhanced access to greater numbers of patients (e.g., clinical trials in Eastern Europe), access to cheaper labor rates (e.g., data managers in India), and access to emerging markets (e.g., China).

PV. What is the biggest advantage to being in a global relationship?

TERRY SIMMONS. Because improving safety and reducing costs are at the very heart of almost everything we do at Hospira, we view our relationships with global suppliers as a tremendous business advantage. In fact, these relationships help us achieve a number of benefits, including application of global standards in areas such as information technology, document services, real estate management, and telecommunications; access to local networks with expert knowledge of the geographic markets in which we do business; creation of a single source for data management that is compatible with our global vendors; and consistency of contracts, payment terms, and services. For example, by using one global temporary service, we gain a standard process on screening, hiring, orientation, and payroll. With a supplier supporting and implementing our global system, we are able to free up management time.

SALLY GOOSTREY. Vendors are responsible for making the relationships work across country lines. They are responsible for the delivery of services and working through problems between their internal organizations.

BARBARA LEVINE. The biggest advantage to using global vendors is that they can combine strong central management with the ability to tap into a global network of local, on-the-ground units to deliver a seamlessly executed project. Local resources also facilitate faster response rates and more cost-effective results.

JOHN VOGEL. There are a number of advantages,

MARK WREN. Global processes developed in the past have been challenged, simplified, and the new customer support teams retrained. The overriding need to comply with regulatory guidelines still necessitates global processes; however, managers can take advantage of local knowledge and culture. To improve customer satisfaction, local issues can now be resolved by staff members who understand the local infrastructure, its potential limitations, and the most appropriate way to resolve the issue. To further improve responsiveness and customer service, the technology used by the original customer support team has been modified to ensure it truly is scalable and able to be used from anywhere in the world. Outdated workflow has been removed to aid flexibility, while still ensuring that the key information related to the issue can be captured and suitably recorded for reporting purposes. Global managers quickly learn that they need to be excellent relationship managers. They have to ensure that their local operations deliver the services required to the exacting service level. This responsibility spans multiple continents and time zones and involves personnel who are employed by the local supplier reporting to the manager via matrix management.

PV. What technologies and/or tools are best suited for managing work flow processes?

SALLY GOOSTREY. A global change management tool is very important for a global infrastructure or application environment. In addition, tools for global management of equipment and asset tracking can be very helpful. It's also important to have a centralized help desk and triage group for problem resolution.



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JOHN VOGEL. Secure Websites have proved valuable for exchanging information, providing up-to-date status reports, and conducting lessons-learned exercises.

BARBARA LEVINE. Internet/Web-based applications are essential for acquiring and managing data, ensuring consistent data collection from multiple locations, sharing information, and providing real-time access to study information and status to both the vendor teams and the customer. For example, we use a Web-based application, InDrums, to link headquarters, affiliates, and clients throughout a project, providing an easy flow of ongoing, updated information that keeps the project on track and on schedule.

PV. What lessons have you learned — bad and good — from being part of a global supplier team?

SALLY GOOSTREY. Every country is different, and it's crucial to emphasize seamless delivery from the vendor.

BARBARA LEVINE. The key lesson is that there are some "essentials" to managing global projects successfully. First, it's critical to have local project management in participating countries to ensure local support and a full understanding of each country's unique legal, cultural, and regulatory environments. Second, it's critical to have a centralized process for data collection to ensure worldwide quality and consistency. Third, it's vital to provide strong training and ongoing communications to local country teams through regular online and phone communications. Finally, it's absolutely necessary to offer local language help-desk support throughout the project.

MARK WREN. Companies have to be very open about their exact needs and priorities. If they do not share the full information up front the relationship will later be compromised. If the vendor does not deliver, the project fails. A company or a project is only as good as its weakest supplier.

JOHN VOGEL. Personal relationships are very important in emerging countries. A small supplier that has good relationships with local hospitals and clinics can be very effective in initiating a clinical trial and enrolling patients. Bigger is not better in many parts of the world. Global suppliers often rely on small local vendors to actually do the work. But you need to know who is representing your company and determine whether the local vendor will be adequately integrated into the communication and decision-making network.

TERRY SIMMONS. At Hospira, we have invested the appropriate resources to ensure our team has

the global experience to successfully execute business on a global level. Having a staff that is experienced with international laws, cultures, and ethical practices is invaluable.

PV. Even in long-term relationships some conflicts will arise. How do you plan for potential conflicts during negotiations?

TERRY SIMMONS. When working globally, conflict is inevitable. We believe our cross-cultural relationships and insights have prepared us well. When negotiating contracts, we do our homework and bring along accurate information and data as backup. When handled correctly, a contract conflict can result in a stronger relationship.

SALLY GOOSTREY. First, establish a clear resolution line of command. Clarifying the governance of the agreement and the relationship cannot be over-emphasized. While managing global operations, it's important to recognize the communication challenges across time zones. Everyone needs to make concessions to ensure smooth communications. For example, someone in the United States may have to be on a call at 9:00 p.m. to accommodate the Asia Pacific region. A robust RCA (Root Cause Analysis) program is important to ensure ongoing improvements to the environment.

JOHN VOGEL. Plan for conflict; it's important to negotiate a governance plan that addresses change and conflict and to understand each party's management structure. Also, carefully define the escalation process and timeline. Additionally, try to resolve issues at the lowest possible level but have a clear pathway to escalate when necessary. A negotiating consultant colleague of mine, Ira Asherman, points out that it is important to differentiate between what you want and what you actually need in order to say yes, and that you need to take into account the other party's wants and needs.

BARBARA LEVINE. As with any vendor/client relationship, it is crucial to document, up front and in clear terms, all agreed upon processes and procedures, as well as all deadlines and deliverables. A complete, shared understanding of how the project will be executed, what will be delivered, and when are keys to minimizing the potential for conflict. Common expectations and goals are important for ensuring projects run smoothly, are delivered on time, and achieve successful results. ♦

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

Experts on this topic

SALLY GOOSTREY. Principal, The W Group, Malvern, Pa.; The W Group is a technology management consulting firm that assists chief information officers in solving the complex challenges of managing the business of IT. For more information, visit thinkwgroup.com.

BARBARA D. LEVINE. VP and Practice Leader, TNS Healthcare, New York; TNS Healthcare, which is part of TNS, provides globally consistent solutions and custom advisory services to support product introductions, brand, treatment, and sales-performance optimization, as well as professional and DTC promotional tracking. For more information, visit tns-global.com.

TERRY SIMMONS. VP, Administration, Purchasing and Real Estate, Hospira, Lake Forest, Ill.; Hospira develops, manufactures, and markets medication delivery systems,

specialty injectable pharmaceuticals, and critical-care devices, as well as custom manufacturing services. For more information, visit hospira.com.

JOHN R. VOGEL, PH.D. Drug Development Consultant, John R. Vogel Associates Inc., Wailea, Hawaii; Vogel Associates is a drug development consultancy that works with pharmaceutical companies and pharmaceutical service providers to enhance results achieved through outsourcing. For more information, visit jrvogel.com.

MARK WREN. Director of E-Service and Support, Phase Forward Inc., Waltham, Mass.; Phase Forward is a provider of integrated data collection and data management solutions for clinical trials and drug safety. For more information, visit phaseforward.com.