Contract Services

Using Virtual Private Networks to Gain Competitive Advantage

Mark Tuomenoska

By offering virtual private networks (VPNs), contract services providers can help their customers gain a competitive advantage in the race to innovate and patent a product and reach the market. In this article, the author describes the benefits of VPNs, how they work, and the alternatives that contractors should consider when evaluating VPN solutions.

In the pharmaceutical industry, time to market is everything. Companies race to innovate, receive a patent, reach the market, and finally, garner a profit—all before product exclusivity has expired. This fast-paced drive to success means that pharmaceutical companies must use every advantage to get ahead. However, few companies have the resources required to evaluate and implement all the available opportunities, and few companies possess the networking-savvy personnel required to maintain communication technologies. Because communication technologies are so intricate, outsourcing the maintenance of these technologies is a favorable alternative. This article discusses how contract services providers can better serve their customers by offering virtual private networks (VPNs) and how pharmaceutical companies can use VPNs to gain an advantage in such a highly competitive and regulated industry. The author explains how VPNs work, how pharmaceutical companies can benefit from using this technology (e.g., in regulatory compliance), and the alternatives contract services providers should consider when evaluating VPN solutions.

Benefits of VPNs
VPNs offer individual users and computer systems secure communication when

Mark Tuomenoska is chairman and founder of OpenReach, Inc., 660 Main St., Woburn, MA 01801, tel. 781.933.7580, mark@openreach.com.

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using the Internet. Special-purpose VPN software is used to guarantee the authenticity and privacy of data as well as the identity of the people communicating—a function that allows companies to take advantage of the low-cost and ubiquitous nature of the Internet while ensuring the security of the information.

Companies that use VPNs can experience the following benefits:

**Increased speed and flexibility.** VPNs operate independently of the underlying telecommunications infrastructure. As a result, they can be deployed quickly using any Internet connection. A collaborative investigation between two companies can be established in minutes and maintained for months. New acquisitions can be brought on-line by using the VPN as either a temporary or permanent solution.

**Improved security.** VPNs guarantee the identity of individuals and systems, ensure the privacy and integrity of transmitted information, and limit the access of each participant to the resources that are authorized for use. Rather than build security into each application and service individually, VPNs build security into the communications infrastructure only once for all applications. External and internal communications also benefit from this security implementation.

**Regulatory compliance.** By offering a VPN solution with a built-in public-key infrastructure (PKI), contract services providers can ensure that their clients’ companies comply with 21 CFR Part 11 requirements for electronic records and signatures. Because PKI identifies and authenticates network users and encrypts and decrypts data (using digital keys, certificates, and signatures), it ensures that the communications meet full regulatory compliance.

**Greater resiliency.** VPNs provide a layer of insulation between networked services and applications and the physical transport network. This insulation allows companies to change one part of the system without affecting the other. This function has become particularly important considering the recent bankruptcies of carriers (i.e., network providers), which prove that the viability of large service providers can no longer be guaranteed. Unlike legacy data networks that are provided by a single carrier and are, therefore, subject to the fortunes of that carrier, a VPN allows network managers to diversify their telecom portfolio and to quickly implement changes if they are required.

**Improved performance.** The development and deployment of new pharmaceutical research and modeling applications continue to drive demand for network capability and performance. VPNs can take advantage of the overcapitalization and build-out of the Internet protocol (IP) industry to provide performance that exceeds that of conventional networks. A VPN allows a company to harness the power of these public networks for private-enterprise communications.

**Reduced costs.** VPNs help reduce costs because they use the Internet rather than private data networks. By using a VPN, companies can save 30–50% on domestic communications and 40–90% on international communications and gain better performance and increased reliability than with legacy networks.

**How VPNs work**

A VPN consists of four basic elements: VPN gateways, VPN remote-access software (RAS), VPN management and authentication systems, and IP transport services (see Figure 1).

**VPN gateways.** A VPN gateway is a computer that initiates and terminates secure connections called tunnels. Tunnels can be established between two gateways, in which case the gateways secure traffic for an entire network, or between gateways and individuals who are using VPN RAS. VPN gateways are used as a stand-alone or a combination configuration, and both support router and firewall functions. The stand-alone gateway is ideal for a large research center that already has an IP infrastructure (i.e., router and firewall). A combination VPN gateway is ideal for small offices with a minimal IP infrastructure.

**VPN RAS.** VPN RAS is used by individual PCs and personal digital assistants (such as a Palm Pilot) to establish secure connections to VPN gateways and is ideally suited for mobile users and individual extranet partners. VPN RAS is avail-
Table I: A side-by-side comparison of VPN alternatives.

<table>
<thead>
<tr>
<th>Capabilities</th>
<th>RYO</th>
<th>Carrier</th>
<th>MSP</th>
<th>Overlay</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time to deploy</td>
<td>Long</td>
<td>Medium</td>
<td>Fast</td>
<td>Fast</td>
</tr>
<tr>
<td>Costs:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Capital Expense</td>
<td>High</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td>Labor Expense</td>
<td>High</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td>Network independence</td>
<td>High</td>
<td>Low</td>
<td>Medium</td>
<td>High</td>
</tr>
<tr>
<td>Availability of technology</td>
<td>Broad</td>
<td>Limited</td>
<td>Moderate</td>
<td>Broad</td>
</tr>
<tr>
<td>Geographical coverage</td>
<td>Broad</td>
<td>Limited</td>
<td>Moderate</td>
<td>Broad</td>
</tr>
<tr>
<td>Direct control of topology and policy</td>
<td>High</td>
<td>Low</td>
<td>Low</td>
<td>High</td>
</tr>
<tr>
<td>Security</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>High</td>
</tr>
</tbody>
</table>

Many companies that require heightened security use digital certificates for VPN authentication. Digital certificates provide very high levels of security but can be completely transparent to the end user. The only caveat is, although they allow easy access to the end user, digital certificates often require more support from the IT department, which is another reason to outsource VPNs.

Authentication and authorization. Contract services providers must ensure the availability, health, and performance of the network. The task of monitoring and alerting becomes increasingly difficult in a broadly distributed and diverse environment in which problems can arise—from users entering the wrong password, to gateways being improperly configured, to physical connections slowing or failing altogether. Most VPN gateways include simple monitoring and alerting functionality that notifies IT staff if a problem arises. In addition, VPN systems can be easily integrated into common network management systems such as HP OpenView (Hewlett-Packard Company, Palo Alto, CA).

IP transport services. Another benefit of VPNs is the ability to use an IP connection virtually (from dial-up to wireless to DSL to cable to T1 to fiber optic) to establish a secure connection.

VPN alternatives
When offering VPNs to their customers, contract services providers should consider various options to determine what is best for their customers while still keeping in mind the breadth of their own capabilities. Four types of VPN solutions are roll-your-own (ROYO), traditional carrier services, independent managed service providers (MSPs), and VPN overlay services. In each instance, the VPN elements remain the same; however, trade-offs may
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**Contract services providers can better serve their customers by providing a VPN option that increases flexibility, speed, resiliency, security, performance, and regulatory compliance.**

be necessary with time-to-deploy, physical outreach, security implementations, budget, and required IT resources.

**RYO VPN.** Numerous vendors sell all the elements that are required to build a VPN. The benefit of the RYO approach is that the contract services provider is in complete control of the network, from its design and implementation to the daily management. The RYO solution also requires a contract for Internet connections, which serve as the transport for the VPN. Although this approach provides the greatest control, it requires significant capital and labor costs to implement the network and maintain it.

**Carrier services.** Nearly every major telecom carrier offers VPN services. These services come complete with the VPN systems and Internet connections, which provides one-stop shopping and simplifies operations. With carrier services, the carrier is responsible for the network’s design, implementation, and management. These services can reduce capital and labor costs but at the expense of company control. VPN connections are limited to locations within the carrier’s service area, which may not encompass international locations or may prevent connections to strategic partners who subscribe to the services of another carrier. Contract services providers should consider these factors when providing this option to customers.

**MSPs.** MSPs provide the ease of implementation associated with carrier services but with more flexibility. An MSP includes all the labor-intensive tasks of setting up and operating the VPN, but does so independently of the physical transport. Most MSPs maintain contracts with several carriers and can select the most appropriate carrier on the basis of coverage, availability, and cost. In some cases, the MSP may even incorporate the capital charges into the contract as a component of the service offering, thereby eliminating labor and capital costs.

The downside of the MSP approach is that companies lose control of their network policies, which is a similar drawback of carrier services. When IT managers must make changes, they must call the MSP, and the MSP makes the changes for the customer. The MSP itself is a contractor—a very specialized one. Therefore, it is possible to partner with an MSP so that the customer has only one contractor to work with; however, the extra time required for communication between the third party and the client often makes this an unwieldy option. Instead, companies are better served by contracting directly with the MSP and using their regular contract services provider for all other outsourcing needs.

**Overlay services providers.** VPN overlay services providers operate similarly to a VPN MSP. Both provide implementation and management services for the customer, but VPN overlay services providers accomplish these tasks by using sophisticated technology and automation tools, which can result in low overall costs. In addition, overlay services providers give companies direct control of network topology and policies instead of causing them to depend on the MSP to make changes. The drawback of overlay services is that the company still must procure and manage transport services from a telecom carrier. Unlike the MSP option, a partnership between overlay services providers and contract services providers is much more feasible and probably the best option of the four solutions. In this case, contract services providers have the advantage of more control, a wider reach than carrier services, and less technological maintenance than an RYO VPN. Overlay services providers essentially provide the most service for the least work. Table I provides a comparison of the four solutions.

Summary

VPNs give pharmaceutical companies a competitive advantage by allowing research laboratories and strategic partners to be connected quickly and securely, by supporting real-time collaboration that shortens the drug discovery timeline, and by reducing operating expenses, which maximizes profits and contains the cost of healthcare. Contract services providers can better serve their customers by providing a VPN option that increases flexibility, speed, resiliency, security, performance, and regulatory compliance, which can result in a cost savings of 90%.

VPNs provide a complete networking infrastructure that includes many components such as servers, software, authentication systems, and management controls. Companies that desire the highest level of control can build their own VPN by purchasing the components and designing, implementing, and managing the network themselves, or contract services providers can work with other service providers for reduced capital and labor costs.

The RYO VPN approach provides a company with ultimate control yet requires significant labor and capital costs to implement and maintain the VPN. Carrier services include a VPN system with telecommunications connections but may pose limits on the locations that can be part of the VPN. MSPs allow a company to select from multiple carriers to ensure appropriate coverage but leave the IT staff without direct control of the users and policies. Finally, VPN overlay services providers offer contract services providers the control of an RYO solution without the labor requirements. Overlay services providers use technology and automation tools that simplify complex management tasks; however, companies must still contract their own telecommunications services.
The outsourcing industry and Wall Street were taken by surprise when Quintiles (Research Triangle Park, NC) founder and chairman Dennis Gillings made an offer to privatize the company. Upon further reflection, investors may well decide to take him up on it.

The company announced in October that Gillings had formed a new entity, Pharma Services Company, that had made an offer to buy the outstanding shares of Quintiles for $11.25 per share. The stock had traded below $9.00 per share the day before the offer. The Quintiles board of directors appointed a special committee of independent directors to assess the offer. The committee then hired investment bank Morgan Stanley to advise it.

The management buyout would be financed through a combination of debt and equity. Pharma Services Company arranged an equity commitment of $298 million from One Equity Partners LLC, the private equity arm of Bank One Corporation, and debt commitments totaling $620 million from Citicorp North America, Inc., and Salomon Smith Barney, Inc. Gillings owns or has options for 7.3 million shares of Quintiles stock, or about 6% of shares outstanding, and management controls about 8% overall.

The drop-off in stock price reflects both general concerns about the outsourcing industry’s prospects considering the current retrenchment among pharmaceutical companies and the particular problems faced by Quintiles itself. The company has seen its revenues erode steadily since they peaked in late 1999. Corporate revenues have been dragged down by problems in the contract sales business even as contract research revenues have improved. Quintiles’s profits have been volatile, despite several efforts to cut costs. Management has been working to overcome problems in staff turnover and service quality but has not tried to narrow the focus of service offerings as competitors such as Covance have.

In an effort to get better returns from its service businesses and pharmaceutical expertise, Quintiles initiated a new strategy in 2001 that takes an at-risk position in client companies. The company provides equity and debt financing for select companies through its PharmaBio Development investment unit and fronts sales force start-up costs for certain contract sales clients. In return, Quintiles earns fees for services and royalties from product sales with future royalties estimated from $500 million to $1 billion.

Many analysts believe that PharmaBio has added a substantial level of uncertainty to Quintiles’s future prospects, making it difficult to project future performance and therefore stock value. Given this uncertainty and recent performance problems, some outsourcing industry analysts seem inclined to support the buy-out offer.

### Table I: CRO third-quarter revenues and growth rates.

<table>
<thead>
<tr>
<th>Service Provider</th>
<th>Revenues (US dollars in millions)</th>
<th>Change (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>AAI International</td>
<td>19.6</td>
<td>−17</td>
</tr>
<tr>
<td>Albany Molecular</td>
<td>19.0</td>
<td>24</td>
</tr>
<tr>
<td>BioReliance</td>
<td>21.6</td>
<td>16</td>
</tr>
<tr>
<td>Cardinal Health PTS</td>
<td>354.0</td>
<td>18</td>
</tr>
<tr>
<td>Charles River Laboratories</td>
<td>84.6</td>
<td>16</td>
</tr>
<tr>
<td>Covance</td>
<td>221.0</td>
<td>13</td>
</tr>
<tr>
<td>Icon Clinical Research</td>
<td>46.9</td>
<td>29</td>
</tr>
<tr>
<td>Inveresk</td>
<td>55.9</td>
<td>19</td>
</tr>
<tr>
<td>Kendle International</td>
<td>41.0</td>
<td>4</td>
</tr>
<tr>
<td>LSR</td>
<td>30.0</td>
<td>16</td>
</tr>
<tr>
<td>Omnicare CRO</td>
<td>34.0</td>
<td>8</td>
</tr>
<tr>
<td>Parexel</td>
<td>119.4</td>
<td>17</td>
</tr>
<tr>
<td>Patheon</td>
<td>108.7</td>
<td>26</td>
</tr>
<tr>
<td>PPD</td>
<td>146.0</td>
<td>35</td>
</tr>
<tr>
<td>Quintiles</td>
<td>458.8</td>
<td>−1</td>
</tr>
</tbody>
</table>
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CROs and CMOs continue to experience double-digit revenue increases with preclinical research activity leading the way.

Patheon purchases a US site

Patheon (Toronto, Canada) fulfilled a major strategic objective with its recently announced purchase of the Aventis Pharmaceuticals manufacturing and development site in Cincinnati, Ohio. The transaction is expected to close on 31 December 2002, assuming no problems arise during due diligence.

The acquisition provides a US base of operations for Patheon’s Pharmaceutical Development Services (PDS) business. In recent months, Patheon executives have emphasized the need for a US site for PDS because they cannot recruit enough scientists to the Toronto area to achieve their business growth objectives. PDS grew 70% in the 2002 fiscal year and garnered revenues of $25 million (US) in the first three quarters of the year.

The deal is also important because the Cincinnati facility has larger-scale manufacturing capabilities than Patheon’s Canadian sites, which will enable the company to bid competitively on large-volume products. The transaction will add 11 new commercial manufacturing relationships to Patheon’s portfolio because Aventis had already established 10 contract manufacturing relationships at the facility. Although none of the contract relationships has been identified by company, one of them is reported to account for 13% of projected revenues. These contract relationships reflect Aventis’s efforts to maintain the viability of the site in recent years. However, even with the 10 contracts, the site’s use rate was just 50%, and capital investment was sufficient only to maintain the plant’s operations and regulatory compliance.

The deal has the hallmarks of a typical Patheon facility acquisition, especially the very favorable price for assets ($35 per square foot, including the equipment but excluding the 120,000-ft² warehouse) and the five-year supply agreement with the seller for the products manufactured at the site. Patheon will invest $23 million in the site in the next three years, including $13 million for the expansion of the PDS facility and a new information system and $10 million for sustaining investments. Favorable financing from state and local government agencies will help reduce the ultimate cost.
Outsourcing revenues strong

Contract research and manufacturing organizations continued their strong performance during the third quarter of 2002, with double-digit revenue increases still the rule (see Table I). As has been the case for nearly two years, preclinical research activity is leading the way, driven by a big early-stage pipeline and changes in sponsor outsourcing practices.

Contractor results also are being helped by continued acquisition activity. Recent examples include the acquisition of clinical CRO Barton & Polansky by Icon Research, preclinical CRO Springborn Laboratories by Charles River Laboratories, and central lab Virtual Central Laboratory CL by Covance. Although the acquired companies are small in relation to their acquirers, their performance has had an immediate positive effect on the acquiring companies, which can be seen when comparing the acquirers’ quarterly results with those of the previous year.

In the clinical research arena, the numbers suggest that some major market-share shifts are in the works. Several companies such as Quintiles, Kendle, AAI, and Omnicare had single-digit or no growth, and PPD and Icon had growth rates that were double the mid-teens average for all contractors.

FYI

Masters degree program

The Instrumentation, Systems, and Automation Society (ISA) has established a masters degree program with a consortium of universities, including Indiana State University and Oklahoma State University.

ISA’s masters degree program is designed to allow students and professionals to obtain a masters degree in instrumentation, systems, and automation through distance learning options such as Internet, videotape, and correspondence.

For more information, contact the ISA, PO Box 12277, Research Triangle Park, NC 27709, tel. 919.549.8411, fax 919.549.8288, info@isa.org, www.isa.org.