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Chapter 25

Outsourcing in the Pharmaceutical Industry

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OUTSOURCING IN THE PHARMACEUTICAL INDUSTRY

Most, if not all, major pharmaceutical companies have outsourced, or are evaluating the benefits of outsourcing, one or more of their noncore business functions to a third-party service provider. Over the last five years, pharmaceutical companies have primarily been outsourcing all or part of their back-office information technology (IT) infrastructure, such as the mainframe, mid-range, desktop, or application maintenance functions. Recently, however, pharmaceutical companies have become more and more innovative in the types of business functions that they consider ripe for outsourcing. Functions that are being considered include human resources (operations or payroll), financial transaction processing (particularly accounts payable), procurement, distribution and logistics, and clinical data management.

Why Outsource?

As with most other companies, the leading factors motivating pharmaceutical companies to outsource include:

- Overall cost savings
- Flexible/variable pricing (not fixed/dedicated resources)
- Access to a broad pool of competent, trained personnel
- Continued and early access to state-of-the-art technologies and processes
- Rapid standardization or globalization

Outsourcing Options and the “Offshoring” Issue

There are several different types of outsourcing options to be evaluated. Currently, the most common options are “onshoring” (where the provider of services is in the same country as the recipient of services), “offshoring” (where the provider of services is in a low-cost country far from the country where the recipient of services is located, such as, for U.S. companies, India, the Philippines, China, or some of the Eastern Bloc countries), “nearshoring” (where the provider of services is from a lower-cost country close to the recipient country’s borders, such as, for U.S. companies, Canada, Mexico, or the Caribbean), and finally, and likely most common, a hybrid of all or some of these types.

Offshoring is the most controversial of the various types of outsourcing, largely due to the perception that offshoring means the loss of U.S. jobs. Despite the negative press surrounding offshoring, leading analysts continue to state that most, if not all, major companies have implemented it or have considered it as a strategic sourcing option. With heightened focus on offshore outsourcing by internal management at all levels, it is important to understand the key due diligence and legal considerations unique to an offshore outsourcing transaction, as well as the current state of anti-offshoring legislation.

Due Diligence

One of the concerns that companies have about outsourcing is the implicit loss of control over a business function's day-to-day operations. This concern is heightened in an offshore transaction because the personnel responsible for the daily operations are not only not down the hall, they are not even in the same country. Because of the perception that the loss of control is greater when offshoring, the due diligence process surrounding offshoring is often more comprehensive (and more lengthy) than that for an onshore transaction.

Key questions that should be considered as part of the due diligence for an offshore outsourcing company or a U.S.-based company with offshore operations include:

- What is the financial viability of the offshore enterprise? What is the relationship with the onshore enterprise, if any? How will disputes be handled? How will notices be served? Will there be an onshore presence for service of process purposes?
- What are the business continuity options offered by the outsourcing service provider? Is there a secondary site? Can documents be moved between sites or back onshore?
- What experience does the offshore service provider have in the U.S. market? Who are its U.S. references?
- Does the offshore service provider have procurement and financial responsibility for obtaining certain software and hardware required for service delivery? Are there any specific requirements necessary to enable compatibility between the customer's and the service provider's systems? Does the service provider have expertise in all of the customer's technologies and processes?
- What type of data, network, and physical security infrastructure does the service provider have in place?
- Does the offshore service provider have the ability to recruit a broad employee base to allow for growth?
- Will there be a good cultural fit? Are there any language or cultural barriers? Does the service provider have the necessary language capabilities?

- Can the service provider provide onsite resources if requested? What are the relevant visa/immigration issues? Which company is responsible for the cost of travel when meetings or knowledge transfer is necessary?
- What lines of communication will the service provider put in place?

Unique Legal Issues

In addition to the myriad legal issues that arise in connection with outsourcing, there are several issues that are specific to or have increased significance in an offshore deal. Examples include:

- Data privacy
- Import/export laws
- Immigration issues
- Proprietary rights
- Local law concerns
- Enforcement issues
- Ability to relocate/terminate

Regulatory Compliance—A Key Differentiating Factor

The regulatory regime of the pharmaceutical industry mandates that both the customer and the service provider understand the specific compliance requirements applicable to the specific outsourcing transaction at hand. A key part of negotiations will involve determining which laws the customer and the service provider will be responsible for monitoring and complying with and how the costs will be allocated for changes required by new laws (including different interpretations of existing laws). Some questions to consider include:

- Which company will be responsible for interpreting regulations specifically promulgated for implementation by the pharmaceutical industry?
- If the customer retains responsibility for interpreting such pharma-specific laws, how will the service provider implement them? Will the customer provide guidelines or protocols?
- Will the service provider have validation responsibilities? Will the service provider have to validate its own software and hardware? Will it have to validate the customer's software and hardware or maintain already validated software and hardware? Will the service provider follow the customer's validation procedures? Who will determine when software or hardware has actually been "validated"?

- How will Sarbanes-Oxley compliance be handled? What are the service provider's responsibilities? The customer's auditors will want reassurance that the service provider will provide SAS 70 reports if and when required.
- For business processes, is the customer or service provider best suited for monitoring and complying with laws specific to the service? For example, in HR deals, will the customer retain the legal compliance function or will the relevant employees be terminated or transferred to the service provider?

Other Major Legal Issues

In addition to the industry-specific and offshore-specific issues discussed previously, there are many other issues for legal, business, and technical teams to consider in connection with an outsourcing transaction. Some of these key legal issues are set forth below:

- Scope of services
- Terms applicable to the transfer of employees and assets
- Structure of and approval rights over project staff
- Responsibility for third-party consents (e.g., software access/use rights)
- Performance standards and benchmarking
- Regulatory compliance issues
- Approval rights over service locations (and right to force relocation)
- Ownership and use rights to existing and newly developed IP
- Audit rights
- Rights to terminate; exit rights and termination assistance
- Applicable fee structure, including adjustment mechanism, inflation risk, tax responsibility, and invoicing

Conclusion

The complex nature of outsourcing transactions requires that the customer's negotiating team be knowledgeable not only about its business and current and future service environments, but also terms applicable to such issues as asset transfer, employee transfer, data privacy, audit, insurance, regulatory compliance, tax, business continuity, and risk management. In order to achieve a good business and legal deal and construct a contract that has the flexibility to survive for the duration of the deal (which can be for as long as 10 years or longer), the team must fully understand the many

issues that can arise in an outsourcing transaction and be able to formulate reasonable positions and alternative approaches.