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Tales From the Front: Trends and Best Practices in Outsource Contracting

Free Industry Expert Update

Thursday, June 22, 2006 – 12:00– 1:00 p.m. EST
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The background of the slide features a low-angle, perspective view of several modern skyscrapers with glass facades, reaching towards a bright, clear sky. The buildings are rendered in a light, semi-transparent style, creating a sense of depth and architectural grandeur.

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Trends and Best Practices in Outsource Contracting

June 22, 2006

Presented by Paul Dennis Connuck

Kramer Levin Naftalis & Frankel LLP

Goals of Today's Session

- Share my opinion related to tips and tools that may assist in optimizing your current outsource efforts
- Highlight potential “traps” to avoid as you work to create high performing partnerships
- Answer any questions you might have, so please submit them at any point during the presentation via the ? Tool bar on your screen

And being a lawyer, I would be remiss if I did not include a disclaimer....

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Growth in Outsourcing continues in Biotech & Pharma

- Over time, outsource rates in drug industry may begin to approach those seen in the financial services industry, which has outsource rates approaching 30-50%

“[T]he drug business is similar to software and financial services. It derives value from technology and information by combining ideas and data in new ways.” (2004 CFO / A.T. Kearney report)

- Current growth in outsourcing approximating 20% per annum
- Recent Outsourcing Survey showed >50% respondents expected their outsource spending to grow more than 6% in the next year (*Contract Pharma Magazine, May 2006*)

Potential Drivers within Industry to Outsource

- Need to focus on core competencies
- Lack of capacity and/or capability
- Lifecycle management needs
- Strategic Preference
- Cost Savings

Hypothesis For Success

Outsourcing involves the creation of a relationship in which the sponsor retains all operational, commercial and regulatory responsibility with respect to the products and services provided by the supplier.

Tips for Assessing and Managing Risk

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Tip 1: Assess the optimal project stage at which to outsource

Initial strategic financial analysis:

- ▣ Evaluate projected costs and capital expenditures
- ▣ Timing and cost tradeoffs between outsourcing at different Phases
- ▣ Price sensitivity and volume discounts that might be available via multiple products with the same partner
- ▣ Include Tax implications/incentives
- ▣ Determination of optimal stage to outsource

Tip 2: Objectively assess and manage internal company concerns early in your process

Common Internal Company Objections/Roadblocks:

- ❑ Internal employee resistance to outsourcing
- ❑ R&D team concerns over potential loss of continuity and/or loss of synergies if you outsource portions of discovery or development tasks
- ❑ Fears that other products are impacted as overhead costs are now covered by fewer in-house products or services
- ❑ Fear over loss of control
- ❑ Lengthy contracting cycles

Tip 3: Always Perform Due Diligence on Contractor Feasibility and Fit

Factors that should be considered in a preliminary, due diligence feasibility analysis include:

- Contractor's expertise, reputation, and record of regulatory compliance
- Contractor's facilities, production capacity
- Proposal principal dimensions: quality, speed, cost, relationship
- Contractor's IP portfolio and position
- For any new offshore partners: legal / cultural / economic / communication / political considerations

How does each proposal impact YOUR financial, technological, risk and get to market strategy?

Tip 4: Risks to assess and manage

- ▣ Agreement on process “ownership / responsibility”
- ▣ Quality of project oversight and management
- ▣ Scalability and flexibility – ability of vendor to provide the required continuous, expanding or contracting services
- ▣ Financial and business stability of contractor
- ▣ Sponsor focus, commitment and allocation of sufficient resources to outsourcing management
- ▣ Agreement on intellectual property: uses / exclusivities / ownership
- ▣ Internal data and other controls
- ▣ Quality assurance
- ▣ Regulatory compliance

Tip 5: Evaluate if going offshore

- ❑ Legal / cultural / economic / communication / political considerations (*for offshore transactions*)
- ❑ Fluctuating currency exchange rates – (*Does a weak dollar dilute gains from low wages?*)
- ❑ Any issues with negative U.S. image and publicity?
- ❑ Increased transportation costs, duties and tariffs associated with foreign production
- ❑ Regulatory compliance
- ❑ Access to patient populations (CRO)
- ❑ Sufficiency of protection of IP rights
- ❑ Calculate your total end cost after all of above, and don't just focus on a unit price.

Tip 6: Traps to avoid

- ❑ Selecting contractor for tasks beyond its core competency
- ❑ Contractor conflict of interest
- ❑ Instability in research and development alliances
- ❑ Lengthy contracting term
- ❑ Inefficient, late or quality-deficient services or production
- ❑ Shortcutting due diligence process
- ❑ Insufficient time to negotiate contract
 - Involve your legal team early in the process

Win Win Outsourcing Agreements

Establish a team ethos that assumes ownership across the companies in a co-operative, non-adversarial relationship

Basic Structure of the Agreement

The Contract documents typically comprise:

- ▣ Terms and conditions
- ▣ Services schedule: a detailed description of the scope of services
- ▣ Service level schedule: a selective set of performance standards
- ▣ Pricing schedule
- ▣ Inventory schedules: lists of equipment, software, contracts and people

The contract must:

- ❑ Integrate the commercial, legal, technical, quality and financial issues
- ❑ Balance risk and reward
- ❑ Balance certainty and flexibility
- ❑ Allow carefully managed change control
- ❑ Provide price predictability
- ❑ Provide a clear method for dispute resolution
- ❑ Provide a plan for termination / expiration

Contract should be integrated:

- ❑ Is there consistency in key areas?
- ❑ Examine the linkages between services and pricing
- ❑ Does it reflect your overall business strategy and objectives?
- ❑ Does it reflect the commercial strategy for the project and the original business case?

Know how to deal with changes:

- ▣ Volume change
- ▣ Addition/subtraction of a business unit
- ▣ Merger/acquisition
- ▣ Process for removing a service stream
- ▣ New services
- ▣ New territories
- ▣ Legal/regulatory changes

Pricing issues to consider:

- ▣ How do prices change over the term?
- ▣ Inflation risk?
- ▣ Is price responsive to technology and regulatory changes?
- ▣ Who controls refresh rate for chosen units or resources?
- ▣ Need to balance your desire to pay for usage with your need to reserve capacity

Best Practices for Governance and Relationship Management

- Governance structure (*i.e.*, project management office) must be set up early as single point of contact for relationship
- Implement a robust measurement, reporting and meeting timetable
- Consider establishing annual reviews between the companies
- Include audit needs in the agreement

Questions?

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Thank You!