Gaining the Competitive Edge
The Life Science C-suite’s Top 3 Outsource Considerations

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Executive Summary
This past year has been economically challenging for all industry sectors and the life science industry, while full of promise, has not escaped unharmed. As James C. Greenwood, President and CEO of the Biotechnology Industry Organization (BIO), expressed in his annual address to association members, the biotech/life science industry is facing tremendous financial pressure. “A full forty percent of current publicly-traded biotech companies are down to their last 12 months of cash and about a third of those companies ended 2008 with less than six months of cash.”

It’s clear that to survive the changes in the current economic environment, including the globalization of products and services, life science companies must run lean and efficient organizations. Outsourcing enables virtual companies and start-ups to have the flexibility and scalability needed to get off the ground, entrusting industry experts to perform streamlined processes, while avoiding the time and expense associated with infrastructure build out and hiring and training specialized personnel. Emerging life science companies are now able to bring products to market without investing significant capital in manufacturing or distribution facilities, and the associated systems and software. In addition, established companies are choosing to contract services to avoid costs and eliminate excess capacity by outsourcing distribution and related activities and either divesting warehouse facilities or repurposing the square footage for core initiatives. By outsourcing, companies are able to shift fixed costs to variable costs – paying only for what they use. Additionally, companies can reduce the overall capital invested in their businesses, yielding higher returns on invested capital.

From Vertical to Virtual
In today’s reality, outsourcing has proven to be a strategic advantage across the life science spectrum. A Third Party Logistics (3PL) provider, Business Process Outsource (BPO) providers, Clinical Research Organization (CRO), Contract Manufacturing Organization (CMO), or Contract Sales Organization (CSO), all have the specialized knowledge and expertise needed to give manufacturers a competitive edge.

Even though the state of the economy poses an ongoing challenge for securing capital, today’s entrepreneurs require far less financial support to start a life science company – thanks to the benefit of outsourced services – than those who entered the market just a few years ago.

Despite the challenging economy, the U.S. market for outsourced pharmaceutical manufacturing continues to grow at a rate of 10 to 12% annually. According to a recently released Health and Life Sciences Market Monitor Report produced by the independent investment bank Harris Williams & Co., the $43.5 billion general outsourced pharmaceutical services industry is growing at an 8.9% compound annual growth rate (CAGR). Due to the advantages provided by outsourced services, such as minimizing capital investments and avoiding heavy on-going fixed costs, Biotechnology companies have nearly doubled in number over the past five years.

One of the many fiduciary responsibilities held by the C-suite – increasing economic value, or return on invested capital – can be positively impacted by reducing costs, both operating and capital, through outsourcing. This white paper seeks to assist members of the life science C-suite by providing executives with three key areas of consideration when contemplating outsourcing – business considerations, financial considerations and partnership considerations.
Top 3 Outsource Considerations

In its latest outsource report, the research and advisory firm Gartner Inc. cites cost reduction as the number one reason organizations choose to outsource. Findings of a study by EquaTerra, a BPO expert sourcing advisory firm, echoed that conclusion when 56% of its pharmaceutical respondents listed cost reduction as outsourcing’s primary benefit. Coming in second (at 44%) was improving stakeholder ROI by dedicating and redirecting focus to more strategic activities.

The increased number of outsourced service providers available to the life science C-suite is a testament to the success of the model in achieving the aforementioned goals. However, negotiating the minefield of outsourcing providers and offerings – and selecting the ones that will work best with an organization – can be a daunting task. Manufacturers considering outsource opportunities will gain a competitive edge by thoroughly evaluating business, financial and partnership considerations when contemplating what and whether to outsource.
Determining What to Outsource

In the next five years, outsourcing in the pharmaceutical segment will increase as companies are required to focus on efficiency improvements to compete in today’s market. Companies are expected to take a much more critical view of nearly all internal operations – including those they have traditionally managed and viewed as core to the organization. Certain financial services, contract management and order-to-cash processing are now all easily outsourced as well. Customer Service and Medical Affairs may also be effectively managed outside company walls, depending upon the product line being considered. It wasn’t very long ago that commonly outsourced activities, such as manufacturing, clinical trial management and warehousing and distribution, were considered core to the organization and therefore remained “in-house.”

Using core competency as the sole outsourcing “filter” has proven to be a somewhat flawed model in recent years as functions typically understood as “essential” have been successfully outsourced with great success. While core vs. non-core may in some cases continue to serve as an appropriate filter when determining what to outsource, it is just one of many points of consideration life science manufacturers may use to evaluate potential outsourcing opportunities.

Consider the Following Potential Outsource Evaluation Filters:

| Non-Core: | All non-core competency functions/sub-functions should be evaluated as outsourcing opportunities. |
| Problem Areas: | A function/sub-function currently causing issues or problems for the organization should be considered. (Outsourcers may serve as effective change agents.) |
| Subject Matter Experts: | Rather than hiring highly paid, underutilized experts, who are difficult to find and easy to lose, consider outsourcing to a team of experts, and pay only for required services. |
| Subsidiaries Considered for Divestiture: | To prepare in advance for the sale of a business unit, outsource services that are currently shared with or provided by corporate. |
| Expansions: | Functional areas currently in growth mode are advantaged by the immediate scalability outsourcing affords. |
| New Business Lines: | Mitigate risk by contracting out support services for new business lines rather than burdening a new venture with significant upfront capital investment and heavy fixed cost and other long-term commitments. |
| Market Uncertainty: | Protect against the risk of significant over or under investment expressed by rapid market changes, both favorable and unfavorable. |
| Industry Trends: | Consider outsourcing functional areas typically outsourced in the industry – those your competitors have chosen to outsource. |
| Political Hotbeds: | Outsource functions that have or will draw negative attention to the company (union issues etc ...). |
| Complex Business Functions (Pain Points): | Consider outsourcing functional areas that require significant staff, time and specialized computer systems to administer. |
Regulatory Risk Mitigation Requires Specialization
The warehousing and distribution of healthcare products – especially pharmaceuticals, medical devices and biologics – requires compliance with a multitude of regulations. Local, state, federal and international requirements must be met to ensure product quality and consumer safety. Overseen by individual state boards of pharmacy, state laws differ from state to state, greatly increasing the challenge of meeting the varied regulatory and licensing requirements. The regulatory environment for managing 50 individual state requirements is complex, yet must be assured. Federal regulatory requirements are also demanding, mandated by congressional laws that are enforced by the U.S. Justice Department through the Food and Drug Administration (FDA) and the Drug Enforcement Agency (DEA).

In addition, regulatory requirements differ depending upon type of product, storage conditions, and the classification of the organization requiring assurance for each individual product type.

Non-compliance with state or federal regulations may result in serious charges levelled against companies and individuals, and hefty fines and punishments may be issued, including incarceration. The complexity of coping with multiple regulatory bodies, coupled with the serious ramifications resulting from non-compliance has created an independent field of regulatory specialists to help pharmaceutical manufacturers mitigate their regulatory risk.

3PLs offer the regulatory specialization needed to successfully conduct business in the highly regulated healthcare industry. Although the product manufacturer is primarily responsible for regulatory compliance relative to its products, the 3PL provider can help ensure compliance with warehousing and distribution-related requirements. As a result, 3PLs have developed intricate processes, procedures, and networks of systems to ensure regulatory compliance, managing through the maze of required regulations.
3PL-Related Regulations and Standards

DDN and other 3PL outsourcers have effectively developed methodologies and procedures to ensure compliance with a multitude of regulators and industry best practices such as those that follow:

**UNITED STATES**
- Federal Communications Commission (FCC)
- Federal Trade Commission (FTC)
- The Federal Register (FR)
- Office of Textiles and Apparel (OTEXA)
- International Trade Data System (ITDS)
- United States Court of International Trade
- United States Trade Representative (USTR)
- U.S. Bureau of Industry and Security (BIS)
- U.S. Bureau of Industry and Security-Denied Persons List
- U.S. Customs and Border Protection (CBP)
- U.S. Department of Commerce (DOC)
- U.S. Department of Commerce-Import Administration
- U.S. Food and Drug Administration (FDA)
- U.S. Census Bureau-Automated Export System
- U.S. Census Bureau-Foreign Trade Statistics
- U.S. Census Bureau-Schedule B Export Codes
- U.S. Consumer Product Safety Commission
- U.S. Department of Transportation (DOT)
- U.S. Environmental Protection Agency (EPA)
- U.S. Fish and Wildlife Service (USFWS)
- U.S. Government’s Official Web Portal
- U.S. Government Export Portal
- U.S. International Trade Administration (ITA)
- U.S. International Trade Commission (ITC)
- U.S. International Trade Commission-Tariff Information Center
- USDA Animal and Plant Health Inspection Service (APHIS)

**CANADA**
- Canada Border Services Agency (CBSA)
- Canada Border Services Agency-Customs Tariff
- Canada Revenue Agency (CRA)
- Canadian Automated Export Declaration (CAED)
- Government of Canada-Department of Foreign Affairs and International Trade
- International Trade Canada
- Statistics Canada

**INDUSTRY**
- American Production & Inventory Control Society (APICS)
- Council of Supply Chain Management Professionals
- Export Administration Regulations
- Inbound Logistics Magazine
- International Air Transport Association
- International Inco Terms
- International Warehouse Logistics Association (IWLA)
- Logistics Management Magazine
- Logistics World Magazine
- NAFTA Customs
- U.S. Customs and Border Protection
- Warehouse Education Research Council (WERC)
Scalability
Outsourcing allows manufacturers to scale up without investing the time and money required to hire, train and maintain staff and allows for immediate reduction of services without requiring staff elimination or maintaining excess physical assets. When considering true outsource/in-house scalability comparison both direct and indirect costs must be taken into consideration. For example, call centers not only require systems, labor and supervision, but also occupancy, utilities, phone costs, technology, training, etc. Fully utilizing an in-house call center staff is difficult for any company. By outsourcing a call center, a company pays a fee for the resources used. Such outsourcing provides ultimate scalability by converting a fixed cost to a variable cost.

Expertise
When considering outsourcing of a functional area evaluate your current in-house staff by asking the following questions:
• Do the internal personnel currently managing this function require high salaries and benefits?
• Do they have specific expertise making them difficult and expensive to train or replace?
• Is there adequate bench strength internally – a backup for every position?
• Is the depth of management sufficient to manage the functional area consistently and successfully?
• Are internal resources providing adequate service levels?
• Does this department have a track record of continuous improvement?
• Does the department have the resources to apply best practice within this functional area?
• Is this department using the latest technological advances?
• Is this department excelling in service efficiencies that enhance customer relationships?

As the last of the baby boomers retire over the next 5-10 years, companies will lose a high percentage of employees that hold the greatest depth of knowledge and expertise. The resulting decreasing labor pool will present a challenge for companies. Outsource providers are staffed with highly specialized personnel – providing access to a larger talent pool and a sustainable source of skills. In addition, outsourced services are provided under a legally binding contract providing a clear accountability advantage over internal services.
Outsourcing - An Economic Value (EV) Boost

In the field of corporate finance, economic value (EV) is a way to measure management’s ability to create value for stakeholders. Economic value is defined as company’s net operating profit after taxes minus a capital charge for the investment on capital employed in the business.

Economic value is positively impacted by outsourcing’s avoidance of capital deployment. By outsourcing, EV is boosted by taking capital assets off the books. According to Karl Pichler, an associate at Stern Stewart – the company that conceptualized and trademarked the term economic value added (EVA) - looking at outsourcing simply as a technique to reduce capital costs is too narrow a view. "Outsourcing is a key strategic component in capital management," said Pichler. "Not so much to avoid the capital charge, but more to make capital variable and to reduce overall operating costs and capital costs.”

Whether your financial metric is EV, return on investment (ROI) or internal rate of return (IRR), the strategic use of outsource partners can improve the financial health of your company.

DDN’s FDA/DEA-approved, VAWD-certified, temperature-mapped warehouse includes more than 10,000 square feet of refrigerated and frozen space.
Cost Reduction Achieved Through Shared Services

As life science executives contemplate outsourcing options, strong consideration should be given to the savings achieved through shared services. In the shared services outsource model, multiple companies within the same industry are able to further increase efficiencies and reduce costs by using third-party providers, also referred to as shared-use distribution providers. To achieve optimum benefit from 3PL shared services, it is important to utilize an industry specific provider. The warehousing, tracking and distribution of drugs, biotechnology products, and hazardous materials requires Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) level compliance such as high-level security and the use of pharmaceutical grade warehouses.

Perhaps the most regulated of all industries, the life science industry presents one of the most demanding distribution and supply chain management challenges. Regulatory requirements, the need for lot control and quality assurance require 3PLs servicing the life science market to create and maintain best practice levels of accuracy, productivity and efficiency.

By sharing space in an FDA/DEA-compliant 3PL facility and by outsourcing related I.T. services and systems – such as warehouse management systems, contract management, order to cash and accounts receivable – 3PLs are able to spread costs across multiple client manufacturers. As a result, the overhead required for each client is lower and start-up risks for new products are minimized.

Capital Outlay

Internal business units fight a continuous battle for the resources necessary to keep pace with changing technology and business standards set by customers and regulatory agencies. Often, internal groups don’t receive authorization for needed capital investments until after a regulatory observation has been made or a customer complaint received.

Outsource companies are required to look at the changing healthcare landscape and invest proactively in best practice as a means of remaining competitive. They are quick to adapt to changing market demands and regulation and are able to spread required investments across multiple client companies. This aggregation eliminates the redundancy and expense of each company building a unique solution and ultimately removes cost for the entire channel; companies may look to outsourcers as a way to maintain a competitive base without maintaining expensive infrastructure.
Partnering with the right outsource provider reduces cost, mitigates risk and improves operational efficiency. However, choosing the wrong outsource provider may result in significant issues with cost, quality, and customer satisfaction. We’ve compiled this evaluation checklist to assist with your outsource partnership selection process. As you evaluate each section provide a score for each provider ranging from 1-9, 1 representing “poor fit rating” and 9 representing “excellent fit rating.” Then tabulate the results to determine each potential partner’s total score.

Outsource Provider Evaluation Checklist

**Conduct a Needs Assessment (GAP analysis)**

1. Evaluate the strengths and weaknesses of the organization.
2. Establish how each organizational/functional area affects the organization's profits, cash flow and ability to grow and adjust to market circumstances.
3. Identify needs that require evaluation by organizational leaders.
4. Determine whether outsourcing is the best way to address the identified issues.

**Identify Outsource Providers**

1. Form an Outsourcing Decision Committee.
2. Define your requirements.
3. Search for providers on the Internet, in Industry publications and directories and through resources provided via Industry organizations and trade shows.
4. Consider the following:
   - Are your interests aligned with the provider?
   - Does the provider have expertise in your business and your industry?
   - What particular services does the provider offer?
   - Is a provider’s location important?
   - Is the potential provider respected in the marketplace?
   - Does the provider have established facilities with a scalable plan for expansion to accommodate the potential growth of your business?
   - Does the provider have the flexibility to accommodate rapid changes to your business model?

**Develop a Comprehensive RFI/RFP/RFQ**

Develop and implement an RFP process that clearly articulates the desired services and defines management expectations. Ensure that your business goals line up with those of your potential partner. Objectives and goals must be clearly defined, understood and well communicated.

**Conduct Telephone Interviews with Short List**

Compile a list of questions based upon the requirements stated in your RFP/RFQ in addition to questions targeted to help ascertain regulatory capabilities, customer service levels, resourcefulness, overall knowledge of the organization and experience in the industry. Consider adding the following reference related-questions to your own customized list.

1. Request a recent new client reference.
2. Request a longest-standing client reference.
3. Request the smallest client reference (learning how a provider treats its smallest client is a good barometer of client services).

**Contact References**

Consider adding the following suggested questions to your own customized list.

1. How reliable is the outsource provider?
2. Is the outsource provider known for quality products/services?

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Outsource Provider Evaluation Checklist Cont.

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<th>Outsource Provider 1</th>
<th>Outsource Provider 2</th>
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<td>3.</td>
<td>Does the outsource provider typically meet deadlines?</td>
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<td>4.</td>
<td>How safe is my data/product etc? Any history of security issues?</td>
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<td>5.</td>
<td>Will the outsource provider be fair and transparent in his financial dealings with my organization?</td>
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<td>6.</td>
<td>Does the outsource provider comply with statutory laws and regulations?</td>
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<td>7.</td>
<td>Have you had any “culture” conflicts with this outsource provider?</td>
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Perform a Site Evaluation
Evaluate the vendor’s ability to provide the required services. Visit your outsourcing partner’s workplace to meet its team and gain an understanding of its processes and methodologies.

Conduct Cultural Compatibility Evaluation
G. Johnson identified the following elements used to describe or influence Organizational Culture. Ask your potential partner to describe its culture based upon the following elements, then compare your company’s culture to determine whether there is a culture fit or clash.

- **The Paradigm**: What the organization is about; what it does; its mission; its values.
- **Control Systems**: The processes in place to monitor what is going on. Role cultures tend to have vast rulebooks, while power cultures rely more heavily on individualism.
- **Organizational Structures**: Reporting lines, hierarchies and the way that work flows through the business.
- **Power Structures**: Who makes the decisions, how widely spread is power, and on what is power based?
- **Rituals and Routines**: What is the rhythm of management meetings, board reports, etc...? Are they sufficient or more habitual than necessary?
- **Stories and Myths**: Learn what the organization values by asking questions about its people and events.

Regulatory Understanding
Make certain your potential partner maintains necessary certifications to ensure that your organization complies with regulatory requirements including Sarbanes-Oxley and has an understanding of your industry-specific regulations (FDA, DEA).

Evaluate Geographic Location
Research whether your outsource provider’s geographic location is favorable.

Solidify Contract
- Service Level Agreements
- Regulatory, Privacy, Information technology and security requirements
- Intellectual property determinations
- Implementation and transition requirements and provisions

Does Your Partner Have a Well-defined Implementation/Transitioning Process Plan?
The implementation process shifts the dialog and direct responsibility from the executive office to the operators. Building transition requirements and provisions into the outsourcing plans will ease the transition and reduce complications such as product or service supply interruption, plans for production factors, and the mutual commitment by both teams.

Will Your Partner Assist with a Change Management Plan?
Your partner should assist with a change management plan that includes a communications timeline. Communication with internal audiences is key to ensuring the buy-in of staff. Defined and tailored messages will help minimize potential resistance to outsourcing.
Conclusion

Ernst & Young’s bi-annual global pharmaceutical report states that the pressures facing the life science C-suite are greater than ever before, and suggests that current global financial conditions require accelerated timetables for drug makers to make transformational changes in their organizations. According to Pamela Spence, UK pharmaceutical leader at Ernst & Young, “Many companies are facing initiative overload and need to find a way to increase the speed of change by prioritising, allocating resources effectively and exercising rigor in project management.”

Outsourcing can assist life science companies in efforts to speed change, allocate resources and improve project management while driving down operating costs and minimizing capital investments to gain a competitive edge.

By producing a sound outsource plan and taking a disciplined approach to evaluating the required business, financial and partnership considerations, companies can build outsourcing relationships that yield meaningful benefits for the long term.
About Us
A subsidiary of the 151-year-old Dohmen Company, DDN is headquartered in Menomonee Falls, Wisconsin, with distribution facilities located in Memphis, Tennessee and Ontario, California. DDN has become the largest privately held provider of outsourced services to the life science industry by streamlining processes, reducing costs and improving efficiencies for emerging, mid-tier and market-leading life science companies. By providing superior business processes and operations, DDN frees manufacturers’ resources for R&D, acquisitions, and other core initiatives. For more information, please call 888-374-8873 or visit www.ddnnet.com.

References
6 Pharma Times, Recession threat means Big Pharma “must speed up transformation plans.” http://www.natap.org/2008/newsUpdates/111308_01.htm