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Establishing and Managing a Vendor Network for Clinical Supply Manufacturing Services

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This article presents some essential operational and evaluation aspects of the Request for Information/Request for Proposal (RFI/RFP) process when conducted for the purpose of establishing a vendor network for clinical supply manufacturing services.

Note: Portions of this article are being reprinted with permission from Pharmaceutical Outsourcing.[1]

Introduction

The need to find cost-effective ways to operate is of paramount importance in face of the current economic challenges facing the Pharmaceutical Industry (Pharma). The industry is faced with the requirement for innovation, technical expertise, and high quality while at the same time needing to drive down costs against aggressive timelines. These same organizations are looked upon to enable the portfolio and constantly challenged with new, complex problems to solve. Additionally, Pharma has evolved to be global in reach across both clinical development and commercial product areas. The need to supply global clinical trials, while assuring global regulatory support, presents an added challenge to the industry during these cost sensitive times.

One way that Pharma has dealt with containing and reducing costs is through outsourcing. The fundamental technique for evaluating a pool of potential vendors against a block of work is through the Request for Information (RFI) and Request for Proposal (RFP) process. This is a well established process across all industries and is likely here to stay within Pharma, particularly during this period of focus on cost-effective sourcing. However, it is recognized that the process itself can be laborious and in order to be successful requires more effort and internal alignment than is typically considered or performed.[2] Nevertheless, the economic benefit obtained from using the process is too meaningful and measureable for RFIs and RFPs to disappear.[3] Numerous references and online aides regarding the basic concepts and processes of RFI/RFP are available, much of which are focused on the structure and content of these tools.[4,5] This article presents some essential operational and evaluation aspects of the RFI/RFP process when conducted for the purpose of establishing a vendor network for clinical supply manufacturing services. Based on Pfizer's experience across a number of projects, these essential aspects are focused on the following areas:[1]

- Establish and communicate realistic demand projections for the services under evaluation
- Assemble an appropriate team of Subject Matter Experts (SMEs)
- Identify key evaluation criteria at each step of the process
- Determine what measurement methods are appropriate as some may be more subjective than objective
- Make the RFI/RFP process work for both the buying organization and the service provider
- Evaluate output and document decisions based on that evaluation

Sourcing professionals in Pharma should ask themselves the following questions:

- Do I have a clear understanding of what products/services I need to buy and how I want them to be provided?
- Do I know why I am using the current vendors in my network of service providers?
- Do I have the documentation to support the initial selection of these service providers?

Through the use of a well defined RFI/RFP process and by paying attention to some of the essential aspects discussed in this article, those questions can be answered affirmatively.

Once a vendor network for clinical supply manufacturing has been established, a practical approach to management needs to be put in place for that group of vendors. Careful consideration needs to be given to the type of work being conducted. This is not commercial manufacturing, where validated products are routinely made dozens or hundreds of times a year and metrics are easily captured. This article provides an overview of the collaborative approach developed by Pfizer for clinical services and includes the following aspects:

- Vendor segmentation to define management approach
- Assignment of a central point person, the Relationship Manager
- Engaging internal and external stakeholders
- Vendor Governance
- Performance Management
- Risk Assessment

Incorporation of the practices described in this article can help an organization successfully establish a vendor network to support clinical supply manufacturing and implement a practical approach to vendor management.

Establishing a Network

Establish and Communicate Demand

Better engagement by potential vendors on the RFI/RFP process can be expected when information is provided not only on the type of work within scope, but also the anticipated volume of that work in the foreseeable future. Due to the nature of Pharma work in the clinical development phase, it is often difficult to give definitive forecasts for manufacturing associated with that type of work. However, it is important that sponsors of this work, like Pfizer, invest the time required to gain a reasonable understanding of the expected and potential needs for both the immediate term and into the next year or two. There are many reasons to do this, including possibly leveraging volume-driven cost savings or influencing capital investments on the vendor side. Guaranteed spend/volume commitments can be used for price concessions, particularly if long term commitments can be established. Additionally, a realistic forecast can help determine a vendor's true ability to support the projected workload and what investments might be needed on their side to ensure continued productivity and efficiency.

It is also important to truly understand the intent of the sourcing exercise. Is it due to a large increase in the volume of work (e.g. capacity outsourcing)? Is there a need to explore cost savings against the current vendor network? Are external cost savings versus internal support being explored? Is there a need to access capabilities of the supply base not within internal competencies (e.g., competency outsourcing)? Typically, several of these drivers will be applicable, but an understanding of their relative importance helps to effectively design and execute the sourcing and selection process.

Giving potential vendors a view into projected needs and rationale for conducting the sourcing exercise is important for engagement. Vendors are inundated with RFI/RFP requests in the current environment that tend to go no further than the discussion stage, sending the message that many of these efforts are simply for benchmarking purposes. A well-stated and honest rationale for the sourcing project can help eliminate that fear.

Assemble Team of SMEs

The process for evaluating and on-boarding vendors for clinical supply manufacturing activities, including the RFI/RFP steps, is heavily reliant on a team effort within Pfizer. It is important to have a team lead that is responsible for the overall project, possesses a strong understanding of the work within scope, and has the authority to hold team members accountable for timelines and deliverables. While the mechanics of the RFI/RFP process and commercial assessment is typically led by a member of the Procurement organization, technical SMEs play a critical role on the team by being accountable for developing assessment tool criteria and evaluating technical and quality competencies based upon vendor responses. For clinical supply manufacturing projects at Pfizer, the team typically comprises members from Clinical Supply Sourcing, Quality, Analytical, Formulation Development, and Procurement. More frequently, a team member from the Environmental, Health, and Safety organization has been getting pulled into RFI/RFP discussions, particularly for projects that pose material handling challenges. For a large Pharma company that is well represented across all of these disciplines, it is reasonable to assemble this multi-functional team. Small, emerging companies often have sourcing professionals who need to source activities outside of their knowledge base. In those situations, it is highly advised that consultants be utilized to provide technical guidance in the areas that are lacking internal resources. A sourcing exercise conducted without the appropriate base

of knowledge to evaluate potential vendors is a recipe for disaster, as it is easy to then overly influence selection based on cost criteria.

Identify Evaluation Criteria

Defining and implementing an evaluation process early on is key. Ideally, this would occur prior to receipt of RFI/RFP responses in order to reduce bias. Many approaches can be utilized to score response information; these can range from very simple to very complex methods. Potential evaluation options vary from simple yes/no responses to numeric values with category weightings. An example of a weighted scoring method used to evaluate service providers in the clinical supply manufacturing space is shown in Table A.

One important point to consider is the level of quality evaluation at this stage. It is certainly important to include quality criteria to ensure that the vendors being assessed have the appropriate regulatory and compliance history experience to support the desired work and meet the GMP requirements for the geographic areas where trials are planned. Regulatory agencies are continually increasing expectations that Pharma fully understand and are accountable for activities conducted at their outsourcing partners.[6,7] However, overly emphasizing those aspects at this early stage could prevent the buyer from evaluating some newly emerging potential partners that could bring significant value to a relationship. At the end of this process, a formal quality-driven audit will be the real opportunity to thoroughly test the quality, regulatory, and compliance aspects of the potential partner, including the identification of any showstoppers.

It is also important to provide RFI/RFP evaluators with a common set of criteria to score respondents (e.g., what warrants score of 5 vs. 1 for any particular category shown in Table A). Due diligence to this aspect is important to obtain a good comparison across potential service providers. Table B provides examples for a few of the areas evaluated in Table A. This scoring methodology provides a framework to compare vendors in an objective way and to help provide supporting rationale for sourcing decisions.

Buyer and Service Provider Interactions

A good communication plan when conducting an RFI/RFP exercise is essential to its success. While many of the recommendations provided here are based on common sense, they are worth repeating.

Considerations for Buyers

It is important for organizations initiating an RFI/RFP to

Category	Weight*	Vendor X*	Vendor Y*	Vendor Z*
1. Job Type Considerations	50%	4.4	4.7	1.7
A. Technical Capability to Perform Scope of Work	40%	5.0	5.0	2.0
B. Capability to Perform Work at Required Scale	30%	3.0	4.0	2.0
C. Projected Cycle Times	15%	3.0	5.0	1.0
D. Ability to Leverage API Mfg and/or Formulation Dev	10%	4.0	4.0	1.0
E. Scale-up and Commercial Launch Support	5%	4.0	4.0	1.0
2. Cost Considerations	20%	4.3	2.4	1.3
A. Job Type Costs – Costs to run typical jobs	80%	4.0	2.0	1.0
B. Pfizer-Specific Material Set-up Costs	10%	5.0	3.0	1.0
D. Analytical Testing Costs	10%	5.0	5.0	4.0
3. Quality Considerations	20%	4.4	3.4	1.6
A. Regulatory Audit Experience	60%	4.0	3.0	2.0
B. Completeness of Meeting EU Regulations	40%	5.0	4.0	1.0
4. Analytical Testing Considerations	10%	5.0	2.0	5.0
A. Analytical Testing Capabilities	100%	5.0	2.0	5.0
Total Score		4.4	3.6	2.1
*Weightings and score examples are for illustrative purposes only and not necessarily reflective of actual values used within Pfizer.				

Table A. Example scoring method.

Aspect Evaluated	5* Excellent	4	3* Average	2	1* Poor
Technical Capability to Perform Scope of Work	All required job types fall within routine remit of facility		All required job types have experience base within facility, but may not be routine		Cannot perform all required job types
Projected Cycle Times	Projected cycle times are shortest of respondents		Projected cycle times are average compared to other respondents		Projected cycle times are significantly longer than most respondents
Job Type Costs – Costs to run typical jobs	Quoted cost is lowest of respondents		Quoted cost is average compared to other respondents		Quoted cost is significantly higher than most other respondents
Regulatory Audit Experience	Significant regulatory audit history with high positive outcome rate		Moderate regulatory audit history with mostly positive outcome rate		Limited regulatory audit history and/or unfavorable outcomes from audits
Analytical Testing Capabilities	Able to support critical test and 50% of all tests probed		Able to support critical test and 70% of all tests probed		Limited analytical support: cannot provide critical tests
*Criteria examples are for illustrative purposes only and not necessarily reflective of actual values within Pfizer.					

Table B. Scoring criteria.

have a well defined plan in place. When seeking a vendor network for clinical supply manufacturing, these aspects include having a well-written work scope document and clearly defining the information transfer process. Guidelines for response time and format of response need to be clearly set and communicated. It is also important to set realistic expectations regarding turnaround. While certain situations may warrant very aggressive timelines for turnaround of an RFI/RFP, organizations can expect better quality information and a wider base of service providers willing to participate when timelines are reasonable. It is also important to ensure that there are sufficient opportunities built into the process to allow time for the vendors to ask clarifying questions after any point of information transfer.

Perhaps the most important point for consideration is to provide feedback to RFI/RFP participants at the end of the process. This practice is a good professional courtesy and will help maintain credibility; it will also help assure active participation by the potential vendor pool in future projects.

Considerations for Service Providers

The key message for service providers of clinical supply manufacturing services is to treat the RFI/RFP process seriously if there is interest in the work and particularly if there is interest in working with the potential buyer. This includes effectively communicating whether or not participation is possible and desired. Formally recognizing and declining a request to participate in a sourcing exercise is better than no response at all. If participation is chosen, then delivering on the information transfers thoroughly and on time is a must. Doing otherwise can negatively impact the vendor's credibility with the buyer organization in both the short and long terms.[3]

Considerations for Both

The RFI/RFP process works best when both buyer and provider have a single primary contact in place to manage the communication flow. This helps to minimize confusion and assures compliance to timelines and associated commitments. The key contacts can also work together to facilitate clarification meetings and teleconferences as needed throughout the process.

Documented Output

The value of keeping detailed documentation of RFI/RFP efforts and other vendor evaluation exercises cannot be stressed enough. The data to support vendor selection and utilization decisions can be used for numerous purposes. Some practical examples based on experience include the following: (1) justifying approval of purchase orders, (2) demonstrating that a particular vendor recently "discovered" by a colleague has already been evaluated through a thorough process, (3) showing a new organizational leader that a defendable approach was utilized to establish a vendor network, and (4) providing a logical starting point when initiating the process for similar blocks of work or refreshing information on the current vendor pool.

The methods and tools used to document the identification and establishment of a vendor network through the RFI/RFP process can vary from the simple (e.g., retention of evaluation spreadsheets presented in Identify Evaluation Criteria section of this article) to the highly complex. A pragmatic approach to meet this objective generally entails assembling a presentation deck that includes background for RFI/RFP need, scope of work, explanation of how vendors were selected to participate in RFI/RFP, description of

evaluation criteria and scoring, and data that led to final vendor selection decisions.

Managing a Vendor Network

Vendor Segmentation

Appropriate segmentation of your vendor network is important to help determine the level of vendor management needed for that relationship. The resultant vendor management approach should then be variable and appropriate to the specific vendor relationship. Not all vendors need to receive the same level of operational, quality, procurement, and leadership oversight.

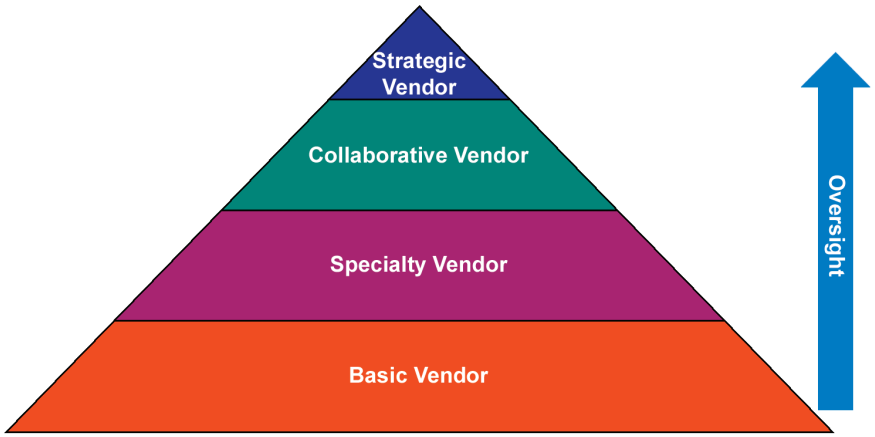

Figure 1. Vendor segmentation approach.

Pfizer Pharmaceutical Sciences developed a tiered approach to vendor classification as shown in Figure 1. These categories were defined based on both the value and risk associated with the work in scope, strategic value to the organization, frequency of work, and anticipated length of the relationship as shown in Table C. The level of quality, operational, and procurement oversight are commensurate to the tier rating and is also provided in Table C.

Relationship Manager

For vendors deemed as very important or critical to your business, it is recommended that a Relationship Manager be appointed. This individual is responsible for the overall health of the partnership. The Relationship Manager can work with his/her vendor counterpart to identify opportunities for maximizing current and future opportunities that drive mutual value and continuous improvement. A Relationship Manager

	Basic	Specialty	Collaborative	Strategic
Value/Risk of Work	Low risk purchases (e.g., readily available materials and components; routine services)	Project specific business value	Very important to business	Critical to meeting company objectives
Relationship	- Short term (i.e., transaction based)	- Short to mid term	- Mid to long term - Some strategic value - Continuous improvement on service, cost, quality is a focus	- Long term - High strategic value (e.g., multi disciplines, sites, programs, etc.) - Collaborative engagement with shared benefits
Relative use	Frequent and infrequent possible	Infrequent	Frequent	Frequent
QA Oversight*	Material Suppliers: QA assessment based on material type and intended use GMP and GMP/GCP Interface Contractors; As needed basis, short term focus during use	Material Suppliers: QA assessment based on material type and intended use GMP and GMP/GCP Interface Contractors; As needed basis, short term focus during use	GMP and GMP/GCP Interface Contractors; Proactive, ongoing Material Suppliers: QA assessment based on material type and intended use	GMP and GMP/GCP Interface Contractors; Proactive, ongoing
Operational Oversight	Tactical; sufficient to ensure terms of purchase agreement and applicable compliance requirements are met	Short term focus during supplier operations based on risk assessment	Proactive and ongoing relationship management *Level of review of tactical work is greater than for strategic supplier*	Proactive and ongoing relationship management
Procurement Oversight	Tactical only	Procurement Tier as applicable	Health Check (annual)	360 Survey; Health Checks

Table C. Vendor segmentation definitions and level of oversight.

also plays a key role in the following oversight activities:

Advocacy
- Provides a voice for the Vendor and is a resource for team members
- Helps ensure cultural compatibility

Communication
- Facilitates transparent and open lines of communication
- Establishes alignment on joint deliverables/commitments

Decision Making
- Ensures alignment of priorities and resources across parties
- Resolves disputes with mediation skills

Monitor and Feedback
- Drives performance management
- Performs regular risk assessments and addresses issues

Engaging Your Stakeholders

It is critical to engage internal stakeholders who have interests that will be affected by the vendor's performance. It is important for the overall health of the partnership to have everyone's interests represented and for all stakeholders to be aligned and working towards the same goals. In addition, value can only be derived from collaborative relationships that maximize joint outcomes internally and externally while supporting equitable business opportunities. Vendors support an outside organization's objectives while fulfilling their own interests in the growth and prosperity of their business. The closer the alignment is between organizations the healthier the collaboration will be. Key elements to consider for managing your stakeholder network include the following:

- Conduct a global evaluation of vendor capabilities, risk, and performance to set realistic expectations
- Ensure there is goal alignment to help manage multiple and conflicting priorities across groups
- Establish Service Level Agreements and collect the appropriate metrics
- Deliver a unified message and direction to set clear expectations
- Solicit feedback on stakeholder satisfaction to construct a productive environment
- Highlight accomplishments and how they can be applied more broadly
- Practice proactive damage control when an undesirable event occurs

Vendor Governance

A robust governance framework that includes senior leader involvement is essential to a successful partnership. This should also include an escalation pathway for problem-resolution to course correct as needed. Defined teams responsible for the day to day interactions along with the Relationship Manager should actively monitor the agreed to standards for quality, performance, and cost and recalibrate when needed to ensure there is proper alignment.

Communication forums with defined frequency, governance topics, and attendees should be held with the vendor and be face to face where possible. Establishing a formal plan that provides channels for informal and formal communication and timely interaction is critical. The changing nature of business needs will require that relationships evolve and open communication will ensure they progress correctly. The governance structure can assist with monitoring vendor's investments and emerging capabilities to ensure that the direction of the business is supported.

Performance Management

A formalized performance management process that continuously maps the needs of the business and measures the vendor's ability to meet those needs is critical to vendor management. Effective performance monitoring provides the following:

- Increases the flow of communication between your organization and the vendor
- Allows for better insights into a vendor's performance
- Helps to identify, prevent, and mitigate supply risk
- Rationalizes vendors based upon performance information
- Weeds out low performers and high-risk vendors
- Provides opportunities for top performers to grow their business
- Assists with uncovering continuous improvement opportunities

In order to monitor performance, meaningful metrics based on performance expectations need to be established and should be site- and operations-based if a vendor has multiple locations and provides discreet services. Metrics can be rolled up further into a Vendor Scorecard for an overall score to capture the holistic value of the relationship. A balanced scorecard approach that integrates metrics for operations, quality, and value perspectives is recommended. An example is provided in Table D.

Risk Assessment

Periodic risk assessments based on the knowledge of activities, performance metrics, and information available at the time of the assessment are vital to managing your organization's risk and the health of the vendor relationship.

Once vendor risks are identified, a proper oversight plan is needed to address any potential adverse impacts. An

Supplier Name	
Scorecard Frequency	Monthly
Performance Period	Jan-13

Green - 90-100%
Yellow - 70-89%
Red <70%

Monthly Rating	YTD Rating
100.0%	100.0%

Category	Metric	MONTH #	MONTH Total	MONTH Perf	MONTH Wgt*	MONTH Rating	2013YTD #	2013YTD Total	2013YTD Perf	2013YTD Wgt*	2013YTD Rating
Quality 30%	Substantiated Complaints	0	0	100%	6%	6.0%	0	0	100%	6%	6.0%
	Commitments completion on time	0	0	100%	3%	3.0%	0	0	100%	3%	3.0%
	Investigations & Deviations - no reportable events	0	0	100%	5%	5.0%	0	0	100%	5%	5.0%
	Investigations completion on time	0	0	100%	3%	3.0%	0	0	100%	3%	3.0%
	% CAPA completed on time	0	0	100%	3%	3.0%	0	0	100%	3%	3.0%
	Batch Record Conformance	0	0	100%	5%	5.0%	0	0	100%	5%	5.0%
	PharmSci Vendor QA Dashboard Rating	-		3.0	5%	5.0%	-		3.0	5%	5.0%
Operations 30%	On-time delivery performance	0	0	100%	7%	7.0%	0	0	100%	7%	7.0%
	Quantity Accuracy	0	0	100%	5%	5.0%	0	0	100%	5%	5.0%
	Quality Right First Time	0	0	100%	7%	7.0%	0	0	100%	7%	7.0%
	EH&S Rating	-		3.0	5%	5.0%	-		3.0	5%	5.0%
	Operations Survey	-		4.0	6%	6.0%	-		4.0	6%	6.0%
Technology 20%	Technology Survey	-		4.0	20%	20.0%	-		4.0	20%	20.0%
Value 20%	Overall Value Contribution (Survey)	-		4.0	20%	20.0%	-		4.0	20%	20.0%

*Weightings shown are for illustrative purposes only and not necessarily reflective of Pfizer process.

Table D. Example scorecard for vendor performance management.

effective mitigation plan requires close collaboration with the vendor and all the relevant stakeholders. Both organizations should work in partnership to develop and monitor mitigation plans to reduce identified risks to an acceptable level and track and address areas of non-compliance. Lastly, mitigation plans should be fair, reasonable, measurable, and fit for purpose. Parameters for evaluating, categorizing, and prioritizing risks should include the following:

- Risk likelihood (i.e., probability of risk occurrence)
- Risk consequence (i.e., impact and severity of risk occurrence)
- Thresholds to trigger management escalation and activities

For any given risk, techniques and methods should be explored to avoid, reduce, and control the probability of risk occurrence. However, some risks may be acceptable and simply monitored.

Summary

Establishing and subsequently managing a vendor network for clinical supply manufacturing services poses many challenges to Pharma innovators. The RFI/RFP process provides tools that can guide much of this effort and lead to a fair, consistent, and well documented approach. The vendor management approach chosen can range from very simple to highly complex; a fit for purpose plan should be developed to address the needs of the organization and service provider. The application of aspects provided in this article can help both buyers and service providers get the most out of the RFI/RFP process and vendor management practices as they pertain to clinical supply manufacturing services.

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