

Remedial Construction & Non-Stockpile Sector

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Remedial Construction & Non-Stockpile

- Number of companies in sector
 - 7
- Overall understanding, engagement and interest in CBDAIF
 - Reasonable understanding of purpose but not sure how remedial construction & non-stockpile fits into JPEO CBD when the mission is related to Chemical Materials Agency
 - Minimal engagement and response to queries
 - High Interest in meeting outcomes as they want to understand what is going on in the JPEO CBD arena

General Comments for JPEO CBD

- **RFPs being released are poorly written. They do not clearly describe what is required. They are incomplete, confusing, difficult to respond to and to cost. Their release is continually delayed sometimes by years not months. How can we develop a system and retain people when these opportunities slip many years. This procurement/proposal process is broke.**
- **Industry is being task to spend their IR&D funds on future opportunities but the JPM folks are not willing to talk to industry. There is an attitude that industry is the enemy and not a partner. And this is years before there will be an RFP on the street. When the JPMs are in the writing stages of an RFP they refuse to talk to us. The more we know the better proposals we can write and the more competition you will have.**
- **We are forced to no bid many opportunities because there is an incumbent doing the work and without early information about opportunities we cannot and will not spend Bid and proposal money on these "sole source" type opportunities. If you want competition then you need to foster it. If you have the contractor you want then just continue to use him.. It saves us all money by not writing proposals and evaluating proposals.**
- **ABPIs are useful when the info provided is specific. Last years' APBI was very disappointing, we should have been given a refund. Specific APBIs are very good for a specific program. Draft RFPs should always be provided.**
- **As funding for non medical programs declines there will be less industry expertise to support your programs. Serious consideration of the above comments are required.**
- **Why didn't other JPMs provide questions?**

Response to Questions JPM TMT

- **Are DoD's intentions for the T&E and Advanced Manufacturing facilities clear to Industry?**
 - **Answer:** No. The perceptions for both of these Medical Counter Measure Initiative (MCMI) proposed acquisitions are based upon information disseminated during industry day presentations, answers to questions submitted by industry and information available on the Natick website. Our lack of confidence and the level of uncertainty in DoD's intentions is growing due to the facts that the ADM RFP release has been substantially delayed and the requirement for the T&E facility is now rumored to being reevaluated. Formal procurement communications have ceased despite the Natick website notice of the intention to keep interested parties informed while informal communications with sponsors appear to be held in abeyance. Recently published Congressional authorization language questions program need and the potential for unwarranted federal duplication. There is also speculation among potential responders that the DoD is still discussing/evaluating what exactly will be in the RFP when, and if, it is released and it is also our understanding that the requirement(s) for the T&E facility are now being reevaluated from the ground up. Despite these uncertainties our understandings for these two initiatives are as follows.

Response to Questions JPM TMT

- **ADM:** Advanced development and manufacturing of medical countermeasures for biodefense is a national priority that requires the DoD to establish an agile and flexible **capability** for the advanced development of medical countermeasures. As such it is our understanding that a consortium of industry partners may provide this capability with existing facilities and that the DoD ADM program does not necessarily require dedicated facilities or the construction of new facilities to meet this need. The MCM ADM capability concept is intending to advance currently accepted practices used for FDA-regulated advanced development of MCMs through the use of transformational manufacturing technology, platform technologies and advanced regulatory science. The overall goal of this approach is to decrease MCM development times through to FDA approval, as well as ownership costs, and response times by utilizing modular, flexible and disposable processes and by “pushing” regulatory science.
- As defined the DoD MCM ADM capability is expected to incorporate mature platform/expression systems into manufacturing capabilities, will conduct advanced development of a given MCM through to FDA licensure, will utilize flexible and scalable manufacturing technologies adaptable to surge requirements and will be sustained by individually funded MCM product programs, warm base, and **industry use**. The ADM capability may be used to support whoever is awarded the individually funded MCM product programs, which may be the ADM contractor or other such entities as may be awarded an individual developmental contract. The level to which other awardees may use the ADM capability would be dependent upon their own experience and capabilities.
- Key capabilities being sought by the DoD MCM ADM program include utilization of modular self contained clean room suites, utilization of disposable or single bioreactor technology for process development, scale up and manufacture of CT material and licensed product to include fill and finish. Capabilities must also include test and evaluation of MCM candidates to include animal model development, and non-clinical in-vivo testing as defined in the “animal rule” until such time as the MCM T&E capability is on-line. It is also desired that the ADM consortium provide capabilities and a skilled workforce for other aspects of advanced development to include pre-clinical, clinical, regulatory science and strategy, FDA interactions, and licensure with the additional requirement for providing training to governmental and industry workforce for the same.

Response to Questions –JPM TMT

- Also requiring additional clarification is the definition of “dedicated” as it is used in reference to a domestic industrial base. “Dedicated” is typically thought to infer wholly committed to a particular purpose; a business concept that is antithetical to “cost sharing” among multiple sponsors. As such it is difficult to understand just what the DoD is asking the partners of the consortium to commit to. If the government is requesting a dedicated commitment and is not willing to make up whatever financial shortfalls may arise due to an unreliable or insufficient industrial customer base, the financial risk to the increases to to such levels that the contractor may run the risk of financial failure, and thus become unavailable for manufacturing capability.
- It is an unfortunate reality that it will likely be very difficult to attract investment in a program that shares cost but not priority of use. All potential investors and/or partners will want to see a business plan that would ensure to the maximum extent possible a fair return on their investment. The expectation that they will need to sell services unused by the government to 3rd parties without being able to give said parties a commitment to delivering on these services in a timely fashion will make dependence on other revenues tenuous at best. Would it not be more achievable that capabilities/facilities be primarily dedicated to the DoD effort with work for others being used to offset actual costs and expenses to the maximum extent possible rather than relying on these revenues to maintain the viability of the operation? An approach that would allow DoD to ‘jump to the head of the queue’ only upon declaration of a National emergency would serve to normalize the operating concept with those of other defense-critical industries and provide additional comfort to potential offerors and their subcontractors.
- Other areas of uncertainty at this time are the contracting instrument to be used as well as the provisions for cost “sharing”, IP rights protection, indemnification and cost accounting standards as these areas have not been well defined.

Response to Questions –JPM TMT

- **T&E facility**: The MCMI T&E facility is understood by us to be a DoD owned and contractor operated FDA-compliant National Center of Excellence dedicated to animal test and evaluation according to the animal rule for the advanced development of MCMs for biological agents to include capabilities for high containment, NHP studies, aerobiology and telemetry at sufficient scale and throughput to handle several MCMs concurrently. The timeline shared on the ADM Industry Day anticipates that the facility will be available for use in 2018, and until such time the requirements for animal T&E in support of MCMs will be provided by recipients of awards to develop specific MCMs, or by the awardee of the anticipated ADM contract on an as needed basis. The current intent for this facility is that it will be operated as a GOCO facility on a fee for service basis. (In addition to the aforementioned comments it is worth noting that reliance on the ADM contract to provide T&E capabilities on a ‘stop-gap’ basis presents substantial risks to both the ADM and T&E objectives. The ADM offer will of necessity have a planned obsolescence for T&E capabilities that offerors and team members are likely to find objectionable.)

Response to Questions –JPM TMT

- **How does industry understand the T&E and Advanced Manufacturing Facilities will impact current and future medical product development contracts (cost, risk, FDA sponsorship, IP rights)?**
 - **Answer:** Absent more detailed understanding of the acquisition solution and DoD implementation, these impacts are difficult to define or to forecast. Generally, the concept of requirements-based contracts for T&E and advanced manufacturing services should enable reduced costs and risks. FDA sponsorship and IP rights are generally influenced less by such requirement-based contracts. Some considerations of factors most to cost and risk are illustrated below.
 - *Contracting* – Multiple award, ID/IQ contracts with incentive fee and term promote competition and performance; however given the finite / limited number of MCM products to be developed they have a number of drawbacks. They are also more costly for DoD oversight and administration as well as requiring longer performance schedules to allow for re-competition at each task or sub task. Conversely, the use of a single award to a consortium with multiple partners would allow the consortium to rapidly respond to the government's requirements using the specific partner with the best capability and availability to meet the government's needs. Single-site performer pitfalls are mitigated with geographically distributed capabilities. An FDA warning letter for site-specific deficiencies at a manufacturing site doesn't result in a loss of all capability. Similar operational risks of single site solutions (e.g., disruption by natural disaster, work stoppage, etc) are mitigated by multiple—potentially redundant—capacities.
 - Reliance on commercial contracts to 'maintain the warm base' isn't realistic if contract services are subject to DoD disruptions. If this strategy is pursued, it is more realistic for DoD to allow fulfillment of commercial contractual obligations prior to initiation of DoD work. Given the plethora of CRO/CMOs competing for commercial biopharmaceutical business, the DoD contractor competing in this market would need incentives to attract non-government customers.

Response to Questions JPM TMT

- *FDA sponsorship* – Contracts should be structured to maximize the contract performers' authority, accountability and responsibility for contract performance. Responsibility, accountability and authority for FDA applications and regulatory compliance should not be shared. Risks and costs increase in proportion to review layers. Whether DoD (e.g. TSG, Army), the IP holder, or the contractor is to act as the FDA sponsor, contracts should clearly delineate and articulate the sponsors accountability, responsibility and authority for FDA communications. For example, if the contractor is designated as the sponsor, then the contractor's animal and human use review processes and procedures should fulfill federal requirements; should not be subject to secondary, actionable reviews within DoD. If DoD or the IP holder is the sponsor, the contractor should be clearly designated as a service provider and not be accountable for DoD-FDA interaction.
- *IP Rights* – Whether DoD seeks to retain its traditional data rights or seeks FAR deviation to allow inventors to retain full intellectual property rights, contracts should be structured to allow the contractor team to maintain IP that existed prior to task initiation and negotiate with DoD concerning IP developed in the process of task planning and execution.

Response to Questions JPM TMT

- **Would a requirement to use these facilities for nonclinical and manufacturing activities impact the desire of Industry to enter into contractual arrangements for medical product development with the DoD?**
 - **Answer:** We believe that the inclusion of nonclinical and manufacturing activities in the DoD's procurements would encourage businesses lacking such capabilities and facilitates and encourage their participation in DoD medical product development and manufacturing activities. Making these capabilities available would enable more offerors to provide a full suite of product development capabilities, and would thus help to ensure a larger, more robust and sustaining opportunity for a larger number of Industry partners overall.

Response to Questions JPM TMT

- **Does industry have recommendations for implementing use of these Facilities that are industry-friendly?**
 - **Answer:** As previously discussed, the government's requirements for the use of these two facilities are not yet entirely clear. It is unclear as to whether the government will require single dedicated facilities for each of the necessary efforts (i.e., dedicated manufacturing facility) or whether the government will accept the idea of a distributed capability to accomplish tasks. For example the manufacturing capability could be found over a multitude of pre-existing facilities dependent upon the task and commercial availability. It is also unclear as to whether the government will require use of any or all of the proposed capabilities noted within the ADM draft SOW. Without some assurance that these capabilities will be utilized by the government on a regular and pre-established basis, there is virtually no incentive for commercial parties to enter into the agreement. In the case of manufacturing, if the government were to provide a timeline or mechanism for giving an extended notice of intent for use of the facilities, the contractor might have enough confidence to schedule work during the non-use times. On the other hand if the government requires the facility to be available for surge work based on little or no advance notice (i.e., the government has priority of use for the facility with no or limited notice) the contractor will be unable to schedule other commercial work in a realistic manner. At that point, any positive impact of the government contract would be negated by uncertainty. Reliance on commercial contracts to 'maintain the warm base' isn't realistic if contract services are subject to DoD disruptions. If a warm base strategy is pursued, it is more realistic for DoD to allow fulfillment of commercial contractual obligations prior to initiation of DoD work. Given the plethora of CRO/CMOs competing for commercial biopharmaceutical business, the DoD contractor competing in this market would need incentives to attract non-government customers.

Response to Questions – JPM CA

- **What is the Likelihood of increased or sustained IR&D funding in your sector?**
 - **Answer:** We will maintain IR&D funding
- **Are there any non-CBD efforts that you have ongoing (e.g. other efforts with DoD, DOE, DHS,...) that we may be able to Leverage?**
 - **Answer:** No response

Response to Questions –JPM P

- **The JPEO has scheduled an APBI for September 2011. Does Industry find the APBI useful? What type of information do you expect to gather when attending? Have the APBI's in the past been useful to our industry partners? In what way?**
 - **Answer:** Yes. We find the purpose of the APBI to be useful. As the PEO states on the website “Advance Planning Briefings for Industry (APBI) keep the industrial base well-informed of future business opportunities, the direction of the Chemical and Biological Defense program and future requirements of DoD. The APBI includes details on Joint Service mid- and long-range science and technology research, development, test, and evaluation plans and programs, future production projections and emerging military requirements.” In attending the APBI meetings, potential contractors seek to obtain information regarding upcoming opportunities over the next year to three or four years. Unfortunately, the information shared at these meetings is overcome by events or changed soon after the meeting. Many of the opportunities presented as potentially full and open become small business set aside or in other manner restricted prior to release of the RFP. However, even with these problems, the meetings are still very helpful in that we can connect with other industry representatives and hold off line meetings. The one-on-one meetings with the PMs also allow industry to develop a much better understanding of the upcoming requirements. These individual meetings provide a forum for industry to meet with the JPM and obtain better clarification as to the needs and desires of the JPM. They also allow industry to discuss industry constraints and market requirements in order to shape the final requirements for the government in a manner that will allow both industry and the government to meet their individual needs.

Response to Questions –JPM P

- **Does Industry find the release of Requests for Information (RFIs) and draft Requests for Proposals (RFPs) in conjunction with an Industry Day useful for the development of proposals?**

Answer: Yes. We believe the release of Draft RFPs and the conduct of Industry Days is very useful in the development of proposals. First, it enables prospective offerors to begin to align their solution to be amenable to the Government's requirements and second, it provides industry with the opportunity to provide the Government with the feedback necessary to inform the final RFP and best position the Government for success. These processes help to ensure that the Government's requirements are met, that the requested products or activities are technically feasible, and that Industry's needs have been addressed. We believe conducting these activities ensures a better procurement process for all parties, and helps ensure a greater probability of the Government receiving multiple offers that meet their requirements and fully encompass the intent of the initiatives presented in the RFP.

- **What are some characteristics of RFPs that best facilitate the proposal formulation and development process?**

Answer: An RFP that includes clearly defined, 'industry-vetted' requirements and specific information on scope, capacity, cadence of requirements, and the anticipated volume of work for at least the initial period of performance is desirable. Alternatively, a Statement of Objectives is also highly desirable since it allows industry relatively greater latitude in the means to satisfy the government's objectives. Clarity without over-specification dramatically improves the offeror's ability to respond to the Government's requests thoroughly and accurately. In addition, RFPs of the complex nature of those referenced above, especially those for which the exact Scope of Work is not yet defined, are benefited by the inclusion of Sample Task Orders that closely mirror real work that could be performed by an offeror during the course of execution of the contract. These Sample Task Orders can allow offerors to demonstrate their technical capabilities and knowledge, as well as give a realistic cost model against which the Government can evaluate them. However, because Sample Task Orders will not encompass the entire scope of work that could be performed, but rather are snapshots of specific tasks, it is recommended that the RFP also require that offerors respond to a broader set of requirements that covers all potential work scope areas. One means of accomplishing both is to include both written proposals for detailed information and oral presentations of technical approach and related operational information. Finally, evaluation criteria should clearly support selection of best value solutions for fulfilling government objectives and requirements.

Response to Questions –JPM P

- **What factors most limit the degree to which you compete for work with JPEO-CBD?**

Answer: Providing sufficient medical countermeasures to protect against biological and chemical warfare threats has proven to be a daunting challenge. Necessary and sufficient requirements sometimes seem subjugated to DoD desires for novel biopharmaceutical solutions which, unfortunately, diminishes Industry's ability to fulfill DoD objectives. Industry and the FDA are both well equipped and experienced for developing and fielding licensed medical products using proven technology and many decades of experience in developing these products. DoD's requirements for novel unproven technologies and novel regulatory strategies along with excessively compressed timelines are substantial barriers to success.

This, in addition to variable and uncertain procurement schedules and significant changes in the scope and structure of large procurements have been a deterrent to participation with the JPEO-CBD's procurements. As a member of Industry, we have devoted significant time and resource to understanding opportunities, assembling teams and beginning to develop solutions based upon formal releases of information related to procurement schedules and scope, only to have the opportunities completely dissolve, or change so significantly that all prior work is nullified. This is frustrating to us and other members of Industry, and for some has led to a decreased or loss of interest in pursuing contracts with the JPEO-CBD. Furthermore, it undermines the credibility of DoD commitment and resources for these programs; traits fundamental to productive industry partnering. Although we remain strongly committed to supporting the JPEO-CBD and intend to pursue opportunities in the future, it would be very helpful if opportunities were more thoroughly shaped and defined prior to release of information, and if procurement schedules were adhered to more closely. We understand the challenges the Government faces and why that leads to procurement delays and changes, but the severity of those changes in recent years for JPEO-CBD's procurements has been a significant deterrent for many offerors whose services and solutions would likely greatly benefit the Mission.

- **With the reduction in DoD demand for protective equipment, what is the impact to our Industrial Partners in terms of ability to maintain the resident expertise required to produce and sustain protective products?**

Answer: No response

Response to Questions –JPM P

- **In the event of surge, what will be required in terms of funding and other resources to increase production from either a minimum sustainment rate or from a cold start?**

Answer: As was demonstrated with DoD procurement of licensed anthrax vaccine, it is *very* costly and takes years to increase capacity of a previously licensed, biopharmaceutical manufacturing process. With few exceptions, biopharmaceutical manufacturing output of FDA licensable product isn't amenable to 'additional shifts – faster throughput' to fulfill sudden increases in demand. FDA regulation of cGMP manufacturing is comprehensive in scope; licensed processes generally don't have variable yields. If 'surge' capacity is absolutely needed, the most cost effective solution is to establish and maintain licensed production that will fulfill surge requirements on a routine basis. Doses manufactured in excess of requirements for stockpile and use should be considered a cost of business. Alternatives require both novel technologies – for example, greatly extended shelf-life that enables episodic production to sustain stockpiles that meet surge requirements, and novel regulatory strategies – for example FDA cGMP deviations that allow a licensed production process to be 'mothballed and restarted' with minimal consistency lot requirements. Such alternative are probably decades away.

Response to Questions –JPM P

- **What areas of protection and hazard mitigation offer the best opportunities for innovation and meaningful capabilities enhancement for the warfighter?**

Answer: It is our opinion that the best opportunities for innovation and meaningful capabilities enhancement lie in the area of the development and FDA licensure of prophylactic MCMs (generally vaccines) using state of the art products, formulations, manufacturing technologies, and routes of administration whenever the threat is either infectious or toxin based. Prophylactic MCMs offer the most efficient and effective means of protection and have little or no logistical burden after initial administration. Prophylactic MCMs, when available, would provide the surest form of protection for the greatest numbers of troops, and generally at the lowest cost. Uncertain health hazards (product safety) and performance impairment are often cited barriers to MCM prophylactic use; FDA licensure should greatly mitigate these concerns and the licensure process provides ample data to predict impacts on unit performance.

As to the question of innovation and meaningful capabilities it would be developing MCM's using state of the art product and processes, to include production and manufacturing technologies, while working hand in glove with the FDA to develop acceptable regulatory strategies for FDA licensure. Much thought and effort has gone into this in the past as well as in the present. The current approach of developing dedicated facilities for T&E of MCM candidates according to the requirements of the animal rule and addressing regulatory science in an attempt to streamline the advanced development process without compromising safety or efficacy is, in our opinion, a good one. An additional recommendation is that to ensure availability of these licensed products in terms of stockpile management and surge production in times of need will require a "dedicated" manufacturing facility capable of managing the various manufacturing technologies and always available to meet the governments needs will be required. It is also worth noting that the concept of "warm base" manufacturing for biologicals is not a concept currently embraced by the FDA. Generally speaking the FDA inspects and approves manufacturing of licensed biologicals at commercial scale thus the concept of "warm base" manufacturing will require an adjustment in the mindset and approach used by the FDA for inspecting and approving manufacturing facilities for licensed biologicals.