

# **Medical Sector Report**

January 2011

**Perceptions of the Current Directions of the DoD Chem/Bio Defense Program**

**Input from 10/22 Companies**

# Funding Constraints: What to do with limited dollars?

- Unnecessary duplication between DoD and DHHS activities.
- Emerging Infectious Diseases: Why is the DoD expanding its role in this area? This is the purview of DHHS. Why take funds to expand DoD capability?
- Budget Predictability. Small companies (the most active in this space) need to know where to apply resources. Need to know what \$ will be available for what MCM's 1, 3, 5 years.
- Focus on what's in front of you. There are viable MCM's in the pipeline and small companies that need to partner with the USG now to advance them.
- Focus on expanding the pipeline where possible. With increased FDA concerns about safety, development costs are increasing and there is greater risk of getting products through the FDA.
- Better adoption of Best Practices from Industry,

# Manufacturing & Development Facilities

(Consistent message from all respondents)

- Unnecessary. Resources are available in the private sector. There is sufficient manufacturing bandwidth at pilot and full commercial scale to address all stated RFP's. Duplication between DoD and DHHS.
- Biggest issue for companies is inadequate funding for advanced development of promising MCM's that are here today. The new advanced development facilities will compete for funding; on-going operating costs.
- Agree with Dr. Rudolph's comments: "Need manufacturing capability – not necessarily a facility"
  - Don't mistake the existence of bricks and mortar for the ability to produce. Place the emphasis on the availability of competent people up and down the line. How do you ensure this?
- Disagree with the [potential] to take funds from HHS SRF for this purpose. Even if DOA, sends the wrong message to industry.
- Overall, a [high] skepticism of the Govt's ability to successfully operate such facilities efficiently but an acknowledgement that companies may have to participate if it moves forward. Larger companies may be less likely to work with Govt because of the [uncomfortable] precedent it sets for drug development.

# Drug Delivery

There are several drug delivery companies in the Medical Sector. They believe their issues are somewhat different than the drug development companies.

- 1) Focus on putting funding behind rapid fill/finish. It should not be funded only in conjunction with platform drug technologies. There does not seem to be a clear rationale for this.
- 2) We have encountered a brick wall so far as having the DOD consider paying for device development. Improvements that enhance the way the vaccine/therapeutic works should be valued independent of the specific countermeasure.

Thanks to General Scarbrough, John,  
Vince, Mike, Pam & All for making this  
such an enjoyable experience.

I'll be looking forward to reports from the  
Forum.

Best wishes,  
Mark