

CBD AIF

Medical Sector Report

January 14, 2010

Medical Sector Composition

- 21 Companies
 - 20 US HQ
 - All w/some track record of Govt funded programs (DOD, DHHS)
- 12 Drug Development
 - 8 Small-Medium Size Companies
 - 4 Large (Bio) Pharma / Systems Integrators
- 7 Service Providers
 - 2 CMO's & 1 Release Testing
 - 4 Tool Companies
 - Target ID, Molecular Biology, Analytical Dvlpt
- 2 Drug Delivery
- Disconnected from DOD Biomedical unless current funded by DOD program
 - Just another development path for their product/services

“A year into it now, how are the [Companies in Medical Sector] dealing with the Weapons System Reform Act of 2009 – trends and issues?”

- 17 Companies Queried
- 10 Responses

Overall Response

- Most companies were unaware of the WSRA
- General sense that it has not yet had an impact on their activities
- Uncertainty/confusion on how it would apply to drug development
- A few critical comments

Selected Responses

[We were] not aware of the Weapons System Reform Act of 2009. It looks like a pendulum swing back towards more T&E, which generally means longer development time and more costs.

To date, we haven't really been impacted by WSARA. Our program team didn't even know what I was talking about when I asked them. I don't think the contracting changes have really flowed down to CBMS yet.

Would the new processes listed in the legislation also apply to other purchases, such as medical equipment? If so, what happens when there is no other appropriate alternative?

Selected Responses

- Significantly and adversely impacted
 - Delayed and dramatically evolving procurement strategy for CBMS MCM advanced development procurements
- Interpretation of the Act must take into account the crucial differences between MCM development and weapons systems development
 - Standard practices utilized in medical product development should be used as a model for MCM advanced product development
 - Focus on businesses that are qualified to deliver the best outcome at lowest risk to DoD/warfighter versus distinguishing between large and small businesses