

GOVERNMENT CONTRACTS FOR BIODEFENSE

Industry Experts Weigh the Benefits and Challenges

Going after government contracts is often viewed as a double-edged sword. Companies may need to invest considerable time and money with no guarantee of success. This can be especially challenging in the Life Sciences space where many companies are pre-revenue. Yet landing a federal award can provide a company or nonprofit with stability, help with recruitment and, in some cases, benefit their local community or the world.

These are just a few of the gov-con topics touched on during a recent panel discussion organized by the Washington Business Journal in conjunction with BDO USA, LLP, which provides tax, assurance and advisory services to clients around the world in a variety of industry-specific practices, including Life Sciences and Government Contracts. Industry participants also delved into the differences between commercial and federal contracts and voiced their concerns about increasing competition, global instability and the potential for more health epidemics amid our changing climate.

The discussion included input from leaders at the Sabin Vaccine Institute, Pharm-Olam, BioFactura, Ology Bioservices, Rapid Micro Biosystems, and BDO.

There's no substitute for experience when trying to move into the gov-con arena, participants agreed.

In fact, years of experience working with the government has been vital for Pharm-Olam, a global contract research organization (CRO) offering clinical research services to support federally funded clinical trials. And a major component of that experience is learning to effectively communicate with contracting and program officers.

Compliance is another crucial aspect of securing federal awards, Ezzelle explained.

"You're offering a solution

to the government toward their mission, but I think as you do that, you have to be mindful of the compliance around the Federal Acquisition Regulations and really stay in touch with things as they change," he said. As examples, he pointed to the new Other Transaction Authorities (OTAs) as well as ongoing procurement processes, such as open solicitations and Broad Agency Announcements.

Being headquartered near the nation's capital can ease an organization's entry into federal contracting, said Sampey, CEO of BioFactura, a biopharmaceutical company that recently received a \$67.4 million award from the Biomedical Advanced Research and Development Authority (BARDA) for the advanced development of a smallpox therapeutic.

"Since we were very close to Washington, D.C., we did end up coming down to D.C. and, on our own behalf, lobbying for certain grant programs, specifically the Small Business Innovative Research (SBIR) program, which is absolutely critical for emerging companies," he said. "We learned a lot about how things work – most importantly, how small companies with great stories could make a difference in legislation."

Rapid Micro Biosystems (RMB) automates testing within pharmaceutical facilities in order to improve efficiency and data integrity by reducing human error.

The company has received approximately \$20 million in awards from BARDA over the last decade to develop a new sterility test for vaccines.

Relationships in the D.C. area have been vital for RMB, given that its headquarters is in Massachusetts, Spignesi explained. The company worked with a local government affairs consultant to help promote awareness of its research and development, which eventually led to government funding.

"With BARDA, they've been a great partner, providing introductions to various groups within the government," Spignesi said. "And BDO has been phenomenal in helping us. They were indispensable in helping us navigate the contracting and costing process in partnering with BARDA."

House manages the Frederick office of Ology Bioservices, which is a full-service Contract Development Manufacturing Organization based in Florida serving commercial and government clients. His office's proximity to D.C. hasn't helped the company win federal contracts, in his opinion, but it has made it easier to establish personal relationships with people at federal agencies. With the Frederick office, he said, "we believe we can give more immediate, personal support to the government by being accessible to meetings in a short time frame."

Similarly, Davis, with the Sabin Vaccine Institute, never

felt like an insider despite working in the District. The nonprofit institute, which advocates for expanding vaccine research, access and uptake globally, only recently won its first government contract – a \$128 million award from BARDA to advance the development of vaccines against Ebola Sudan and Marburg viruses.

"Despite being located here, that's not a space we've played in," he said. "So finding partners that help us in that space or in any other aspect of the business is really key to what we do. That's probably the biggest takeaway for us: knowing when to seek that expertise or niche when it doesn't exist in-house."

Likewise, executives at Pharm-Olam recognize that even a large company with plenty of in-house experts can benefit from outside support. The company often seeks outside consultants for customized program delivery from both operational strategy and compliance perspectives.

Jia-Sobota from BDO agreed there is no harm in supplementing internal expertise with outside help. "Most of the organizations we work with excel at a very niche area and recognize they need help with the government contract itself. Knowing what you do well and sticking with it is key to success."

Over the years, the event panelists have also learned valuable lessons about the differences and similarities



From left to right: **Robert House, Ph.D.**, Senior Vice President for Government Contracts at Ology Bioservices; **Eric Jia-Sobota**, National Co-Leader of the Life Sciences Practice at BDO; **Rob Spignesi**, President and Chief Executive Officer of Rapid Micro Biosystems; **Andrew Stiles**, Managing Director of the Biodefense & Government Contracts practice at BDO; **Brian Davis**, Chief Operating Officer, Sabin Vaccine Institute; **Darryl Sampey, Ph.D.**, Co-Founder and Chief Executive Officer of BioFactura; **Jason Ezzelle**, Chief Commercial and Government Contracts Officer in Pharm-Olam

between commercial and government work. They can share a similar pathway, such as having to go through the Food and Drug Administration when developing and marketing a drug. But the difference in transparency can be huge, Ezzelle said. The federal government tends to be more open than a commercial entity might be about why one proposal was chosen and others weren't.

Panelists also played down the traditional notion of the "curse" of landing a government contract, including the time and money required for contract administration and compliance. They said only the federal government would offer the support and stability needed for their particular industries.

"Where else are you going to find a market where the buyer pays for all of the development of a product and doesn't take one share of your equity?" Sampey asked. "Nowhere. The government takes no equity in my company. They're contracting me. We have technology that we own that is valuable to them, and they pay us to develop it into a product that they buy."

That rings true for Davis, whose Sabin Vaccine Institute has no shares to offer but still needs funding.

"From the nonprofit standpoint, it's one thing to find funding of a million dollars or a couple million dollars," he said. "Trying to find funding from someone who sees everything through

to Phase I, Phase II and beyond, that's very, very, very difficult."

Stiles from BDO added, "If contractors have the foresight during the proposal process to accurately quantify the costs of post-award administration and compliance, you can build it into the program budget for the contract, and it becomes a reimbursable expense."

Working with the government can offer long-term stability to corporations and nonprofits alike. Federal contracts provide up-front funding and the government's commitment to see a product through at least a few initial stages, which can create a kind of safety net for a business.

A single long-term federal contract can even aid in recruiting top talent, Ezzelle said.

"We're in the service business, so our product is our people. Government contracts are very attractive to our staff for a multitude of reasons including stability," he said. "Many of our government contracts have a five-year period of performance. Some of them have a 10-year period of performance. There's no other industry where you start somewhere and say, 'I know I've got my gig for the next 10 years.'"

At Ology, federal contracts help more with retention than recruitment. Most of the company's contracts have been with the Department of Defense, in support of the U.S. warfighter, House explained.

"We have a pretty significant number of veterans in our company," he said. "That tends to help us have a high degree of employee retention, because there's a great investment by the staff in meeting that mission. They believe that what they're doing at the end of the day is for a good cause and not just about the money."

Despite the benefits of working with the government, several panelists expressed concerns about trends and uncertainties in the coming year.

"What keeps me up at night is that the competitive landscape has grown substantially in the last five years" within the government space," Ezzelle said. "We really have to be more thoughtful about the risks that we take and the particular opportunities that we pursue."

At RMB, Spignesi acknowledges that a meaningful economic downturn would negatively affect companies' capital allocation process. But he's not concerned about the upcoming presidential election or potential regulatory changes.

"We think we're resilient," he said. "If anything, our technology will help customers operate more efficiently and safely if the regulatory environment or economic environment changed."

For his part, Davis worries about what the next "nasty, surprise epidemic" will be and where it will occur – especially

given the potential for bioterrorism.

"Whether it's influenza that comes back like it did 100 years ago, or whether it's Ebola, whether it's somebody who wants to mess around with another disease that's not that well known," he said, "the next epidemic is out there. It's going to come. We don't know which one, and we're all working hard to try to prevent and address that. Climate change is having an impact on that stuff. And so what was never seen by humans before will all of a sudden start being seen."

House, who shares the same concern, is heartened by the recent executive order intended to promote the development of better vaccinations to protect against seasonal influenza and potential pandemic flu outbreaks.

"I see that as a very encouraging message that the government is interested in making sure the populace is protected," he said. "And I think it creates great opportunities for companies in the biomedical space."

Ezzelle, too, sounded an optimistic note. What the pharmaceutical and biodefense industries need are more young employees with great ideas and passion to further the greater good.

"I would like to see more people getting into our industry and doing drug development," he said. "I think it's growing, but I'd like to see it growing more, because we want to help patients."



"You can't separate the science and the financial – not anymore."

People who know Life Sciences, know BDO.



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