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NDIA Panel

Industry Perspective on Innovating in the Current Conditions

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Aktiv Overview



- Colorado specialty pharmaceutical company, specialized in drug-device combination products developing emergency autoinjectors
- Vertically integrated: R&D, device manufacturing, drug manufacturing, and aseptic fill-finish
- Vision: to establish sustainable domestic manufacturing of emergency autoinjectors for the USG
- >\$60M development contracts funding from DoD and DHHS, 2018 to present
- >\$200M BARDA procurement contract



Generating Innovation in Current Government Contracting Environment



- Government objectives must be clear to Industry to develop needed innovative solutions
 - Successful R&D relies on clear achievable end-states and effective acquisition strategies
 - Predictability and trust required to obtain industry's commitment and realization of potential
- Include consideration of Industry risks as part of planning and contracting
 - Reduction of supply chain risks requires planning, teamwork, and resourcing
 - Domestic production requires commitment and nurturing
 - Commercialization and Scale required to mitigate government funding volatility and compete globally
 - Contracting activities/negotiations are resource intensive; transparency and consistency critical
- Contracting terms must be oriented to achieving overall program goals
 - Strong communication and mutual understanding required of all stakeholders' perspectives
 - Creative application of contracting tools to maximize achievement of interim and long-term program goals and support strategic objectives
 - Align all interim contracts to help set conditions to achieve the program's desired end-state
 - Plan for sustainability and surge capacity early in the program

Increased Risks for Small Business



- R&D contracts tougher on small businesses
 - Tight budgets, unrealistic caps on indirect rates
 - Wide-ranging government data rights (GDR) – what might work for research organization is not feasible for manufacturing organization
 - Flow downs de-incentivize sub-awardees
 - Creates high legal exposure due to extensive IP indemnification requirements
 - Lack of clarity, predictability, and commitment inhibits long-term planning and raising necessary capital
- Private investors required
 - Potential investors must be convinced that commercial opportunities exist
 - Requires accurate projections of long-term production and sales
 - Must maintain competitive edge; broad GDR may undermine
 - Reasonable risk levels assumed in business plans
 - Long-term potential for sustainability evident with a diversified and competitive product portfolio



Discussion

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