



United States Department of
Health & Human Services

Office of the Assistant Secretary for Preparedness & Response (ASPR)
Biomedical Advanced Research & Development Authority (BARDA)



BARDA'S

Regulatory and Quality Affairs Division

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BARDA/ASPR

East Cost BARDA Industry Day
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BARDA RQA PROGRAM SUPPORT



- **Provide regulatory advice and guidance, both before and after contract award**
 - externally to companies interested in BARDA contracts
 - internally to Program staff
- **Members of all Project Coordination Teams (PCTs)**
- **Track and assess regulatory program risks**
- **Perform site visits and audits**
- **Provide regulatory oversight and coordination for what is in the HHS Stockpile throughout product life cycle Consult with FDA on broad topics that are relevant to all MCMs**
- **Prepare traditional FDA correspondence for INDs/EUAs sponsored by BARDA**



We are committed to...



- **Providing better communication and dialogue between the regulatory staff on both sides**
- **Providing “Best Practices” to you so that you can benefit from our past failures/challenges/wins**
- **Helping you:**
 - interpret FDA comments, observations, etc...
 - to strengthen your submissions to FDA
 - to prepare for FDA meetings, inspections etc...



Interfacing with BARDA



Contact information:

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www.phe.gov

- Program description, information, news, announcements

www.medicalcountermeasures.gov

- Portal to BARDA
- Register, request a meeting
- Tech Watch

