Biomedical Advanced Research and Development Authority (BARDA)

Regulatory and Quality Affairs Division

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HHS/ASPR/BARDA
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

• www.phe.gov
  – Program description, information, news, announcements

• www.medicalcountermeasures.gov
  – Portal to BARDA
  – Register, request a meeting
  – Tech Watch

• www.fedbizopps.gov
  – Official announcements and detailed information about all government contract solicitations

www.fbo.gov