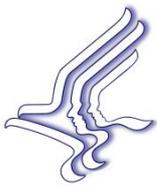




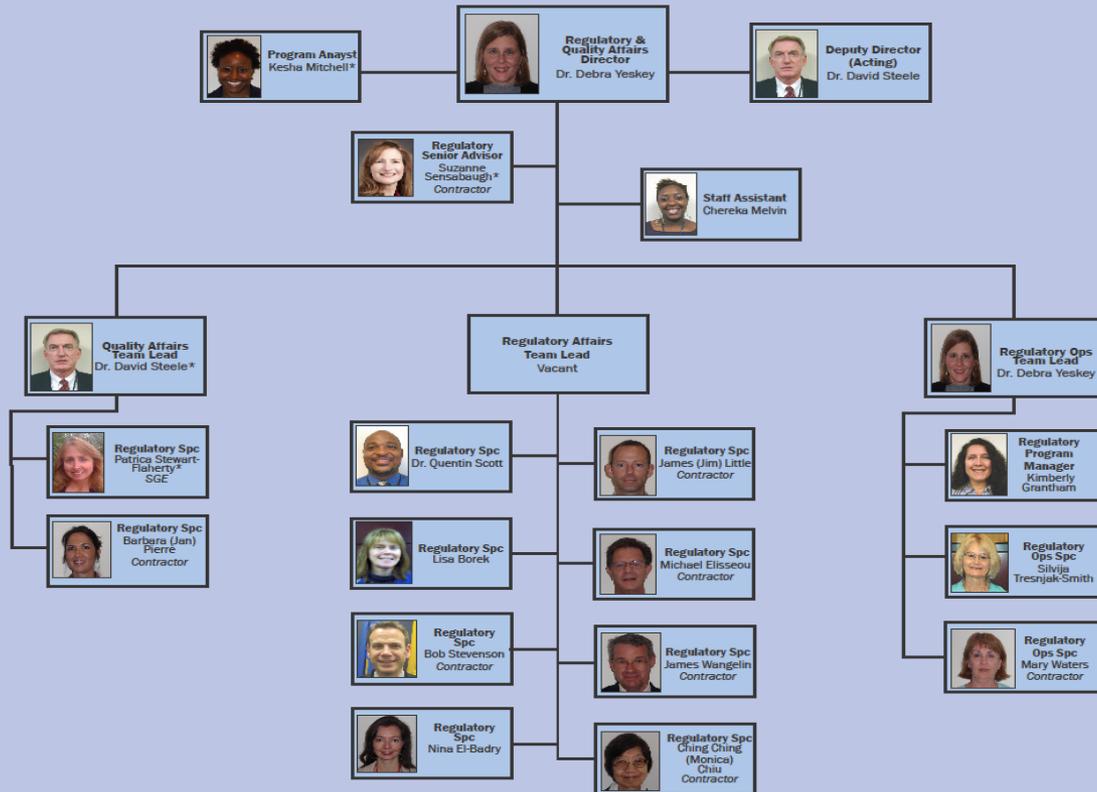
Biomedical Advanced Research and Development Authority (BARDA)

Regulatory and Quality Affairs Division

Debra Yeskey, Pharm.D.
Director, Regulatory & Quality Affairs Division
HHS/ASPR/BARDA

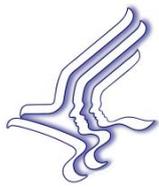


Division of Regulatory & Quality Affairs



* reports to Dr. Debra Yeskey

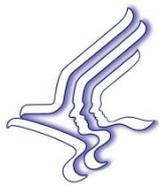
May 2011



BARDA RQA PROGRAM SUPPORT

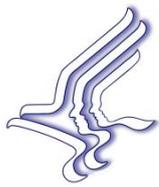


- **Provide regulatory advice and guidance, both before and after contract award**
 - externally to companies interested in BARDA contracts
 - internally to Program staff
- **Members of all Project Coordination Teams (PCTs)**
- **Track and assess regulatory program risks**
- **Perform site visits and 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

