



**ASPR**

# **CGMP Quality Risk Analysis Emergent Bayview Facility**

**BARDA Quality Branch Evaluation**

**April 1, 2020**



# cGMP Compliance Risk

- Substantial evidence of site cGMP non-compliance
- Risk to CIADM Readiness
  - Inadequate Quality Unit Oversight
  - Failure of Quality Systems
    - ✓ Failing to follow site SOP's
    - ✓ Mishandling of cold storage materials: product degradation
    - ✓ Unqualified personnel: QA review
    - ✓ Failed Tech Transfers: Critical Analytical Methods
    - ✓ Loss or misplacement of cGMP supporting data

# Risk Mitigation

- Partner with Emergent Quality
  - Create a Subteam with representatives from BARDA and Emergent Quality
- Quality Agreement
- Remediation CAPA for Readiness based on previous audit reviews
- Site Audits
- Quality Management Plan