



United States Department of

Health & Human Services

Office of the Assistant Secretary for Preparedness and Response



Regulatory and Quality Affairs Support

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Why is RQA Needed



- All contracts geared around eventual FDA approval/licensure/clearance
- Seasoned staff with prior FDA, Industry and consulting experience in Regulatory, Quality and GXP
- Speak, read, know FDA-ese
- Ensure quality is built in not tested in
- Circumnavigating new regulatory paradigms
 - Animal Rule
 - Animal Model Qualification
- Capability to file own INDs/EUAs



RQA Infrastructure





A Day in the Life of RQA...



- Provide **FREE** regulatory and quality advice and guidance on FDA regulations both before and after contract award, externally to companies interested in BARDA contracts
- Reg/Quality SMEs on all Project Coordination Teams
- Track and assess regulatory program risks
- Provide regulatory oversight and coordination for MCMs throughout product life cycle
- Produce and/or facilitate documents that enable end users to use material safely via IND and/or EUA
- Support product infrastructure via submission and maintenance of BARDA sponsored IND studies
- Collaborate with FDA and other PHEMCE partners on broad topics that are relevant to all MCMs



Focus for 2013



QUALITY

Quality is not an act, it is a habit.

Aristotle



Alignment with ICH Q10, FDA Guidance, and GMPs



- How to identify risk and mitigate risk?
 - Due diligence, internal audits, annual reviews, supplier management, FDA signals
- Quality Agreements with suppliers, subcontractors...
- Do you search posted Warning Letters? If not, why not?
- What is your Management Review Process?



In the End...



FDA expects Industry executives and their teams to take a holistic, cross-functional, risk-based, proactive approach to regulatory product development to ensure patient safety and product efficacy ...and so do we.

Invest in compliance, build quality into your product, beginning, middle and end.