Medical Countermeasures Development
Decision Process for Acquisition Management

Decision Gate

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ASPR Acquisitions Management System Policy

- Policy: Signed February 25, 2011
- Establishes Mandate to use Decision Gate Process
- Decision Points Align BioMedical Product Development Projects to FDA Developmental Phases
- Defines the monetary level for appointment of the Milestone Decision Authority
- Identifies other key roles for the process including the Secretariat and the AMCG Director
**ASPR Acquisition Management System - Decision Gate**

**Decision Gates Align with FDA Developmental Phases**
- Discovery
- Preclinical
- Phase I
- Phase II
- Phase III
- File
- Launch
- LCM

**Transition zone**
- Define Rqmts, Prioritize Needs & ID Metrics

**MDA Determined by Obligated Value**

<table>
<thead>
<tr>
<th>Category</th>
<th>Dollar Value</th>
<th>MDA</th>
</tr>
</thead>
<tbody>
<tr>
<td>MAC 1</td>
<td>&gt; $ 300M</td>
<td>ASPR</td>
</tr>
<tr>
<td>MAC 2</td>
<td>$ 200 – 300M</td>
<td>PD ASPR</td>
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<td>MAC 3</td>
<td>$ 50 – 200M</td>
<td>Office Dir</td>
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<td>MAC 4</td>
<td>&gt;$10-50M</td>
<td>Prog Dir</td>
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**MDR/IPR Reviews**

MDR – Milestone Decision Review
- Based on development life cycle defined time points
- Occurs between MDR Reviews

IPR – In Process Review
- Event Driven or Annually at a minimum
- Responsibility of the Project Officer (PO) to inform the MDA in consultation with the Contracting Officer
Decision Gate

- **Purpose:** To determine the status and management of a development project with the capability of improving the potential outcomes through transparent and thorough review and documentation.

- **Decision Gates:** Align with FDA developmental Phases and are Critical “go-no go” points within program.

- **Metrics:** The means to judge performance between and at decision points (to include organizational transitions).

- **Integration/Teaming:** A means to involve stakeholders within decisions and execution.

- **Development:** Tested in BARDA/CBRN since 2008 to begin identification of best practices and lessons learned for greater implementation.
MDR/IPR “Event” Criteria

- Decision Gate Major Milestones
  - First in Human
  - Start of Phase II
  - Start of Phase III
  - NDA / BLA Approval
  - Life Cycle Management

- Review Benefits
  - Entrance / Exit Criteria
  - Promotes Life Cycle Planning
MDR/IPR “Event” Criteria (cont.)

- **Breach** -
  - Cost, Schedule, Performance (Technical) deviations
    - 10% deviation from cost level
    - Projected deviation of 4 months or more
    - Project milestones will not be achieved within the PoP
    - Based on risk assessment of PCT and SMEs
    - Contractor ability to meet technical requirements / objectives of the contract

- **Option Execution** –
  - Review requirement for exercising a contract option
MDR/IPR “Event” Criteria (cont.)

- **Modification Request** –
  - Increases total contract value
  - Alters schedule and achievement of milestones
  - Result of outside factors (FDA as an example)

- **Guidance** –
  - The PCT can request an IPR for the purpose of leadership and stakeholder guidance on issues they are unable to resolve

- **Annual** –
  - If none of the previously mentioned issues is realized all programs >$10M in obligated funds will be reviewed annually
Decision Gate Benefits

• Consistency of management thru standardization of process
• Accurate assessment of project status
• Involvement of Stakeholders – Uniform Strategic Plan
  – Consideration of End User requirements
  – Consideration of Regulatory landscape
• Thorough consideration of options
• Early identification of issues and resolution
• Assessment of resource requirements (e.g. availability of funds)
Format Options

- **Current Practices**
  - Four Part Review Session
    - Contractor Presentations
    - Q&A with Contractor
    - PCT Presentation
    - Government Only Q&A
  - Stakeholder Involvement

- **Optional Format**
  - Two Part Session
    - PCT Presentation
    - Government Only Q&A
  - Stakeholder Involvement
Business Tool Kit Initiative
Business Tool Kit

- Explanation of Examples and Uses
- Work Breakdown Structure
  - Aligned to BARDA Reporting Requirements
- Integrated Management Schedule (IMS)
  - Example includes cross references between documents
- Contract Milestone Chart
  - Used as metrics for progress determination during reviews
- Sample Project Management Plan
- Sample Sub-Contractor Management Plan
- Risk Management Plan
  - Illustrates impact on project if risks are realized
Questions