2 Divisions, 1 Purpose: Regulatory Support for fielding Medical Products for the Warfighter

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USAMMDA
US Army Medical Research and Materiel Command
25 March 2015
Purpose

- Division of Regulated Activities and Compliance (DRAC) and Clinical Support Services Division (CSSD) within the United States Army Medical Materiel Development Activity (USAMMDA) provide tailored regulatory support to product developers across the Department of Defense.

- USAMMDA regulatory teams currently support
  - Over 80 active projects
  - 20 additional potential and/or developing projects
  - 70 clinical studies in varying stages

- USAMMDA integrated regulatory team
  - The Surgeon General (TSG), Dept. of the Army = Sponsor
  - Principal Assistant for Acquisition (delegated sponsor authority)
  - Senior Regulatory Affairs Advisor (advises PAA)
  - Division of Regulated Activities and Compliance
  - Clinical Services Support Division

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Army Efforts/Partnerships Mimic Industry:
Integrated Product Teams (IPTs)

- Typical Members:
  - Program/Project Manager
  - Regulatory Affairs
  - Manufacturing/Testing Support
  - Clinical Management Support
- Team consensus decision with dispute resolution board
- Support tailored to product development strategy
  - TSG Sponsored – active development and management of regulatory strategy, manufacturing, and clinical development
  - Not TSG Sponsored
    - Inexperienced sponsor – active oversight of sponsor’s development efforts
    - Experienced sponsor – consultant to sponsor and IPT

Industry partners are typically sought by Phase 2 and they typically serve as the sponsor through approval (w/ some exceptions).
• All medical products in the Department of Defense (DoD) acquisition framework require FDA approval
  ➢ Regulatory is critical to reduce risk and ensure program success

• Regulatory Management encompasses the processes, procedures, approaches, and standards to assess safety, efficacy, quality, and performance of FDA-regulated products with the goal of expediting product licensure in compliance with regulations (FDA and Army)

• Program delays due to unacknowledged FDA requirements increase cost, lengthen schedule, waste manpower, and increase risk
• Critical to identify if research is FDA-regulated
• Regulatory should be involved as early as possible
  ➢ BEFORE intended use and indications for use are being established
  ➢ BEFORE manufacturing processes are established
• FDA medical product regulations are complex and explicitly required
• Scientific and regulatory development input must be up-to-date
• Maintaining good relationship and good standing with FDA is crucial to continued success
Types of Regulatory Support

• Full
  - TSG-sponsored products funded by the Army and some products funded by other Services (typically Phase 1).
  - DRAC, CSSD personnel provide direct and complete support to product development efforts in one or many of the specific areas

• Oversight (inexperienced sponsors)
  - Ensure compliance with regulations for any sub-contracted work for Army and/or other agencies or partners.
  - Typical examples include review of key regulatory deliverables (e.g., clinical monitoring plans, data management plans)

• Consultation (experienced sponsors)
  - Advice and recommendations
  - Typically for early development and grants management
USAMMMDA Organization Chart

NEW! USAMMMDA Business Office
MISSION:
Provide manufacturing, nonclinical and clinical support services for FDA-regulated medical products throughout the DoD acquisition spectrum, from candidate optimization to product approval.
• Investigational New Drug (IND) manufacturing, testing and accountability
• Clinical study monitoring and data management
• Nonclinical study design and GLP compliance review
• Biostatistical support, including study design and data analysis
• Adverse event reporting and safety surveillance
• Study site visits for cGMP, GLP and GCP compliance
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<tr>
<td>• Adverse Event Review, Causality Assessment, &amp; Reporting to FDA</td>
<td>• Advise and concur on clinical protocol development</td>
<td>• Provide oversight of CRO data management support for all OTSG Studies</td>
<td>• Conduct GMP and GLP facility audits</td>
<td>• Advise and concur on clinical development strategies</td>
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<td>• Product safety surveillance</td>
<td>• Provide clinical site selection and development support, including SOP development</td>
<td>• Provide full support in data collection and management services, including CRF design, data entry and tracking, data cleaning and validation</td>
<td>• Lot release and stability protocol development &amp; review</td>
<td>• Advise and concur on appropriate protocol design</td>
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<td>• Adverse Event Coding (MedDRA) for safety analysis</td>
<td>• Provide clinical trial monitoring services</td>
<td>• Provide full support in technical services in clinical database design, development, testing, validation, and maintenance</td>
<td>• Support IND product manufacturing, testing, shipping, accountability</td>
<td>• Provide data analysis</td>
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<td>• Ensure study volunteer rights are protected</td>
<td>• Provide full and oversight support in medical coding services using the industry standard dictionaries such as MedDRA and WHO-Drug</td>
<td>• Advise on non-clinical study testing requirements</td>
<td>• Provide oversight of CRO statistical support</td>
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<td>• Provide clinical database design and implementation; Design Case Report Forms</td>
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<td>• Advise on assay validation requirements</td>
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<td>• Provide clinical data management support</td>
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<td>• Advise on equipment validation requirements</td>
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<td>• Provide clinical site training</td>
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MISSION:
Provide full-service regulatory support for products through the DoD acquisition spectrum, from individual investigator-initiated clinical studies to products in the advanced development pipeline.
DRAC

• Primary point-of-contact for all formal and informal communications with the FDA

• Develops and executes regulatory strategies for compliant use and FDA approval of Surgeon General, Department of the Army-sponsored drugs, vaccines and devices

• Provides support to IPTs by writing INDs, IDEs, clinical protocols, Investigator’s brochures, annual reports and other regulatory documents

• Provides support for electronic sponsor’s files and submission to the FDA through the electronic submissions gateway (ESG)
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<th>Regulatory Strategy &amp; Consultation</th>
<th>Regulatory Document Submission</th>
<th>Clinical Trials</th>
<th>Licensure</th>
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<tr>
<td>• Representative on tech base IPT</td>
<td>• GLP Protocol Development</td>
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<td>• Pre-IND Package</td>
<td>• Clinical Protocol Development</td>
<td>• Biologic License Application</td>
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<td>• Technical data packages</td>
<td>• Assess data for proposed IND package</td>
<td>• Develop Regulatory Strategy</td>
<td>• Pre-IDE Package</td>
<td>• Annual Report Preparation</td>
<td>• New Drug Application</td>
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<td>• Worksheet creation</td>
<td>• Pre-market manufacturing review</td>
<td>• Regulatory project management</td>
<td>• 513(g) requests</td>
<td>• IB Updates</td>
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<td>• Consultation</td>
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<td>• Drug Master Files</td>
<td>• FDA Meeting Preparation &amp; Coordination</td>
<td>• Safety Reports</td>
<td>• Device Premarket Application</td>
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<td>• Pre-Validation</td>
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<td>• IND Determinations</td>
<td>• Investigational Device Exemption Application</td>
<td>• FDA Meetings</td>
<td>• Label Changes</td>
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<td>• Site Assistant Visits</td>
<td>• Pre-Emergency Use Authorizations</td>
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<td>• Post-market manufacturing oversight</td>
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<td>• Drug Master Files</td>
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<td>• Computer system compliance</td>
<td>• SOP Development</td>
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Initiating regulatory support and partnerships:

- **Regulatory Business Operations Office**
  (usarmy.detrick.medcom-usammda.mbx.regulatory-budget-requests@mail.mil)
- Fill out simple request form
- Meet with DRAC and CSSD team to develop regulatory support plan