

## CRITICAL PATH PHASES

- **Discovery**
  - Tech Data packages
  - Worksheet creation
  - Consultation
  - Pre-Validation
- **Preclinical**
  - Assay Validation
  - Equipment Validation
  - In Vivo Studies
  - Proof of Concept Studies
  - Animal Model Development & Validation
  - GLP Protocol Development
  - SOP Development Support

## MILESTONE "A" REACHED

- **Product Development**
  - Regulatory Project Management
  - Product Manufacturing Oversight
  - Tech Transfer
  - Lot Release Protocols & Review
  - Biostatistics Support
- **Regulatory Submission**
  - Pre-IND Package
  - FDA Meetings & Correspondence
  - IND Preparation
  - IB Preparation
  - Clinical Database Implementation, Configuration & Validation
  - Drug Master Files
  - SOP Development Support
- **Clinical Trials**
  - Database Management
  - Annual Report Preparation
  - IB Updates
  - Safety Reports
  - FDA Meetings
  - Adverse Events
  - Clinical Trial Support
  - Animal Efficacy Studies Support
  - Protocol Development
  - Validation
  - SOP Development

## MILESTONE "B" REACHED

- **Licensure**
  - BLA Preparation
  - Label Changes
  - Annual Report Preparation
  - IB Updates

Several phases in product development may occur in parallel. Regulatory and Quality activities are on-going at USAMRMC. Their activities and oversight are key components to helping the Command achieve quality and regulatory compliance. Each activity produces documents and data that must be managed in an appropriate (compliant) manner.

## USAMRMC Mission . . . .

*Provide medical knowledge and materiel lifecycle management to protect, treat and optimize Warfighter health and performance across the full spectrum of operations*

## USAMRMC Vision . . . .

*We are the world's experts and leaders in the military relevant biomedical research and medical materiel communities, delivering the best medical solutions to enhance, protect, treat, and heal our Warfighters*

### For additional information, contact:

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#### USAMMDA

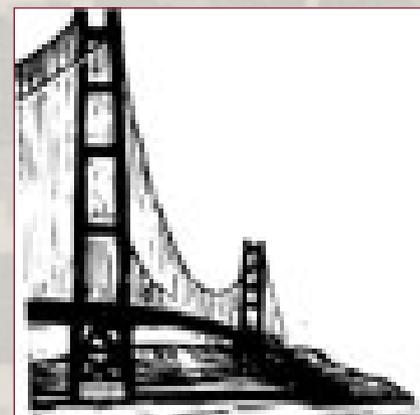
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# USAMRMC



**U.S. Army  
Medical Research  
Materiel Command**

## Division of Regulated Activities and Compliance (DRAC)



*Bridging the Lab Solutions to Our Soldiers*

## USAMMDA

**U.S. Army Medical Materiel  
Development Activity**

*Developing Quality Medical Products  
for U.S. Forces*

*Protect the Warrior; Sustain the Force.*

## Division of Regulated Activities and Compliance . . .

The Division of Regulated Activities and Compliance (DRAC) is the designated Sponsor's Representative to the Surgeon General (OTSG) for the Department of the Army. DRAC's oversight of USAMRMC product development activities ensures compliance with Army, DoD, and FDA regulations and policy.

Three primary operating branches comprise DRAC: Regulatory Affairs Operations (RAO), Biostatistics, and Clinical Operations (CO). Together, the branches ensure that OTSG-sponsored product development activities fulfill all regulatory requirements, including: regulatory filings, clinical monitoring, and product testing and accountability.

DRAC also serves as the liaison to the Food and Drug Administration (FDA) for OTSG-sponsored products and is responsible for directing, planning, and all regulatory activities; including developing regulatory strategies for new product registration and submission to the appropriate regulatory agency.

In addition, DRAC works with other agencies, including Chemical and Biological Medical Systems, Defense Threat Reduction Agency, Navy Medical Research Command, and other partners to ensure regulatory compliance of OTSG-sponsored products.

## Director's Office . . .

- Principal advisor to the Command for Regulated Activities
- Develops and implements DRAC policies and procedures
- Office of Record the OTSG-sponsored FDA submissions
- Ensures compliance for OTSG-sponsored products
- Safety Reporting: Receives, tracks, and reports serious adverse events experienced by subjects participating in clinical trials of OTSG-sponsored products
- Medical Writing and Editing: Includes clinical protocols, Investigational New Drug (IND) applications, investigator brochures, annual reports, and final clinical study reports
- Regulated Systems Management: Ensures compliance to 21.CFR Part 11 activities (electronic document and data management). Coordinating efforts for DRAC to achieve paperless plan for submissions by 2011

## Regulatory Affairs Operations . . .

Three components comprise RAO:

- Regulatory Strategy: Works with product development teams or IPT's from discovery and pre-clinical through regulatory approval (FDA or EPA) for OTSG-sponsored products and provides consultative regulatory support for non-OTSG-sponsored products. Develops and maintains Target Product Profiles (TPP) for OTSG-sponsored products (drug, biologic, or device)
- Regulatory Submissions: Implement pharmaceutical industry best practices and meet FDA requirements in the preparation and submission of regulatory documents
- Document Control: Establishes and maintains official and complete repository of sponsor's regulatory files for research conducted under OTSG-sponsored 510(k)s, investigational and approved drugs, vaccines, biologics, diagnostics, and devices

## Biostatistics . . .

The Biostatistics Group works with colleagues to provide the following statistical and programming services:

- Representation and guidance on IPTs and Clinical Protocol teams
- Review of CRFs
- Randomization and documentation procedures training
- Assistance with the implementation and review of biostatistics
- Statistical programming and analysis through a validated implementation of Statistical Analysis Software (SAS®)
- Study methodology, design, and logistics
- Calculation and review of sample size determination and power analysis
- Development of standard statistical analysis plans (SAPs)
- Final Clinical Study Report preparation
- Attendance with the Investigator team at FDA meetings to provide a biostatistical representative for the Sponsor
- Biostatistics and clinical trial training

## Clinical Operations . . .

- Facilitates efficient and effective performance of FDA-regulated clinical investigations sponsored by OTSG, within the United States as well as foreign locations
- Provides support with a variety of services essential to research; to include assisting with management of OTSG-sponsored clinical research, program planning, clinical monitoring, research methodology, quality risk management and building clinical research capacity through