



Chemical Biological Radiological Nuclear (CBRN) Defense

From FDA product compliance to the fielding and sustainment of detection systems, our analysts, logisticians, engineers, and scientists help ensure our warfighters are equipped and prepared to prevent, respond to, and recover from any CBRN threats.

Supported Clients

Joint Program Executive Office, Chemical Biological Radiological Nuclear Defense (JPEO CBRND)
U.S. Army Medical Research and Development Command (USAMRDC) Office of Regulated Activities (ORA)

Program Management

- Acquisition Strategies and Plans
- Program Reviews and Milestone Decisions
- Continuous Risk Management
- Schedule Maintenance

Strategic Planning

- Streamline Functional Area Processes
- Support Major Defense Acquisition Programs (MDAPs)
- Close Capability Gaps
- White Papers

Lifecycle Logistics Management

- New Equipment Training
- Total Package Fielding
- Provisioning
- Sustainment
- Technical Manuals

Property Accountability

- Defense Property Accountability System (DPAS)
- Logistics Modernization Program (LMP)
- Army Enterprise Systems Integration Program (AESIP)
- Army Equipping Enterprise System (AE2S)
- Web Federal Logistics Information System (WEBFLIS)

Foreign Military Sales

- Letter of Request
- Letter of Acceptance
- Appropriate Defense Security Cooperation Agency (DSCA) Database Budgetary Data
- Life Cycle Sustainment Plans (LCSP)
- Coordinate with Defense Threat Reduction Agency (DTRA)

Quality Assurance

- Lean Six Sigma
- International Standards Organization (ISO) 9001
- Quality Oversight

Financial Management

- General Funds Enterprises Business System (GFEBS)
- Life-Cycle Cost Estimate (LCCE)
- Program Objective Memorandum (POM)
- Automated Cost Estimating Integrated Tools (ACEIT)

Statistical Regulatory Oversight

- Tech Base Programs and Advance Development Programs Technical Assistance
- Statistical Analysis Plans
- Statistical Programming Validation Plans
- Position Papers

Product Compliance

- Food and Drug Administration (FDA) Regulated Non-Clinical, Product Manufacturing and Testing Subject Matter Expertise
- Good Clinical Practice (GCP), Good Laboratory Practice (GLP) and Good Manufacturing Practice (GMP) Subject Matter Expertise
- Clinical and Non-Clinical Studies Regulatory Compliance
- Research Protocol Development and Review
- Assay Development and Validation
- Contract Research Organization (CRO) Oversight

Submissions Support Publishing

- eCTD Publishing Services
- FDA Electronic Submission Gateway (ESG)
- LIQUENT SmartDesk
- InSight and LORENZ eValidator

Clinical Data Management

- Protocol review
- Data Management Essential Documentation
- Database Development, Testing, Validation, and Maintenance
- Statutory, Regulatory, Policy Compliance –FDA, Army Regulations, Clinical Data Acquisition Standards and Harmonization (CDASH), Good Clinical Data Management Practices (GCDMP), Good Clinical Practices (GCP)