



CASE STUDY:

DEPARTMENT OF HOMELAND SECURITY BIOWATCH PROGRAM

Overview: The Department of Homeland Security (DHS) has established the BioWatch Program as a partnership between federal, state and local governments to counter terrorism in the United States. This Program serves an early detection system that provides continuous monitoring for the aerosol release of biological agents 24 hours a day, 7 days a week and 365 days a year in over 30 major population centers. The Program was developed by the Weapons of Mass Destruction and BioDefense Early Detection Division within Department of Homeland Security (DHS) in conjunction with the Environmental Protection Agency, the Centers for Disease Control Laboratory Response Network and other partners.

At the heart of the Program is a team composed of field, laboratory, and public health personnel responsible for daily collection and testing of air samples, providing analysis, result reporting and emergency response activities. Air sample filters are collected daily on a 24-hour collection cycle and transported to a BioWatch laboratory within the Laboratory Response Network (LRN) for analysis.

Business Challenge: DHS sought a prime contractor to manage all aspects of the BioWatch Program. The role of the prime contractor was designed around the mission, goals and objectives of the Program including:

- ◆ Manage the staffing of the BioWatch Program locations - 126 scientific staff across 28 laboratories in 32 major metropolitan nationwide
- ◆ Augment existing BioWatch Program locations as needed, including meeting surge capacity requirements (in the event of an actual BioWatch Actionable Result)
- ◆ Provide Program management
- ◆ Maintain existing equipment and supplies at all lab locations
- ◆ Manage the DHS Annual BioWatch National Workshop
- ◆ Coordinate with other Federal Agencies to provide air sample testing at National Special Security Events (NSSE)

With 32 full-time recruiters operating in offices across North America, Astrix has a robust recruiting engine currently operating in over 26 states, with the ability to expand into other states when needed.

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Service Provided: In July 2012, Astrix was awarded the Prime Contract for the BioWatch Laboratory Staffing Program operated by the DHS. In order to support the BioWatch mission, Astrix provides the following services in the capacity of Prime Contractor:

- Extensive Program/Project Management activities that assist in development, implementation, and long-term operational stability of the Program, along with continuous improvement of procedures, directives, and guidelines:
 - ◆ Contract management/compliance
 - ◆ Maintain required security clearances
 - ◆ Train and maintain surge staff personnel
 - ◆ Recognize/identify cross-training opportunities that reduce costs and negate risk associated with absenteeism and turnover
 - ◆ Provide/update cost estimates and actual costs incurred
 - ◆ Maintain and update project schedules
 - ◆ Draft technical reports
 - ◆ Maintain standard operating procedures
 - ◆ Maintain training and qualifications report
 - ◆ Draft/approve corrective action reports
 - ◆ Safety inspections and reports
 - ◆ Chemical/reagent/equipment inventory
 - ◆ Manage hazardous waste disposal compliance
 - ◆ Maintain government furnished equipment (GFE) inventory
 - ◆ Maintain business continuity report
 - ◆ Maintain physical security in BSL2 and BSL3 labs
- Tasked with the ordering and supply of government furnished equipment (GFE) including analytical instrumentation, fume hoods, reagents, disposables and personal protective equipment for the BSL2 and BSL3 facilities we occupy. Astrix provides DHS with a dedicated full time Laboratory Logistics Manager (LLM) to facilitate the contractual requirement to have a ninety-day supply of all materials required for continuity of operations and/or surge support.
- Astrix technical staff collaborate with DHS on a number of quality and technology initiatives. Due to the potential public health implications with both positive and negative results, BioWatch laboratory operations are under strict quality control guidelines including daily QC samples, quarterly proficiency samples and bi-annual independent third party audits.
- Participate in training exercises for BioWatch staff.
- Provide flexible and coordinated staffing models that identify and select highly skilled scientists that all possess significant Subject Matter Expertise (SME) in the laboratory sciences as it relates to the analysis of select agents. Our staff, many of which have over ten years of Biosafety/Biosecurity experience and advanced degrees, often interface with other leading-edge federal stakeholders supporting the national security mission including the Centers for Disease Control, Lawrence Livermore National Lab, Environmental Protection Agency and Navy NAVSEA Dahlgren Division.
- Astrix senior staff assist the DHS in the assessment of alternative and developing technologies. For example, the Program currently utilizes Real Time PCR (RT-PCR) for daily samples, but our senior staff participated with DHS technical leadership to evaluate the technical, cost and quality implications of moving to multiplex instrumentation.
- Manage the DHS Annual BioWatch National Workshop, coordinating the agenda, lodging, transportation, travel logistics and expense reimbursement for over 100 Astrix and State/local Public Health Lab attendee's compliant with Federal Travel Regulations.
- Develop consistent audit metrics for training and qualifications, as well as procurement, in order to ensure integrity in testing results and compliances with the QA/QC Program.
- Provide monitoring for the aerosol release of biological agents at National Special Security Events (NSSE) – Presidential Inauguration, Super bowl, College Basketball Final Four, Macy's Day Thanksgiving Parade, Rose Bowl Parade, etc. - in coordination with FBI, Secret Service and the CDC.

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Results Delivered: Postcontract award, Astrix was successful in transitioning 100% of existing staff to maintain continuity of mission operations with no loss of service. Astrix maintains a positive (very good-excellent) Contractor Performance Assessment Report (CPAR) for the DHS BioWatch Laboratory Staffing Contract, while also maintaining a dedicated team of scientific recruiters for backfill or staff additions.

Overall performance is monitored on a regular basis through the use of Monthly Status Reports (MSRs), Monthly Staffing and Utilization Reports, and with regular In-Process Review (IPR) meetings where the results and performance are discussed with the Contracting Officer and Contracting Officer's Representative. The performance ratings to date have all been positive, and 100% of required contract deliverables have been delivered on time.

Astrix has successfully provided the following contract deliverables:

■ **DELIVERABLE:** Provide qualified laboratory personnel (7 days a week, 365 days a year, 8 hours a day, with 24/7 readiness) to conduct BioWatch analysis activities.

RESULT: Astrix has maintained a staff which has provided continuous 24/7/365 analysis activities since being designated as Prime Contractor in 2012.

■ **DELIVERABLE:** Provide appropriate staffing levels over the life of the contract to support routine sample analysis. Maintain ability to keep staffing levels from falling below 75 percent at any location for longer than a month and overall staffing levels must never fall below 90 percent per year.

RESULT: The overall laboratory staffing levels from July 2015 to March 2016 resulted in an average of 94.53% which is above the 90% contract requirement. The time to fill a position has also been reduced in the fourth option year and the average days to submit a candidate is 5.47 days, which is below the 12 business day contract requirement.

■ **DELIVERABLE:** Perform operational sample analysis (screen and confirm) within twelve hours of receipt of samples by the laboratory.

RESULT: The laboratory staff assigned to the BioWatch contract currently perform sample analysis in well under the required turnaround time from sample receipt to the reporting of the result, and do so with careful attention to protocol detail and using good laboratory practices (GLP).

■ **DELIVERABLE:** Ensure all laboratory staff are appropriately trained on Program protocols without negatively impacting the ability to complete routine operations.

RESULT: Astrix onboarded a Technical Analyst to develop training that is relevant and can be delivered on-demand. The Analyst developed a modular/phased based approach to training new hires on the BioWatch Program, that has served to reduce necessary training time.

■ **DELIVERABLE:** Ensure that Quality Assurance Program Plan requirements are met.

RESULT: Astrix promoted an ASQ (American Society of Quality) certified quality professional from within the BioWatch Program to serve as a Technical Analyst in charge of assuring that every sample's result is defensible.

■ **DELIVERABLE:** Perform Continuity of Laboratory Operations

RESULT: There have been numerous occasions since Astrix was awarded the BioWatch staffing contract in which laboratory continuity of operations had to be addressed. Whether it was due to a staffing shortage, a special event, or an environmental factor (San Diego Public Health Laboratory roof collapse), the challenge has been met with the same result - Astrix was able to fill the void and maintain laboratory operations.

■ **DELIVERABLE:** Provide laboratory staffing anywhere in the United States and its Territories for specified periods.

RESULT: Astrix has demonstrated throughout its tenure as Prime Contractor for the BioWatch Program that staff can be deployed when the need arises, including during surge activities. In addition, our staffing team has the capability of staffing new BioWatch labs quickly if needed.

■ **DELIVERABLE:** Maintain ability of laboratory staffing to be able to perform, at a minimum, routine operations.

RESULT: Since being awarded the BioWatch Program contract, Astrix has maintained a staff with biology backgrounds that are knowledgeable in real-time PCR as well as other molecular techniques. All staff must pass a formal demonstration of capability prior to handling operational samples independently.

Our transition plans provide a collaborative, disciplined approach based on experience and our understanding of the federal agency community culture, processes, procedures, and requirements. We focus on no impact transitions where 100% of our staff will be working on contract day one.

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