

Design to Deployment: Taking the Lab to the Field



As a Senior Scientist in infectious disease and biological threat detection with MRIGlobal, Jennifer Stone finds new ways to make lab capabilities available in the world's remotest regions

The world is smaller.

With easy access to fast commercial travel options, we can go anywhere on the planet relatively quickly and easily. Worldwide mobility is mostly beneficial, but infectious diseases such as Ebola, avian flu, or Zika, once largely confined to the geographic areas where they originated, now can easily hitchhike into the United States or other countries aboard an unwitting tourist, aid worker, business traveler, or returning military service member.



The possibility of infection has risen exponentially for thousands – even millions – of people who previously never would have encountered these diseases. Similarly, the risk of biological threat exposure for U.S. military personnel has multiplied in far-flung locations as enemy combatants have increased potential to develop dangerous bioagents. In the ongoing fight against infectious diseases and the biological weapons threat, being able to test samples in the field is a powerful defense. It allows faster detection, diagnosis, tracking of outbreaks, and identification and mitigation of biological hazards.

For all our ease of travel, however, it has been virtually impossible to establish and sustain laboratories in many remote locations, where internet access, reliable electricity, and other basic laboratory needs are limited or nonexistent. Samples taken in remote locations still have required transport to fixed-point labs for testing, and those labs may be located hundreds to thousands of miles away. Keeping samples stable during transport often is difficult, and getting results once the sample reaches the lab may take several days, weeks, or even months.

Jennifer Stone, a Senior Scientist in infectious disease and biological threat detection with MRIGlobal, is among the professionals working to overcome these hurdles. Her goal: to improve safety in a mobile world by developing field-forward rapid PCR assays that enable clients to bring the lab to the field.

Start-to-Finish Fundamentals

For government agencies and clinical diagnostic companies, Stone develops detection assays for infectious disease and bioagent threats. She wholeheartedly embraces MRIGlobal's design-to-deployment approach, which saves clients time and money, and means Stone can help create project concepts and see them through to implementation for their planned purposes. Her work entails:

- **Defining the need** - including pinpointing the organism the client wishes to detect, understanding any special requirements for testing in the client's field locations, determining what assay will be most effective for sample testing and identifying the kind of device that will be needed to run the relevant samples and provide accurate results.
- **Determining whether good solutions already exist** - When current technologies and devices generally fit the client's need, MRIGlobal may need only to modify them slightly. Stone must learn what resources will be available in the field and who is likely to be conducting the tests so she knows how simple or complex a device needs to be in its particular application. An end user who is an experienced clinical laboratorian, for example, may have freezers available for reagent storage and may need little or no training to work with a complex platform that runs multiple samples. A typical military user, on the other hand, may need to utilize reagents that are room-temperature stable and an accompanying device that can be used intuitively without training. In all cases, devices need to be small, sturdy, portable, and battery-operated.

When no existing device fits the purpose, MRIGlobal creates a prototype. Demonstrations at points of development invite client feedback, which MRIGlobal incorporates into the model.

If no appropriate assay exists for the project requirements, Stone designs a new one using bioinformatics – the integration of computers and software to understand biological data – to reveal only the organisms the client wants to detect.

- **Conducting lab testing to ascertain how the assay will perform** - When this initial testing is complete, Stone and her team optimize and validate the assay, recording all results to prove out the assay's efficacy. MRIGlobal's breadth of expertise allows the company to take an assay from inception through validation, including FDA clearance, if required.
- **Empowering the client** - Stone and her team create and provide to the client manuals, training materials, and personalized training that describe the assays and how to use them.



Making Lab-to-Sample a Reality

MRIGlobal is uncommon in its ability to present clients with design-to-deployment solutions, Stone said. Many firms are good at one piece of a project or another. They may use bioinformatics but lack lab capabilities for testing. Or, they may be adept at developing and optimizing assays, but not have the skills to complete and keep validation records conducted to the appropriate quality standards.



MRIGlobal's full-spectrum of in-house skillsets include extensive military experience. These capabilities create efficiencies for clients, who work with a dedicated team to accomplish every aspect of the project.

Recognizing the critical need for reliable, field-forward laboratory capacity in the world's most isolated areas, MRIGlobal is demonstrating its design-to-deployment mindset by developing workflows that will, for the first time, "take the lab to the samples" in a consistent way.

One of those examples is the Man-Portable Diagnostic System (MPDS) Program, a Department of Defense program to build a biological identifier capability useable in the field or laboratory for testing surveillance and diagnostic samples. A few devices that can conduct such tests are already in use, but they cannot efficiently deploy to the field. They are too large, may require too much power, and may not provide internet access.



Development of a lightweight, low complexity device for the detection of biological pathogens and infectious diseases.

As the integrating contractor of MPDS, MRIGlobal will ensure that the client is provided a biological identifier capability that is battery powered and only slightly larger than a brick, making it easily transportable and deployable to field locations.

Stone is developing the content for the MPDS that will detect all known genetic diversity of targeted infectious diseases and biological threats and allow the data to be interpreted at the field site. Once complete, the device could be deployed for use by U.S. Special Forces, public health organizations, academic institutions, and others interested in field surveillance and diagnostics.

As globalization continues to make the world smaller, the ability to ask questions and get answers through genomic data becomes increasingly useful. MRIGlobal's design-to-deployment approach, demonstrated through MPDS and other projects, is democratizing technology and ensuring it gets to the areas of the world that need it most.

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About MRIGlobal

Celebrating its 75th year of business, MRIGlobal addresses some of the world's greatest threats and challenges. Founded in 1944 as an independent, non-profit organization, we perform contract research for government, industry, and academia. Our customized solutions in national security and defense and health include research and development capabilities in clinical research support, infectious disease and biological threat agent detection, global biological engagement, *in vitro* diagnostics, and laboratory management and operations.