



Delivering quality services for global health and standards creation In Challenging Environments

An ISO 9001 registered company, we provide quality services to support your team in:

- Infrastructure enhancement in developing countries
- Global health capacity building
- Bureau of standards development

We deliver services to ensure compliance to WHO, ISO, and FDA compliance for healthcare in the US and Africa. Teaming with you, learning your business, and providing custom expertise, Amethyst Technologies controls projects by clearly identifying opportunities for quality improvements, and aligning with your mission.

We are well known for developing quality systems in challenging environments with aggressive deadlines, and currently support Malaria Diagnostics Strengthening, HIV Testing Programs, and DoD emerging infectious disease programs with a variety of key services and an excellent track record of success.



Saving lives and reducing costs worldwide by accurate medical diagnostics and development of standards

- Drug control facility start-up, management, training for WHO compliance
- Training for diagnostics and quality systems to build in-country capacity
- Harmonization of training and healthcare programs across multiple countries
- Independent assessments for global health
- Capacity building for medical diagnostics and pharmaceutical manufacturing
- Infection control programs
- Mobile technology and SMS for healthcare and surveillance
- Quality control for hospitals in compliance to ISO and WHO
- Sustainable “green” lab operating programs
- Medical countermeasures preparedness
- Blood bank quality programs
- Epidemiological data analysis and trending

An ISO 9001: 2008

ISO 17025:2005 Company

CERTIFICATIONS:

SBA 8(a), MDOT MBE, MSDC

DUNS Number: 784983806

NAICS Codes:

541330 541380 541511
541690 811219 334513
541990 519120

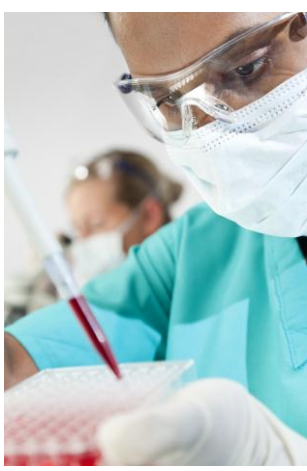
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Because Ensuring Quality and Managing Compliance is So Critical

Amethyst solutions include:

1. Identifying and assessing individual compliance needs for equipment, software, documentation, or processes unique and detailed to each facility.
2. Providing comprehensive report, proposal, and gap assessment, plus opportunities for achieving compliance goals.
3. Executing the plan, with standard operating procedures, development, implementation, and overall program responsibility including training and continued compliance.

Amethyst In Action:

Resources for Improving Malaria Diagnostics in Africa: WHO and FDA Compliance

- Provided lab strengthening to develop centers of excellence for malaria diagnostics across Tanzania to facilitate access to healthcare and provide a place to train community health workers.
- Developed quality assurance and control procedures tailored specifically for the remote labs in Tanzania that covered materials, equipment, labeling, storage, waste, safety, and quality control for performing malaria diagnostic tests.
- Performed comprehensive baseline assessments and periodic reassessments for 16 sites in mainland Tanzania and Zanzibar based on ATL developed checklists.
- Facilitated one and two week training courses on malaria microscopy in Tanzania and Kenya; training more than 100 persons in 2011 that resulted in improvement in malaria diagnostics.

Results? We improved microscopy competency by 50%, reduced false positives from 70% to 15% allowing for accurate diagnosis and reducing drug resistance, and safety practices improved 26%.

Innovative and Proven Effective SMS system for Global Health

Developed a mobile system solution to improve quality assurance surveillance for malaria diagnostics throughout the DOD by collecting patient and site information from the field via text messages and pictures. Data collected with real-time viewing capability included patient and site data. Created a software application in English and Swahili that validated entries and provided feedback to technicians and supervisors.

Results? Stakeholders received access to critical information, travel costs were reduced with access to patient, site, and crosschecking data in remote places, and the new real-time malaria control program delivered efficient and equitable distribution of drugs based on disease prevalence.

Quality Control Consulting for HIV Diagnostics in Africa

- Provided quality control consultants for hospitals in Tanzania to provide training on HIV diagnostics, safety procedures, equipment maintenance, material management, and documentation in conformance to ISO 15189 requirements.
- Managed day-to-day operations for the laboratory including briefing of hospital management and country director.
- Performed emergency on-call HIV testing services.

Results? Quality control services provided confidence in the accuracy and safety of diagnostics and the capacity of HIV diagnostics was increased in remote areas.



Amethyst Technologies LLC

"Rock Solid" Validation

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