



Mitigating risk for your new or renovated laboratories

Is there a transition plan in place for relocation? Are requirements all incorporated? Is your cold chain management program formalized to preserve temperature sensitive materials? If your new or renovated lab cannot meet process and compliance requirements, there will be delays, changes, and additional costs.

As an ISO 9001 registered company, we provide quality services to support your team so you can focus on safety, accuracy, and efficiency in achieving scientific milestones. We control projects by clearly identifying opportunities for quality improvements, and aligning with your mission. We're well known for developing quality systems in challenging environments with aggressive deadlines.

Development and Implementation Expert Services for New and Renovated Facilities

- Transition Programs for relocation of lab activities
- User requirements management
- Equipment validation and calibration (GMP, GLP, ISO, WHO)
- Commissioning for new systems
- Auditing for compliance to internal policies and regulatory agencies
- Change Control management
- Records management including data archiving
- Cold chain management
- Building automation system management and validation
- Training programs
- Standard operating procedures for equipment and quality systems.

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.



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

CONTACT:

PHONE: (443) 543-5576

FAX: (443) 543-5574

info@amethysttech.com

www.amethysttech.com



Amethyst In Action: A Quality Management System for DoD Laboratories

Amethyst created a quality management system including a quality plan and standard operating procedures pertaining to FDA compliance, good documentation practices, maintenance, stand-alone computer systems, calibration, and training procedures for the building management system in BSL3 and BSL4 laboratories.

We then constructed a training program for personnel that covered system functionality, change control, alarm handling, and documentation. We performed annual validation, performance qualification, and calibration for the building management system to verify that facility requirements for cold chain management were achieved, alarm settings were appropriate, and the system notification methods were accurate and up-to-date. This eliminated random alarms and ensured that reported environmental data values were accurate.

Monthly data trending for environmental data in critical areas was provided to achieve DoD

requirements and FDA expectations. We also provided management of archived data and system backups.

Amethyst developed, implemented, and managed the transition to a new lab facility by developing the written plan, which included changing to a new building management system and running in redundant mode initially. User requirements were managed and communicated to the vendor, which facilitated rapid installation with parameters and system "Right the First Time." standard operating procedures (SOPs), test plans, system alarm templates, and training were developed and implemented by us with the building management system vendor.

New equipment was procured for renovated labs, including sterilizers, reverse osmosis deionized water system, freezers, refrigerators, incubators, and centrifuges. We developed commissioning, validation, equipment relocation, and cold chain management plans for GMP compliance. Commissioning, calibration, and validation were performed for equipment in accordance with Amethyst's ISO 9001 and 17025 approved quality SOPs.



**Amethyst
Technologies LLC**

"Rock Solid" Validation

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

CONTACT:

PHONE: (443) 543-5576

FAX: (443) 543-5574

info@amethysttech.com

www.amethysttech.com

