Amethyst delivering for laboratories and healthcare

Every day, Amethyst professionals work in labs, DoD facilities, the healthcare industry and worldwide, with a wide range of expert services from regulatory and healthcare experts, pharmacists, engineers, calibration technicians, technical writers, software developers, and sustainability experts. We deliver excellence and a proven track record, as demonstrated by the following selected client profile.

**An ISO 9001: 2008
ISO 17025:2005 Company**

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Developing and Implementing a Records Management System at a Department of Defense Laboratory

The Challenge: The lab's Quality Assurance (QA) office is tasked with implementing, maintaining, and improving quality systems at the lab and oversees all quality and regulatory compliance programs. They developed and implemented a records management system and Amethyst led the effort. Given our experience in managing sensitive information of this nature, the company is well suited to the task.

Project Development and Implementation: Establishing a records management system for the lab provides the basis for identifying the information held by the organization, in addition to providing for the safe and reliable storage, management, retrieval and disposition of organizational records.

The Records Management System Includes:
- Developing and implementing a document management system built on the MS SharePoint platform for storage, maintenance and control of lab documents.
- Performing an inventory and assessment of all records at the lab to differentiate among the various sources of information and their importance to the lab.

- Determining what documents will be considered records.
- Developing physical and intellectual controls for the records in accordance with basic record principles and DoD regulations.
- Harmonizing with current DoD records control practices by fully implementing the Army Records Information Management System (ARIMS) at the lab for use in the management of hardcopy and electronic records.

Impact to the Lab: Prior to development of the system, the lab did not have optimal intellectual control over records stored at the facility. Procedures were in place to provide for the physical control of records maintained by the laboratory, but there was no system in place to access intellectual information held in the records. The lab had no way of determining what it had in its historical records.

The new system not only allowed for intellectual control over records retained by the lab, but also brought the facility into compliance with current DoD records control practices (ARIMS). Our certified archivist and quality assurance specialist led the team.

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Timeframe: We started work in October 2010 and achieved these successes within 12 months. During implementation, approximately 620 linear feet of hardcopy records and 500 digital records were reviewed, assessed and incorporated into the new program. This was the first formalized effort by the lab to implement a records management program of this kind, and records spanned 50 years.

Results: As a result of our work at this facility, the following policy is now implemented by the lab: Army Regulation 25-400-2, "Information Management: The Army Records Information Management System (ARIMS)."

Amethyst is continuing its work by providing continual support and consultations to all laboratory offices upon request, as well as maintaining the lab records management program in compliance with the latest DoD records management guidelines.

Under the guidance of Amethyst, the lab now has complete access to the information held at its facility and has a reliable means to store, manage, retrieve and dispose of such records. Having the system in place has allowed this DoD facility to more efficiently and effectively achieve its mission objectives.

Amethyst Delivers Innovative, Cost Effective Development and Implementation:

- Quality programs to achieve scientific milestones safely
- Training programs for diagnostics and quality systems
- Equipment qualification and calibration
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- Auditing for compliance to FDA, WHO, ISO, USDA
- Special engineering studies and analysis
- Computer information technology for healthcare, laboratory management systems, mobile data systems, technical training software
- Sustainable "green" laboratories operation programs
- Cold chain management
- Environmental monitoring and building automation system management
- Commissioning and qualification for clean rooms, HVAC systems, utilities.

PROJECT AT A GLANCE:

- Implementation of MS SharePoint Document Management System

- Inventory and Assessment of 620 Linear Feet of Hardcopy Records and 500 Digital Records

- Intellectual and Physical Control of Lab Records

- Compliance with DoD Records Control Policy AR
- 25-400-2

- Safe and Reliable: Storage, Management, Retrieval and Disposition of Records