

NETWORKED AGILENT OPENLAB CDS AND OPENLAB DATA STORE

A Secure Data Management Solution
A Win for Flamma's IT and Lab Operations

Customer Profile:

Flamma



Chignolo d'Isola facility

Flamma S.p.A. is a worldwide specialty pharmaceutical chemical manufacturer with over 60 years of experience and know-how in the field of chiral building blocks, such as high-value amino acid derivatives.

Headquartered in Bergamo, Italy, the company's capabilities include the manufacture of chiral starting materials and intermediates for the pharmaceutical and biotechnology industries. Flamma also manufactures materials for the nutraceutical and cosmetic industries, and develops and produces related compounds classified as Active Pharmaceutical Ingredients (APIs) and finished products.

Choosing a data management solution to meet regulatory requirements

In serving the world's leading pharmaceutical manufacturers, Flamma ensures its products meet regulatory requirements. To facilitate 21 CFR part 11 compliance, the company sought to upgrade its Agilent chromatography systems to an integrated solution with secure central data storage.

Chartered with managing and safeguarding the company's information assets including analytical data, Flamma's IT department embarked on the important task of choosing an efficient, easy-to-use, flexible solution. The choice? A networked Agilent OpenLAB CDS system with OpenLAB Data Store.

"The IT department has the responsibility to manage and safeguard the company's data. Therefore, one of our important tasks is to choose a system that is efficient, easy to use and flexible."

PAOLA PRANDI, IT MANAGER, FLAMMA



Benefits gained

- Secure, central data storage streamlines compliant data management across cGMP manufacturing sites
- IT-managed licensing, disaster recovery and backups, save time and free scientific staff to focus on analytical work
- Centralized system management and data storage reduce hardware infrastructure costs
- Win-win solution strengthens collaboration between IT and laboratory operations

The situation

Flamma has two cGMP facilities in the city of Bergamo: Chignolo d'Isola and Isso. Together, the quality control (QC) laboratories at these two sites use three Agilent GC and seven Agilent LC systems. Prior to the OpenLAB CDS upgrade, these GCs, and LCs were controlled by stand-alone Agilent EZChrom and ChemStation chromatography data systems (CDS) running different versions of software. Data backups to DVDs, performed in duplicate at each individual workstation by laboratory staff, were time-consuming and tedious.

The solution

Upgrading the standalone Agilent CDS to networked OpenLAB CDS with OpenLAB Data Store was the solution chosen. Residing at the Chignolo d'Isola facility, OpenLAB Data Store provides secure central data storage for data produced at both sites. Agilent staff assisted with the installation and training.

The OpenLAB networked solution provides local instrument control, central system administration and a lab-wide view of all connected instruments. OpenLAB Data Store data management software delivers the added benefits of central data storage and fast retrieval of data from anywhere over the network.

The result: time savings, increased efficiencies and reduced costs

The OpenLAB solution enabled the IT department to achieve its goals while reducing hardware infrastructure costs for maintenance and data centralization. At the same time, responding to customer needs for regulatory compliance and laboratory needs for easier, more efficient software and data management, resulted in stronger collaboration between departments.

With the networked solution's central system administration capabilities, the labs now routinely engage IT department services to manage licensing and software and data backups, freeing scientific staff to focus on their work. The labs welcomed a solution that saves them time—at least a half-day per month total—by shifting IT tasks to IT staff, the staff best qualified to perform these tasks properly and efficiently. The solution ensures that data is always available and easily retrieved.

The solution also enabled IT to establish a disaster recovery plan for the chromatography data systems.

"Responding to end-customer needs for regulatory compliance and internal needs for easier, more efficient software and data management resulted in greater collaboration between departments."

PAOLA PRANDI,
IT MANAGER, FLAMMA

"Using the networked OpenLAB Data Store solution, we are sure that all of our reprocessed data is always available and easily retrievable."

DR. STEFANO GOBBATO,
QC LABORATORY MANAGER, FLAMMA



Isso facility

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Published in USA, January 27, 2014
5991-3838EN

