

# CHANGES ARE UNAVOIDABLE...

**W**The pharmaceutical production process is strictly regulated in accordance with stringent international pharmacopoeia standards and, in the case of products destined for the U.S. market, must comply with the regulations of the Food & Drug Administration (FDA). Even plant information systems are subject to validation and change control procedures defined by the company's Quality Control/Quality Assurance Manager. All computers or PLCs which manage parameters that are critical to GMP (Good Manufacturing Practice) compliance must be accompanied by a precise documentation system, which is revised whenever modifications are made to the computer or controller during its lifecycle.

## A COMPLEX TOPOLOGY FOR GUARANTEED SECURITY

GlaxoSmithKline (GSK) is a multinational pharmaceutical company that serves 160 markets worldwide. The American firm, which employs 100,000 people in 91 production plants and manufactures over 1400 products, has a market share of 6 per cent and is the world's second largest pharmaceutical manufacturer.

In Italy, the company employs a workforce of 400 in its Parma plant alone. The site comprises a number of buildings housing different departments, each of which is responsible for specific products and their relative packaging processes. The plant specializes in the preparation of various pharmaceutical forms including tablets, syringes, vials, freeze-dried products, nasal sprays and oral solids.

GSK Operation in Parma



Translated from Automazione Oggi

The company network infrastructure extends to both offices and production (Automation), and there is a clear separation between the two divisions. The Automation network is based on Ethernet and each department has its own fiber-optic ring with different optical switch modules (Siemens industrial Ethernet OSM), where the relative PLCs and SCADA systems are connected.

All the rings converge in a 'star center' where other servers are connected, but these rings (and therefore the departments) remain isolated from one another. In fact, the network has around 70 connected devices including PCs and servers used for supervision and monitoring (SCADA/HMI), in addition to data collection systems. The same network also has around 150 PLCs of varying ages and models (mainly Siemens S7 and a number of S5) with traffic and different communication protocols, including some which are not IP-based.

The 'star center' of the network is mainly used for two purposes: to perform hardware diagnostics on all the PLCs, before sending SMS messages to technical personnel in the event of malfunctions, and to automatically check the software installed on the PLC against the archived backups.

The Automation network also includes a Web server that enables remote (off-site) diagnostic checks to be performed on individual PLCs. In fact, users with sufficient permission to access the system can, by means of a VPN connection and an Internet browser, display HTML pages which provide instructions for starting the development environment with the relative design of the PLC to be analyzed. This system is very useful for guaranteeing business continuity and for managing emergencies that exclusively call for specialist intervention.

The segregation of the various rings and access to and from the Internet is managed by various firewalls which are suitably configured. Finally, each department has industrial wireless access points that enable technical personnel to perform diagnostic checks with their laptop in close proximity to the machine, once the electrical control panels and relative PLCs have been installed in a technical compartment above the production floor.

**The greatest challenge? Keeping track of all the changes**

Technical personnel don't always ap-

preciate the need to follow operating procedures to the letter in highly regulated environments such as the pharmaceutical industry. Nor is it easy to keep control over software installed on hundreds of machines using only manual procedures.

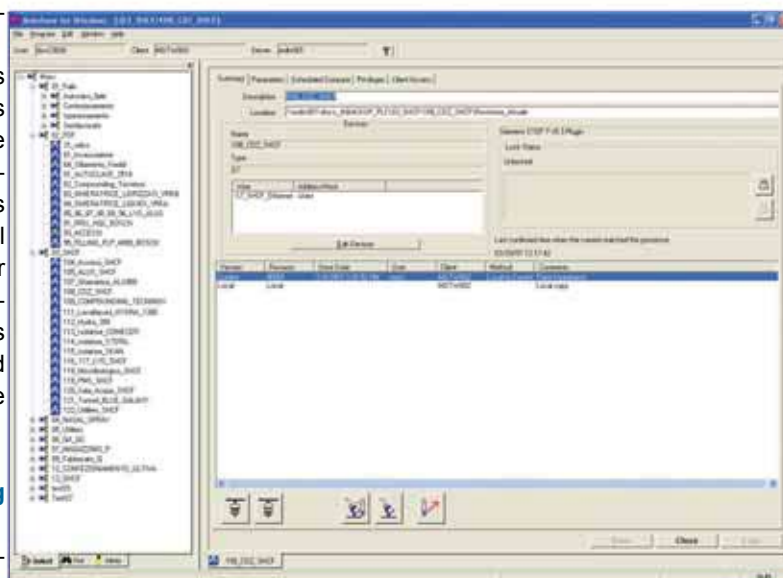
In order to maintain continual compliance and optimum functionality, it was necessary to switch from manual management of the software archive to an automatic system. Even the periodic control of software, which was performed once a year in manual mode, can now be performed once a day in automatic mode. This approach minimizes human error and increases efficiency in terms of technical support and maintenance.

One of the most critical aspects in the configuration of factory networks comprising dozens of different PCs with supervisory and plant monitoring applications (SCADA/HMI), linked to over a hundred PLCs of varying type, is the change control and configuration management of all software installed on the PCs, as well as on the controllers.

Generic off-the-shelf systems for managing the configuration of computers connected over a network are widely available on the market. Nevertheless, most are highly intrusive and are poorly suited to production environments. In fact, their drawbacks are particularly apparent in regimented environments such as pharmaceutical production. Furthermore, these tools are unsuitable for the change management and version control of PLC software.

**The release management project**

The project was implemented by GSK in conjunction



MDT Autosave allows the real-time change management

with a systems integrator with tried-and-tested experience in the pharmaceutical sector: SIA s.r.l., based in Verona. The project was also supported by Siemens (Padua branch) and Vision Automation, distributor of MDT Autosave software in Italy.

Following approval of the project, the network infrastructure was extended to include those departments which were still not connected. In addition, all versions of individual backups

environments. MDT AutoSave is actually an environment consisting of interactive, real-time change management tools for software and industrial applications installed on programmable logic controllers and PCs (HMI/SCADA), intelligent plant devices, software and relative documentation.

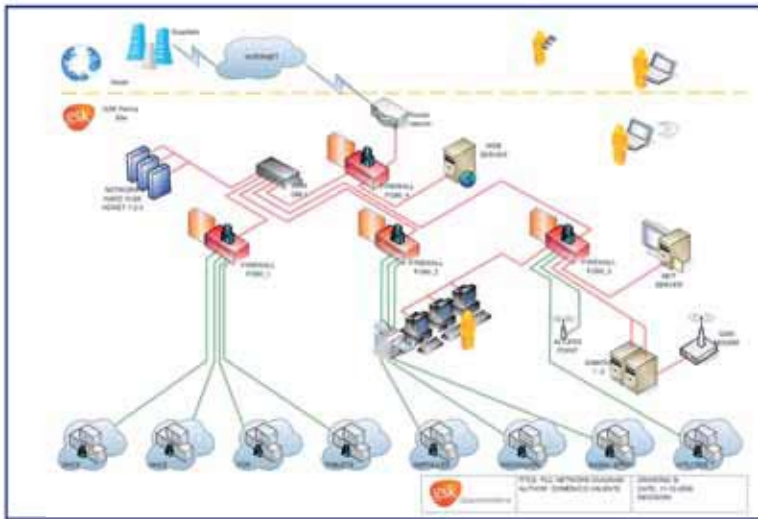
MDT AutoSave integrates all the software needed for industrial plant automation into a single user interface, creating a centralized, documented, controlled and well-defined environment that increases productivity while guaranteeing the secure management of projects and complex installations consisting of industrial devices and software.

MDT Autosave has become the centralized repository for all the software versions of every programmable logic controller present in the system, both those connected over the network and standalone PLCs installed on machines and systems that are not permanently connected to the plant infrastructure.

Besides backup management, MDT Autosave is a vital tool for change control and configuration management. The control application performs periodic checks – automatically and in a non-invasive way – which detect any variations in the configurations and versions of the PLC software. In the event of discrepancies between the version running on the PLC and the version saved and validated on the server, the application generates a report which precisely details every change encountered. This report is automatically sent to the Plant Automation Manager and Quality Control Manager, who decide what actions may be necessary.

#### The benefits of Change Management

In addition to the obvious benefits derived from using MDT Autosave to optimize the control process, the application also makes it possible to considerably strengthen access control. This applies both to access by local users, as well as to external access by authorized third-party maintenance personnel, who have been granted the appropriate permissions to perform remote interventions on components and devices linked over the network (computers and PLCs on production machinery) for the purpose of implementing, installing, configuring and maintaining programs.



GSK complex plant topology grants the security

made of PLC software were standardized. In particular, checks were carried out on the hardware configuration of the controllers and on their network connections with other devices.

At the end of this preliminary alignment phase, the backup images were loaded into the server allocated for software archiving. This server was physically installed in the company's EDP (electronic data processing) room and also functions as a domain server for the Automation network. Only authorized users can access this server.

A further level of protection was implemented by protecting the controller CPUs in write mode only: in fact, a different password was entered for each CPU. Additionally, a number of vital installations which were still managed by PLC S5 (115 and 135), were integrated into the network during this phase.

After having conducted all the tests and produced all the necessary documentation, the project team proceeded to the configuration of MDT Autosave.

#### The MDT Autosave solution

The solution adopted in this production plant is based on MDT AutoSave, the software package distributed in Italy by Vision Automation, which is specifically designed for the configuration management of PLCs and PCs used in factory

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