



# Movicon is permanently FDA 21 CFR Part 11-ready in the pharmaceutical sector

***Movicon consents variable data printing on bottles for OCR print control in the pharmaceutical sector. Good and rejected bottles are divided at the end-of-line reject station.***

SPH Group Srl offers solutions that fully integrate in the pharmaceutical process line thanks to its multidisciplinary approach and skills. The Group is synonymous with quality and flexibility obtained over years of experience in the pharmaceutical, cosmetics and food and packaging industries. By continuously updating their know-how they are able to propose technical solutions in perfect harmony in respect to the Good Manufacturing Practices (GMP) guidelines. Specifically, the SPH Group offer turn-key Solutions to provide technological systems with SCADA control and supervision systems that comply with the 21 CFR Part 11 normative according to client needs. Each

project design engineered by the SPH Group is accompanied with a preliminary study to create an architectural model of the client's plant. Once this has been completed they can then propose the most suitable technological solution that integrates best with the industrial framework in which it is to be deployed. The company, from Abruzzo in Italy, put the client's demands into perspective and support the whole procedure beginning with defining the User Requirement Specifications in detail and then building and validating the most appropriate system accordingly. A feature that distinguishes this group is its capacity to provide the client with a system that



1. Bottle cap sealing machine

perfectly aligns to the functional needs throughout the project development phase.

### System Description

The system is installed downstream in a pressurized cap sealing machine that seals caps any type onto compatible cylinder shaped bottles of various sizes. It prints variable data collected by the Movicon supervisor onto the glass bottles. An Optical Character Recognition (OCR) control is performed using a display system to identify the printed characters. The OCR is used in the Pharmaceutical bottle packaging sector to trace container batch and data. Following this the bottles are led through a screw conveyor to a rotary machine, run on a starwheel mechanism. A

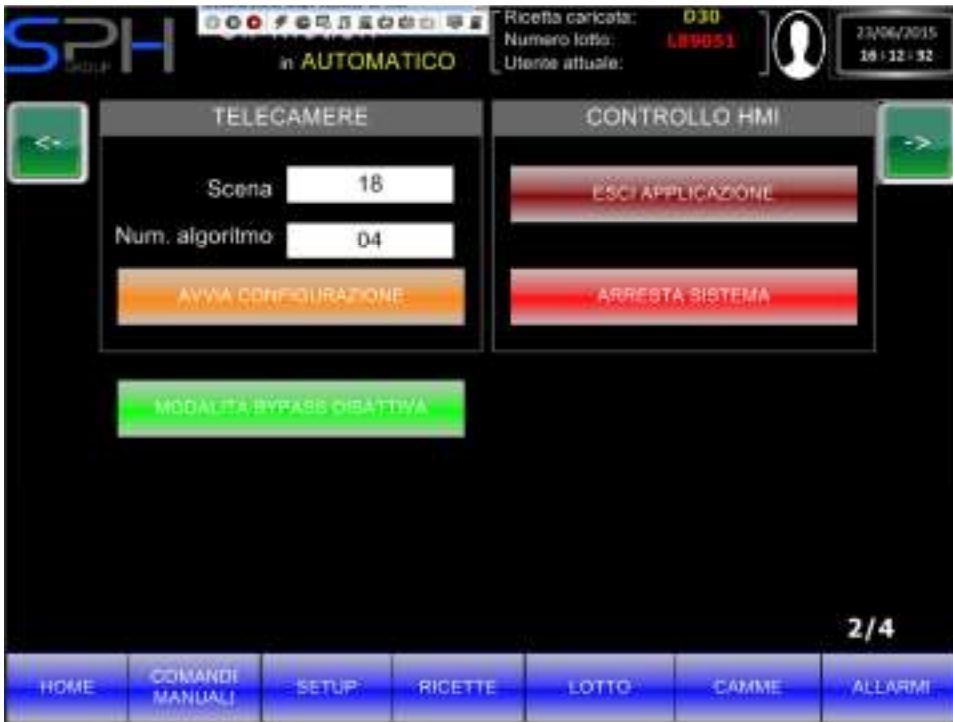
vacuum gripping system keeps the bottles firm in place during their transition through the rotary so that the inkjet printer head can print on them while in motion. This printing process is controlled by an intelligent telecamera display system equipped with various features that include a barcode reader and a product verification management. The OCR is an essential tool in this line of work because it can encode information into a format that can be recognised by both machine and man. Once the bottles have travelled through the starwheel rotary system they are placed onto another screw conveyor which transports them towards the reject station. The reject station divides the good bottles from the rejects according to the feedback obtained by the display system.

### Architecture and Supervision System

The architecture is composed of a HMI panel installed with the Movicon 11.4 supervision software that interfaces with the PLC, the inkjet printer, telecamera control display system and drives with absolute encoders. The advantage gained from using the PLC display system and the Omron drive is that they both communicate with the EtherCat natively.



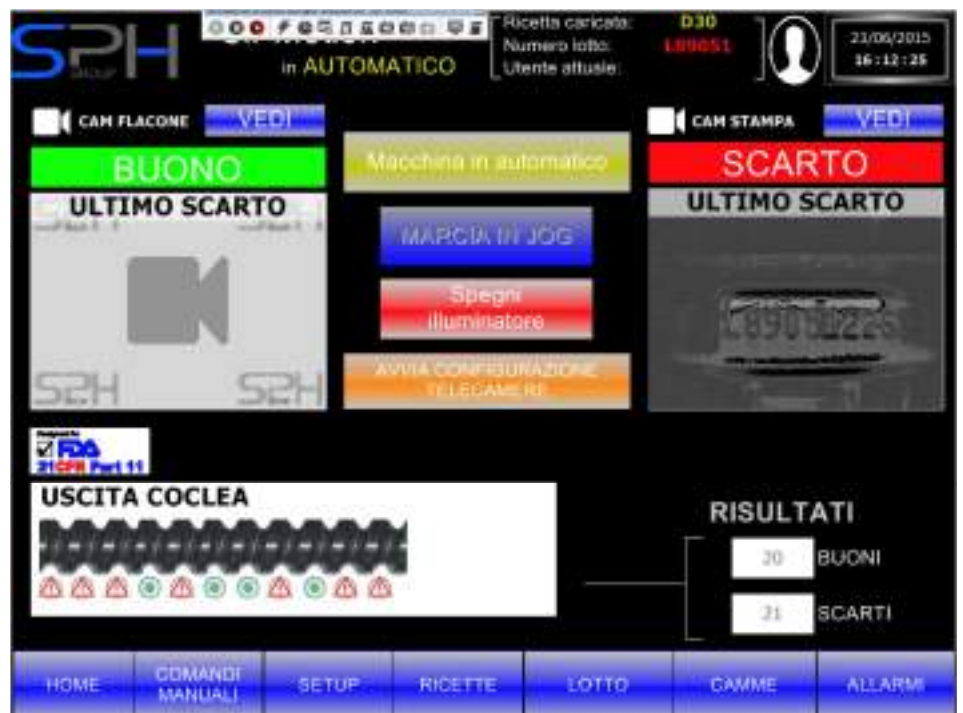
2. CFR 21 Part 11 screen with Trace button



3. Telecamera and HMI control screen

Movicon 11 transmits variable data to the inkjet printer and display system by communicating with messages using the TPC/IP protocol. The final objective requested by the client was to print on bottles and control the print of 300 pieces a minute using OCR. Movicon was chosen out of other supervision systems for its capacity to communicate quickly with both the printer and the display system's telecamera. The capacity to automatically transmit variable data, provide a user friendly display system management and last reject controls are only some of the reasons why the SHP Group chose the Movicon SCADA software. The major advantages of using Movicon are obtained in the ease with which it can be developed, the captivating

graphics, the dynamic use of animations, script and primarily its compatibility with the current 21 CFR Part 11 normative. The objective of this normative, issued by the Food & Drug Administration (FDA), is to obtain a legal equivalence in electronic documents (such as digital records and electronic signatures) in respect to paper documents. In order to create an automation and control system that is 21 CFR Part 11-ready, it is essential that recorded data are traceable to the operator responsible through their Electronic Signatures. In addition, special precautions must be taken against falsification and unauthorized manipulation of electronically recorded data. It must also be possible to identify any intentional or accidental misuse of data and of the electronic



4. Movicon screen displaying bottle rejects following telecamera control check

equipment used to generate it. All the 21 CFR Part 11 requirements are already implemented and ready-to-use in Movicon to allow the easy creation of FDA validated projects.

All of this has been made possible using a sophisticated SCADA system with a simple HMI. Furthermore, Movicon also provides a powerful Trading and Audit Trail management to use for each process data variation or for monitoring values with millisecond precision. This management also provides a complete set of information relating to user name, electronic signature, preselected values and the reasons for recording them.

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