

Brazilian Pharmaceutical Company Uses OPTEL's **Traceability Solution** to Meet **Compliance Regulations**

USE CASE

CUSTOMER PROFILE

One of our customers is a Brazilian company that has operated in the pharmaceutical industry for over 50 years. This national patent record holder owns an industrial complex for all of its pharmaceutical, pharmacochemical, biotechnological, research and development, and innovation initiatives. It has a complete, vertically integrated supply chain for the medication it manufactures, from the development of the initial molecule to the final product. The business employs approximately 5,600 personnel across the country.

CUSTOMER REQUIREMENTS

The client was looking for a system to perform variable data marking and inspection on its packaging to meet the drug track-and-trace regulation in Brazil (RDC 319/19). The company's packaging production lines are manual and required a solution that would fit this unique characteristic. To decide on the final solution, the team prioritized the suppliers that best met the following requirements:

- Fully compliant with current and future ANVISA regulations regarding the Brazilian National Drug Control System (SNCM)
- A robust and user-friendly system for employees
- Stellar customer support
- Quick delivery time to reduce the impact on the product line's performance
- High-performance and versatile solution

“ I can guarantee that the project was very well executed. Now, it works 24 hours a day, 5 days a week, providing security through data verification and ensuring the quality of our product. ”

– Client quote.



THE SOLUTION

For this customer, OPTEL recommended a customized solution that would perform serialization, inspection of printed data, and aggregation of packages in their respective shipping cases.

For the operation of the equipment, the customer provided:

- Electric power: 220V (F+N+T), 60 Hz
- Gigabit Ethernet data network connectivity
- Compressed air: 6 - 8 bar

Serialization:

The installed solution records and controls all traceability events by printing a unique drug identification label onto every sellable unit, which is called 'IUM' in Brazil. The system controls serial numbers that ensure unique IUMs are not reused. IUMs include the following information:

- GTIN
- MS Registration Number (13 digits)
- Serial number
- Expiration date
- Production batch
- Manufacturing date

The equipment offers great marking contrast and font size, thereby meeting a minimum B grading and ensuring good quality human readable information.

Inspection

To verify the printed data (human readable + Datamatrix), vision systems with cameras were installed. The camera has a processing speed compatible with the production line's speed. It was also implemented in a way that eventual production line vibrations do not interfere with the reading quality.

The chosen system inspects and verifies the readings on the packaging. It also rejects the shipping cases if one of the packages does not pass inspection. The system can also provide details as to why packages have been rejected and allows for the reanalysis of discarded packages and shipping cases so that they can be reincorporated into the process without any downtimes.

Aggregation

The solution aggregates up to 7 (seven) levels, validating and checking IUMs on packages and shipping cases. In addition to performing the aggregation process, the system is also capable of identifying and controlling the disaggregation of shipping cases.

Additional information

As per client's request, the system has only internal data storage. It can run and manage traceability processes independently of other systems, such as an ERP.

Manuals for all system components and tools were provided in Brazilian Portuguese.

RESULTS

Getting past the challenges

The biggest challenge for this customer was having to stop the production line to implement the solution. Together with OPTEL, the installation was carried out in only 2 weeks. Employees worked different shifts to accommodate the installation.

Implementation assistance

OPTEL provided full support during qualification and installation as well as training to all employees.

Staff training

The customer's team already had experience with other vision systems. As a result, the change was easily accepted, considering it improved the work compared to what was being done before. The system's user-friendly environment did not require much training.

Final considerations

Today, the customer receives several visits from other companies that want to get to know the equipment that was developed for their manual packaging line.

CONTACT US

To learn more about OPTEL's traceability solutions, contact us at optelgroup.com/contact/.



HAVE QUESTIONS?

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