

Case Study**Contact**

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Acrovision installs *Validator CFR* End of Line Label and Packaging Inspection with 21 CFR-11 Compliance

About

Acrovision's customer is a World leading Pharmaceutical production and supply chain specialist company. They manufacture, pack and supply products to over 40 countries around the world.

Requirement

Our customer was looking to install a new Pill Inspection and Blister Pack Barcode / Text Validation system.

As the environment is pharmaceutical the solution must conform to GAMP and 21CFR part 11 standards, requiring the following compliance:

- **Electronic signatures**
 - o Individual and Multi-level Passwords for all users
 - o Specify Frequency of change / Alpha/Num / Case
 - o Based upon cryptographic methods of originator authentication
- **Electronic records**
 - o Audit trails
- **Back-up and Restore Routines**
 - o Disaster Recovery
 - o "Like for Like" Exchange
- **Validation**
 - o Formally define how all elements of your system operate.
 - o Relevant documentation
 - o Code Control

Our customer turned to Acrovision for assistance in providing such a solution.

Business challenge

There were a few challenges to be overcome such as multiple lines of text to be read at high speed, blister packs were not always a uniform grid and the inspection of white labels on a white background.

The new vision system needed to be integrated into a current Marchesini blister packing machine. Bespoke bracketry was designed and fitted to ensure a seamless installation.

Acrovision Solution

The solution consisted of Cognex High End Colour Smart Cameras, a mix of Co-axle lights / Backlights, Industrial PC's, Control Panels, Framework / Light Enclosure, Validator Software and C# Custom Front-end.



100% inspection of a blister was required to ensure the correct size and colour tablet or capsule has been dosed into the blister. Any missing tablets, incorrect variant or broken tablets will be rejected in a controlled method.

The Foil Inspection part inspected correct DataMatrix barcode, LOT number and EXP code.

All these results were wrapped up with the Validator's batch reporting and logging software.

Result

The customer was impressed that our Validator CFR21 system was able to be custom tailored to their own needs without needing to be an expensive bespoke offering.

Also that Acrovision handled the full turnkey solution – from consultancy, system design, framework / control panel and hardware installation, commissioning and GAMP testing & documentation.

This new offering allows Acrovision to provide a more complete solution to the biotechnology, drug, and medical equipment manufacturing industries, who are always looking to improve their quality and profitability, at an affordable cost.

Acrovision also partner with label applicator / original equipment manufacturers (OEMs) of packaging machinery to provide a complete 21 CFR-11 compliant solution to the end-user.