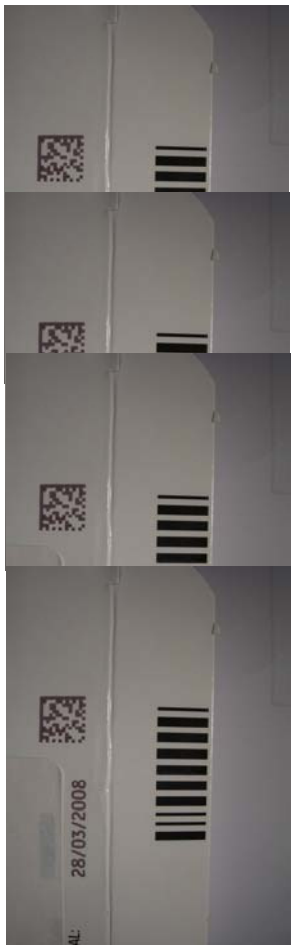
Machine Vision Technology Ltd.

Real Vision for the Real World



Case Study- FDA Document Validation

With reference to the FDA 21 CFR Part 11 rule demanding 200% manual inspection for documentation.

A major pharmaceutical manufacturer approached MVT for a system to automate its validation of the product leaflet enclosed with its product.

Their current method has to account for the huge disparity of production volumes, which range from a small batch of only 250 to 10000s. It is currently achieved by a simple 100% manual method which is slow and prone to operator error.

"There is no such thing as 100% manual inspection" because of human error.

Each product leaflet must carry a unique Pharma code. However, it is possible for this code to be missing, incorrect or mixed in any given batch. It is essential that these problems are identified, because within the pharmaceutical industry, the use and application of the code is driven by the FDA 21 CFR Part 11, EFPIA legislation, traceability and the fight against counterfeiting.

Normal handling practice within the printing and packaging industry has inherent problems with this, relating to size variations, creasing, and mis-loading, which all result in jamming problems.

MVT decided to literally turn the problem on its head and "pick" from above with vacuum. The Pharma code reader is incorporated into an arm and movement, thus incorporating the benefits of **100% automatic inspection** with the huge reduction of cycle times and related costs. The leaflets are then placed in one of two receptacles, good or bad. The complete system is compact, simple, appropriately enclosed and meets pharmaceutical standards.

If you would like more details or a have specific problem that you would like us to consider then do please give us a call.

MVT-Unbeatable benefit / cost ratio from a company with a proven track record

MVT Ltd. Blackdown Mill, Kenilworth Road, Leamington Spa, CV32 6QT Tel +44(0)1926 422043
Web www.machine–vision–technology.co.uk e-mail sales@machine-vision-technology.co.uk