

Cartoners, Case Packers, and Palletizers for Track and Trace Serialization of Pharmaceutical Packaging Lines

By ESS Technologies, Inc. Blacksburg, VA



Robotic Case Packer with Integrated
Serialization System for Bottles



Serialization Case Label With 2D Code and
Barcodes



Serialization System HMI

Introduction

Pharmaceutical manufacturers have many good reasons to implement track and trace technology within manufacturing and packaging processes. Serialization allows manufacturers to ensure the integrity of their product and compliance with emerging pedigree laws. Designed primarily as a response to the increase of counterfeit pharmaceuticals, pedigree and e-pedigree laws (for electronic documentation) require manufacturers to show the complete life cycle of the drugs they distribute, from the manufacturing process through the end-of-line packaging.

Unit level tracking methods have been in place for years. Lot/Expiration codes are ubiquitous on a wide variety of products. But recent changes to the law have shifted the focus to implementing track and trace systems with case packers and palletizers. This can present a number of challenges to pharmaceutical manufacturers, so selecting a qualified packaging machinery supplier to work with the track and trace system supplier is vital. Pharmaceutical companies already invest heavily in capital equipment for manufacturing and packaging. By integrating track and trace serialization technology with automated end-of-line packaging machinery, pharmaceutical manufacturers can meet pedigree requirements and maintain their levels of productivity in a single robust solution.

Packaging Machinery for Track and Trace Lines

Serialization systems track the product from the time it is placed in its primary package (bottle, vial, tube, jar, pouch, etc.) to its final placement on a pallet at the end of the packaging line. This requires integrating inspection and tracking equipment from a track and trace system supplier with the packaging machinery at each step in the packaging process. It's important to select an equipment provider who understands the requirements being faced by pharmaceutical manufacturers. Ideally, the packaging machinery supplier is also an integrator who can work with other OEMs to successfully implement a track and trace packaging line.

The track and trace systems incorporate several types of equipment. First labeling or other types of coding equipment place a unique ID code on the item being packaged, e.g. bottles, cartons, blister packs, bundles, etc. Next cameras and other sensors that are capable of reading the ID are integrated with the packaging

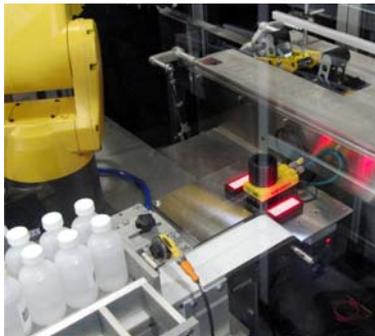
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Cameras At Infeed Record Individual Codes



Camera for Inspecting Bottle Codes Prior to Loading



Overhead Camera Integrated with a Robotic Case Packer

machinery at various stages in the packaging process such as cartoning or case packing. Print and apply labelers are integrated to label the case with information about its contents, and these labels are also inspected for accuracy. Reject systems are integrated to allow improper product to be removed from the production stream.

The packaging equipment to be integrated with the serialization system should also be considered carefully. Automated packaging machinery is better able to handle production speeds needed to factor in the time it takes to record the serialization information without diminishing overall production rates. The process typically begins with the primary packaging equipment. Individual products, be it bottles, cartons, trays, or bundles, are labeled with a unique identifying code during the primary packaging of the product. It is this code that the track and trace system uses to create information about the contents of each carton, case and pallet.

Storing Serialization Data

Track and trace serialization systems incorporate a means for recording and storing the serialization data for each production run. This is usually accomplished through a dedicated PC integrated with the printers, cameras, and sensors. The centralized data point allows the system to distribute serial number information to each packaging level at each tracking point such as when the product is cartoned, when the carton is case packed and when the case is palletized. These systems interface with the packaging machinery controls to allow the exchange of information.

Robotic Track and Trace Inspection Systems

The simplest application for track and trace systems is the pick-and-place inspection of products. Whether the product is an aggregation or an individual carton or bottle, a properly programmed robotic cell with well-designed end-of-arm tool (EOAT) can pick the object, pass it in front of a vision inspection system or a barcode scanner and place it in a bin or on a conveyor, depending on whether the product is rejected or passed downstream for further packaging.

Robotic inspection works well in applications that require an aggregation to be verified after individual products have been bundled, and aggregation scanning equipment cannot be integrated into an existing machine. The stand-alone robotic system can pick the bundle and move it under or over a scanning device. The system allows for rescanning the bundle in the event of a read error. The

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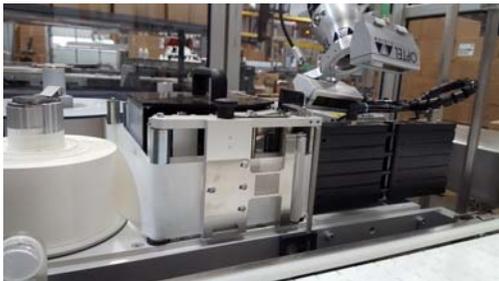


Robot Loading Pharmaceutical Bottles

scanning device can also verify the count, the bottle or carton status and create a list of each item in the bundle. The robot places rejected bundles in a reject bin to be reworked or discarded.

Track and Trace Cartoners and Case Packers

Pick and place inspections systems are not the only robotic application for track and trace packaging machinery. Robotic systems can be used in an end-to-end packaging line to help track the first product in all the way to the finished pallet, ensuring the integrity of every product, every case, and every pallet throughout the production process. For example, a packaging line for pharmaceutical bottles begins as each filled and closed bottle is marked with a unique serial number, which may be printed on the label, on the bottle or on an RFID. In a cartoning application, sensors verify the code as each bottle enters the cartoner infeed, which may be robotically loaded. After the carton and any required leaflets are loaded, cameras and/or sensors verify the carton contents before it is sealed and labeled.



Case Labeler with Inspection Camera

In a case packing application, bottles may be conveyed directly to a case packing cell with integrated serialization system. As products labeled with unique identifying codes enter the infeed and collation zone, cameras on all four sides of the product capture the code and store it in the system microprocessor. The products are then collated and loaded into the erected RSC case.



Barcode Scanners On Palletizer Infeed
Conveyor

Robotic case packers for track and trace applications incorporate EOAT that uses a unique suction cup with integrated vacuum sensors that allow the EOAT to verify that it has picked all of the bottles in the pack. Automatic leaflet feeders with track and trace inspection verification may be added to the case packer to automate the full case loading process. Camera inspection systems take a picture of the loaded case and compare it to a picture of a correctly loaded pattern to verify that all components have been correctly packaged.

Cases with complete patterns are tagged as “good.” Incomplete cases are not tagged, causing them to be automatically rejected at the case packer discharge. Good cases are then labeled with track and trace information about the contents of the case. The label may include a 2D code, a barcode, human-readable code, a writable RFID tag, which is encoded after the case is packed, or a combination of all three. By tracking each serial number in the pack

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Single Cell Palletizer with Trace
Serialization System



Dual Cell Palletizer with Track & Trace
Serialization System



Single Cell Palletizer with Stainless Steel
Pharmaceutical Washdown Option

pattern and applying that information to a unique case, the manufacturer can know at all times exactly where each bottle is in the packaging process. This process would be the same if the product being case packed was a carton, bag, blister pack, or bundle.

Track & Trace Pallet Cells

Robotic palletizers also integrate easily with track and trace systems. Prior to palletizing, labeled cases are verified at the case infeed conveyor. The system either presents the label to the barcode reader or a barcode reader positioned on the conveyor can read the label before the case is picked. In either scenario, incorrect cases can be rejected for rework. Robots can also be programmed to position the case label so that it can be seen and scanned at pallet's final location.

Robotic palletizers can be integrated directly with track and trace case packers to create a complete end-to-end system. High speed case packers integrated with stand-alone robotic pallet cells can handle up to 20-25 cases per minute using two robots, one to case pack and one to palletize. Track and trace packaging lines requiring lower speeds, between 5-6 cases per minute, can incorporate case packing and palletizing with a single robot to create a very compact track and trace packaging solution.

Labelers and scanners are also integrated with robotic palletizers. Fully loaded pallets are also labeled using RFID tags, bar codes or readable codes to fully verify the contents of the pallet.

Conclusion

By integrating OEM serialization systems with packaging machinery, pharmaceutical manufacturers can secure their supply line from counterfeiting and meet current and future pedigree requirements. The investment in integrated equipment provides a streamlined process that can be easily reconfigured for future applications.