VERISTA

MANUFACTURING SOLUTIONS

CASE STUDIES

Top 5 Global Medical Device Manufacturer Expands to Meet Market Demand for Covid Antigen Tests

CLIENT OVERVIEW

A global leader in diagnostics instruments and tests

CLIENT CHALLENGE

The Client had successfully brought a later flow testing platform to market. With the need for rapid Covid testing, the test was modified for the Covid virus. Demand for testing greatly exceeded client production rate of 7500 units per hour, so they turned to Verista's expertise to better meet market demand.

SOLUTION

- Business processes were analyzed to identify parameters for production scaling.
- Verista supplied personnel to lay the groundwork to ramp up production.
- Personnel provided foundation for quick manufacturing expansion with validation expertise.
- Operational Change Management was completed throughout project lifecycle from inception to completion.

RESULTS

- Verista completed production expansion within agreement scope and provides ongoing support as needed.
- Verista built upon QMS system data and performed additional validation for new manufacturing lines.
- Allowed client to meet US government demand for 150 million antigen tests.
- Verista's expertise in creating ten additional production lines in the project lifecycle allowed the client to expand 40% in the following quarter.

MANUFACTURING

Six Leading Injectable Manufacturers Automate Tray Count Operations

CLIENT OVERVIEW

Three top pharmaceutical companies and three major CMOs producing billions of doses of vaccines and other injectable

CLIENT CHALLENGE

When inspecting and counting of trays is a manual process, it can result in significant time and cost saving losses such as:

- Quality, compliance and reporting issues due to human errors
- Low throughput, oftentimes requiring 2x labor coverage, due to manual counting
- Employee safety and satisfaction concerns resulting from repetitive motion, eye strain and needle poke

SOLUTION

After careful analysis of various client environments, Verista has developed solutions that directly improve the speed, accuracy and compliance of these manufacturing operations with the utmost importance placed on getting safe and quality products to market as quickly as possible. The Verista COUNTQ® system is an automated, high-resolution vision inspection solution that manages count reconciliation of tray loaded injectables (vials, syringes and ampoules).

To meet our clients' constantly changing product mix, the system allows for auto adjustment of the camera and light mechanism to seamlessly accommodate for variations in product height and tray type. Furthermore, the solution incorporates sophisticated inspection, optional deep learning capabilities and methods which are needed to achieve reliable results that standard machine vision can't attain for difficult-to-inspect formats (e.g., ampoules, needles). The systems can support an unlimited number of 'recipes' to ensure compatibility with multiple product and tray types.

RESULTS

All clients have expanded their use and quantities of COUNTQ systems due to improved accuracy and quality in tray counting and reconcliation, significantly higher throughput, reduced labor costs and risk, unmodifiable records that meet all 21 CFR Part 11 requirements, and secure, configurable tray and batch reporting with complete audit trail and image collection capability.

Test Stand for Top 5 Global Medical Device Manufacturer

CLIENT OVERVIEW

Medical Device Manufacturer

CLIENT CHALLENGE

- Customer needed to automate the manual testing of a complex device and achieve automated data collection for each part.
- 124 different inspections (vision, digital, analog) were required in a 350 second cycle time.
- Many dissimilar third party devices needed to work together (Torque Sensors, Servos, Oscilloscope, GigE Cameras, Stepper Drives, Spectrometer, etc.).

SOLUTION

- Verista V&SI led the development of a Functional Specification to define overall scope.
- Verista developed a plan for all the motion sequences of the machine to achieve the required inspections.
- Verista proposed utilizing our custom software to manage the automation and maintain 21 CFR part 11 compliant record keeping for every tested device.
- Verista designed and built the system achieving all inspections within the time budget.
- All mechanical design, electrical layout, automation, and software were developed by Verista Engineering and the system was built in our Fishers, IN facility.
- The system incorporated an Articulation Cradle responsible for physically manipulating the knobs and levers of the device

RESULTS

The system takes up less than 1/4th the floor space versus the manual inspection stations and provides an audit trail and data logging to customer SQL and MES.

Powder Fill Test System for Biopharmaceutical Developer

CLIENT OVERVIEW

Global Biopharmaceutical Developer

CLIENT CHALLENGE

The manufacturer of the customer's powder filling line was no longer in business. There was no documentation for the critical filling components (auger, mixer, dosing funnel, and fill cup) and the customer had no specifications to allow them to reverse-engineer these components and validate the process. Operators load filling components into the test stand and a line scan camera with telecentric optics measures to a very high precision. The system reports the measurements to operations to ensure the components are still in specification.

SOLUTION

- Verista engineered line scan solution for measurement of components 12" in length.
- Custom routine for measurement of auger flute by auto-imaging of parts at different rotations.
- Operational control of set points, sequential software application to step through device testing.
- Auto-recognition of component being tested: supports augers, dosing cups, glass tubes, through Verista developed test fixtures.
- Complete washdown assembly.

RESULTS

Verista reviewed the application and proposed a solution that would accurately measure these critical components and provide data to allow characterization of performance. This solution allows the customer to run correlation studies necessary to validate dosing output based on component dimensioning. The measurement results allow the customer to order replacement components and keep their powder fill line in production.

LABELQ Reel to Reel Label Ablator for Top 20 Pharmaceutical Developer

CLIENT OVERVIEW

Major Pharmaceutical Developer

CLIENT CHALLENGE

The client required a laser ablation system to imprint variable data on preprinted label reels. They needed flexibility to support multiple label sizes, a user-friendly HMI, and the incorporation of a Domino laser system. The request was for the operator to set up the label printing parameters via a PanelView HMI; at runtime, this information would be sent to the Domino printer for selection of the correct configuration

SOLUTION

Our team modified Verista's platform to laser mark configurable data on various size rolls and types of product labels. The machine operates in a reel-to-reel configuration with unmarked labels unwinding and passing through a laser print area and rewinding on a standard 3" opposite side core at up to 300PPM. The machine is part of the V&SI LABELQ series and can include machine vision inspection, thermal transfer printers, and 21CFR Part 11 reporting features.

RESULTS

The introduction of standard Verista V&SI product (LABELQ) allows for:

- Modification of the print position, type, and size through HMI
- Custom label web tensioning assembly and routine for continuous operation
- Integrated laser safety with shutoff
- Multiple sizes of labels down 0.5" and up to 6" of width.
- Standard product options: machine vision inspection, reject marking, incorporation of thermal transfer printing, 21CFR reporting, others.

"Love the constant communication and the level of knowledge and expertise that Verista offers."
- CapEx Manager, Top 10 Med Device

"They've made it easy to do business. Responsive to our needs and challenges. Great partner."
- Project Manager, Top 20 Pharma

"Our #1 company."
- Director of Automation Engineering, Top 20 Pharma

UNLOCKING SOLUTIONS FOR A REGULATED WORLD