

Four Leading Injectable Manufacturers Automate Tray Count Operations

Impact: Significant Time and Cost Savings, Reduced Risk, and Improved Compliance

CASE STUDY



Two top pharmaceutical companies and two major CMOs producing billions of doses of vaccines and other injectable products



CLIENT CHALLENGE

A critical component of the manufacturing process of vaccines and other injectable pharmaceuticals is the inspection and counting of trays through the manufacturing process. Since these activities are typically manual, they 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.

NUMBER OF INSTALLATIONS

- √ Top 5 Pharma implemented 9 COUNTQ systems, across 3 sites, analyzing billions of doses
- √ Top 25 Pharmas implemented multiple COUNTQ systems
- ✓ Top 5 CMO's implemented 10 COUNTQ systems

SYSTEM CAPACITY

- ✓ 1 tray, 950 ampoules or more, every 15 seconds
- ✓ Supports standard fill line capacity of 300 vials per minute
- ✓ 100 million vials per year can be accommodated with one machine

CLIENT BENEFITS

- √ 21 CFR Part 11 compliant for comprehensive audit trail
- √ Specification criteria can be set to a known (accept or reject based on a set value) or unknown count (report the number of products in the tray)
- ✓ HMI (Human Machine Interface) images clearly indicate acceptance and reject counts to the operator
- √ Automatic generation of lot and batch reports
- ✓ Built-in security with data stored locally in the machine with un-alterable records
- ✓ Option for Data Historian Connectivity and integration with MES



RESULTS

All clients have expanded their use and quantities of COUNTQ systems in their operations.



Improved accuracy and quality in tray counting and reconciliation



Secure, configurable tray and batch reporting with complete audit trail and image collection capability



Significantly higher throughput



Unmodifiable records that meet all 21 CFR Part 11 requirements and helps identify product shrinkage



Reduced labor costs, risk and improved worker happiness due to fewer repetitive and hazardous tasks

Verista is a leading business, technology and compliance company that enables clients to improve health and improve lives.

We help clients solve their most critical and complex challenges across the GxP lifecycle, from preclinical and clinical to commercialization, manufacturing and distribution - bringing together decades of knowledge, the most advanced engagement platforms and transformative technologies. This allows clients to benefit from the ease, efficiency, and trust that results from working with one partner who excels across specialties.

Verista's clients trust the company's 650+ experts to deliver consistent, safe, and high-quality results across the product development lifecycle in the areas of quality and compliance, manufacturing solutions and life sciences consulting.

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