

Summary

Manual counting and QC methods with hand-counting trays and scales were negatively affecting accuracy, customer satisfaction, and FDA/GMP compliance at Sharp Packaging Solutions, Allentown, PA. In May 2013, Sharp performed a thorough validation study on the Kirby Lester KL1 tablet counter. Based on the successful completion of the validation study, Sharp now uses KL1 devices for hourly QC checks on all bottling lines and for small quantity bottle filling. "After we completed validation testing, we found the KL1 met every expectation," says Ron Bates, Sharp's Senior Project Engineer for New Business Development.



Sharp
Packaging Solutions

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Setting

Sharp, a global leader in contract pharmaceutical packaging, employs 1,400 employees in three Pennsylvania, U.S. facilities as well as Belgium and the Netherlands. Sharp supplies complex commercial and clinical packaging solutions to the pharmaceutical and biotechnology industry.

Challenges

Sharp fulfills greater than 100 pharmaceutical bottling projects per month on fully automated bottling lines. A major compliance requirement for a bottling line is to assure accurate product counts. The challenge for Sharp was to find a solution to decrease QA inspection time during commercial bottling and increase filling accuracy for small manual filling production runs.

Solution

Following a thorough validation study on the KL1, Sharp found the device met their challenges and substantially improved the company's bottle filling processes. Sharp purchased seven units with multiple "contact part kits" dedicated to handle every unique product. Since the KL1 is portable, several different bottling lines, departments and facilities use the devices.

Results

- 1. Accuracy:** Three different oval tablets were selected for validation activities (small, medium, large). Each size was tested for the following counts: 1, 10, 25, 40, 75, 195, 260 and 300, with no count errors. A repeatability test was conducted using 300 tablets; no counting errors were documented over 10 repeatability trials.
- 2. Labor savings:** Sharp Quality's 2013 validation study included financial impact, but the projected results are expected to exceed initial expectations. ROI is expected to be reached within 10 months per device -- in labor savings alone (not including product loss that was known to occur with manual methods and ensuing customer financial penalties).
- 3. Reliability and ease of use:** "The KL1 is far superior to a scale," says Mr. Bates. It is not impacted by environmental factors and does not need to be calibrated for individual jobs.
- 4. Removable contact parts:** The top funnel, inside channel and bottom tray can be removed from the KL1, and Sharp maintains an inventory of dedicated "contact part kits" for every product they package. "Being able to change contact parts was instrumental in making the decision to move forward with the Kirby Lester technology," says Mr. Bates.
- 5. Versatility:** The KL1 can be used for a wide variety of processes, including smaller count runs, return counts, reconciliation counts, and waste counts. The KL1 is also portable and is used by multiple Sharp departments.

(below) A Sharp technician conducts a stock bottle check with the KL1.



"The KL1 devices decrease counting time and improve accuracy. If you are in the business of verifying in-process counts of bottles, the KL1 should get a serious examination."

Ron Bates
Sharp Packaging Solutions



KirbyLester
exactly.

(below) Sharp orders a KL1 "Contact Part Kit" for every product line, maintaining absolute product integrity and eliminating any chance for cross-contamination.



"The first thing my customer asks: 'What other products are used in your machinery?' We assure them that when required, they'll have their own contact parts throughout production. Why is this so important? Some products are very valuable and the customer doesn't want any waste. Other products are toxic or potent. To mitigate any analytical testing when required, we dedicate all product contact parts, including the KL1."

Ron Bates

Sharp Packaging Services 2013 Validation Study High-Level Findings

"The KL1 has several benefits over tray or scale counting:

1. Reliability and speed of counting application. Scales rely on product weight, which varies. So with larger size bottle counts, scales may need to be reset.
2. A throughput of 15-18 tablets per second. The entire process of getting a bottle, dumping it into the Kirby Lester and taking a tray out takes roughly 10 seconds for a lower count bottle (i.e., 30 count) and around 12-15 seconds for a larger count bottle.
3. A validated asset that does not require calibration between jobs.
4. No need to program the KL1 depending on the product.
5. The KL1 operates off a product's physical features instead of its weight, preventing tablet weight variations from having an effect on counting processes.
6. Operation is not impacted by external factors such as if the unit is balanced, if there is an air vent nearby or how a counting bowl may be situated. All of these factors impact a scale's accuracy.
7. The KL1 can count up to 9,999 tablets while a typical scale may lose reliability because it is based on tablet weight.
8. An Inventory Mode that allows for continuous pill counting for accurate counts of bulk, returns and daily reconciles in controlled drugs.
9. Cleaning the KL1 is straightforward and requires no specialized equipment."

"The KL1 is a validated counting device created specifically for pharmaceutical needs that has the accuracy of a counting tray and the quick counting function of a scale. Through the use of Kirby Lester's KL1, the required QA manning for production lots that utilize counting trays will be reduced. This can result in a savings of QA Inspector manning."

"While each KL1 has a reasonable up-front cost, they will pay for themselves in QA manning alone. For example, it would take approximately 22 lots of 30-count tray-inspections in order for each KL1 unit to account for its cost. With the large number of bottle lines run each month, the unit will quickly pay for itself."

"While the KL1 has approximately the same inspection time as a scale, the added reliability, ease of use and ability to detect broken tablets makes it far superior to a scale. KL1 can be used for bottle counts, drug returns, and can count up to 9,999 tablets. The KL1 is not impacted by environmental factors and does not need to be calibrated or set up for individual jobs."