

ADVANCING ASEPTIC FILLING: EVALUATING THE REVOLUTIONARY SA25 WORKCELL

Singota® Solutions is a CDMO located in Bloomington, Indiana, USA that specializes in Parenteral, Early Phase Drug Development and Aseptic Filling projects.

In the realm of aseptic filling solutions, the SA25 Workcell, designed and built by Vanrx (now Cytiva), stands out as a major step forward in manufacturing technology. This revolutionary concept marked the inception of a fully robotic aseptic filling system, capable of precisely filling drug products into vials, syringes, and cartridges—all without human intervention.

A Revolutionary Design: Vanrx's design team, armed with extensive expertise in Contract Development and Manufacturing Organization (CDMO) aseptic processing, embarked on a mission to eliminate the root cause of problems in existing fill line technology: human intervention. The SA25 Workcell's groundbreaking design goal dictated that all filling operations would occur entirely within an isolator under a Grade A environment, without glove ports.

Pioneering Approach: The SA25 Workcell utilizes several cutting-edge technologies. The use of semiconductor-grade robotics and control systems, tray handling of Ready-to-Use (RTU) components instead of individual containers, and the utilization of nested press-fit vial closures and stoppers combine to achieve the key benefits of the equipment. Collaborating with Schott, Datwyler, West, and ARaymondLife, the design team formed the "Matrix Alliance," ensuring that component tolerances and presentations would align with the system's objectives.

Time Savers and Line Changeovers: The lack of gloves and associated reduced aeration time to reduce VPHP levels saves batch start-up time. The SA25's simplified material handling system has allowed rapid presentation changes, accomplished within a few hours without cumbersome rail adjustments. This flexibility extends to successfully filling vials, syringes, and cartridges of various sizes.

Batch Records: By elimination of the need for vial washing and depyrogenation, the use of the SA25 streamlines batch records, making them simpler and more concise. The system's control and data collection capabilities have indeed provided electronic, time-dependent data, ensuring meticulous record-keeping.

Line Losses and Consistency: Small line losses, a result of precise fill control and specialized flow path assemblies, have proven invaluable for clients dealing with precious API. The consistency and repeatability from batch to batch has been outstanding and has impressed even the most discerning Quality Persons (QP's) during client audits.

Six Years of Excellence: Singota was the first CDMO in North America to adopt the SA25. For the past six, going on seven years now, Singota Solutions has utilized the SA25 across presentations spanning vials, syringes and cartridges of various sizes and processing a wide range of small and large molecules.

A review of the SA25's performance over this period offers invaluable insights for drug developers contemplating CDMOs like Singota for their parenteral development endeavors using the SA25.

Bottom Line Performance: Singota's realm of providing early parenteral drug development for start-ups and biotechs is characterized by limited and expensive API, small batches, tight and shifting schedules, evolving formulations and changing presentations. In this challenging environment, the SA25 has performed extremely well. Versatility, high yields, low losses, precise and repeatable fill parameters batch to batch have been proven out.

Contamination Control: The use of semiconductor industry robotics with ultra-low particulate emissions, carefully prescribed air flow monitoring and management, RTU pre-sterilized components, matrix-format vials, and the elimination of human intervention have resulted in zero sterility failures. Yes, zero.



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Press Fit Vial Closures: As discussed earlier, one of the enabling technologies is the use of press fit vial closures, in lieu of the typical aluminum crimping style. They have performed extremely well- no CCIT problems whatsoever. Initially there were some concerns, questions, and resistance to their use by the client base. The concerns were not technical performance based, but rather fear of something new. Questions as to “who else is using these”, and “how long have they been in use?” were not uncommon. Supplier testing has shown superb CCIT results since inception. Singota has observed little resistance if any at all in the last couple of years.



Note that if a client is involved in a trial where a placebo is manufactured with an aluminum crimp, and the active product utilizes the press fit closure, that does present a dilemma in using the SA25 as the two products are visually different. Also, the removal of the press fit closure if necessary for laboratory work can be a bit more cumbersome than with the aluminum crimp without some practice, and some dexterity, but this has been a minor issue.

Supplier Synergy: The SA25's success story is incomplete without acknowledging the invaluable support from dedicated suppliers. Pre-sterilized flow path assemblies and nested components have been pivotal to the SA25's design. The innovative press-fit vial closure system, replacing traditional aluminum crimping, has been a game-changer. Collaborative efforts from suppliers like ARaymondLife, West, Datwyler, and Schott have set a benchmark for cooperation, ensuring seamless integration of components and timely support for SA25 users.

In summary, Singota's SA25 Workcell has been a remarkable piece of equipment. Its performance, and utilization by Singota underscored by zero sterility failures and importantly, client satisfaction, reaffirms its status as a pioneering solution in the world of parenteral drug development. Through continued strategic partnerships and a relentless pursuit of learning and excellence, Singota Solutions continues to redefine industry standards, one batch at a time.

Singota Solutions is a US based CDMO in Bloomington, Indiana. Singota specializes in formulation development and aseptic fill finish for injectable projects. Once a formulation is established, Singota utilizes state of the art robotic filling technology and focuses on smaller batch size requirements. For more information, visit Singota.com to explore how Singota has established itself as a one-stop solution for all your developmental needs.

Contact solutions@singota.com to schedule a meeting with our business development team to further discuss your current or future projects.