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USP <797> & <800> Solutions From Veltek Associates, Inc.

Combining experience, innovation, performance, GMP manufacturing, GLP testing services, and unrelenting service has propelled VAI® as the ultimate innovative leader in the market.

President & CEO: Arthur L. Vellutato Jr.

Founded: 1981

Employees: 200+

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VELTEK ASSOCIATES, INC.

Company Background

For nearly 40 years, Veltek Associates, Inc. (VAI®) has pioneered the design and manufacture of hundreds of cleanroom solutions that surround contamination control. These innovations, many of them landmarks in the industry's history, allow our customers to overcome challenges, and reach their business goals. Plus, VAI clients have more than a solutions provider, they have a partner and trusted advisor. With today's complex healthcare challenges, and increasing regulations, a true partnership is more important than ever.

For us, it's simple. Innovation is about listening to industry challenges directly from our customers and not stopping until we find the answer. Together with our clients, we have been developing new solutions for the cleanroom industry for more than 40 years attaining over 150 worldwide patents. Our innovations have allowed our clients to do remarkable things — from biotechnology breakthroughs to pharmaceutical discoveries — that help millions of people every day. From our early days of developing the first sterile garments to our latest innovations, VAI develops products that revolutionize and simplify cleanroom operations.

Product Overview

VAI's Sterile Chemical Manufacturing Division (SCMD) has addressed the needs of the pharmaceutical, biotechnology, and healthcare industries by designing a complete range of sanitizers, sterile disinfectants, sporicides, lubricants, cleaners, and process cleaners for cleanroom environments. VAI's SCMD products are used at hundreds of healthcare facilities, pharmaceutical, and biotechnology organizations worldwide.

SCMD manufactures a complete range of cleaning agents and disinfectants that are used daily in cleanroom operations. VAI capabilities for manufacturing products include the ability to fill aerosol, bulk, and unidose packages in a classified filling operation. Our filling operations are coupled with the validated and proven ability to irradiate a final product. Assurances are taken in every aspect of chemical manufacturing concerning sterility and particulate removal. Our chemical manufacturing operations mirror current GMP's and enforces the adherence to USP methods and specifications for testing of all manufactured products. VAI is an EPA and FDA registered facility and possesses worldwide registrations.

SCMD has taken another advancing step in product quality assurance by incorporating USP Water for Injection (WFI) into the majority of our products. The validated WFI systems in our chemical manufacturing facility incorporate an added advantage to the use of our products. The mission of VAI's SCMD is to manufacture top-of-the-line quality products that address any regulatory requirements demanded.

SCMD has chemical manufacturing capabilities to produce both VAI products and contract custom manufacturing designs. VAI's SCMD uncompromising cGMP manufacturing style and our complete adherence to USP specifications has assured outside organizations that their products will not only be produced and tested as sterile, but moreover, their product will be completely documented and validated.

VAI's Disposable Products Manufacturing Division (DPMD)

DPMD has addressed the needs of the healthcare, pharmaceutical, biotechnology, semi-conductor, medical device, and electronics industries by designing a complete range of sterile and non-sterile disposable garments. Product lines include: sterile disposable garments, sterile and non-sterile face masks, and non-sterile cleanroom apparel.

Disposable garments are packaged in VAI's, patented, Easy2Gown fold system. The Easy2Gown design is a fold that makes a proper aseptic gowning procedure an easy process instead of a routine challenge. Additionally, VAI offers barrier gowns for use where handling hazardous drugs or chemicals, where exposure to bloodborne pathogens, or where liquid splashes are a concern. USP <800> gowns have been designed and tested specifically for compliance with the USP <800> guidance for handling of hazardous drugs.

VAI offers four face masks with varying levels of barrier capabilities for use in clean and critical environments. VAI's PF-2 face masks are made of 100% rayon. The PF-2 face masks allows for excellent breathability, comfort, and protection, while maintaining filtration efficiency. VAI's PF-4 face masks are made up of three layers of non-woven material that includes a soft layer to prevent skin irritation or allergy problems. VAI's FaceVector masks are made up of three layers of SBPP materials which has soft layers that help prevent skin irritation or allergy problems. Finally, VAI offers a National Institute for Occupational Safety and Health (NIOSH) approved N95 filtering face mask. These N95 masks have a 95% filter efficiency level effective against particulate aerosols free of oil.

VAI offers a complete line of wipers, using various clean substrates and packaging to meet the needs of our diverse types of customers. Our wipers come in multiple chemical saturations, sizes, absorbency, and material. Our wipers are sterile or non-sterile and either saturated or dry. The sterile versions are sterility assured through gamma irradiation at a 10-6 SAL or through aseptic filling. All materials are quality assurance tested and released to specifications defined by IEST and ASTM test methods. Our wipers can be used in both aseptic and non-aseptic wipe downs of filling and packaging machinery, stainless steel, Lexan, polycarbonate, glass, and any critical surface that requires cleaning.