Aseptic Blow-Fill-Seal Cap Insertion Isolator

Springs Fab Project Manager / Engineer
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Project Scope: Engineering & Design, Fabrication & Assembly, Laminar Airflow Test, Cycle Development, Micro-Biological Qualification, Ammonia Leak Test, GMP

The Aseptic Blow-Fill-Seal Isolator was developed for a major pharmaceutical OEM. The function of this unit is to sanitize caps and aseptically convey them into a blow-fill-seal molding machine built by the OEM. The isolator provides HEPA filtered laminar vertical airflow, and decontamination of the isolator interior and product. Sanitization is accomplished with an integral vapor hydrogen peroxide (H_2O_2) system. Materials used are T316L stainless steel and tempered safety glass doors, configured in hinged swing mounts to allow for ease in cleaning and product loading. All controls are self contained, including PLC, blowers, liquid hydrogen peroxide, and software.

Springs Fab designed, fabricated and completed factory acceptance testing. FAT included cycle development of the decontamination system, microbiological qualification with BI indicators, complete laminar airflow tests, and system leak testing.

The Isolator is offered as an option by the OEM, providing assurance of meeting critical FDA requirements in the operation of a blow-fill-seal molding machine.

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