

CUSTOMER:

A large, global manufacturer of sterile injectable pharmaceuticals expanded their more than 1.4 million- square foot facility located in the eastern U.S. Each year this site produces nearly 25 percent of all sterile injectables administered in U.S. hospitals, and more than 400 million of the company's globally distributed units.

CHALLENGE:

With a recent acquisition within the manufacturing complex, the facility increased their manufacturing footprint by more than 65,000 square feet. The plan for the additional manufacturing space included creating new capacity in the main facility, allowing some of the current manufacturing space to be re-purposed in the future as new manufacturing opportunities arise (e.g., contract manufacturing). Both the newly acquired and current manufacturing space must meet aseptic conditions to ensure the purity and safety of the products made.

RECOMMENDED SOLUTION:

To meet these cleanroom requirements, AAF Flanders developed a solution comprised of:

- AstroClean™ unidirectional airflow modules
- AstroHood® S-I terminal supply hoods with an energy-saving damper (ESD)
- MEGAcel® II eFRM HEPA filters, which have superior durability and a 50% lower pressure drop than glass media filters

IMPLEMENTATION:

To ensure compliance with cleanroom industry standards, operators of a new sterile injectables space requested that AAF Flanders supply a turnkey unidirectional flow module that would:

- Fit their architectural footprint.
- Be installed easily.
- Meet airflow and velocity requirements for the space.

In response, AAF Flanders delivered the AstroClean unidirectional airflow module, which came equipped with the energy-efficient MEGAcel II eFRM membrane media HEPA filter. The module provided unidirectional airflow above the barrier isolator to maintain aseptic conditions during the vial processing stages. In addition, AstroHood® S-I terminal supply hoods with an energy-saving damper (ESD) were installed within the surrounding cleanroom to maintain ISO 14644-1-level cleanliness. Combined, these products offered unmatched system integrity and energy optimization.

With the module, hoods, and HEPA filters installed, the sterile injectables manufacturer has brought the additional manufacturing capacity online, and the entire facility is in full operation.

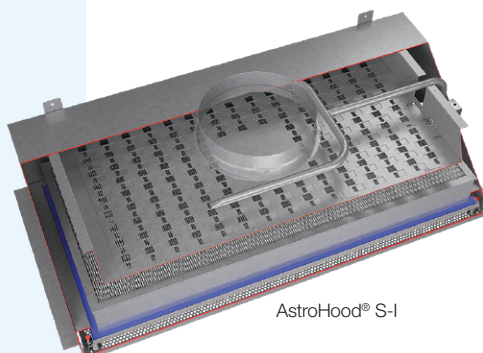
CONCLUSIONS:

The recommended solution of the AstroClean module, AstroHood S-I hoods, and MEGAcel II eFRM HEPA filters allowed the end user to meet aseptic condition standards and achieve the required ISO classification for the surrounding area. Further, the plenum design met their architectural footprint and achieved their intended air velocity at a particular airflow volume. AAF Flanders delivered a tailor-made solution on time and on budget that performed exactly as required and expected. The fact that the factory acceptance testing went off without a hitch created trust and brought the manufacturer peace of mind. Based on the success of this installation, the end user requested additional proposals for high purity air filtration solutions.

Manufacturing capacity expanded successfully
+
Airflow, velocity, and cleanliness requirements met
+
Energy efficiency optimized
↓
Peace of mind for the customer



AstroClean™



AstroHood® S-I



MEGAcel® II eFRM