

BioPharm Company Studies, Tests, and Proves the Reliability of MEGAce[®] II Filters

CASE STUDY - PHARMACEUTICAL

Customer Profile

- BioTechnique™ is a United States-based manufacturer of highly potent and cytotoxic sterile injectable biopharmaceuticals
- Located in Madison, Wisconsin
- BioTechnique manufactures:
 - Liquid and lyophilized high value sterile injectable dosage forms for live attenuated viruses, antibody drug conjugates, nanoparticles, and cytotoxics
 - Products not amenable to terminal sterilization that present specific environmental health and safety handling challenges to the manufacturing staff that handle them



BioTechnique™ Entrance

The Filtration Situation

Air handling represented a unique challenge to the BioTechnique facility, since all of the products that BioTechnique produces must be manufactured in an aseptic environment. If a HEPA filter was somehow compromised and did not provide at least a 99,97% reduction in non-viable particulates, it could cause potential microbial growth in a product required to be sterile. Risk assessment analysis showed a potentially critical impact to patients if non-sterile products were used, which was unacceptable.

A HEPA breach can be detected during the prescribed AQL sterility sampling of the product, during required environmental monitoring, or during the biannual HEPA certification process. However, a more substantial engineering solution was needed to ensure that the products manufactured by BioTechnique maintained the highest possible quality standards.

After the product is formulated, filled, inspected, labeled, packaged, tested, and released, there is no more opportunity to detect a quality issue.

BioTechnique management therefore mandated, after assessing the potential impact to patient safety, that the Engineering Department seek a solution to improve the reliability of the manufacturing process and the quality of the product, while at the same time reducing the facility's energy consumption.

In late 2014, the company embarked on a Lean Six Sigma project to improve the reliability of its manufacturing facility and reduce the energy costs of maintaining the Grade A (ISO 5), Grade B (ISO 6), Grade C (ISO 7), and Grade D (ISO 8) areas. Federal, state and local energy incentives, such as the State of California Title 24 program, have encouraged many pharmaceutical firms like BioTechnique to initiate energy conservation projects.



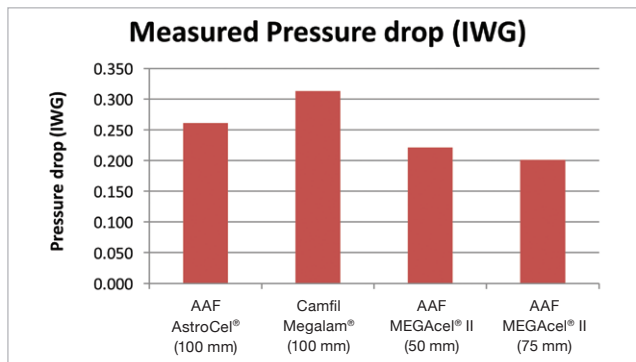
MEGAce[®] II Pharmaceutical Grade ePTFE Filtration Technology increases uptime, decreases risk, and offers less worry. Damage proof plus corrosion proof equals leak free performance.

BioPharm Company Studies, Tests, and Proves the Reliability of MEGAcel® II Filters

The Study

BioTechnique™ undertook an engineering study to determine the return on investment by purchasing the new PAO compliant ePTFE filter media, compared to traditional glass media. The study was designed to determine the optimal filter pack depth of the ePTFE filter media to install, relative to the legacy microglass filter media.

To ensure no statistical bias, BioTechnique constructed a test rig that would allow testing in a controlled environment, ensuring that the testing methodology was statistically sound and reproducible, and would produce meaningful data to draw a defensible conclusion. The study was composed of tests that were conducted three times, each time using three filters of each type, including two traditional microglass HEPA's and the 50 mm and 75 mm ePTFE HEPA filters. This study therefore utilized 36 different tests, resulting in a statistically meaningful study.



Study Results

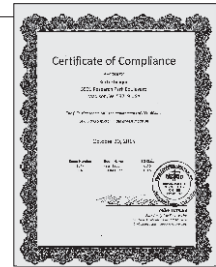
This graph represents the data collected in February 2015 for the four filter types. The ePTFE 50 mm had approximately 30% less pressure drop than the 100 mm microglass HEPA. The ePTFE 75 mm had a 36% less pressure drop than the 100 mm traditional microglass HEPA.

BioTechnique calculated the total projected annual energy savings due to the lower pressure drop ePTFE HEPA filters to be 9.350 kWh.

MEGAcel® is a registered trademark of AAF International in Europe and other countries.

Certification and Test Results

In October 2015, two competing sets of filters (AAF MEGAcel II filter and Camfil Megalam® filter) were installed in two separate ISO 5 critical rooms and tested for FDA Certification multiple times.



Throughout the test run, MEGAcel II filters responded with a perfect 100% first pass success rate, while the Camfil filters recorded a disappointing 10.8% failure rate, requiring the filters to be replaced and retested.

The results confirmed that AAF's MEGAcel II Pharmaceutical Grade ePTFE Filtration Technology is not only completely PAO compatible, it also performs at the highest level in critical areas.

The Installation

Because the MEGAcel II filters were significantly lighter, installation was accomplished with a single person, while the microglass HEPA filter install was a two-person job. This labor savings advantage was especially important when installing such a significant amount of filters. The filter could be held in one hand and a screwdriver in the other, allowing for a faster installment. An additional advantage was the stress-free nature of the install—with the stronger and more robust filter, there was less worry about damage to the filter itself.

The Benefit

These tests demonstrated that HEPA filters constructed of ePTFE media are significantly stronger and more reliable than traditional microglass media.

- AAF's MEGAcel II filters outperformed the competition with a 100% leak-free certification.
- ePTFE filters reduced filter failure and environmental monitoring excursions, resulting in lower production loss and labor costs.
- Utilizing ePTFE filters increased BioTechnique's time between recertifications, increasing cleanroom uptime.
- The lighter weight of the MEGAcel II filters allowed for a quicker installation – a labor savings advantage.
- ePTFE media has a dramatically lower pressure drop than traditional microglass media, resulting in significant energy savings for Grade A and Grade B cleanrooms.



AAF International
European Headquarters
Robert-Bosch-Straße 30-32, 64625 Bensheim
Tel: +49 6251 80368 – 0, Fax: +49 6251 80368 – 20
aafintl.com

AAF has a policy of continuous product research and improvement and reserves the right to change design and specifications without notice.

©2017 AAF International
and its affiliated companies.

ISO Certified Firm CASE_101_EN_052017