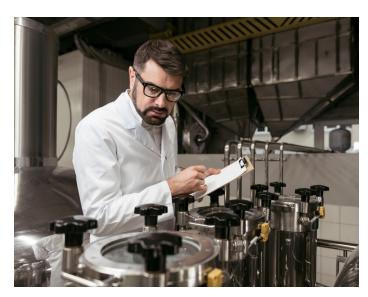


How a Leading Biotech Company Solved Its Long-Running Issues with Better Borosilicate Sight Glasses



Process observation is critical to many biotech and pharmaceutical applications. Sight glasses and visual flow indicators are widely used by operators and plant managers to view what's going on inside their systems. From fermenters and bioreactors to process vessels and compounding tanks, sight glasses provide effective and reliable real-time monitoring for biotech applications. In these key processes, sight glasses and/or flow indicators must incorporate a hygienic design that can be installed and maintained in a way that doesn't risk contaminating the product.

While contamination is never good in any industry, biotech applications are unique in that they're heavily scrutinized by regulatory agencies, matched only by the pharmaceutical industry. Sight glasses used in biotech processes, along with any accompanying sanitary fittings, must meet the FDA-mandated requirements for sterile processes, all while still providing proper process viewing. That's why sterile-compatible sight glasses, lights and clamps are used, which offer hygienic designs.

The Biotech Challenge

Recently, a large A&E consulting firm that specializes in designing and specifying superior processing systems for its clients noticed a trend in biotech applications. While these processes require the best sight glasses that industry has to offer – both due to system and regulatory requirements – these applications are often plagued with inferior sight glasses that can't meet the standards required by the environments in which they're placed. This leads to sight glass failures, which are especially costly for biotech companies. Beyond having to replace the glass, when an inferior sight glass fails, it can cause product contamination as the glass breaks down and leaches harmful chemicals into the process, ruining entire batches of product.

Always pushing innovation with its customers, the A&E firm needed to find a sight glass supplier with products that wouldn't just meet its customer's expectations but exceed them. That's why they were drawn to LJ Star, a key supplier with an extensive line of process observation equipment and a proven track record of providing products that are made to not fail.

Case Study



If a sight glass fails to maintain a sterile connection, it could lead to system contamination, lost product, and a snowball of negative effects from failing to meet FDA and other regulatory requirements. These violations are typically published, harming a company's reputation and relationships with customers. However, a hygienic connection isn't enough. Without efficient process viewing capabilities, sight glasses won't be able to help technicians identify and prevent:

- Unbalanced fluid levels
- Corrosion or leakage
- System blockage
- Harmful chemical reactions
- Damaged process vessels

As a great test for the A&E firm's ability to solve difficult problems, a leading biotech company that works in caustic chemical environments recently approached the firm for assistance in their processing system design. They were having trouble with under-performing sight glasses that required frequent maintenance and change-outs. The sight glasses, made by another sight glass supplier, could not handle the higher temperatures and pressures of the company's demanding application. After a long back and forth with the supplier, and several failed sight glasses, the biotech leader needed a different solution.

False Advertising

Like many in the biotech space before them, the A&E consulting firm soon found that the only way to ensure proper sight operations for its customer was by choosing the right product. For demanding applications, that all starts with choosing the right glass. Glass failure can be catastrophic, risking the lives of operators and causing unplanned downtime and product recalls. That's why it's so important to specify the right type of glass.

For the company's application, and many applications in the biotech space, borosilicate glass is required. Some companies try to get by with inferior products that don't meet all the industry certifications, and in other instances they may even unknowingly specify the incorrect glass or metal ring materials. For harsh or sterile applications, borosilicate products are a crucial investment that allows companies to succeed in those demanding environments.

While cheaper and more readily available, soda-lime glass has critical limitations when it comes to temperature, pressure, and corrosion resistance. Even when using tempered soda-lime glass, this type of glass is not rated for applications above 300°F. Soda-lime also easily etches and is prone to leaching unwanted chemicals into the process fluid. Borosilicate glass outperforms soda-lime in almost every way, offering:

- Temperature capabilities up to 536 °F
- · Low thermal expansion
- Broad-spectrum corrosion resistance
- Superior process visibility

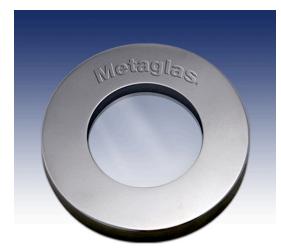


While the biotech company believed they were originally getting a similar performance level to borosilicate glass, laboratory testing and a chemical analysis of the glass they were using proved that not to be the case. Unable to meet the temperature, pressure, and tension thresholds of true borosilicate glass, the product from the other supplier was deemed to simply be soda-lime rather than the borosilicate glass that it claimed to be due to the laboratory testing and analysis.

The Power of Superior Products

Needing a company that could supply sight glasses with true borosilicate, the A&E firm turned to LJ Star for help. With LJ Star's line of METAGLAS® Safety Sight Glass Windows, the biotech company was able to achieve efficient process viewing while meeting the application's critical requirements. Proven to have superior resistance to thermal and chemical stresses, METAGLAS® sight glasses are perfect for biotech applications where visual process control is essential.

Where soda-lime glass failed, the borosilicate sight glasses from LJ Star were able to withstand the high temperature and pressure requirements of the company's processes. The low thermal expansion of LJ Star's borosilicate glass, combined with mechanical prestressing, allows these sight glasses to resist even the most extreme and



sudden temperature changes. All METAGLAS® borosilicate meets DIN7080. With these exceptional safety characteristics, LJ Star's sight glasses were made for the extreme operational conditions of the company's operations, as well most any other biotech application.

Better Designs, Backed by Documentation

Without proper documentation, biotech companies will not use a sight glass due to the regulatory risks that go along with undocumented products. Not only was LJ Star able to help supply the company with a quality sight glass made with borosilicate, but they were also able to quickly provide complete documentation for the product. This, along with fast shipping, allowed the company to get operations up and running as quickly as possible.

Whether it's a standard LJ Star product, or a custom design, all LJ Star products have the documentation needed for proper regulatory compliance. LJ Star's sight glasses are exactly what they say they are... no false advertising.

Seeing the Difference: Sight Glasses that Last

Since switching over to sight glasses from LJ Star, the biotech company has maintained clear and efficient operations, with minimal maintenance and downtime. They haven't had any subsequent issues with LJ Star's replacement, proving the superior reliability and performance of borosilicate glass.

Case Study



About LJ Star

LJ Star Incorporated provides an extensive line of process observation equipment – sight glasses, lights, sanitary fittings, and level gage instrumentation. Product lines include METAGLAS® Safety Windows, Lumiglas® Explosion Proof Lights and Cameras, the MetaClamp® Sanitary Sight Window, Visual Flow Indicators, Sight Ports, Sanitary Clamps, Magnetic Level Gages and Gage Glass. METAGLAS® is the #1 selling fused sight glass, proven in thousands of installations around the world. Unlike some other sight glasses, it meets stringent DIN 7079 and DIN 7080 quality standards, and it is approved for USP Type I use. For additional information, contact LJ Star Incorporated, P.O. Box 1116, Twinsburg, OH 44087. Phone: 330-405-3040. Fax: 330-405-3070. Email: getmoreinfo@ljstar.com. Website: www.ljstar.com.