Product Segregation vs. Multi-Product Acceptance

Facility and Equipment Design Solutions That Meet The Challenge

The Challenges

1. Avoiding cross-contamination

Contract development and manufacturing organizations (CDMOs) serve a variety of clients through multi-product facilities, which can pose a risk of cross-contamination. To ensure safe, effective products – and ultimately reduce and eliminate the threat of cross-contamination – CDMOs must make smart investments in facility design, equipment and technology.

2. Preserving the aseptic process

The pharmaceutical manufacturing industry is under immense pressure to be more cost-effective and reduce timelines for life-saving medicines. Increased collaboration with equipment vendors is essential to achieving flexibility and speed, without compromising quality.

3. Outdated facilities

Retrofitted and outdated facilities make it difficult to establish one-way product flow, impeding their flexibility and adaptability. Air-handling systems and flows must be designed to allow for the capture of airborne particles. Newer facilities should be designed as such, with the appropriate people and product flows to ensure product containment.

The Experts

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GRAND RIVER ASEPTIC MANUFACTURING

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BAUSCH+STRÖBEL

bausch-stroebel.com

SKAN

skan.ch/en/

The Solutions

Grand River Aseptic Manufacturing (“GRAM”) recently completed construction of a state-of-the-art, multi-product facility designed from the ground up with safety, quality and flexibility top of mind. Working closely with SKAN and Bausch + Ströbel, GRAM invested in the right facility design, equipment and technology to support the varied needs of its current and prospective clients. Together, they hand-picked best-in-class equipment, supported by the latest technology, and designed a facility with EHS and cross-contamination controls, engineering controls and a defined new product assessment process. The following are solutions they found to industry challenges.

1. Risk analysis protocols

It is crucial to perform a multi-product risk assessment that identifies gates for potential cross-contamination and ensures procedural or engineering controls are in place to mitigate risks.

2. Select the right equipment

Flexible equipment supported by modern facility design and proven processes eliminates risk. Equipment with disposable product paths and in line checking systems with automation and recording solutions for real time monitoring are important components.

3. Prepare for regulatory challenges

To ensure regulatory agencies and clients that CDMOs can effectively manage a multi-product facility, CDMOs must have robust procedures for evaluating client products and the selection of the appropriate PPE and engineering controls.

The Future

1. Advanced digital capabilities

The ability to offer more engineering controls will be key as the expectation for product containment and segregation increases. In addition to process reliability and efficiency, advanced digital solutions will be required for monitoring as well as tracking products and processes.

2. Modular production systems

Modular designs of the future, such as the VarioSys system, allow for the benefits of segregation without the expense of separate fill lines. They add flexibility and dedicated filling equipment within a single isolator system, and systems based on commercial filling technology for easy scale up to larger batches.

3. Investing in the future

GRAM's new large-scale fill/finish facility includes space for future growth. The CDMO recently ordered its second Bausch + Ströbel fully integrated high-speed vial filler with washer, depyrogenation tunnel and capper with 100% automated fill weight checks, a SKAN isolator for its filling line and another lyophilizer auto-loader, plus a VarioSys system that will arrive in Q1 2022.

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Discuss A Project

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