

# VarioSys® Aseptic Filling Line

## Case Study

**VARIOSYS®**

Leveraging Maximum Flexibility



# Evonik Birmingham Laboratories

## Alabama, USA

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Evonik Birmingham Laboratories in Alabama, is a contract development and manufacturing organization (CDMO), which specializes in formulation development and commercial aseptic manufacturing of complex parental drug products as well as the production of biodegradable PLGA-based polymers.



## The Challenge

To better address the current and emerging requirements for the commercial powder and liquid filling of our customer's products, we undertook an extensive review of all aseptic systems on the market.

A top priority was to identify a **single platform-based** system with sufficient modularity to handle **powder, liquid, suspension and combination projects at clinical and commercial scale, as well as lyophilization** where required.



# The Solution

VarioSys® literally checked all of the boxes for us!

The design is isolator-based and incorporates the ability to fill powders and liquids in multiple container configurations, handle potent compounds, and features fully integrated in-line lyophilization solutions from GEA. And it can do all of this at commercial volumes.

The system design also allows for maximum efficiency and flexibility for the entire manufacturing operation. Line change-overs from one vial size to another, for example, are extremely efficient with minimal to no need for tooling. Plus, there is the benefit of reducing personnel resource requirements during change-overs.

Using SKAN's PSI-L modular isolator system with short decontamination cycle, the line is equipped for maximum flexibility so that we can easily exchange one Bausch+Ströbel L-Flange module for another.

This allows unit engineers to develop a myriad of line configurations with minimal disruption.

For the Evonik Birmingham Laboratories CMO team and our customers, the incorporation of the VarioSys® system into our production capability portfolio was a fantastic decision!

# VarioSys®

## Powder and Liquid Filling Line



- Vial washing, sterilization and depyrogenation
- Liquid / powder dosing and stoppering
- Lyophilization
- Capping
- External vial washing



# VarioSys®

## Key Benefits

- Minimizes operator interaction & manual handling during aseptic filling
- 100% fill weight check or in-process weight check
- Automated loading / unloading system (ALUS) for lyophilizer to reduce operator interventions
- High level of flexibility compared to traditional filling lines
  - SKAN's modular isolator design
  - Exchangeable L-flange units from Bausch+Ströbel



**“Off-the-shelf filling lines are easy -  
But a fully modular platform that can  
handle virtually any liquid, powder,  
suspension or combination configuration  
at clinical or commercial scale?  
Now that’s challenging!  
VarioSys® has helped Evonik address a  
large, growing area of customer need for  
the cGMP production and aseptic filling  
of complex parenterals.”**

**Brad Cates**

**Director – Demand Realization | Health Care | Nutrition & Care**





**EVONIK**

**Leading Beyond Chemistry**