

# Executive Q&A

## AST Revolutionizes Aseptic Fill/Finish



**Josh Russell**  
VP, Sales & Marketing  
AST, Inc.

With over 50 years of experience designing, manufacturing and servicing innovative, high-quality and highly automated processing equipment, AST, Inc. has revolutionized the aseptic fill/finish industry.

In 2006, AST leveraged its deep experience and close customer relationships to launch the groundbreaking ASEPTiCell®. Utilizing robotics and advanced automation, the ASEPTiCell® was the industry's first aseptic multi-format fill/finish machine capable of processing ready-to-use nested vials, cartridges and syringes on the same line.

Today, AST offers customers a comprehensive range of products and services to support drug product development, clinical trials, and commercial fill/finish requirements.

### Next-Generation Isolator Technology

AST's isolator is a next-generation modular fill-finish isolator designed in collaboration with Germfree. As a 100% American-made and serviced product, the isolator will be available at significantly reduced lead times with a resilient, adaptable manufacturing philosophy and streamlined, localized supply chain.

Key features of the innovative isolator include:

- User-friendly, side-hinged doors that are more accessible and don't block laminar airflow
- Sleek, modern aesthetic design with no gapping or incongruities
- Compact, flexible footprint able to fit rooms with 10 ft ceilings
- Prioritized visibility and accessibility
- Optimized airflow systems
- Innovative VPHP solution using CURIS System's Pulse™ technology for 1-hour decontamination cycles
- Ergonomic, fortified stainless steel gloveports for easy glove installation
- Comprehensive sensor coverage, integrated PAO generator, and state-of-the-art HMI
- Semi-automated HEPA filter changeout by a single operator and simplified air distribution membrane installation

### Speed to Market

"We are very much a modular company in terms of design," said Josh Russell, AST's VP of Sales & Marketing. "Speed to market is super critical, especially for these critical therapies people are looking to roll out."

He explained AST's modular approach: "We configure standard pre-designed modules, like grabbing the right tools for the job from a toolbox. If we don't have an existing tool, then there is a lead time impact. But generally, we capture 90% of requirements with our existing solutions which allows very rapid configuration and delivery."

### Innovative Decontamination System

AST's isolator integrates CURIS System's 7000ei 7% hydrogen peroxide vapor decontamination system. Compared to typical 35-40% hydrogen peroxide systems, the 7% solution provides:

- Equivalent biodecontamination efficacy
- 60-minute cycle times (including aeration) instead of hours
- Minimal material degradation and residual off-gassing
- Inherent operator safety even in event of a breach

"Lower concentration means a non-hazardous environment which equals safer personnel," remarked Russell. "At 7%, if there is any leak it is automatically at safe 1 ppm operator exposure levels."

The rapid cycle times are enabled by CURIS' Pulse technology which injects and recirculates the vapor to maintain the precise concentration level.

### Future Innovation

Looking ahead, Russell sees opportunities for advancements in tech transfer strategies, cell and gene therapy manufacturing, and further contamination control enhancements aligned with Annex 1 guidance.

"We're showcasing many of these innovative features on this filling line and when combined with the AST isolator, this offers a fully integrated, turn-key solution. It's an exciting step forward as we continue advancing contamination control strategies."

With its pioneering technology and forward-looking vision, AST is well-positioned to continue leading aseptic fill/finish into the future.