

OPTIMA

The Optima Pharma Division plans, develops and produces filling, closing and process technology for pharmaceutical products requiring the highest cleanliness standards. This is characterized by high process reliability and flexibility. Optima Pharma's extensive turnkey portfolio is completed by pharmaceutical freeze-drying and isolators. As a technology partner for pharmaceutical companies, Optima Pharma improves the life of patients and users worldwide – making them an ideal partner for companies like Nexus Pharmaceuticals. Nexus Pharmaceuticals specializes in innovative processes to make difficult-to-manufacture, high quality, FDA-approved specialty & generic drugs that fulfill a critical unmet medical need.

Bringing Pharma Manufacturing Back to the USA

Approximately 40% of generic drugs sold in the USA are manufactured overseas, something Nexus seeks to change. The company is bringing pharma manufacturing back to the USA. To achieve this goal, Nexus has built a three-story, 84,000 sq. ft., high-tech manufacturing facility in Pleasant Prairie, WI and will re-establish generic pharmaceutical manufacturing in the U.S. over the next ten years. Commercial production is planned to begin in 2022. The key facts: \$250M investment over 10 years, 77 new local jobs by 2022, 400+ jobs in total. It is the only project of its kind in the past 30 years.

The challenge

The trend for products within operating room settings moving towards pre-filled syringes instead of preparation from vials or ampoules drove the need for this product. Highest patient safety is essential. Nexus needed a high-quality solution that met the product and customer needs and sought innovations that would reinvent how acute and critical care medicines are manufactured and delivered. A state-of-the-art manufacturing solution with the highest quality was the ultimate goal.

The reputation of not only Optima's machines but also of the integrity of the people within the organization was key in Nexus' decision-making process. Optima references for nested syringe lines in integrated turnkey solutions were an important deciding factor. According to Nexus management, local support and trust in sales and project management were significant in vendor selection, especially during the pandemic. Optima's U.S. subsidiary Optima Machinery Corporation in Green Bay, WI is in close proximity to Nexus' new facility. The benefit is clear. One lesson learned during the pandemic is that "Logistics is key".

The solution

For Nexus, Optima Pharma has realized a syringe filling line existing of the following machines:

- OPTIMA DBA-S to remove the outer bag
- OPTIMA DBA-SBA to remove the outer bag as the syringe nest is in a double bag
- OPTIMA TRR for tyvek removal
- OPTIMA H6-10 high performance syringe filling and closing machine
- METALL+PLASTIC isolator

The Technologies

OPTIMA

- Double bag removal
 - Advantages: A no-touch transfer solution with minimized complexity and capital cost
- Filling line
 - Advantages: Tried and true filling and closing system from a nested filling technology leader
- Isolator
 - Advantages: Highest quality containment system offering industry leading decontamination cycle times through award winning DECOpulse® bio-decontamination system
- IPAS
 - Advantages: Intelligent Production Assistance Services allow for the most efficient setup, operation and troubleshooting

To media fill in record time

Optima Pharma's Comprehensive Scientific Process Engineering (CSPE) accelerates the processes from line design to production start-up. Comprehensive process simulations and integrated factory acceptance tests for complete lines are an essential part of this. In addition to filling and closing systems and isolators, freeze-drying systems can now also be set up, tested under realistic conditions and as a functioning complete unit. As a total system provider, Optima Pharma now handles further qualification measures in-house, including essential parts of the cycle development. This significantly reduces the time required between installation and start of production at the customer's site, and the overall time from product development to market launch is shortened for customers.

Combining the latest technology, the comprehensive CSPE turnkey approach, and digital features, the requirements of Nexus will be successfully met. The stage is set for the future of pharma production in the USA.