Excellence in design, project management, and execution resulting in superior process transparency and customer experience.

Kinston, North Carolina
Ready-to-Sterilize (RS) Expansion
West Pharmaceutical Services, Inc. is a leading manufacturer of packaging components and delivery systems for injectable drugs

- 110 million of our components and devices are used daily, which are designed to improve the delivery of healthcare to patients around the world
- Headquartered in Exton, PA with global locations
- 2015 sales of $1.4 billion USD
An Introduction to DME:

- Advanced Technology Facility Design
- Conceptual through Detailed Engineering and Construction Administration
- Pharmaceutical & Biotech Subject Matter Expertise
- BIM 3D Design
Introduction to the West Kinston, North Carolina Site:

- 200,000 sq. ft. that manufactures a variety of rubber components that serve the injectable and healthcare market
- Capability to bring in basic rubber components and produce a finished rubber component with option of West’s B2 and Westar Ready-to-Sterilize (RS) processes
- Transparency and a highly visual customer experience is a dominant feature of the facility
Westar® RS Serves the Needs of the Pharma industry

- Components are washed and rinsed with Water for Injection (WFI) and packed in an ISO 5 cleanroom
- All product lots are tested and accompanied by a CofA for specifications, such as:
  - Endotoxin
  - Bioburden
  - Particulate
  - Silicone level (if applicable)
A Project was Launched to Expand RS Production to Kinston, NC

Key Features:

- Process flow developed to integrate RS into the existing facility with allowance for future expansion for Envision (vision inspection) and Ready-to-Use (RU) sterilization processes
- An addition of 22,000 sq. ft to house all the new processes and equipment
- Vapor compression water-for-injection (WFI) system
- Continuous environmental monitoring system
- ISO 8 through ISO 5 cleanrooms
- Pharmaceutical Stopper Washer
- Micro lab
Kinston hosts a significant number of customer visits for audits and project-development meetings.

The Westar RS area was designed to make the process accessible to customers without gowning and disruption of production.

Visitors are able to walk down a tour aisle and view all of the rubber extrusion, molding and Westar processes.

The transparency of the process adds to customer confidence in West’s capabilities, making the facility and additional marketing tool.
New Glass Wall System was Developed for a Revolutionary Customer Experience

- The project team realized that there were no glass wall systems available that met the demand to provide a superior customer experience and transparency.
- The team developed a custom floor-to-ceiling glass wall design with minimal obstructions.
  - ISO 5 was an additional challenge as it required the development of an additional glass air return wall.

View from customer tour hallway
Additional Views of ISO 5 Window Details

ISO 5 to Viewing Corridor

Return wall support
Best Practices and Lean Principles Utilized to Optimize Facility Design

- Company wide lean best practices implemented to establish the optimal future state process early in the project
  - The team developed a lean future state process as an output for the basis of design (BOD).
- Overhead and labor cost in equipment maintenance were minimized by accessible equipment layout
- Efficient process flow through facility with considerations for future expansion established
- New process area had to be designed around existing IT room that couldn’t be moved
- Existing warehouse was optimized for a 50% reduction in required floor space
3D Modeling Optimized Layout and Ensured a Superior Customer Experience

- The visual tool was utilized to simulate the viewpoint of the customer through the facility
- 3D models were also valuable in providing clash detection among the HVAC, plumbing and electrical systems

Customer Tour Aisle: Concept

Customer Tour Aisle: Reality
Additional Controls Put in Place to Safeguard Condition of ISO 5 Spaces

- Improved confidence in HVAC unit through implementation of fan wall technology
  - Fan wall provides multiple fan units that can adjust to ensure proper air flow if any one fan fails

- Utilization of additional fan filter controls to optimize laminar air flow in the ISO 5 room
  - Independent control of each fan filter unit (FFU)
  - Centrally located control terminal interface outside cleanroom
  - Ability to track and adjust performance and alarm status of each FFU
Cleanrooms Designed and Constructed to Minimize Contamination and Optimize Cleaning

- Wide floor coves were utilized
- The rooms were laid out to minimize any obstructions on the walls
- Elimination of wall bumper rails
- The fit and finish of the cleanroom was closely scrutinized for gaps and ridges
Euro Return Walls Utilized

- Minimize visual wall clutter
- Eliminate return grills
- Easier to clean
Cleanroom also Optimized with Return Wall Windows

- Windows designed to accommodate return air flow
- Provide visibility to other areas without sacrificing cleanroom performance
WFI Room Conveys Dedication to Excellence

- WFI room is a routine point of review in customer audits
- Clutter free layout
- Utility support processes placed in separate area
Mezzanine Laid Out to Ease Maintenance

- Worked within existing roof height
- Curbing and pads to minimize leakage
- Provide ease of access to roof
Continuous Monitoring of Cleanroom Conditions and Lab Equipment

- ISO 5 rooms continuously monitored for:
  - Room pressurization
  - Temperature
  - Humidity
  - Particle Count

- Lab equipment continuously monitored for temperature and humidity

- Alarm reporting direct to supervisory personnel

- Validated separately from building management system

- Provides ability to verify conditions at time of production and track and trend data
Clear Communication with the Team was a Key to Success

- The team closely tracked budget and schedule metrics
- Numerous challenges and opportunities that influenced project were managed by team
- Result of team effort:
  - Completion of a major expansion with minimal impact on team members and existing production
  - No safety issues
  - Project was on schedule and met budget
West Recognized by FOYA for Raising the Bar for Primary-Component Manufacturing

Judges comments:

- West’s Kinston site is a primary-component supplier that is raising the bar on how these components are manufactured.
- While expanding to introduce new RS product capabilities, it took the opportunity to upgrade its facilities to align with industry trends as well as meet drug manufacturers and regulators requirements.
- The facility expansion was designed with transparency and compliance in mind.

“FOYA is recognizing West Kinston facility with an Honorable Mention for its industry leading efforts to align with the primary-component manufacturing process with current industry trends and standards.”

- Pharmaceutical Engineering Magazine May-June 2016
Why We Won – Raising the Bar for Component Manufacturing

• Development of a glass wall system that provided a revolutionary customer experience and transparency
• Attention to detail
• A facility design and layout that provides superior transparency of the process to the customer
• The team leveraged the early development of Building Information Management (BIM) into a basis of design (BOD) that proved invaluable throughout the construction process
• The facility layout utilizes a modular design to allow for future expansion
Thank You to All of the Vendors Who Assisted with the Project:

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<tr>
<th>Role</th>
<th>Name/Company</th>
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<tbody>
<tr>
<td>Designer/Architect</td>
<td>Eric Walker AIA, CCS</td>
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<td>Engineering</td>
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<td>Major Equipment Suppliers/Contractors</td>
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Questions?

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