

Product

- Co-packaged Combination Product
- Unique and Novel Closed System Transfer Device (CSTD) Performance

Industry Challenge

- Testing strategy not established
- No direct CSTD established testing standards available
- Novel system and components could not be tested by typical approaches

West Resolution

- Review product testing needs, unique aspects of the product, unknowns and associated risks
- Performed product feasibility testing
- Created custom testing strategy in alignment with established standards as much as possible



Testing
Strategy



CSTD

**Closed
System
Transfer
Device**