



Integrated Solutions Fill-Finish Support Services

When it's time to move your injectable drug product to clinical testing or commercialization, drug developers need a partner who can help provide an integrated solution that will not only streamline drug product development, but also provide the necessary expertise and partnerships to accelerate drug products to market.

Many drug developers are challenged to find fill-finish options for the broad variety of drug product packaging and containment options available on the market. With a partner that is uniquely positioned to help Simplify the Journey™ from concept to commercialization, drug developers receive the flexibility, quality, speed and expertise they need, with fill-finish support services from early development through small-scale commercialization.

Through our Integrated Solutions program and partnerships with Contract Manufacturing Organizations (CMOs), West can assist drug developers with the following fill/finish services:

- Sample Preparation for Product Testing
- Fill-Finish Implementation Support
- Clinical and Commercial Filling
- Analytical Testing
- Program Management

Sample Preparation for Product Testing

During drug product development West supports drug developers by performing small-scale filling services that enable early screening, gross compatibility testing and performance/functional studies.

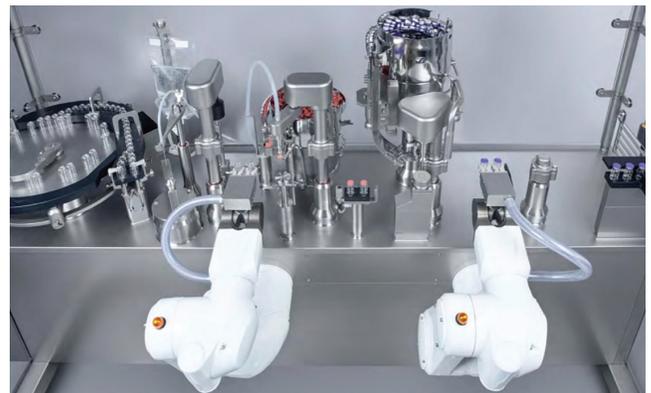
Drug Product Characterization Filling Services

- Filled with drug product*, water or placebo
- Samples prepared as Not-For-Human-Use (NFHU)
- Plunger placement and vial crimping conducted using pharmaceutically representative methodologies
- Processed within ISO 5 conditions/cleanroom

**contingent on safety review*

Process Characterization Filling Services

- Filled with water or placebo
- Samples prepared as NFHU
- Processing steps conducted using pharmaceutically representative methodologies (Bausch + Stroebel flexible filler)
- Processed within a Controlled Not Classified (CNC) room



Courtesy of Bausch and Stroebel

Fill-Finish Implementation Support

West's fill-finish implementation consulting service was established to provide drug developers with support based on West's unique experience and relationships with various equipment vendors and CMOs. Services include:

- Process Development Engineering Services
- Equipment Vendor and CMO Selection Consulting
- Filling Line URS Consulting
- Change Parts and Machinability Assessments
- Troubleshooting and Investigation Engineering Services
- Technology and Process Transfer Engineering Services

Clinical and Commercial Filling

To facilitate the path to market, West has developed unique collaborations with CMOs to support drug developer needs for clinical and commercial fill-finish manufacturing services. One such partner, Swissfillon, specializes in flexibility, quality and speed, and with expertise in complex biologic fill-finish from clinical through small-scale commercial opportunities. Swissfillon enables fill-finish for West's SmartDose® platform of wearable injectors, including the 10mL cartridge.

Analytical Testing

To simplify product qualification and reduce development risk, West provides comprehensive analytical services for filled containment systems.

- QC Testing
- Release Testing
- Combination Product Testing

Program Management

West provides integrated program management across device and fill-finish activities, to streamline project execution and simplify the supply chain.



Courtesy of Swissfillon AG and Optima Packaging Group GmbH

For more information visit [westpharma.com](https://www.westpharma.com)

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