eurofins | BioPharma Product Testing

Sterile Fill/Finish Manufacturing

The bio/pharmaceutical industry is constantly pushing the frontiers of medicine with the production of biologics, mRNA, viral vectors and ATMP's. With the increased product complexity and shorter timelines, these changes can often introduce additional risks to the sterile fill/finish process, resulting in production delays, additional costs, and safety concerns. Ongoing regulatory changes, such as Annex 1 guidance move to eliminate human interventions and provide PUPSIT to prove filter integrity. Between the challenges of discovery and regulation additions, the choice of your CDMO is critical to the success of your pipeline. Eurofins BioPharma Product Testing network of laboratories can help eliminate human error and other associated risks when producing small batches of sterile GMP product for Phase 1 and 2 trials using our state-of-the-art Closed Robotic Isolator vial filler at our San Diego, CA, laboratory.

Why Choose Eurofins BioPharma Product Testing?

We perform compounding of batches in an ISO 8 clean room followed by ISO 5 single or dual sterile filtration using sterile, single use, closed filtration systems with aseptic connectors.

We are able to support additional products and multiple batches quickly, and automation offers less cleaning time.

We offer agility for personalized medicines with the potential to make multiple batches of personalized medicines each day. Our worldwide GMP laboratory network can support the required CMC testing on the product.

Vanrx Microcell Vial Filler

The Vanrx Microcell Vial Filler is a uniquely designed and fully integrated isolator that fills vials for small batches of GMP product, processing units quickly with precise filling volumes. This gloveless, closed, and completely robotic system is designed to reduce human error, time, and contaminations.

In alternative systems, star wheels, vibratory bowls, and conveyors could be sources of risk. Without these pieces, this Vial Filler eliminates the associa- ted risks, interruptions, or human interventions.

This state-of-the-art vial filler is capable of handling multiple sizes of vials and producing multiple batches of various drug products on a single machine thereby providing maximum flexibility to clients.

Key Features

- Sterile filtration occurs in an ISO 5 hood using single-use, pre-sterile, closed filtration systems that utilizes Readymate® aseptic connectors.
- Qualified to fill up to 2,500 2 mL vials, with the capability of producing small volume sterile products ranging from 0.15 mL to 50 mL per vial, including filling and capping.
- Pre-sterile, nested vials, nested caps, and snapcap technology to eliminate human interaction with the product during fill, results in lower particle counts.
- Vapor-phase hydrogen peroxide decontamination implemented initially and between cycles.
- Standardized technology eliminates risks of conventional filling technologies while allowing shorter timelines.

Focus on High Value Products

Our focus is on small batches of drug products where line loss is a critical parameter, such as biologics, mABs, proteins and enzymes. Our teams support formulation, development, stability, release testing, and all other required CMC testing.

Comprehensive GMP Testing Services

Method Development & Validation • Release Testing • Raw Materials Testing
Cell Banking Services • Virology Services • Facility & Process Validation
Chemistry • Biochemistry • Molecular & Cell Biology • Microbiology
Stability Testing & Storage • Primary & Secondary Package Testing

Flexible Service Models

Fee For Service (FFS)
Full-Time-Equivalent (FTE)
PSS Insourcing Solutions®

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