# Aseptic Fill Finish

## We provide custom live virus and fill/finish services

## CDMO for Biotherapeutics and Vaccines

With aseptic filling operations in the U.S. ABL provides the flexibility and logistical responsiveness needed to support global clinical trials. Meeting demanding timelines is what we do—whether a comprehensive GMP production program or a standalone drug product fill—we integrate vialing, inspection, labeling, testing, storage and distribution activities for the provision of clinical trial materials.

ABL stands shoulder-to-shoulder with our clients as a catalyst for life-changing innovations. We've supported fill/finish projects for SARS-CoV-2 (COVID-19) vaccine candidates—and are available for new projects NOW.



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LOTS

## ABL has filled hundreds of GMP gene therapies, vaccines, oncolytic vectors and other immunotherapies at facilities located at our US based facility

The race to clinic is competitive. Partner with one of the best viral vector and protein fill/ finish CDMOs.

## Viral vector and protein fill/finish services

Live virus fill/ finish in several standard vial configurations- with 100% visual inspection and ADQ procedures.
• Primary packaging and labeling
• Release testing and stability programs
• On-site Quality Assurance oversight of all operations
• Fast turnaround of phase material (as quickly as 1 week)
• Commercial-ready facilitiesProviding liquid fill/finish services to

biopharmaceutical companies developing live virus, recombinant protein and monoclonal antibody products. Exceeding expectations for clinical trial materials in our internal BSL-2 facilities for both product development (PD) and GMP operations.

## Operational excellence meets speed and flexibility

## Global viral vector expertise coupled with state-of-the-art facilities

ABL provides aseptic drug fill/finish services using a fully automated Flexicon FPC50W filling machine installed within a Grade A Restricted Access barrier (RABS) system. A bracket approach is applied across the qualified fill configurations to a maximum lot sizeof 3000 vials, where one configuration of each size/component material of construction is re-qualified every six months.

## Standard fill capabilities:

- Broad range of production scales: < 50 to thousands of vials per lot
- 0.5 mL to 100 mL vial size accommodation
- In-line weight checks on every vial
- QC inspection, GMP lot release and stability testing
- Labeling, packaging and shipping
- AQL Inspection

- Standard materials include Type 1 borosilicate glass and Crystal Zenith® vials (in 2mL and 5mL size with rubber stoppers and tear off aluminum seals)
- Line speed ranging from 9 vials per minute to 20 vials per minute, depending upon fill configuration
- Ambient temperature fills
- VHP room changeover post-fill

## Liquid drug filling capabilities

## Viral vectors

**Monoclonal antibodies**

**Virus-like particles**

**Recombinant proteins**

**Diluent and placebo**

# Reserve your project today

contact us today