



BIO•PHARMA
S E R V I C E S

— THE POWER TO MAKE —

DRUG PRODUCT
FILL FINISH



Overview

Ajinomoto Bio-Pharma Services offers a unique range of formulation and aseptic filling in vials, prefilled syringes or cartridges to address production needs that span from small early stage clinical products to larger scale commercial products.

- Aseptic Formulations
- Aseptic Vial Filling
- Aseptic Syringe Filling
- Aseptic Cartridge Filling
- Lyophilization
- Terminal Sterilization

6 Independent Filling Suites

9 Formulation Suites

Manual and Automated Visual Inspection Suites

- Monoclonal Antibodies
- Recombinant Proteins
- Adjuvants
- Plasmid DNA
- Peptides
- Vaccines
- Small molecules
- Oligonucleotides
- Suspensions



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EXPERIENCE THE
POWER TO MAKE

info@US.AjiBio-Pharma.com

AjiBio-Pharma.com

ASEPTIC VIAL FILLING

Aji Bio-Pharma offers a comprehensive range of vial batch sizes, including comprehensive media fill configurations. We employ an aseptic filling process that requires less manufacturing line and minimizes product loss.

VIAL FACILITY CAPACITY

- Vials from 2 mL to 100 mL
- Clinical batch sizes from 100 to 20,000
- Commercial batch sizes to 60,000
- Line speeds up to 3,000 vials/hour

DOSAGE FORMS

- Parenteral products
- Viscous products
- Suspension products
- Complex formulations of liposomes, adjuvants, crystallized proteins

TECHNICAL CAPABILITIES

- Nitrogen overlay
- High speed vial labeling
- Continuous environmental monitoring
- Peristaltic and rotary piston pumping
- Integrated from vial washing through capping
- Single-use disposable technology
- 100% non-destructive weight checks
- Re-stoppering and re-capping functions
- Specialized crimping system
- Decreased stainless steel to glass contact



ASEPTIC SYRINGE FILLING

Aji Bio-Pharma offers comprehensive prefilled syringe contract manufacturing services, including parenteral manufacturing, on our high-speed prefilled syringe line. Our prefilled syringe production facilities utilize a Restricted Access Barrier System (RABS) technology to ensure the required sterility for fill finish.

PREFILLED SYRINGE CAPACITY

- Prefilled syringe sizes: 1 mL – 5 mL
- Capabilities for 0.5 mL, 10 mL and 20 mL with change parts)
- Maximum lot size: 50,000 syringes
- Line speeds up to 4,000 syringes/hour (1 mL long)
- Glass or polymer syringes

TECHNICAL CAPABILITIES

- Restricted Access Barrier System (RABS)
- Automatic Tyvek® Lid and Liner Removal
- 5 Head Peristaltic Pump or Rotary Piston Pump Systems
- Mechanical Filling & Stoppering
- Vacuum Stoppering
- Break-Free, glide force and injection force testing



HIGHLY POTENT VIAL FILLING

The high potency facility has been designed for safe handling and manipulation of very low OEL compounds (down to 1 ng/m³) while maintaining aseptic conditions and cGMP compliance.

The fill line and lyophilizer unit are fully integrated and contained in an isolator system.

VIAL FACILITY CAPACITY

- Line speeds up to 7,000 vials/hour (2 mL vials)
- Vials from 2 mL to 20 mL
- Lyophilizer capacity: 5 m²

TECHNICAL CAPABILITIES

- Integrated from vial washing through capping
- Fully contained and integrated
- Single-use disposable technology
- Zero dead volume fills
- Peristaltic and volumetric pump capabilities
- 100% non-destructive weight checks
- Continuous environmental monitoring



ASEPTIC MULTI-PURPOSE FILLING LINE: VIALS, SYRINGES & CARTRIDGES

The multi-purpose line provides a 50% increase in aseptic fill finish capacity with the ability to process larger batch sizes and volume ranges.

Nested Read-to-Use (RTU) components minimize component preparation and packaging.

CAPACITY

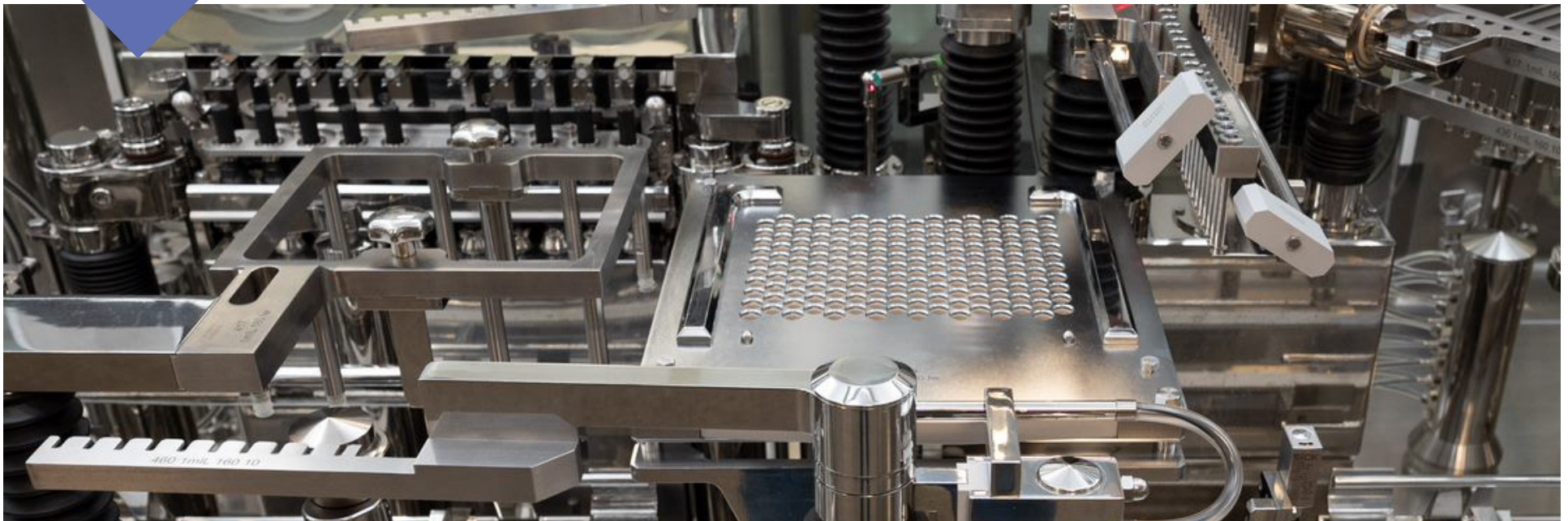
- 24,000 syringes/hour (1 mL long)
- 6,000 vials/hour (2 mL)
- 11,000 cartridges/hour (3 mL)

RESTRICTED BARRIER ACCESS

- Tub loading & debuggng
- Vial capping
- Syringe tub outfeed

ISOLATOR

- Filling
- Stoppering





ASEPTIC FORMULATION

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Certain drug compounds may require complex drug formulation to overcome challenges with stability, efficacy, potency, or safety during clinical and commercial phases.

Ajinomoto Bio-Pharma Services' dedicated formulation scientists are highly knowledgeable in manufacturing various complex formulation utilizing the following instruments:

- Dynamic light scattering
- Differential scanning calorimetry
- Karl Fischer titration
- FT-IR spectroscopy
- Microflow imaging

Operating in nine formulation suites, we leverage the use of microfluidizers, homogenizers, and tangential flow filtration for manufacture complex formulations.



FORMULATION SERVICES

- Simple liquid
- Lyophilization
- Sustained release
- Complex liquid development including nano-emulsions
- Liposomes & nanoparticles
- Suspensions
- Conjugations of PEG & peptides



VISUAL INSPECTION

Ajinomoto Bio-Pharma Services conducts visual inspection before releasing syringes or vials for clinical or commercial distribution.

Our current visual inspection process is 100% manual. In 2022, on-site automated visual inspection lines will be operational.

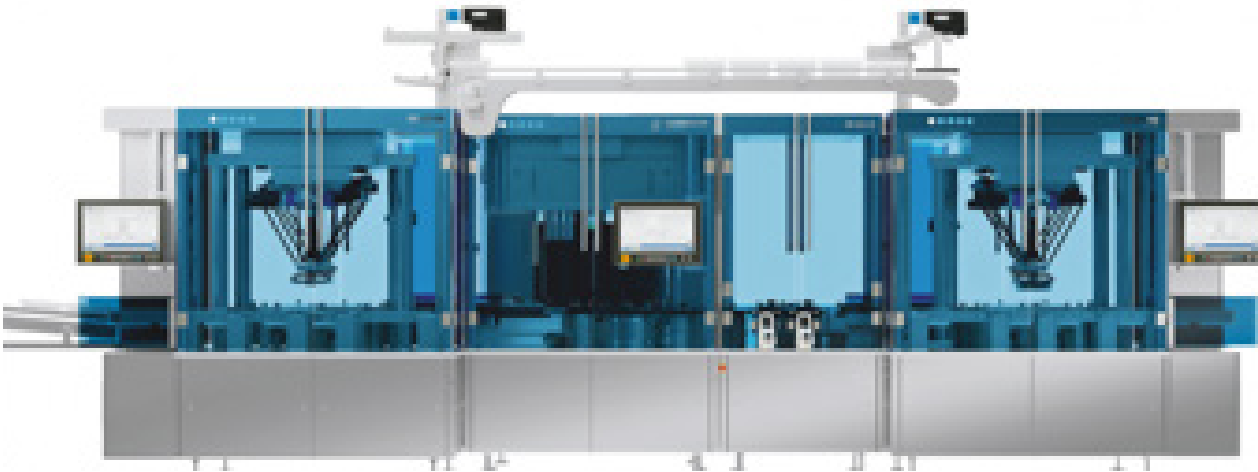


SEMI-AUTOMATED VIAL INSPECTION LINE

- High voltage leak detection
- Range: 2 mL - 100 mL vials
- Volume: ~4,800/hr
- Two inspection lanes; 2 booths/ lane
- HVLD can run in line or separately

AUTOMATED SYRINGE INSPECTION LINE

- High voltage leak detection
- Range: 1 mL - 10 mL syringes
- Volume: ~24,000/hr
- HVLD integrated inline





TERMINAL STERILIZATION

Aji Bio-Pharma offers terminal sterilization services for syringe and vial configurations.

This includes product evaluation, cycle development and final terminal sterilization based on developed and validated cycles.

IDEAL FOR SEALED SYRINGES & VIALS

- Sterilization feasibility studies
- Cycle development
- Cycle validation
- GMP batch sterilization

SYRINGES

- Size: 0.5 mL to 5 mL
- Load: 26,880 to 86,400 syringes per load

VIALS

- Size: 2 mL to 100 mL
- Load: 5,712 to 120,960 vials per load





PACKAGING & LABELING

Ajinomoto Bio-Pharma Services offers both clinical and commercial packaging solutions. Our labeling and packaging solutions offer greater safety and efficiency for your supply chain with our Drug Supply Chain Security Act compliant track and trace service.

CAP CODING

- Lot traceability with OCV or 2D coding

AUTOMATED VIAL LABELING

- 2 mL to 100 mL vials
- LOT/EXP/2D barcode labeling

SYRINGE LABELING

PACKAGING

- Automated vial cartoning and printing
- Enclosed product insert
- Tamper evident sealing
- Serialization
- Semi-automated aggregation to pallet level



SHORT TERM STORAGE

All drug products are stored under ICH storage conditions.

- $-80^{\circ}\text{C} \pm 10^{\circ}\text{C}$
- $-20^{\circ}\text{C} \pm 5^{\circ}\text{C}$
- 2°C to 8°C

VALIDATED WORLDWIDE SHIPPING



**WITH AJINOMOTO BIO-PHARMA SERVICES,
YOU HAVE THE POWER TO MAKE**

You have the power to make a difference by delivering new therapeutics that improve quality of life and inspire a healthier world.

You need a manufacturing partner who has the power to make your every challenge their own and who shares your unwavering tenacity and dedication from pre-clinical programs to commercial successes.

Together we have the Power To Make.

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