

Sterile Injectables Fill & Finish

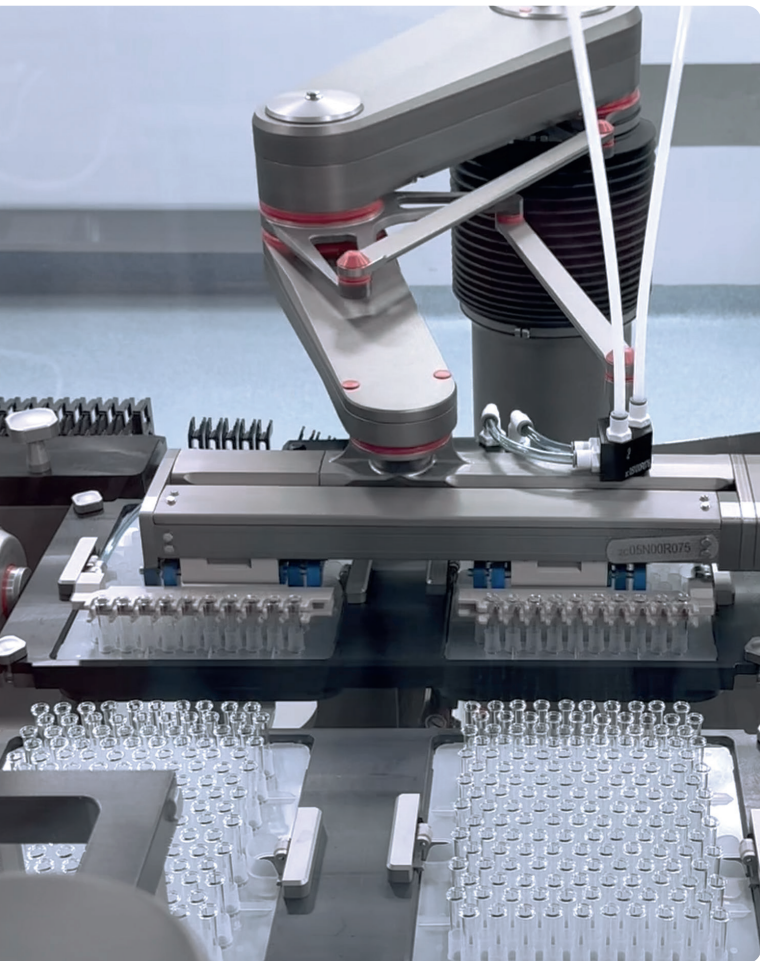


State-Of-The-Art Filling Suites
for Biologics and Small Molecules
in Vials, Syringes & Cartridges



Cost Effective and Customized Solutions

- Sterile filling of vials, syringes, and cartridges under isolator (EU GMP Annex 1 compliant)
- Robotic line for filling of vials, syringes and cartridges, in glass and COP
- Additional capacity of 40M units/year from 2027
- Integrated end-to-end cold chain management



Your Partner for Biologics and Sterile Injectables

Aenova is a leading, globally oriented CDMO providing Annex 1-compliant and highly flexible Fill & Finish solutions for biologics up to BSL-2 at its sterile injectables site in Latina.

High-Speed Fill & Finish – Commercial Scale

- For Biologics up to BSL 2
- oRABS filling line
- Vials, pre-filled syringes (PFS)
- Automated aseptic filling
- Fully Annex 1 compliant
- Indicative capacity: 80+ million units/year
- 100 % IPC

Medium-Speed Fill & Finish – Clinical and Commercial Scale

- Isolator filling line in operations in 2027
- Vials, pre-filled syringes, cartridges
- Fully automated, robotic aseptic filling
- Fully Annex 1 compliant
- Indicative capacity: 40 million units/year from 2027
- 100 % IPC, re-filling

AENOVA OFFERING

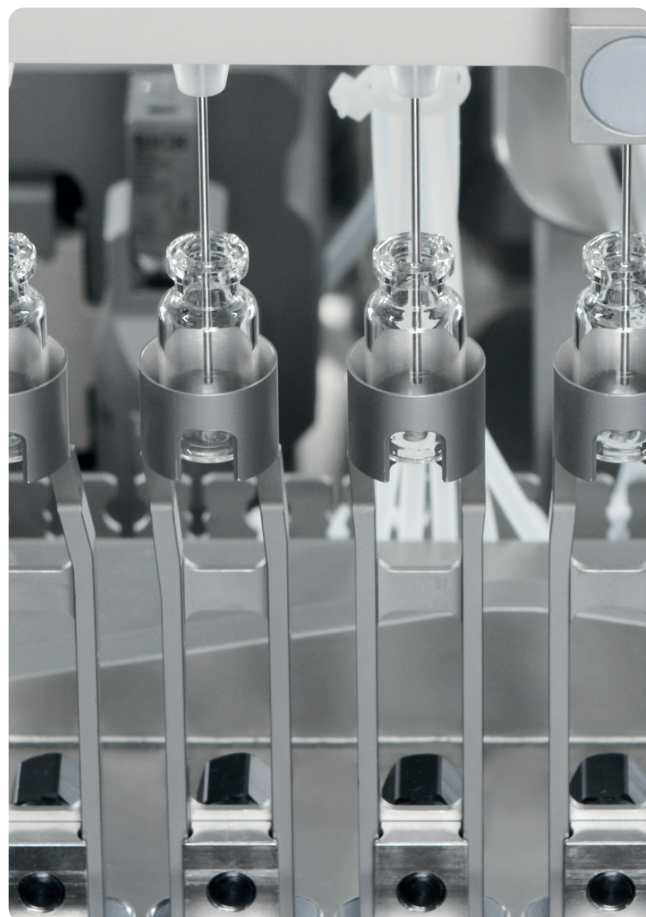
Superior Manufacturing Solutions

Advanced Fill & Finish suites for flexible, scalable manufacturing.

- Small molecule APIs up to OEB-3
- Large molecule biologics
- Complex molecules with sensitivity to shear stress, oxygen, light, and hydrogen peroxide exposure
- Late clinical phases, pre-registration and commercial manufacturing

Integrated Product Lifecycle Services for Development, Manufacturing & Supply

- Material control and cold chain management (from drug substance to drug product)
- Formulation development and technical transfer
- Process characterization, optimization and scale-up
- Process validation and regulatory support
- Microbiological, chemical & biochemical quality control
- On site storage at 2-8°C
- Commercial launch with rapid ramp up and end-to-end supply chain management
- 100 % IPC



FILL & FINISH CAPABILITIES

Two Sterile Production Lines. One Trusted Partner for Your Success.

Medium-Speed



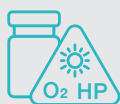
PFS from
0.5 ml to 50 ml



Vials from
2 ml to 50ml



Cartridges from
1 ml to 20 ml



Oxygen, light
and HP sensitive
products



Batch sizes from
few liters to 650l



Annex 1
compliant



SUS or SS vessels
sterile filtration
(PUPSIT)



Temperature con-
trolled compounding

High-Speed



PFS from
0.5ml to 10ml



Vials from
2ml to 10ml



Pre-use post-
sterilization integrity
testing (PUPSIT)



Oxygen, light
and HP sensitive
products



Batch sizes
from 10l to 750l



Annex 1
compliant



SUS or stainless
steel vessels



Temperature con-
trolled compounding

Our Sterile Injectables Center of Excellence

Aenova's Center of Excellence for Sterile Injectables in Latina provides high flexibility Fill & Finish solutions with full Annex 1 compliance. With state-of-the-art technology and our well-established expertise, Aenova Latina is ready to provide cost effective and customized solutions on a variety of Fill & Finish lines:



	Medium-Speed	High-Speed
PFS	0.5 ml – 50 ml	0.5 ml – 10 ml
Vials	2 ml – 50 ml	2 ml – 10 ml
Cartridges	1 ml – 20 ml	N.A.
Process- Compatible	Oxygen/Light/HP Sensitive Products	Oxygen/Light/HP Sensitive Products
Batch sizes	Few liters* – 650l	10l – 750l
Compliance	Annex 1	Annex 1
Equipment	SUS and/or SS vessels sterile filtration	SUS and/or stainless steel vessels
Temperature	controlled compounding	controlled compounding

* to be evaluated based on process



Robotic filling line under isolator GMP ready in 2027. Further sterile capacity expansion planned for 2028 - 2030.



Biologics/biosimilars Fill & Finish products: Highest dosing precision and lowest line losses

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