



ADVANCED THERAPIES

# RECIPHARM'S COMPREHENSIVE SERVICES



mRNA



Virus



Microbiome



Analytical



Fill & Finish

## A global and flexible CDMO

We provide advanced therapy pioneers with expertise-driven process development and GMP and RUO manufacturing services of RNA, viral vector, microbiome, oncolytic viruses, and recombinant protein vaccines. Our global network of facilities offer drug substance, drug product and end-to-end manufacturing solutions for therapeutics and vaccines with capacity to support customers from early process development through commercial production. Recipharm Advanced Bio has a proven track record in commercial production and clinical batches across Advanced Therapy Medicinal Products (ATMPs).





# RNA

## Integrated services in one facility

**Providing a range** of integrated services in one facility, our RNA and plasmid offering encompasses the entire development and manufacturing value chain, maximizing efficiency and eliminating tech-transfer.

**Recipharm Advanced Bio collaborates** closely with customers to meet the needs of even the most unique RNA projects, including mRNA therapeutics, self-amplifying RNA, circular RNA and lipid nanoparticles (LNPs) with the capabilities and resources to deliver RNA medicines to market at any scale, utilizing the latest technologies to deliver high yield, quality and purity.

**In conjunction with MIT**, Recipharm Advanced Bio is currently developing the world's first continuous and truly integrated nucleic acid manufacturing platform. Continuous flow, process analytics and machine learning come together in a rapid GMP manufacturing platform with less waste and lower costs.

## Capabilities

- Plasmid manufacturing: 3 L and 30 L single-use (SU) xRNA (m-, sa-, cir-) generation up to 100 g
- *In vitro* transcription (IVT) from 1 mL to 50 L SU bioreactor
- Flexibility on capping and tailing strategies
- Chromatography and filtration-based purification
- Platform process for quick turnaround
- LNP formulation up to 50 g
- Experience in jet, tee and microfluidics mixing technologies





# VIRUS AND VIRAL VECTOR


## Pre-clinical to commercial launch

**Our comprehensive, fully integrated** development and manufacturing services for live viruses and viral vectors in the EU and US offer a seamless journey from pre-clinical to commercial launch.

**Recipharm Advanced Bio is dedicated** to meeting the changing needs of AAV, Lentivirus and oncolytic virus therapeutics, implementing a platform-based approach across a wide variety of species and serotypes. Our global process development team has extensive experience supporting plasmids, and a broad range of virus types and cell lines.

## Capabilities

- SU Plasmid manufacturing: 3L, 30 L and 300 L
- Vector engineering, cell culture optimization and serotype selection services available
- Proprietary upstream platform offering high titer and high full capsid percentage
- Downstream toolbox offering flexibility to address purity requirements
- Established platform manufacturing unit operations and analytical methods
- Cell-based and egg-based oncolytic virus manufacturing expertise



# MICROBIOME AND LIVE BIO- THERAPEUTIC PRODUCTS

## Development services and cGMP manufacturing

**Recipharm Advanced Bio supports** the development and cGMP clinical and commercial manufacturing of aerobic and anaerobic organisms for single strain or multi-strain consortia products.

**Backed by over 15 years' experience** and the production of hundreds of species, we supported the commercial approval of the first orally administered microbiota product for *Clostridioides difficile* infection.

**Drawing on unparalleled experience** and capabilities in LBP production, Recipharm Advanced Bio leverages a vast knowledge and best practices to consistently achieve high cell densities and cell viability.

## Capabilities

Experience with over 225 species and 105 genera of aerobic, anaerobic, spore-forming and fungal microbes, including:

- Aerobic organisms
- Obligate and facultative anaerobes
- Genetically engineered strains
- BSL-2 and spore-forming containment



# ANALYTICAL SERVICES

## Competitive Analytical services

**Experts in analytical development and optimization** across multiple modalities with phase appropriate qualification and validations assessed for each unique program – Designed for Advanced modalities.

US and EU analytical services available. Experts are well-versed in both compendial and non-standard assays.

**Engineered for what's next** – capacity to tackle projects of any size with cutting-edge analytical technologies.

## Capabilities

- >15 years expertise developing and qualifying analytical methods
- Accelerated onboarding by highly-trained scientists
- Simplified workflow with test samples concentrated at one site
- Savings vs traditional CRO analytical services
- Complete services offered in central locations reduces shipping and handling costs
- Development, manufacturing, and analytics provide high-value offering to sponsors
- Purpose-built analytical labs designed for efficiency and flexibility
- Standard panel of assays for each modality and defined new method development pathways
- Lean approaches to process-building and laboratory management



# STERILE FILL-FINISH

## Best-in-class, sterile fill-finish services

**Recipharm Advanced Bio's fill-finish services** provide a fit-for-purpose solution for high value therapeutics for low line loss and best-in-class sterility assurance.

**Semi and fully automated fill-finish capabilities** span across multiple ATMP modalities and sites to ensure flexibility necessary to meet clinical demands. We have a comprehensive range of line configurations and vial formats that can be adjusted to a program's specific requirements.

### Capabilities

- Automated robotic filling in a ISO 5/Class 100 (Grade A)
- A range glass and SiO<sub>2</sub> coated vial formats: 2R, 6R, 10R, and 20R
- Integration of syringe and cartridge formats available
- As low as <10 mL line loss per batch
- Single-use product flow paths
- 100% manual or semi-automated visual inspection
- As low as <0.5% filling tolerance
- Lyophilization services available across EU and USA





Recipharm Advanced Bio, is a contract development and manufacturing organization (CDMO) focused on serving companies seeking to develop and commercialize advanced therapy medicinal products (ATMPs).

Recipharm Advanced Bio's specialized CDMO capabilities include pre-clinical to clinical development and manufacturing and commercial production of novel biological modalities encompassing live viruses and viral vectors, live-biotherapeutic products, plasmid DNA and xRNA therapeutics.

Led by an agile management team and robust technical experts with a proven track record in both process and analytical development and GMP manufacturing, Recipharm Advanced Bio offers the knowledge and resources necessary to help customers deliver promising new therapies to critical patient needs across the world and to advance the future of global health.

## Notes





ADVANCING TOGETHER



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