

Recipharm

# OUR FULL SERVICE OFFERING



## A LEADING GLOBAL CDMO

Recipharm is dedicated to meeting your evolving needs through commercial and operational excellence, scientific know-how and customer connectivity. Our worldwide reach and localised market expertise allow us to anticipate your needs and provide tailored, reliable services to consistently deliver on time and in full.

### GLOBAL AND AGILE

With facilities around the world, delivering to over 400 customers, we are global in nature yet local to you. When we work together you benefit from the security of a global partner, without compromising on the flexibility you and your project deserve.

### SERIOUS ABOUT SUSTAINABILITY

The Science Based Targets initiative has validated our near-term science-based emissions reduction targets. We are committed (and are on track) to:

- Increase our sourcing of renewable electricity to 100.0% by 2024.
- Reduce absolute Scope 1 and 2 Greenhouse Gas emissions by 42.1% by 2030 from a 2021 base year.
- Reduce absolute Scope 3 Greenhouse Gas emissions by 25.0% within the same timeframe.

### ACCELERATED ADVANCED THERAPIES

Our advanced process development and manufacturing services for AAV, RNA, plasmids, oncolytic viruses, microbiome and recombinant proteins are designed to expedite the journey of ATMPs through clinic trials.



# RECIPHARM ORAL DOSE

 Bengaluru
  Leganés
  Monheim/Zwickau
  Paderno Dugnano
  Pianezza
  Queluz/Odivelas
  Uppsala

## DRUG SUBSTANCE

Small molecule				●●			
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## SOLIDS

Tablets	●●	●	●●	●		●	●
Effervescent tablets	●●	●				●	
Capsules	●●	●	●●	●		●	
Coated pellets	●		●				
Granules, powders	●●	●	●●			●	

## SEMI-SOLIDS

Suppositories						●	●
Gels, ointments, creams	●					●	
Pre-filled syringes, cartridges							
Terminal sterilisation							

## LIQUIDS

Sprays					●	●	
Aerosols							
Suspensions, emulsions	●				●	●	
Liquids	●				●	●	

## SPECIALS

Beta-lactams							
Controlled drugs	●●	●	●		●	●	
Analytical specialty lab	●						

## PACKAGING

Blisters	●●	●	●		●	●	●
Bottles, jars	●●	●	●			●	●
Tubes	●					●	
Sachets	●		●			●	
Secondary pack pre-filled syringes			●				

● Manufacturing ● Development

## GMP LICENSES & ISO

FDA (US)	●	●	●	●	●	●	●
EU GMP	●	●	●	●	●	●	●
PMDA (JPN)	●	●	●	●	●	●	●
Clinical trial material (IMP)	●	●	●	●	●	●	●
Veterinary products				●	●	●	
ISO 13485	●						
ISO 14001	●	●	●	●	●	●	●
ISO 45001/OHSAS 18001	●	●	●	●	●	●	●

# RECIPHARM STERILE DELIVERY

 Bengaluru
  Benslimane
  Brescia
  Cuxhaven
  Kaisersberg
  Lenoir
  Masate
  Wasserburg
  Watertown

## FILL & FINISH

Vials		●	●	●		●	●	●●	●
Ampoules			●				●		
Pre-filled syringes/cartridges		●				●		●●	
Lyophilisation in vials				●		●		●	
Dry powder fill									
Beta-lactams			●						
Vaccines		●		●	●	●		●	●
Blow-fill-seal					●●				
Terminal or bulk sterilisation			●		●	●	●	●	
Parenteral development	●								

## INSPECTION & PACKAGING

Manual		●	●	●	●	●	●	●	●
Semi-automatic		●	●		●	●	●	●	
Automatic		●	●		●	●	●	●	
Labeling		●	●		●	●	●	●	
Pouching					●				
Packaging incl. serialisation		●	●		●	●	●	●	

● Manufacturing ● Development

## GMP LICENSES & ISO

FDA (US)			●		●	●		●	
EU GMP			●		●		●	●	
PMDA (JPN)					●			●	
Clinical trial material (IMP)			●	●	●		●	●	●
Veterinary products			●						
ISO 13485					●				
ISO 14001			●		●		●	●	
ISO 45001/OHSAS 18001			●		●		●	●	



## VIRAL

### RAW & STARTING MATERIALS

	 Cuxhaven	 Oeiras	 Watertown, MA
Plasmid DNA production		●	●
Pre-MVSS rescue from plasmid	●	●	
Proprietary cell line licensing (Cevic, Expres2ion, Advec)	●	●	
Cell bank production (MCB/WCB)	●	●	●
Master virus seed production (MVSS/WVSS)	●	●	

### DEVELOPMENT

Process development (USP, DSP, formulation)	●	●	●
Analytical method establishment (IPC, QC lot release)	●	●	●

### MANUFACTURE, FILL & FINISH

Drug substance (non-GMP/GMP)	●	●	●
- Avian-based production (eggs, chick-embryo fibroblasts)	●		
- Cell culture-based production (primary, continuous cell lines)	●	●	●
Drug product (non-GMP/GMP)	●	●	●
Sterile fill & finish (liquid)	●	●	●
Sterile fill & finish (lyophilisation)	●		

### QUALITY CONTROL RELEASE & STABILITY

In-process control, drug substance & drug product testing	●	●	●
Quality control lot release testing	●	●	●
Control cell generation	●	●	
Assay qualification & validation	●	●	●
Stability studies	●	●	●

## NUCLEIC-ACID-BASED

### RAW & STARTING MATERIALS

Plasmid cloning			●
Plasmid DNA production		●	●

### DEVELOPMENT

Process (IVT, DNA digestion, RNA purification)		●	●
Analytical assays		●	●
mRNA encapsulation			●

### MANUFACTURE, FILL & FINISH

Fermentation & plasmid expansion		●	●
Plasmid linearisation, transcription, capping, tailing		●	●
mRNA encapsulation (lipid nanoparticle formulation)			●
Drug product (non-GMP/GMP)		●	●
- Vials		●	●

### QUALITY CONTROL RELEASE & STABILITY

In-process control sample testing		●	●
Quality control release testing		●	●
Assay qualification & validation		●	●
Stability studies		●	●

## MICROBIOME

### RAW & STARTING MATERIALS

	 Cuxhaven	 Oeiras	 Watertown, MA
Strain selection		●	●
Colony isolation		●	●
Cell bank production (MCB/WCB)		●	●
Proprietary media		●	●

### DEVELOPMENT

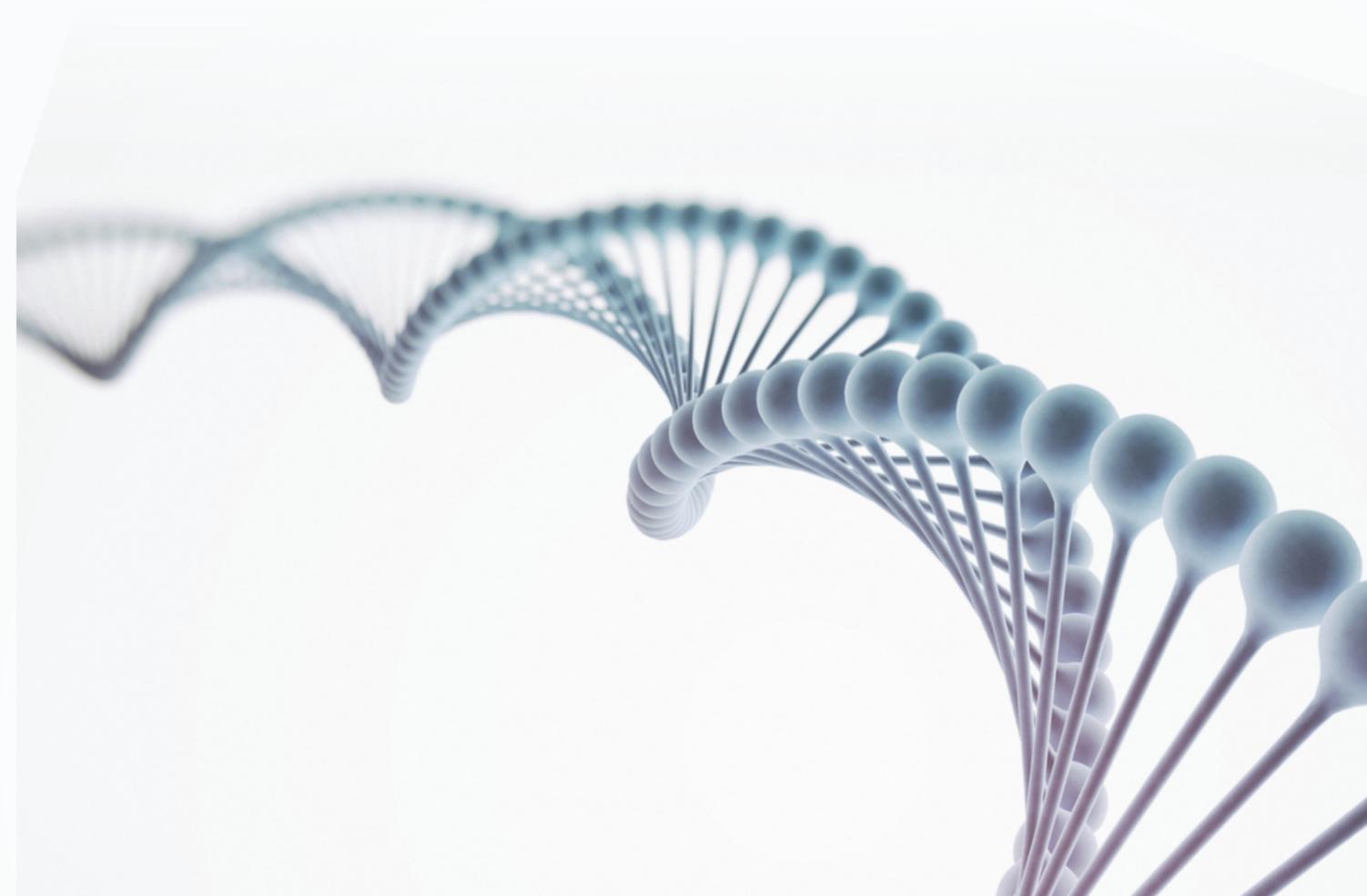
Process (USP, DSP, formulation)		●	●
Analytical assays		●	●
Analytical method transfer & development		●	●

### MANUFACTURE, FILL & FINISH

Drug substance (non-GMP/GMP)		●	●
Drug product (non-GMP/GMP)		●	●
- Capsules		●	●
- Bottles		●	●
- Vials		●	

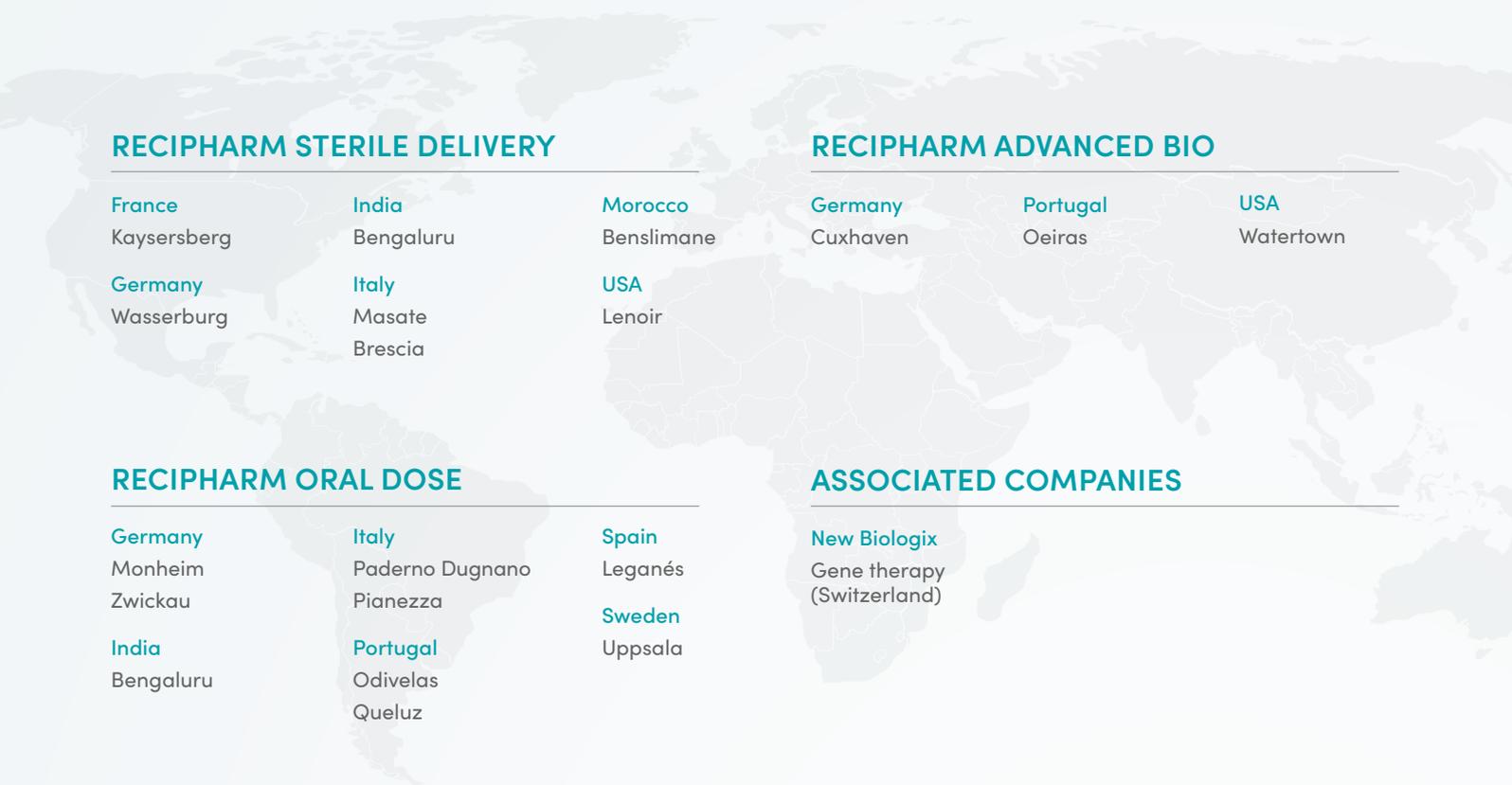
### QUALITY CONTROL RELEASE & STABILITY

In-process control, drug substance & drug product testing		●	●
Quality control release testing		●	●
Assay qualification & validation		●	●
Stability studies		●	●



# A GLOBAL NETWORK WITH LOCAL EXPERTISE

Our ever-expanding alliance of expertise and modalities now encompasses a worldwide network of sites and business capabilities, delivering to over 100 markets. Our global infrastructure provides you with unrivalled access to local expertise and specialised support – regardless of the geographical market or project size.



# SERIOUS ABOUT SUSTAINABILITY

