

**PORTON**



# A CUSTOMER-CENTRIC, INNOVATIVE AND RELIABLE CDMO WITH GLOBAL SOLUTIONS

OEB 1 to 5

Sub-g to Metric-ton Scale

Pre-clinical to Commercial

**PORTON**

Enabling the Public's  
Early Access to Good Medicines



Small Molecules



Tides



Biologics &  
Conjugates



Advanced Therapy  
Medicinal Products

Linked in



business@portonpharma.com  
www.portonpharma.com

© PORTON US\_202502



# About Porton

Porton Pharma Solutions, a global company with R&D and GMP-compliant manufacturing facilities across the US, EU and China, provides customer-centric innovative and reliable CDMO solutions for Small Molecules, Tides, Biologics and Conjugates (ADCs, AOCs, PDCs, RDCs, etc.), and Advanced Therapy Medicinal Products from pre-clinical to commercial stages.

2017-2024

## Transformed into a Global Leading CDMO

Acquired J-STAR Research Inc. (USA), Xiaogan Plant (China), Fengxian GMP Plant (China), and Building Slovenia GMP Plant (Europe)

2013-2015

## Became a Public Company

1<sup>st</sup> USFDA Inspection Passed and Listed on Shenzhen Stock Exchange

2005-2008

## Started CMO

Changshou (China) Site Started in 2006



5

Regulated Markets Approval



~20

Global Sites



~4300

Global Employees



~1200

R&D Chemists



2000+

Total Capacity (m<sup>2</sup>)



1000+

Global Customers



3500+

Milestone Projects



\$ 414-435 M

2024E Revenue\*

\*Data as of December 31, 2024

# Global Presence

 **Mengeš, Slovenia**  
R&D and GMP Manufacturing, DS

 **Copenhagen, Denmark**  
Office

**South Plainfield, New Jersey**  
R&D and GMP Manufacturing, DS

 **Turnhout, Belgium**  
Office

**Cranbury, New Jersey**  
R&D and GMP Manufacturing, HP DS & DP

 **Root, Switzerland**  
Office



**Chongqing**  
Headquarters  
R&D and GMP Manufacturing  
DS, DP

**Shanghai**  
Headquarters  
R&D and GMP Manufacturing  
HP DS & DP  
Biologics and Conjugates

**Xiaogan**  
Manufacturing  
RSM

**Yichun**  
GMP Manufacturing  
DS

**Suzhou**  
R&D and GMP Manufacturing  
ATMP

HP: High Potency (OEB 5 <1 µg/m<sup>3</sup>)  
DS: Drug Substance, which is synonymous with Active Pharmaceutical Ingredient (API).  
DP: Drug Product, which is synonymous with Finished Dosage Form (FDF).

# Global Solutions with Capacity in USA, EU and China



Under Construction



## Drug Substance Capacity

Site	Reactor Volume (m <sup>3</sup> )	Reactor Volume Range (L)	Number of Reactors	Temperature Range (°C)	Reaction Pressure (Mpa)
Shanghai <sup>GMP/HP</sup> Fengxian	75.5	200 to 6,300	46	-80 to 200	-0.1 to 5
Chongqing <sup>GMP</sup> Changshou	834.3	5 to 10,000	323	-80 to 200	-0.1 to 5
Jiangxi <sup>GMP</sup> Yichun	519	200 to 5,000	197	-70 to 140	-0.1 to 1.6
Hubei <sup>non-GMP</sup> Xiaogan	565	1,000 to 6,300	118	-100 to 150	-0.1 to 0.6
New Jersey <sup>GMP/HP</sup>	1	5 to 100	18	-80 to 200	-0.1 to 0.095
<b>Total</b>	<b>1,994.8</b>	<b>5 to 10,000</b>	<b>702</b>	<b>-100 to 200</b>	<b>-0.1 to 5</b>

## Drug Product Capability and Capacity

### Cranbury, New Jersey

#### Solubility Enhancement

- Particle Engineering
- Co-processing

#### Dosage Form Development

- OSD
- Liquid & Lyo Powder

#### GMP Clinical Phase I & II Production

- OSD
- Non-sterile Liquid

### Beibei, Chongqing

#### Tablet

- IR
- MR
- Double-layer Tablet

- 1 B doses
- 60 M doses (HP)

#### Capsule

- IR
- MR
- Micro-pellet Filler

- 200 M doses
- 60 M doses (HP)

#### Injectable

- Ampoule
- Vials for Powder & Liquid

- 55+ M units

#### Semisolid

- Cream
- Ointment
- Gel Paste
- Gel Patch

- 50+ M tubes

(Maximum Annual Output Capacity)



Process Design, Route Scouting, Development and Optimization for APIs and Intermediates



non-GMP and GMP Manufacturing for APIs and Intermediates, pre-clinical to commercial



Pre-formulation Research and Process Development & Optimization



GMP Manufacturing for Drug Products, from Pre-clinical to Commercial Batches



Comprehensive Analytical R&D and Quality Control



IND/NDA Dossier and CMC Solutions



# Tides CDMO Services



## Peptides

- Linear Peptides (<50 aa)
- Cyclic Peptides (<50 aa)
- Peptide Modification
- Key RSMs and Intermediates



## Oligonucleotides

- ASO, siRNA
- miRNA
- Aptamer
- sgRNA
- Oligo Modifications



## Drug Delivery Materials

- Ionizable Lipids / Cationic Lipids
- Polymers for Drug Delivery
- Complex/Conjugate Polysaccharides
- Other Lipids



Early Stage  
Development  
Services



Process  
Development  
and DS  
Manufacturing



Formulation  
Development  
and DP  
Manufacturing



Analytical  
Development  
and QC



Regulatory  
Affairs



# Biologics and Conjugates CDMO Services



## Conjugates

- ADC
- AOC
- PDC
- RDC



## Targeting-vehicle

- Antibody
- Peptide
- Small Molecule



## Payload

- Cytotoxic Drugs
- Oligonucleotides
- Radionuclide
- Fluorescers



## Linker

- Cys (-SH): S-S, Maleimide Group (mc, mcc, etc.)
- Lys (-NH2): Activated Acid (CO-OSu, etc.)
- Short Peptide (VC, GFGG, etc.)



Early Stage  
Development  
Services



Process  
Development  
and DS  
Manufacturing



Formulation  
Development  
and DP  
Manufacturing



Analytical  
Development  
and QC



Regulatory  
Affairs



## Plasmid

- Supercoiled Plasmid
- Linear Plasmid
- LcDNA
- Off-the-shelf GMP Helper Plasmids for Lentiviral Vectors



## mRNA

- Non-replicating mRNA
- Self-amplifying mRNA
- Circular RNA
- LNP Formulation Library



## Viral Vectors

- Lentiviral Vectors
- Adeno-associated Viral Vectors
- Adenoviral Vectors
- AI-guided AAV Library Construction and Screening



## Investigator-Initiated Clinical Trial Services in China

- Produce Samples for IITs
- Connect with Local Authorities and Medical Institutions
- Support in Reviewing the IIT Study Protocols
- Prepare Documents as a CDMO Partner to Medical Institution for Project Approval and NHC Registry Review
- Support in Finding Reliable Necessary CRO and Medical Writing Partners



## Analytical Development and Testing

- Physicochemical Testing
- Characterization Testing
- Microbiology Testing
- Molecular Studies
- Biochemical Testing
- Cell Functional Testing
- FACS Testing

## Enabling Chemical Technologies

### ◇ Particle Engineering

- Controlled Particle Formation
  - Crystallization
  - Precipitation (amorphous)
  - DS-DP Co-processing (composite)
- Controlled Post Processing
  - Filtration, Drying, Milling, etc.

### ⚙️ Material Science & Engineering

- Solid Form Screen/Selection/Studies
- Characterizations of DS, Excipient, SD-DP Intermediate and DP
- Pre-formulation Evaluation

### ⚗️ Process Engineering

- Process Simulation
- Continuous Processing & Process Control
- Reactor and Equipment Selection/Design
- Scale-up / Production De-risking
- Column & Membrane & Other Separations

### ⚗️ Reaction Engineering

- Reaction Kinetics, Mechanism/Pathway, Selectivity
- Reaction Thermodynamics
- Reaction Simulation
- Reaction EHS (safety, e-factor, etc.)

### 📦 Computational Chemistry & Data Science

- Molecular & Thermodynamic Simulations
- ML-based DoE, Statistical DoE
- Other Computation Methodologies

## Operational Excellence

### 📄 Intellectual Property (IP)

- Audited by 8 of Global Top 20 Pharma (100% Success Rate)
- ISO27001 Information Security Certification

### 🌿 Environmental Health & Safety (EHS)

- 180+ EHS Audits and Inspections
- 10+ Global Top 20 Pharma EHS Audits
- ISO14001 Environmental Management System
- ISO45001 Occupational Health and Safety Management System

### ⚙️ Quality System

- One Porton One Quality System Strictly Following ICH Guidelines
- 5 Authorities GMP Inspections
- 800+ GMP Audits of Customer
- GMP Audits by 17 of Top 20 Global Pharma (100% Success Rate)



### 📄 Regulatory Affairs

- 8 APIs Passed PAI and Approved
- 60+ APIs of Successful PPQ
- 15+ On-going NDA Projects

### 📁 Project Management

- Customer-centric
- Lifecycle Management
- Efficient and Transparent Communication

### 🌐 Supply Chain

- Supply Chain Visibility
- Back Integration
- Local for Local Supply