PORTON

Enabling the Public's
Early Access to Good Medicines

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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


Small Molecules


Tides


Biologics & Conjugates


Advanced Therapy Medicinal Products

About Porton

With over 4300 employees, 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

1st 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^3)

1000+
Global Customers

3500+
Milestone Projects

$ 522 M
2023 Revenue

Data as of June 30, 2024

Global Presence

Mengeš, Slovenia
R&D and GMP Manufacturing, DS

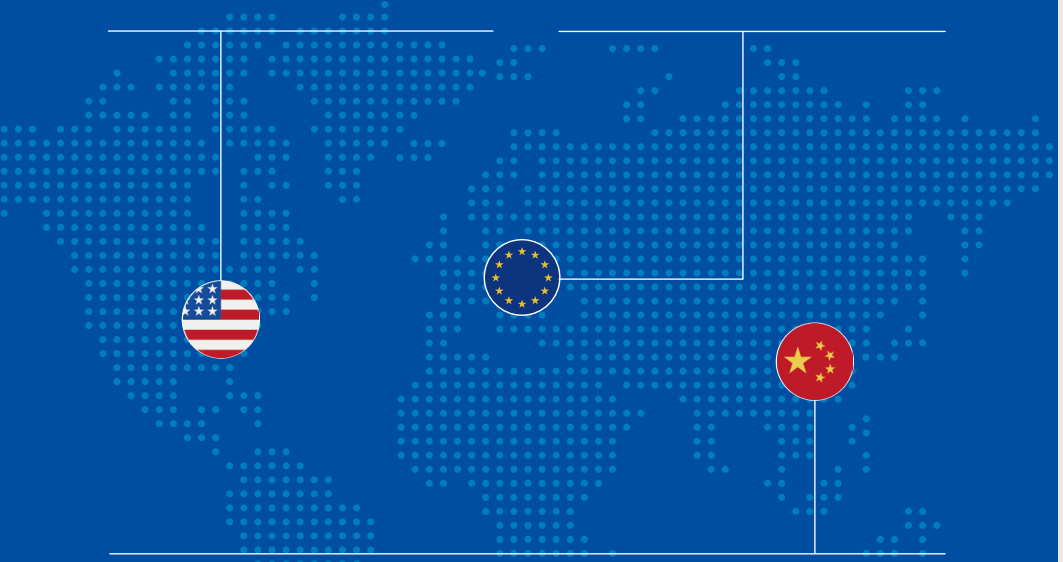
Copenhagen, Denmark
Office

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

Turnhout, Belgium
Office

Cranbury, New Jersey
R&D and GMP Manufacturing, HP & 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

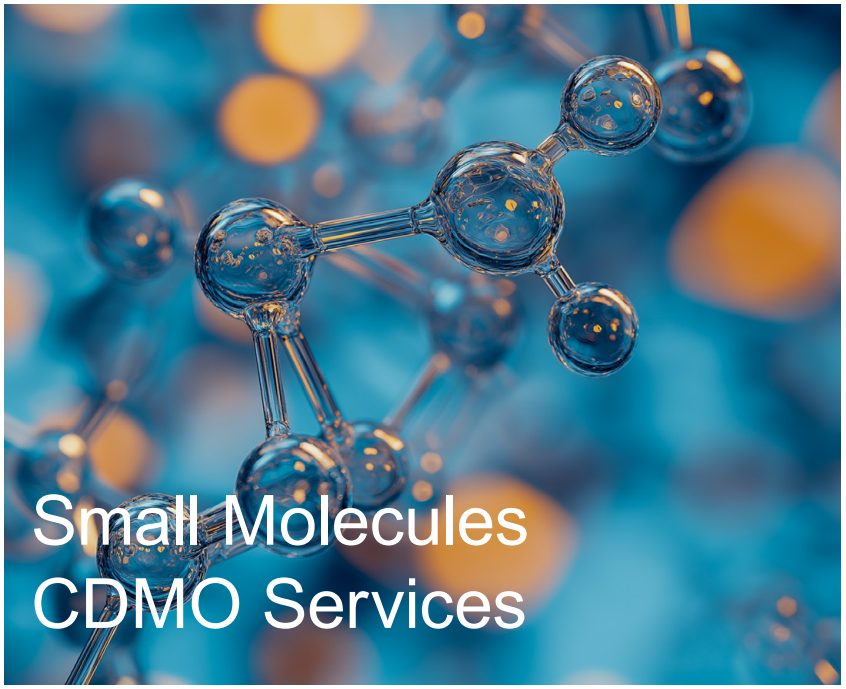
Xiaogan
Manufacturing, RSM

Yichun
GMP Manufacturing, DS

Global Solutions with Capacity in USA, EU and China

	Pre-Clinical	IND	Phase I	Phase II	Phase III	NDA / BLA	Commercial
USA	DS Solid Form (Polymorph, Salt, Co-crystal) Studies & Crystallization Process Development / Particle Engineering / DS-DP Co-processing / Metal Catalysis / Flow / Preformulation						
	DS Process Research & Development / non-GMP & GMP Deliveries						
	DP Formulation Design & Development / GMP Deliveries						
	HP API / Drug-Linker non-GMP and GMP Deliveries / Conjugation non-GMP & GMP Deliveries						
	Stability Study						
EU	DS Process Design & Optimization						
	DS GMP Deliveries						
CN	DS Solid Form Studies (Polymorph, Salt, Co-crystal) / Crystallization Process Development / Pre-formulation / Particle Engineering and Co-processing						Life Cycle Management
	DS Process Research & Development						
	Flow Chemistry, Biocatalysis, Metal Catalysis, Photochemistry						
	DP Pre-formulation Eva. / DP Formulation Development						
	Process QbD Studies & Validation						
	DS & DP GMP Manufacturing [Small Molecules, Drug Products, Synthetic Macromolecule (Peptide, Oligonucleotide, Lipid, etc.)]						
	HP API / Drug-Linker GMP Deliveries						
	Biologics and Conjugates (ADC, AOC, POC, etc.) & GMP Deliveries						
	Analytical Method Development, Qualification & Validation						
	Stability Study						
	Regulatory Affairs						

Under Construction



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

non-GMP and GMP Manufacturing from Pre-clinical to Commercial for APIs and Intermediates

Pre-formulation Research and Process Development & Optimization

Pre-clinical to Commercial Batches GMP Manufacturing for Drug Product

Comprehensive Analytical R&D and Quality Control

IND/NDA Dossier and CMC Solutions

Drug Substance Capacity

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

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	Capsule	Injectable	Semisolid
• IR • MR • Double-layer Tablet	• IR • MR • Micro-pellet Filler	• Ampoule • Vials for Powder & Liquid	• Cream • Ointment • Gel Paste • Gel Patch
• 1 B doses • 60 M doses (HP)	• 200 M doses • 60 M doses (HP)	• 55+ M units	• 50+ M tubes

(Maximum Annual Output Capacity)

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

- Lonizable 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

- 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)

FDA U.S. FOOD & DRUG ADMINISTRATION · World Health Organization · EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH · Pmda · 国家药品监督管理局 National Medical Products Administration

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