PORTON | 20th

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

Your New Modality Integrated CDMO Partner

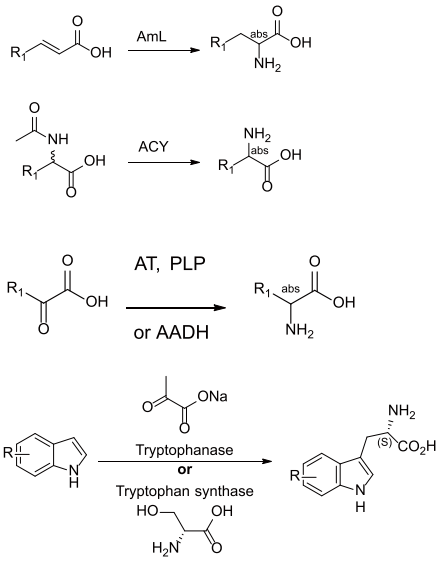
# Tides, Biologics and Conjugates CDMO Services

OEB 1 to 5 | Sub-g to Metric-ton Scale | Pre-clinical to Commercial

Enabling the Public's Early Access to Good Medicines

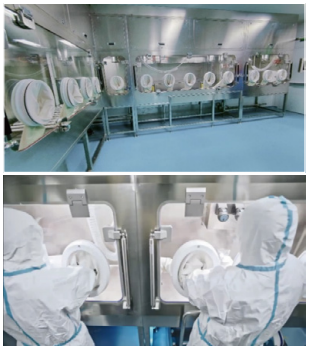
# Unnatural Amino Acid

- Green and Economical Approaches to Supply Unnatural Amino Acids for Peptide Preparation
- From R&D to Compound Production (up to hundreds kg)
- Porton Free-to-operate (FTO) Enzymes




# Payload-Linker Development and cGMP Manufacture

- CMC Service for IND and NDA
- Single-batch Production Capacity Reaches Kilogram Scale
- Equipped with a 10 m² Lyophilizer with a Single-batch Capacity of ~3 kg
- Equipment Design: Equipped with Weighing Isolators, Filtration-drying Isolators, Sampling Isolators, and Isolators Upstream of the Lyophilizer - that Meets OEB 5 Requirement
- Passed the EU QP Audit



# High Potent Lab and cGMP Manufacturing Facility

- Equipped with Negative Isolators to Meeting the Standard Operational for High-potency Compounds
- Process and Analytical Development
- Payload-Linker Production for Toxic Batch from 100 g to Kg
- Purification
- Equipped with High Pressure Liquid Chromatography Such as DAC150, DAC100, DAC50,DAC30 etc.
- Lyophilization
- T-manifold Freeze Dryers and 0.5/2 m² Lyophilizer Equipped Isolators

# Peptides

## CMC Research

- Process Development & Optimization
- Toxicological Batch and FIH GMP Batch
- SJR & QRA
- Process Validation and Commercial Production
- IND & NDA & ANDA

## Molecule Type

- Various Modified Peptides
- Peptides & PDC & RDC

## Technical Type

- SPPS
- LPPS
- Hybrid

## QRA

- Synthesis
- Cleavage
- Purification
- Lyophilization

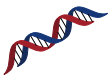
Brand: CS Bio
Model Specifications: 136-M
Capacity: 10 mg~ 1 g

Brand: Jianbang
Model Specifications: 20/100 L
Capacity: 100 g~ 3 Kg

# Oligonucleotides

- 16~100 mer Oligonucleotides
- Oligonucleotide Conjugates
- Custom Monomer and GalNAc
- Mg ~ g Scale Sample Preparation for Pre-clinical Studies
- Process Development and Scale-up Mfg. (non-GMP & GMP)

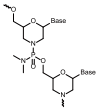
ASO



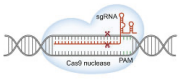
siRNA

Aptamer

CpG ODN

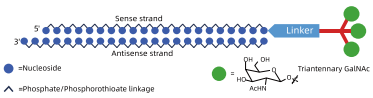


PMO

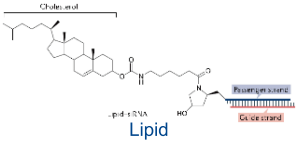


sgRNA

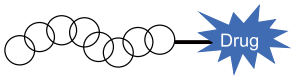
## Multiple Delivery Systems




GalNAc



Lipid




Peptide Conjugates (POC)


Antibody Conjugates (AOC)

Cytiva Oligosynt™
50 mg ~ 70 g/batch

Cytiva OligoPilot™
50~700 g/batch

# DSP Capacity

## Process Development

- Buffer
- Resin
- Elution Gradient
- Capacity
- Fraction Merging Strategy
- Filtration
- Filling
- Lyophilization

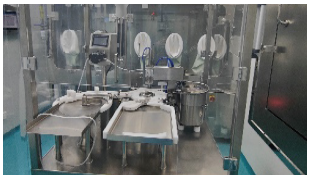
## Purification | Class D Workshop

RPC(YMC)
DAC200(~60 L/h), DAC300(~120 L/h)

Thin Film Evaporator
50 L/h(1 m²)

## Lyophilization | Class C Workshop

Tofflon
5 m²(input: ~75 kg/batch)
10 m²(input: ~150 kg/batch)



DS Filling
2000 vials/h (2R)
1100 vials/h (8R)

# Biologics/Antibody

## Cell Line Development

- Top Clone Titer Reach up to 9 g/L
- 14 weeks from DNA to Top 3 Clones

## Upstream Process Development

- 3~15 L Lab Scale
- Applikon My-Control System
- Thermo Scientific G3Lab System

## Downstream Process Development

- Yield>75%, Purity>99%
- Cytiva AKTA Pure 150 M
- Cytiva AKTA Avant 150

| Vial thaw | Seed Train | Wave | Bioreactor | Clarification |
|---|---|---|---|---|
| AC | Virus Inactivation | AEX/CEX | Virus Filtration | UF/DF |

## GMP Manufacturing

### Upstream

- GMP Cell Banking
- 50/200/500 L Sartorius Bioreactor
- Single-use System

### Downstream

- Cytiva AKTA Process
- Merck Viral Filtration System


mAb


BsAb


Fusion Protein


Nanobody


Enzyme

# ADC

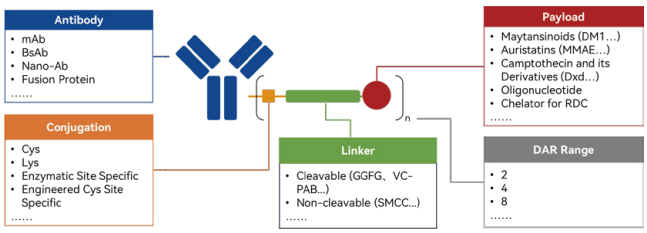
## Process Development

### Conjugation

- Mg~g Lab Scale
- Evaluating Key Process Parameters and Determine Range
- Process Scale Up

### Purification

- Free Drug Removal
- Target DAR Capture
- Enzyme Removal




## GMP Manufacturing

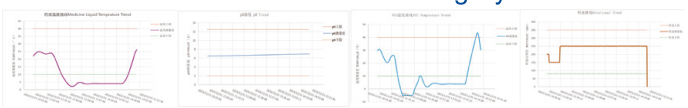
### Conjugation

- 10~100 L Glass Reactor
- 50~200 L Disposable Reactor
- Single Use System

### Purification

- Ultrafiltration System
- AKTA Ready Single-use Chromatography System

### ADC Customized On-line Monitoring System



Medicine Liquid Temperature Curve | pH Curve | TCU Temperature Curve | Rotational Curve

# Fill and Finish Product

## Pre-formulation Development

- Solubility and Stability
- Key Parameter: Tm, Tagg, Tonset, Rh, B22/G22/KD

## Formulation Development

- PH/buffer Screening
- Excipients Screening
- DOE Design

## Packaging Selection

- Vial
- PFS

## Process Development

- Freeze-thaw
- Mixing
- Filtration
- Filling
- Lyophilization

## GMP Manufacturing

### Antibody DP Filling (Vials & PFS)

- Vial Size: 2~20 R
- Liquid Capacity(vials/hour): Up to 4,500
- PFS Size: 1~5 ml
- PFS Capacity(Pcs/hour): Up to 4,500

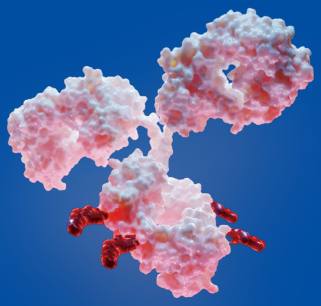
### ADC DP Filling & Lyophilization

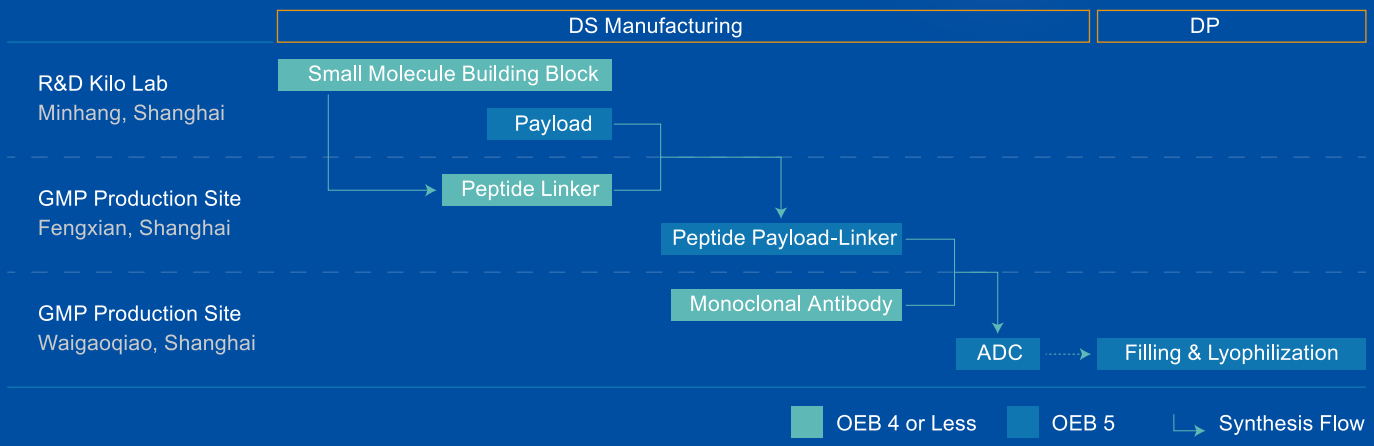
- Vial Size: 2~50 R
- Liquid Capacity(vials/hour): Up to 3,600
- 5 m² Lyo Capacity (vials/batch): Up to 23,000

Case Study:

# One-stop Service for ADC

- Integrated project management for Payload-Linker and ADC DS & DP.
- Dedicated high potent lab and facility to support OEB 5 development and manufacturing.
- One Porton One Quality policy.
- Efficient material transfer: R&D center and manufacturing sites are within 1 hour distance from each other.






# One-Stop and Fully Integrated Services for New Modalities

DS DP

## Cranbury, New Jersey

Payload-Linker
R&D and Manufacturing

- Payload-Linker (10~100 L)
- Bioconjugation (10 L)
- Non-GMP
- HP & Non-HP
- Bioconjugation (200~500 L, GMP)

DS DP

## Pudong, Shanghai

Biologics & Conjugates
R&D and Manufacturing

- Antibody (200~500 L)
- Bioconjugation (10~200 L)
- GMP & Non-GMP
- HP & Non-HP
- Antibody (500~2000 L)
- Bioconjugation (200~500 L)
- GMP

DS DP

## Minhang, Shanghai

Oligonucleotides, Peptides, Payload-Linker
R&D Center

- 50 L
- Non-GMP
- HP & Non-HP

DS

## Fengxian, Shanghai

Oligonucleotides, Peptides, Payload-Linker
Manufacturing

- 200 L
- GMP
- HP & Non-HP

*UNDER PLANNING

HP: High Potency (OEB 5 <1 μg/m³ )
DS: Drug Substance, which is synonymous with Active Pharmaceutical Ingredient (API).
DP: Drug Product, which is synonymous with Finished Dosage Form (FDF).

## About Porton New Modality CDMO Platform

Porton New Modality CDMO Platform operates multiple R&D centers and GMP manufacturing sites in Shanghai, China, and New Jersey, USA respectively. It provides fully integrated, one-stop-shop CDMO solutions for global pharmaceutical companies and drug development institutions, covering all stages from preclinical development to commercial launch for peptides, oligonucleotides, payload-linker, biologics and conjugates. The platform offers a comprehensive range of services, including Tides and Payload-Linker preparation, conjugate drug developability research, cell line construction, upstream and downstream process development, conjugation process development, formulation development, analytical method development, GMP manufacturing of drug substance (DS) and drug product (DP) for tides, biologics and conjugates, stability studies, clinical trial material production, and CMC services such as pharmaceutical documentation support for regulatory filings.

SM Building Blocks | Payload-Linker | Peptides | Oligonucleotides | Biologics | ADC | Fill-finished Product

Porton Pharma Solutions Ltd.
business@portonpharma.com
www.portonpharma.com



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