

PORTON

Enabling the Public's Early Access to Good Medicines

NEWSLETTER

Q3 2024

Porton Pharma Solutions Ltd.



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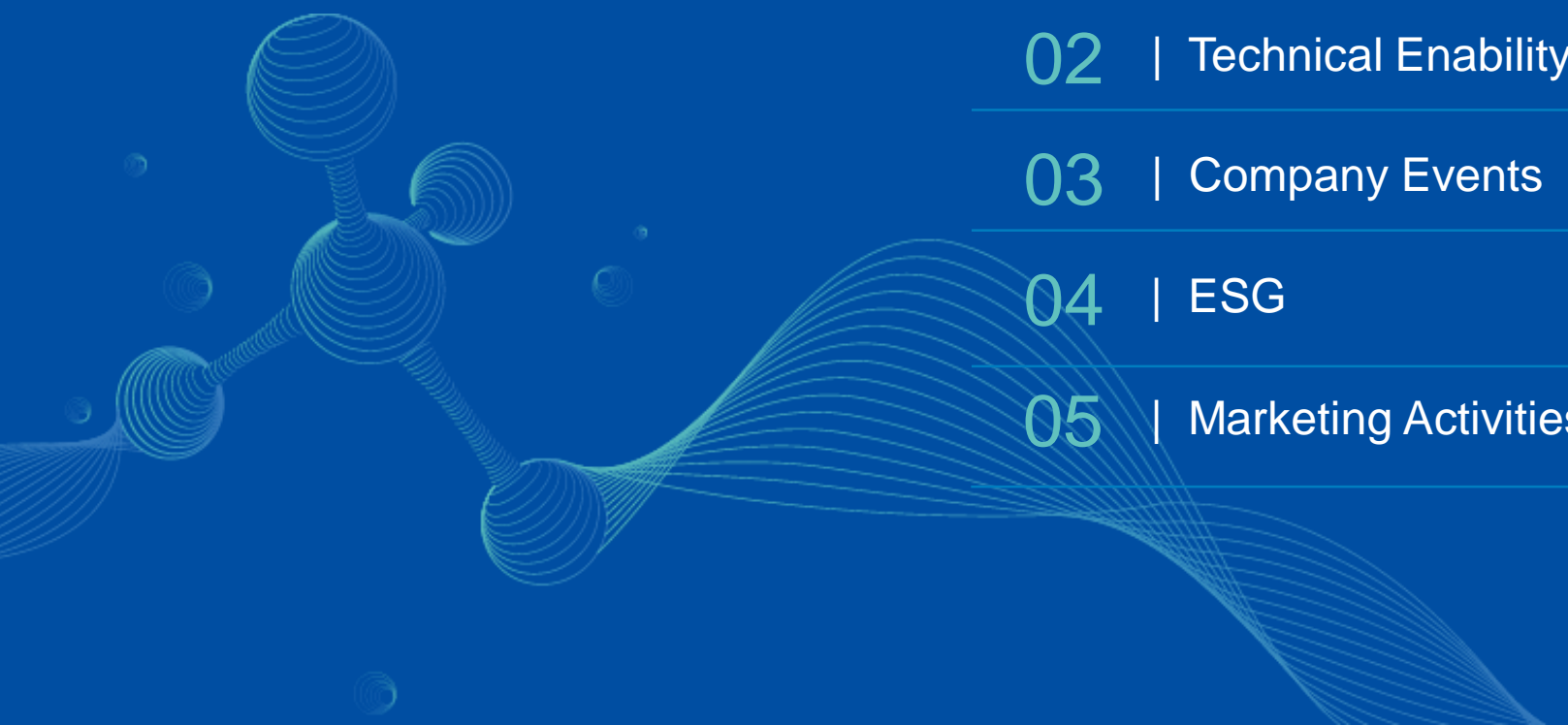
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Services & Solutions

By integrating cutting-edge technologies and expertise in Biologics, Conjugates, and Tides, Porton aims to deliver innovative solutions that meet the complex demands of the pharmaceutical industry.

Biologics and Conjugates CDMO Services

As a subsidiary of Porton Pharma Solutions, a globally recognized CDMO, Porton Biologics and Conjugates CDMO Platform offers comprehensive, one-stop drug development and manufacturing services for biologics and conjugates, including ADCs, AOCs, PDCs, etc.

[Read more](#)

Tides CDMO Services

With R&D platforms including peptides, oligonucleotides, conjugated drugs, high performance liquid chromatography, and Tides analysis, the Porton Tides CDMO Services Platform is committed to providing integrated CMC solutions for global customers, covering all types of new drugs from pre-clinical to commercial.

[Read more](#)

PORTON
One Stop CDMO Services for Conjugate Products

ADC, AOC, PDC, PDC, SMOC, Conjugated Protein, Protein Conjugate, Antibody-Drug Conjugate

Wuxi, Shanghai
- CMO & ODM
- PDC, AOC, PDC
- Phase I-III Clinical

Wuxi, Shanghai
- CMO & ODM
- PDC, AOC, PDC
- Phase I-III Clinical

Fuzhou, Shanghai
- CMO & ODM
- PDC, AOC, PDC
- Phase I-III Clinical

Carle Place, New Jersey
- Phase I-III Clinical
- PDC, AOC, PDC
- Phase I-III Clinical

Operational Excellence: IP, QA, EHS, RA, PM, Supply Chain

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www.portonpharma.com

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Targeting-vehicle

- Antibody
- Peptide
- Small Molecule

Linker

- Cys-L-Linker (S-S, Maleimide Group (m), mcs, mcs)
- Cys-L-Linker (Addressed Ad (CO-CO), etc.)

Conjugates

- Cytotoxic Drugs
- Oligonucleotides
- Polysaccharides
- Fluorochromes

Standard Timeline for Conjugates IND Project

	ADC	AOC	PDC (Antibody-Drug)	PDC (Antibody-Target)
Top Material Delivery	8 Months	8 Months	8 Months	8 Months
US Filing	14 Months	14 Months	11 Months	13 Months
CMF Filing	10 Months	10 Months	13 Months	10 Months

Operational Excellence: IP, QA, EHS, RA, PM, Supply Chain

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

Wuxi, Shanghai
- CMO & ODM
- PDC, AOC, PDC
- Phase I-III Clinical

Wuxi, Shanghai
- CMO & ODM
- PDC, AOC, PDC
- Phase I-III Clinical

Fuzhou, Shanghai
- CMO & ODM
- PDC, AOC, PDC
- Phase I-III Clinical

Beihai, Chongqing
- CMO & ODM
- PDC, AOC, PDC
- Phase I-III Clinical

Operational Excellence: IP, QA, EHS, RA, PM, Supply Chain

END-TO-END CMC SERVICE - FROM PRE-IND TO COMMERCIAL

Pre-Clinical | Phase I | Phase II | Phase III | Commercial

Chemical Research Service: Process Research & Development, Process Validation and Process Optimization

Process Validation: Clinical Batch Manufacturing (GMP), Testing, Release and Stability Study

Commercial Supply: Analytical Method Development, Qualification & Validation

Advanced Quality Control: Testing, US Data Management & Analysis

CMC Director

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Tides CDMO Services Platform

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Peptides

- Linear Peptides (<10 aa)
- Cyclic Peptides (>10 aa)
- Peptide Modifications
- Key Residues and Interactions

Oligonucleotides

- ASO, mRNA
- PNA
- Antisense
- siRNA
- Oligo Modifications

Conjugates

- Small Molecule Drug Conjugate
- PDC
- ADC (Antibody-Drug)
- ADC (ADC, Peptide)

Drug Delivery Materials

- Injectable Lipids / Cellular Lipids
- Polymer for Drug Delivery
- Complex Conjugate Polysaccharides
- Other Lipids

Sterile Formulations

- Lyophilized Product
- Liquid Product
- Prefilled Syringe
- Auto-injector

Complex Injectable

- LAMP
- Emulsion
- Microspheres
- Nanoparticles

Operational Excellence: IP, QA, EHS, RA, PM, Supply Chain

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Porton J-STAR Cutting-Edge Technologies

As a contract chemistry R&D organization, J-STAR serves as an outsourcing partner to the pharmaceutical and biotechnology industries, and it is at the forefront of cutting-edge technologies in the pharmaceutical and chemical sectors.

Specializing in enabling technologies and advanced solutions for drug development and manufacturing, Porton J-STAR offers integrated DS-DP services in the USA.

[Read more](#)

Solid Form Studies

Solid Form Screen

- Polymorph
- Salt
- Co-crystal
- Amorphous
- Amorphous Solid Dispersion

Solid Form Characterization

- Structural Analysis
- Thermal Analysis
- Microporosity
- Surface Area
- Batch-to-Batch Consistency

Solid Form Phase Mapping

- Form Relationship
- Form Phase Map
- Excipient Solubility
- Drying/Storage Conditions

Solid Form Selection

- Selection Based on the Most Optimal Solid Form Properties

Simulation Assisted Evaluation

- Virtual Solid Form Selection & Solubility
- Formulation Feasibility
- Excipient/Co-crystal Selection
- Crystal Morphology Prediction
- Stability & Aggregation Prediction

Single Crystal Structure

- 3D Structure
- H-Bonding
- Crystal Packing
- Ability to Generate
- Single and XRPD Pattern

Solid Form Evaluation

- Crystallinity
- Hygroscopicity
- Solubility
- Stability
- Processability

Solid Form Risk Assessment

- Risk Assessment Based on Comprehensive Form Understanding

High Potent API & Potent Compounds

Optimized HPMAs, ADCs and potent compounds development and manufacturing (see GMP and cGMP) tailored to your specific needs in our new 3000 sq. facility equipped with Cleanroom (Manufacture) (Manufacturing) capable of less than 30 ng/m³ contamination.

HPMA scale-up capabilities from bench scale to 100-liter scales

cGMP capability (10L - 100L)

Excellent track record at cGMP manufacturing at kilogram scale with effective containment controls

High-Potency R/D Lab Capabilities

Two Extract Walker Banker Isolators	Non-GMP
16 HPMAs Linear Glove Box Fan: 16	6 Hoods
QEL target length: 10	ICM Filters

Segregated warehouse for material storage and stability

One quality control lab for in-process and material release testing

Structural Elucidation/Impurity Identification

Structural Elucidation/Impurity Identification Capabilities

- We can achieve highly confident structure elucidation with as little as 100 µg of isolate to acquire 1D/2D NMR data in conjunction with high-resolution MS data.
- We have over 100 years of cumulative scientific experience, most of which is from big pharma, in NMR, LC-MS and low-level impurity isolation.

Advanced Instrumentation

- 5 NMR systems, one 500 MHz 1D/2D Cryoprobe
- Orbitrap Fusion 170
- Mass Range: m/z 40-3000
- Mass Accuracy: 3 ppm RMS
- 4 LC/MS systems, including UPLC with QQQ/TOF detectors
- 4 Preparative Isolation Systems, Waters SFC 150 A7 Prep Scale PDA/MS (see Equipment)
- Waters Prep Scale 200MS stopped gradient 150L Analytical Scale HPLC system
- 4 Flow Chromatography systems, HPLC and DDX
- Generator: EP-2 Elite HPLC Compatible Propagator

Results

- 100+ Clients: 10 Big Pharma
- 200+ Structure confirmations
- 30+ IND/NDAs filings
- 120+ Structure elucidation, more at 51%
- NMR
- Many dozens of quantitative NMRs

Molecular Simulation & Data Science

Knowledge is key, and we are the experts!

Capabilities

- From molecular up to quantum mechanics
- From small molecules up to new molecules in gas, liquid, and solid phases
- AIMS modeling

Applications

- Virtual solvent screening for pharmaceutical crystallization
- Virtual solvent and solid form screening for impurity/rejection
- Observed crystal form (Phase) selection using salt, co-crystal, copolymer
- Crystal phase optimization
- Solubility and stability improvement prediction
- Mechanical properties predictor
- Molecular and crystal form analytical properties predictor
- AIMS-based DfE

Flowchart: Problem Solving Process (Unstable Solid Form Crystallization) vs. Virtual Solvent Screening (Co-crystal/Co-solvent Screening) vs. Virtual Solid Form Screening (Enthalpy of Solvation of Polymorphic Crystal)

Analytical Development/Quality Control

Analytical Capabilities

- Integral Role of QAC - Full Analytical Support
- Fast-paced Method Development
- ICH Q10 Compliance - Part 11 Compliance
- cGMP Method Validation / Sample Testing - cGMP
- Challenging Separations
- Stability Studies - cGMP
- Structure Elucidation / Impurity Identification
- Valve Software - Part 11 Compliance

QC Data Integrity

- Agilent Openlab - Part 11 Compliance
- ChromStation - Part 11 Compliance
- Valve Software - Part 11 Compliance

Phase Appropriate/User-Friendly

Stage 1 (R&D)	Stage 2 (GLP)	Stage 3 (GMP)
Interfaced Purpose	Method Optimization	Method Validation
Initial Method Development	Performance Qualification	Approval and Continuous Monitoring

More...

Technical Enablement

Porton Pharma Solutions Ltd. and Industry Elites at Pharma Crystallization Summit 2024

September 26-27, 2024

As a proud gold sponsor of the Pharma Crystallization Summit 2024 (PCS 2024), the Crystallization Team at Porton, with locations in New Jersey (USA) and Shanghai (China), offers expert services in polymorph discovery and selection, crystallization process development, particle engineering, DS-DP coprocessing, and pre-formulation evaluation.

The technical experts from Porton, Dr. Jian Wang, and Dr. Yuriy Abramov, served as forum hosts and participated in the entire event. We invited industry elites from around the world to join us at the Crowne Plaza Hotel in Princeton, New Jersey, USA.

[Read more](#)



Porton's Latest Achievements in Globalization, Technological Development, and Innovation

September 9, 2024

As one of the world's leading CDMO companies, Porton Pharma Solutions attended the CPhI Milan. We engaged face-to-face with industry elites from around the world to gain deep insights into the latest trends and developments in the pharmaceutical industry. Additionally, we shared our extensive industry knowledge and product development experience, jointly exploring product innovation to drive forward industry innovation and high-quality growth.

To better interact with industry peers, we have specially arranged two professional presentation sessions at booth 5C17 on the second day (October 9). Our two technical experts provided cutting-edge technical insights and industry perspectives.

PORTON

October 9, 2024 (Wednesday)
Porton Booth 5C17

CPHI
Milan

11:15-11:45
Porton Slovenia Capabilities: Driving Innovation and Excellence in the CDMO Industry

13:30-14:00
Integrated DS-DP Development via Particle Engineering

Dr. Francesco Fontana
R&D Director
Porton Pharmatech

Dr. Jian Wang
SVP, Head of Global Chemical Engineering and Technology Center

[Read more](#)

Published Breakthrough Results in Crystal Growth & Design and Reported them at the 2024 Crystal Engineering Gordon Research Conference

Dr. Yuriy Abramov and Dr. Jian Wang from Porton's team of global chemical engineering and technology published a Communication paper titled "Is It Salt, Cocrystal, or Continuum? Successes and Limitations of Computationally Efficient Periodic System Calculations" in *Crystal Growth & Design*, the American Chemical Society journal. This peer-reviewed journal focuses on publication of new research results in theoretical and experimental studies of the physical, chemical, and biological phenomena and processes related to the design, growth, and application of crystalline materials. The topic of this publication was invited to be shared at the 2024 Crystal Engineering Gordon Research Conference - a premier, international scientific conference focused on advancing the frontiers of science through the presentation of cutting-edge novel research.



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Crystal Growth & Design > Vol 24/Issue 10 > Article

COMMUNICATION | April 25, 2024

Is It Salt, Cocrystal, or Continuum? Successes and Limitations of Computationally Efficient Periodic System Calculations

Yuriy A. Abramov*, and Jian Wang



Crystal Growth & Design
Cite this: *Cryst. Growth Des.* 2024, 24, 10, 4017–4024

<https://doi.org/10.1021/acs.cgd.4c00195>
Published April 25, 2024

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Company Events

Strategic Collaboration with Geneseed Biotech

July 29, 2024

On July 29, 2024, Porton Advanced announced a strategic partnership with Guangzhou Geneseed Biotech to jointly advance biotherapeutics development services. Leveraging Porton Advanced's end-to-end gene and cell therapy CDMO platform and resources, particularly its extensive experience in nucleic acid therapies, combined with Geneseed Biotech's proprietary core technologies in circRNA drug concept validation and process development, both parties will jointly advance technological innovation and clinical translation of innovative circRNA therapies.



[Read more](#)

ESG Update

In July, to continuously build a 'firewall' for trade secret protection and administer a 'preventive shot' against leaks and violations, Porton upgraded the 'Trade Secret Protection Management System' and conducted a training session for all employees.

In July, to comprehensively improve the Porton's Environmental, Health, and Safety (EHS) management level and strengthen employee safety awareness and behavior standards, the Group EHS Department, in collaboration with the Changshou Site, co-hosted training on 'Behavior-Based Safety (BBS)' methods and their practical application.

In August, Porton organized a training session themed 'Water Management for Pharmaceutical Companies,' to systematically enhance water resource management capabilities.

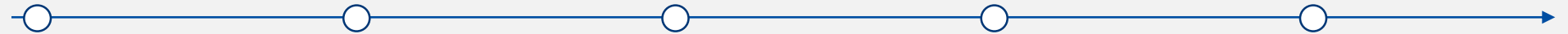
On the occasion of the first 'World Duchenne Awareness Day,' Porton joined DMD patient families to participate in the '13th China Rare Disease Summit' in order to echo this year's theme, 'Raise your Voice for Duchenne!'

To continuously foster a compliant and fair working atmosphere and cultivate employee compliance awareness, the Audit and Supervision Department carried out three training sessions on anti-fraud and anti-bribery.



Marketing Activities

China Gene & Cell Therapy Innovation Forum (CGCT 2024) July 5-6, 2024 Shanghai, China	Cell Therapy Product Development and Registration Application Case Sharing Session July 25, 2024 Chengdu, China	BVS and Bonnevillle Labs BI(O)LYMPICS Event August 1, 2024 California, USA	2024 CMC-China August 15-16, 2024 Suzhou, China	Scientist Solutions Life Science Vendor Show August 28, 2024 California, USA
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Biomedical - CGT New Era" Cell and Gene

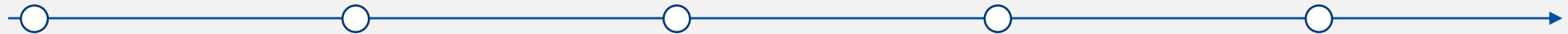
Therapy (CGT) Roadshow ChemOutsourcing 2024
 August 29, 2024
 Shanghai, China

September 3-6, 2024
 Parsippany NJ, USA

BIOHK2024
 September 11-14, 2024
 HongKong, China

Nordic Life Science Days 2024
 September 18-19, 2024
 Sweden

Pharma Crystallization Summit 2024
 September 26-27, 2024
 NJ, USA



Upcoming Events

Event	Date	Venue	Booth
22nd San Diego Biopharma Conference	October 5	California, USA	/
CPHI Worldwide	October 8-10	Milan, Italy	Booth: 5C17
AAPS PharmSci 360	October 20-23	Salt Lake City, USA	Booth: 2431
2024 AIChE Annual Meeting	October 27-31	San Diego, USA	/
Bio-Europe Fall	November 4-6	Sweden	Booth: 108
Biofit	December 3-4	France	/





A Customer Centric, Innovative, and Reliable CDMO with Global Solutions

Please contact us to help you on your next development project and achieve your business goals.



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Contact Us

