

PORTON



Enabling the Public's Early Access to
Good Medicines

NEWSLETTER

April 2025

Porton Pharma Solutions Ltd.





Contents

01 | Technical Enabling

02 | Services & Solutions

03 | Company Events

04 | Marketing Activities

Technical Enabling

Challenges and Advances in CMC Process Development of BsADCs

April 23, 2025

Antibody drug conjugates (ADCs) have seen significant breakthroughs and reached numerous milestones since 2000 when the first ADC was approved by the FDA and have shown great promise for the treatment of cancer. First generation ADCs were designed to use the affinity of an antibody towards a specific cellular target to bring the cytotoxic payload to the tumor, for example.

However, some level of off-target toxicity was often seen with many ADCs because other cellular interactions could occur prior to the payload physically reaching its intended target or the payload could cleave off. These events could lead to unintended death of non-cancerous cells.

[Read more](#)

The image displays a 3D molecular model of an antibody with a blue and orange color scheme. Below it is a slide titled "Challenges and Advances in CMC Process Development of BsADCs". The slide includes a diagram of an antibody structure and a list of key considerations for its design and development.

Introduction

Antibody drug conjugates (ADCs) have seen significant breakthroughs and reached numerous milestones since 2000 when the first ADC was approved by the FDA and have shown great promise for the treatment of cancer. First generation ADCs were designed to use the affinity of an antibody towards a specific cellular target to bring the cytotoxic payload to the tumor, for example. However, some level of off-target toxicity was often seen with many ADCs because other cellular interactions could occur prior to the payload physically reaching its intended target or the payload could cleave off. These events could lead to unintended death of non-cancerous cells.

To minimize these unintended side effects and subsequently improve the clinical efficacy of new therapies beyond conventional monoclonal antibodies, researchers have been searching for more selective binders to the target. To achieve this, peptide, nanobody, fusion proteins, and bispecific antibodies (BsAbs) have been evaluated to enhance specificity and selectively deliver cytotoxic payloads to tumor cells.

These newer types of ADCs include bispecific ADCs (BsADCs), conditionally active ADCs, immune-stimulating ADCs, protein degrader ADCs, and dual drug ADCs. These drugs all employ the targeting power of the antibody to ferry the cytotoxic payload safely through the body to the tumor cell to increase the effectiveness of the treatment while minimizing or even eliminating side-effects and other off-target toxicity.

Immuno-stimulating ADCs (ISADCs) and protein-degrader ADCs (PDADCs) attempt to treat cancer through different modes of action than traditional ADCs. Bispecific ADCs and dual drug ADCs are more like traditional ADCs but address the problems of drug resistance and tumor heterogeneity by enhancing selectivity and activity. This report will focus on the design, development, and conjugation methods for BsADCs and their characteristics.

Design of Bispecific ADC

- Antigen Binding Site**
 - Stable antigen selection
 - High antigen or dual epitope
 - Optimizing internalization
 - Stiffly relationship
 - Linking the transportation
- Linker for BsADC**
 - Character in site-specificity
 - Stiff in cleavage
 - Enzyme-independent linker
 - Linker conjugate strategy
- Payload for BsADC**
 - Drug effect and toxicity
 - Stable stability
 - Drug length of action
 - BSB
 - Systemic toxicity effect
- Fc Region for BsADC**
 - Modifying chain
 - Modifying isotype
 - Considering the relation of BsADC and ADC
 - Linker generation strategy
- Fc Region for BsADC**
 - Containing or non-containing
 - Combination to Fcγt
 - Combination to Fcγr
 - BSADC and ADC

Comprehensive Analytical R&D and QC Expertise in Pharmaceutical Development

April 27, 2025

This white paper details **Porton's** extensive capabilities in Analytical R&D and Quality Control for pharmaceutical drug development. It highlights our expertise in method development, structure elucidation, and method troubleshooting.

Our goal is to ensure the highest standards of **quality and efficiency in drug development and manufacturing.**



Enabling Technology

Comprehensive Analytical R&D and QC Expertise in Pharmaceutical Development

Hui Chen, Ph.D.
CEO & GM of Porton J-STAR

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

WHITEPAPER PORTON

Abstract
This white paper details our extensive capabilities in Analytical Research and Development (R&D) and Quality Control (QC) for pharmaceutical drug development. It highlights our expertise in method development, structure elucidation, and method troubleshooting. Our goal is to ensure the highest standards of quality and efficiency in drug development and manufacturing.

Introduction
In drug development CMC (Chemistry, Manufacturing, and Controls), we must address several common challenges, including demanding timelines, tight budgets, and stringent regulatory requirements. This white paper outlines our approaches for analytical development and method validation, detailing how we effectively balance these challenges. Structure Elucidation is a key component of our analytical team. Structure Elucidation is the process of determining the order or arrangement of atoms and the composition of a chemical compound. This process is critical in our services to help analyze the known and unknown components of a client's purchase order. We have also built a world-class team for structure elucidation, equipped with state-of-the-art instruments that can address the most challenging structure elucidation issues.

Analytical Method Development / Validation Approaches
Analytical method development / validation is a dynamic process that must be tailored to the specific properties of the compound and the stage of drug development. Our approach ensures that methods are fit for purpose and adaptable to the evolving requirements of drug development.

Fast Pace & Cost-efficient Method Development

1. **Generic HPLC methods** are employed for quick evaluation of reaction completion during the initial stage of process development, minimizing the cost of analytical development and sample testing.
2. **Retrospective Approach to Method Development**
 - Objective: Enhance method development efficiency by applying a retrospective approach.
 - Approach: Start with the development of the Drug Substance (DS) method, then incorporate starting materials and intermediates to evaluate overall method suitability. Optimize the method as needed.
3. **Harmonize Testing of Regulatory Starting Materials (RSM), Intermediates, and DS**
 - Objective: Simplify and streamline testing processes by harmonizing the analytical methods for RSM, Intermediates, and DS.
 - Approach: Develop a unified method that can effectively analyze all stages, reducing redundancy and overhead of human error, and improving efficiency.
4. **Method for In-Process Control Testing**
 - Objective: Maximize instrument efficiency by using a shorter version of DS method for in-process controls.
 - Approach: Utilize a shorter mobile phase gradient with the same column and mobile phase composition/concentrations to minimize error and maximize efficient use of each instrument.
5. **Evaluate Method Specificity During Process Development**
 - Objective: Ensure adequate specificity of analytical methods throughout the process development.
 - Approach: Continuously assess and adjust conditions to ensure they provide the necessary specificity for the current process.

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

[Read more](#)

Services & Solutions

Porton Advanced's End-to-End CDMO Solutions Accelerates IND Approval of Tasly's Innovative Dual-Targeting CAR-T Therapy

April 16, 2025

Porton Advanced announced its CDMO support for TASLY PHARMACEUTICAL CO., LTD's Innovative Dual-Targeting CAR-T Therapy, "P134 Cell Injection," which has received IND approval from China's NMPA. This breakthrough CAR-T therapy is indicated for recurrent glioblastoma (GBM).

As the exclusive CDMO partner for this program, **Porton Advanced** provided comprehensive process development and manufacturing services, including plasmid, lentiviral vectors and final CAR-T cell products. We successfully manufactured dozens of batches of clinical-grade investigational products for Investigator-Initiated Trials (IITs), with all batches passing quality control on the first attempt.



[Read more](#)

Company Events

Porton Reports 18% Sales Growth in Q1 2025

April 25, 2025

Porton Pharma Solutions Ltd. (SZSE: 300363) is pleased to share the first quarter results 2025, which have propelled us towards the fulfillment of our annual business objectives. **The Q1 2025 reported sales growth of 18% to ¥801.1 Million.** This resurgence in revenue growth is primarily attributed to the strong performance of our overseas markets.



[Read more](#)

Marketing Activities

Previous Events

Interphex

CPHI Japan 2025

Applied Pharmaceutical
Chemistry 2025

20th Annual Garnet E. Peck
Symposium

11 STILLE

April 1-3

April 9-11

April 10

April 10

April 26

Javits Center, NYC

Tokyo, Japan

Boston MA, United States

West Lafayette, IN, United States

Colorado State University,
United States



Upcoming Events

[Stay Updated on the Latest Developments, Click to Schedule Your Appointment](#)

Events	Date	Venue	Booth
Swiss Biotech Day	May 5-6	Basel, Switzerland	/
2nd ADC Linker & Conjugation Summit	May 6-8	Boston MA, United States	/
BIO Korea 2025	May 7-9	Seoul, Korea	J30
ASGCT Annual Meeting	May 13-17	Portland, United States	1448
Boston ABI Lab Lunch and Learn	May 15	Natick MA, United States	/
The Fifth China Gene & Cell Therapy Innovation Forum (CGCT 2025)	May 16-17	Shenzhen, China	/
CPhI Americas 2025	May 20-22	Pennsylvania Convention Center, Philadelphia, United States	405
ChemSpec Europe	June 4-5	Koelnmesse, Germany	4T29
BOS Basel 2025	June 11-12	Basel, Switzerland	62
EWOC: Empowering Women in Organic Chemistry	June 12-13	Chicago, Illinois, United States	/
BIO International Convention	June 16-19	Boston MA, United States	/
The 7th Grant Symposium	June 18-20	Minneapolis MN, United States	/
The 28th ACS Annual Green Chemistry & Engineering Conference	June 23-26	Pittsburgh, PA, United States	/
CPHI China	June 24-26	Shanghai, China	E2A32

Customized Development and Manufacturing Technical Solutions for Conventional and New Drug Modalities

OEB 1 to 5

Sub-g to Metric-ton Scale

Pre-clinical to Commercial



Small
Molecules



Tides



Biologics and
Conjugates



Advanced Therapy
Medicinal Products

Operational Excellence

IP

QA

EHS

RA

PM

Supply Chain

Global Site Compliance



PORTON



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.



LinkedIn

Porton Pharma Solutions

business@portonpharma.com
www.portonpharma.com

Contact Us

