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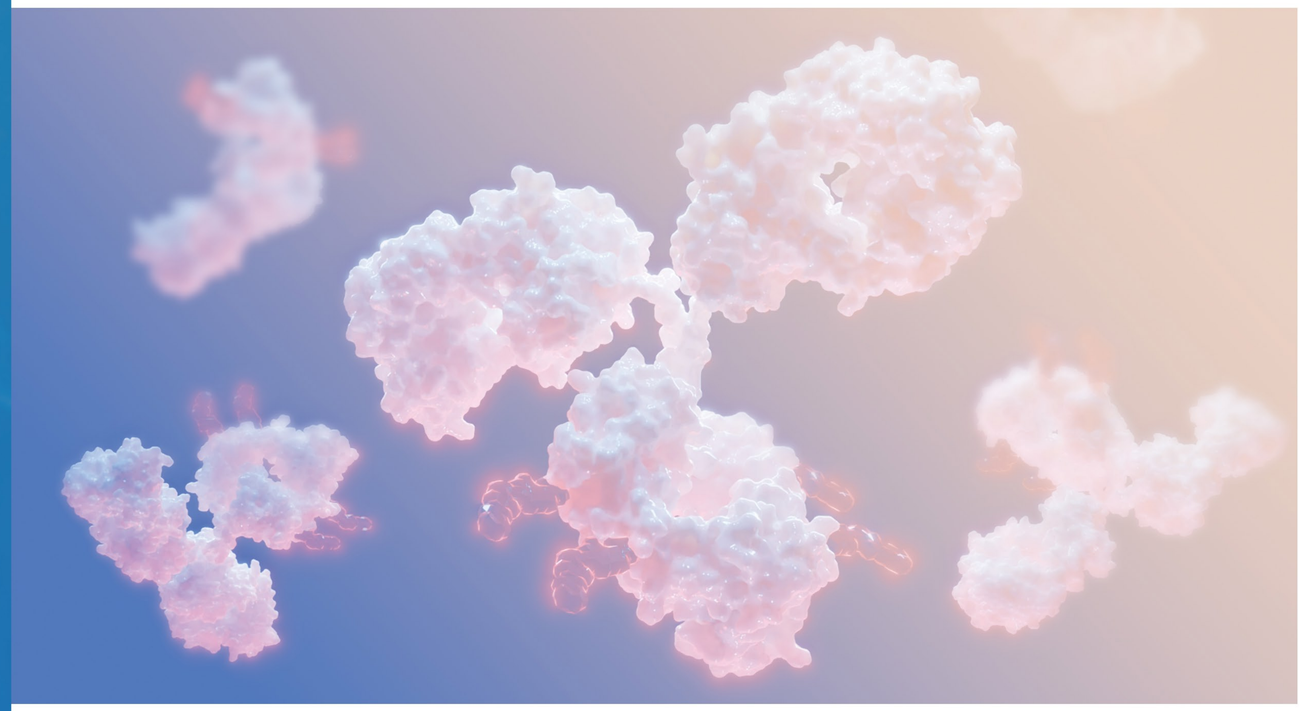


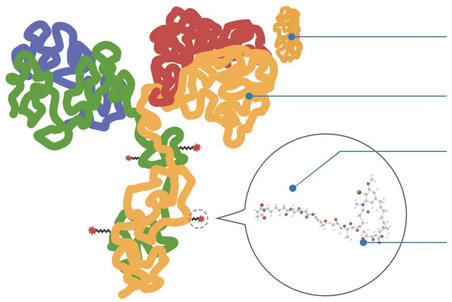
Integrated Antibody Drug Conjugates (ADCs)

Application Solutions

ADC OVERVIEW 01

ADCs (Antibody-drug Conjugates) are a new type of targeted therapy drugs composed of antibodies, small molecule cytotoxic drugs and linkers. Compared to other conventional chemotherapies, ADCs offer the advantages of killing cancer cells without the normal cells. ADCs provide highly efficient targeting and low toxic side effects in treatment of solid tumors, autoimmune and other similar diseases.

ADC Structural Diagram



Key Functions

Target Antigen	Identifies target cancer cells
Antibody	"Guiding System" of cytotoxic molecules
Linker	Links antibodies and drugs, controls drug release in cancer cells
Cytotoxic Drug	Destroys cancer cells

Mechanism of ADCs

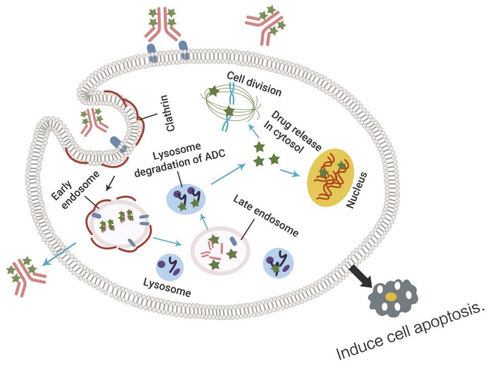
Step 1: ADCs identify antigens in body circulation.
Requirements: Stable coupling chain and low hydrophobicity of ADCs.

Step 2: ADCs attach to tumor antigens.
Requirements: Highly-expressed antigens on tumor cell surface.

Step 3: After endocytosis, ADCs are early endosomes, late endosomes and lysosomes.
Requirements: Endocytosis into cytoplasma and there should be a low antigen recycling rate.

Step 4: Degradation of lysosome with ADCs to release drugs in cytoplasma.
Requirements: ADCs kill target cells.

Step 5: Cytotoxic small molecule drugs work to cause target cell apoptosis.
Requirements：ADCs kill target cells.



02 R&D PROCESS

Discovery → Research → Production

Discovery

1 Discover Targets
Identify targets through genomics and proteomics research.

2 Develop Monoclonal Antibodies
Experiments based on immunohistochemistry, cell culture and function identification.

3 Linker Design and Synthesis
Based on antibody structures and target characteristics.

Research

4 Evaluate and Screen ADCs
Evaluate ADCs in vitro and in vivo experiments and conduct screening with high-throughput technologies.

5 Pharmacokinetics and pharmacodynamics research
Determine ADCs dosage and dosing regimen.

6 Preclinical Research
Carry out toxicology, pharmacokinetics, safety assessments.

7 Clinical Trials
Carry out Phase Ⅰ, Phase Ⅱ and Phase Ⅲ clinical trails to ensure safety and efficacy of ADCs.

Production

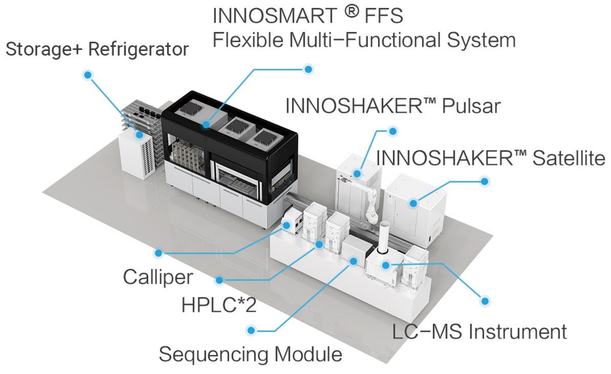
8 Regulatory Approval and Commercialization
Large scale production and market introduction.

TARGET DISCOVERY 03

Initial selection of target antigens is the critical step in the development of ADCs . Selecting a safe and effective clinical and commercial target is essential.

Velsson integrated solution, combined with sample preparation system and analytical platform, streamlines the selection process. Target discovery and screening process provides discovery tools of genes, proteins and cells, to build DNA and RNA NGS liabraries to achieve high-throughput data traceability and automation.

Integrated Analytical Platform



INNOMET™ READER

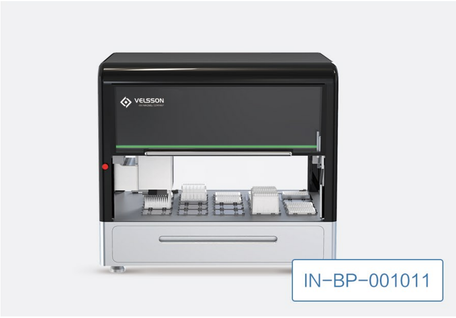
Supports basic ELISA, Western Blot based assays, TRF, TR-FRET (HTRF) and FP homogeneous targeting techniques. Combined with high-throughput microplates or biochips, to evaluate targets efficiently and optimize cost effectively.

INNOMET™ PURI

Isolates disease-associated proteins (potential drug targets) from normal cells and pathological cells with protein chip technologies.

INNOSMART ® FFS
Flexible Multi–Functional System

Built-in modules include PCR, imager , counter, centrifuge, vacuum filter, temperature-control shaker, syringe filter, product filter, liquid distribution module, pipetting module, feeding module and more to cover the entire sample treatment process.



INNOSMART ® D96/D48/D8
Smart Fluid System

a) Parallel operation of 96 pipettes (liquid level detection and tracking)
b) Independent or parallel operation of 48 pipettes (independent pipetting volume, liquid level detection and tracking)
c) Independent or parallel operation of 8 pipettes (independent pipetting volume, liquid level detection and tracking)

04 ANTIBODY DEVELOPMENT

Highly Efficient Antibody Development

After target discovery, the process enters into the antibody development phase. Antibodies provide targeting and toxin delivery, determing the efficacy of ADCs. Thus, it is necessary to produce high-quality antibodies to ensure high specificity and affinity of ADCs.

Velsson integrated solution, based on advanced cell culture techniques and highly efficient protein expression platform provides comperhansive large-scale antibody research and production solution. Other applications include gene synthesis, monoclone pick, cell culture, protein expression and antibody purification.

Gene Sequence Design

INNOSMART ® PROC
Intelligent Laboratory Software Platform

a) Smart design, optimization and assessment of gene sequences
b) Smart mutation and synthesis design of gene sequences
c) Enhancement of process parameters, and microorganism bioimage features
d) Smart design and optimization of plasmid processes

Gene Sequence Synthesis

INNOSMART ® SFS
Smart Fluid System

a) Analysis of gene properties
b) High-throughput gene synthesis
c) Integrated environmental control system to eliminate cross contamination

Plasmid Monoclone

INNOSMART ® MONOCLONE
Monoclonal Selection System

a) Integration of coating, culture and selection
b) Processing throughput of 2,000-3,000 samples/hour
c) Integrated environmental control system to eliminate cross contamination

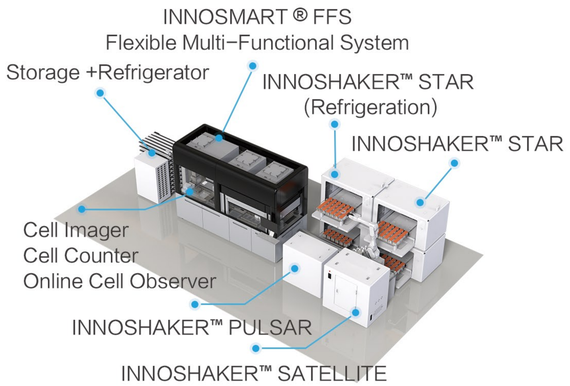
Plasmid Mini-Prep and Maxi-Prep

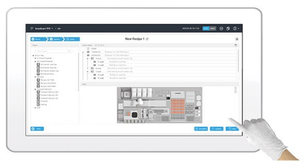
INNOSMART ® DNEX
Plasmid System

a) Magnetic bead and column processes
b) Integrated workflow of seed inoculation, amplification, enrichment, purification and quality control
c) Processing throughput of 150-300 samples per day

Large Scale Culture

a) Scale expression of well plates, tubes and flasks
b) Processing throughput of 100 well plates, +400 tubes, +400 flasks per day
c) Culture monitoring of embedded process





INNOSMART ® PROC
Intelligent Laboratory Software Platform

Data collection and analysis of all operations

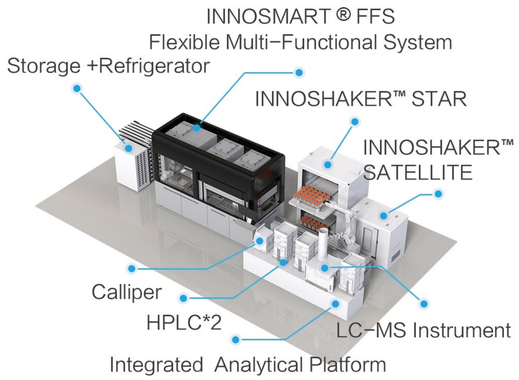
IN-BP-5001006

INNOSHAKER™ PULSAR
Well Plate Shaker Incubator

a) High speed of 1,200rpm
b) Optimized culture of extra deep / deep well plates
c) 18-plate high-throughput culture
d) Fully robotic or manual opertion

Full Antibody Screening

a) Integrated analytics and screening platform of anti-body samples
b) Integrated operations of transfection expression, amplification, purification, sample preparation, analytics and screening
c) Processing throughput of over 500 samples per day



IN-BP-001011

INNOSMART ® D96/D48/D8
Smart Fluid System

Smart benchtop fluid systems

Automatic Mammalian Cell Culture
IN-BP-5001003

Automatic Microorganism Culture
IN-BP-5001004

INNOSHAKER™ STAR
Shaker Incubator

a) Flexible culture of well plates, tubes and flasks
b) Fully robotic or manual opertion

PROCESS DEVELOPMENT 05

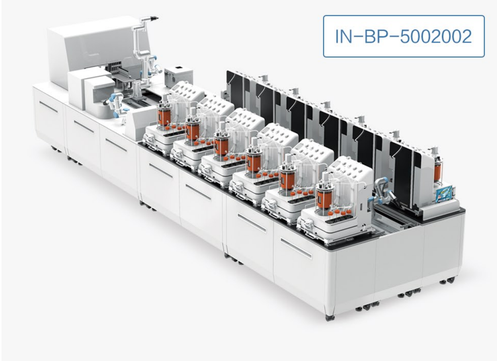
Efficient Culture Development Process

Drug-to-Antibody Ratio (DAR) is a vital contributor to quality of ADCs that significantly effects the drug safety and efficacy. DAR ranging between 2-4 is ideal for potency and effectiveness.

Velsson integrated solution provides an automatic platform for culture process optimization, with precise temperature control and automatic feeding functions to ensure high reproducibility and stability of experimental systems. Modularization is more convenient for production and facilitates linear amplification. The culture platform has excellent scalability and could be equipped with in-line pH, DO and concentration sensors. Additionally, intelligent software ensures the consistency between culture batches.

INNOMENTOR™
Benchtop Biological Reactor

a) Fully automatic culture, sampling, and feeding
b) Fed-batch and perfusion processes
c) AI process software platform to refine intelligent feeding strategies



INNOMENTOR™ PARALLEL
Integrated Parallel Bioreactor Platform

Attains a high degree of efficiency through advanced optimization and evaluation of the production process

06 PROCESS DEVELOPMENT

Enhanced Purification Process

In the downstream purification process, much more attention should be paid to the indices of DAR, linkers and residual amount of aggregates because of difficult ADCs' development process.

Filler Screening

Automatic and rapid screening of filler through micro-column chromatography

Binding Capacity Calibration

Determine the maximum binding capacity with samples of different concentration and-corresponding filler medium

Purification Condition Screening

Determine the best purification condition under different pH values and salt concentrations

INNOSMART ® SFS Smart Fluid System

Process Analytical Technology

Highly efficient pipetting and pumping as well as analytical devices to analyze sample accurately and efficiently

Buffer Preparation

Automation attains quantitative formula of buffers with different pH values and salt concentration in the purification process

PROCESS DEVELOPMENT 07

Preparation Development

The typical preparation formula of ADCs includes, excipient (sugar and salt), buffer solution and surface active agents. Different buffers may be used with Anti-bodies have same linker-payload. Automation systems improve all the preparation processes.

Sample Concentration Selection

Analyze the stability of samples with different concentration automatically

Calibration of pH and Buffer

Prepare the concentration of ADCs for clinical use from 4.0 to 8.0 pH and test the stability of sample under specific condition and time

Surfactant Screening

Surfactant is to reduce polymers by lowering surface tension

INNOSMART ® SFS
Smart Fluid Operation System

Excipient Screening

Sugar and salt are excipients in the preparation of ADCs. There are many different combinations of salt and sugar. Automation accelerates the screening by efficient allocation

Stability Analytics of Temperature and Time

Automation assists in stability tests under different times and temperatures

08 LETHAL PAYLOAD

Streamlined R&D and Evaluation of Lethal Toxin Payload

The payload molecules as the ADC “warheads” are endocytosed and cause significant damage to cancer cells. Many of the molecules selected as payload components are cytotoxins derived from natural products, with high molecular complexity and strong toxicity, which create technical requirements and safety challenges for development and large-scale production.

Velsson integrated solution simplifies the synthetic route and supports efficient design, synthesis and evaluation of cytotoxic payloads in closed systems. This solution runs 7 days a week and 24 hours a day without human intervention, thus reducing the manufacturing costs, as well as improving the product quality.

INNOSMART ® PROC
Intelligent Laboratory Software Platform

a) AI analytics of lead compound synthesis, screening, configuration and optimization
b) High-throughput selection to support combinational chemistry and functional group substitution research

INNOSMART ® D96/D48/D8
Smart Fluid Station

a) Agile synthesis of compounds and polypeptides
b) Fundamental libraries and flexible process editing
c) Accelerates preparation of early intermediates

INNOSMART ® SFS
Smart Fluid Operation System

a) Highly efficient synthesis of compound in normal temperature
b) High-throughput peptide synthesis operation
c) Integrated environmental control to eliminate cross contamination
d) Fundamental libraries and flexible process editing

INNOSMART ® FFS (A/C/D)
Flexible Multi-Functional System

1 Integrated Preparation System

a) Temperature controlled, air sealed and special gas, liquid and solid synthesis
b) Multiple extraction technologies and column purification technologies
c) Analytics and screening
d) Efficient DOE experiments

2 Integrated Operation System

Examples of high-throughput system applications:
a) Automatic system to optimize conjugation reaction conditions
b) Highly efficient DOE experiments

CONJUGATION TECHNOLOGY 09

Conjugation Technology R&D

Linkers provide the chemical combination of modified antibodies and drugs. Modified conjugation methods, drug toxins could be uniformly and securely linked to antibodies, providing a reliable mechanism for targeted delivery and enhancing the stability of the process.

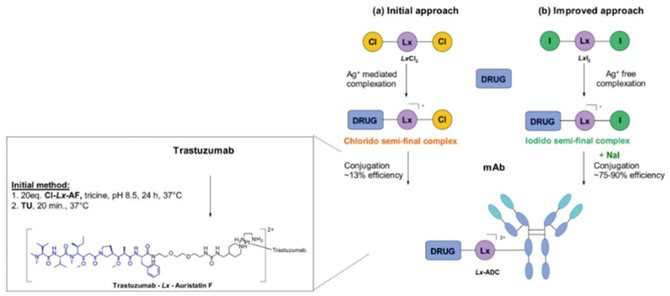
INNOSMART® FFS (Flexible Multi-Functional System) could process sample agents before synthesis, screen conjugation technologies and optimize conjugation conditions automatically. The high-throughput purification and screening in the conjugation process identifies intermediate products precisely and complies with regulations.

INNOSMART ® FFS (B/E/F)
Flexible Multi-Functional System

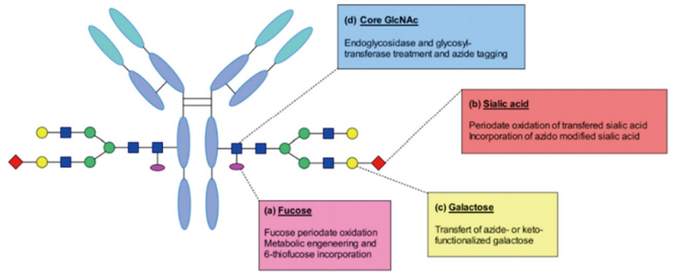
Conjugation Technology

- Screening of conjugation methods
- Optimization of conjugation conditions
- Pre-processing of sample agent synthesis

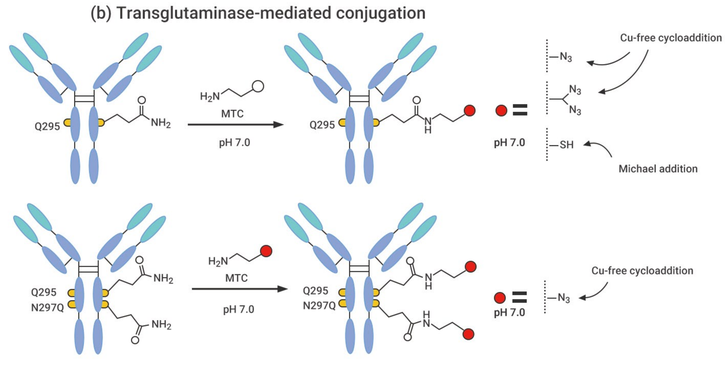
Conjugation with endogenous amino acids



Glycan conjugation



Disulfied bridging strategy



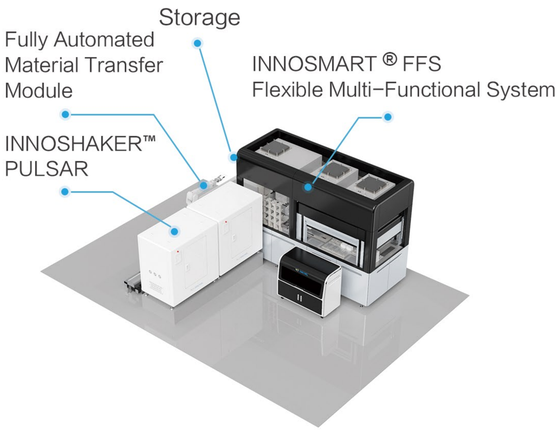
ANALYTICS & SCREENING 10

The analytics and screening of candidate ADCs in vitro and in vivo usually require high-throughput screening technologies and validation methods.

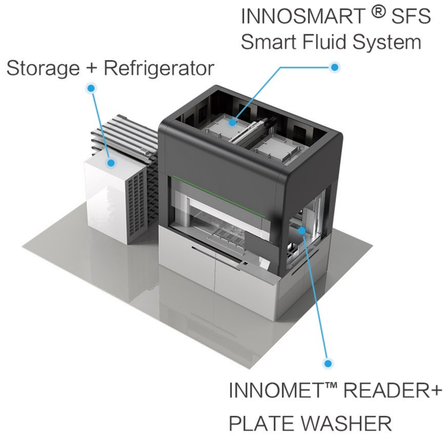
INNOSMART® PROC intelligent laboratory software platform achieves smart experiment design and execution, data acquisition, smart data analysis and AI report generation. Drug activity and toxicity are evaluated by cell culture experiments, enzyme-linked immunosorbent assays and other methods. In vitro screening is conducted to study the pharmacokinetics and pharmacodynamics of selected conjugated drugs and determine ADC dosage and dosing regimen.

Integrated Analytics and Screening Platform

DMPK Integrated Analytical Platform



High-Throughput ELISA Station



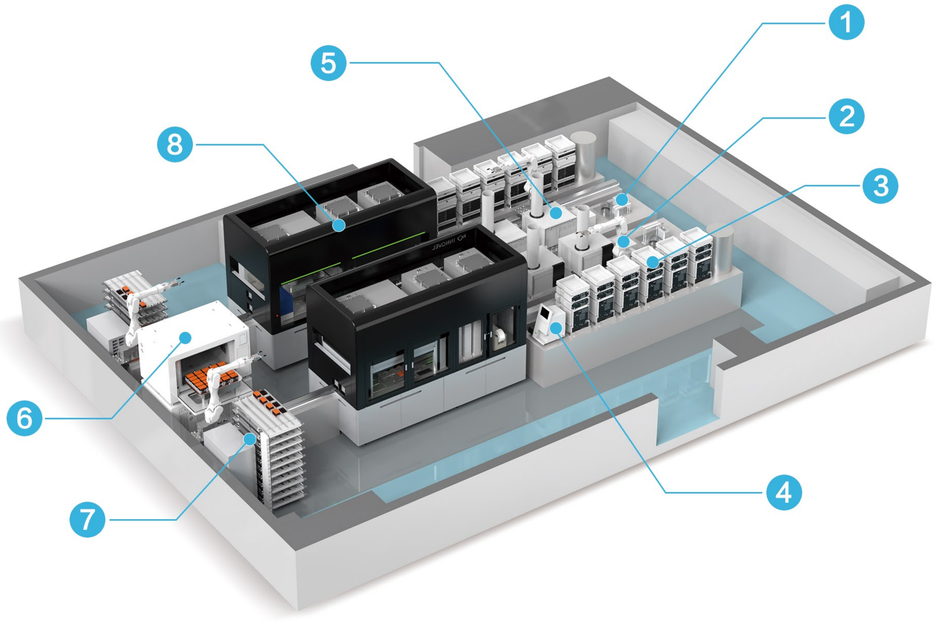
11 QUALITY EVALUATION

ADC Quality Evaluation

The analysis and representation of ADCs include macromolecular, small molecule specific and drug related quality attributes.

With modular configuration, Velsson integrated platform operates different validation at different levels of specificity, accuracy, precision, limit detection, limit quantitation, linearity range and durability, providing efficient and accurate value assessment for CRO, CDMO and pharmaceutical manufacturers.

Integrated Quality Analytics Platform



1. INNOMET™ UV
2. INNOMET™ READER
3. HPLC
4. SCEIX Capillary Electrophoresis
5. Mass Spectrum
6. Automatic Incubator
7. Integrated Storage Unit
8. INNOSMART® FFS

Highly Efficient Production of ADC

ADC production requires high level of safety and regulatory compliance. Velsson's extensive experience in GMP compliance, coupled with robust technical support, offers customers assistance with production of any size. Velsson automated system can be adjusted on demand to fit different size production batches to provide operational cost savings.

Fully Automatic Large-Scale Production System of ADCs

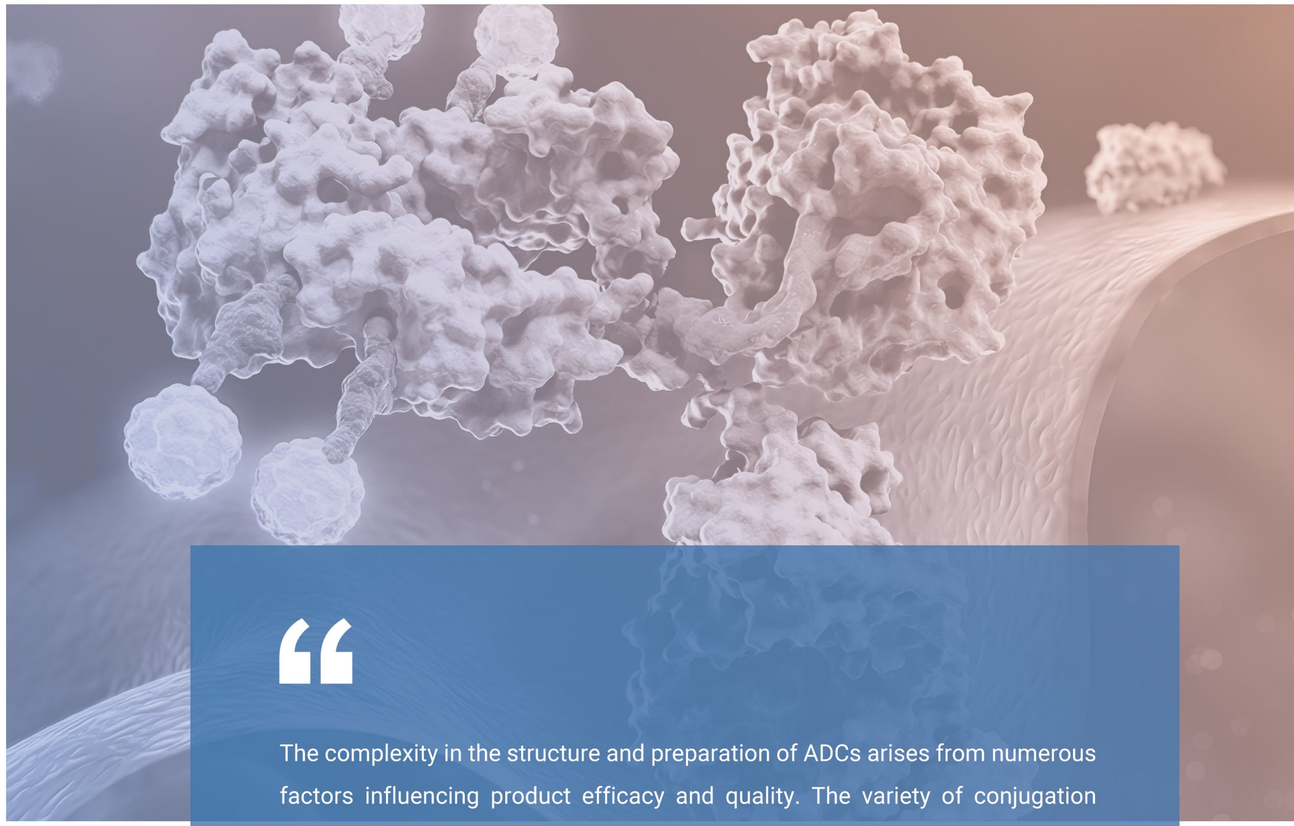
INNOFILL™ Filling

a) Fully automated and sealed manufacturing system
b) High-throughput 40,000 filling per day
c) Well suited for highly active and toxic processes
d) Fully automatic CIP cleaning and drying function
e) Wide selection of consumables for optimal performance

INNOFILL™ Cleaning

a) Designed to deliver effective cleaning on surfaces exposed to highly active and toxic substances
b) High-throughput processing of 40,000 to 160,000 containers per day
c) Wide selection of consumables for optimal performance

Now & Future



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The complexity in the structure and preparation of ADCs arises from numerous factors influencing product efficacy and quality. The variety of conjugation methods leads to notable distinctions in production processes. The technologies associated with antibodies, linkers, and payloads are continually advancing. Consequently, the prevailing direction is towards embracing integrated intelligent solutions.

Over the years, Velsson has pioneered a diverse array of integrated solutions encompassing target discovery, antibody preparation, payload design and synthesis, and linker payload preparation. Velsson's product portfolio spans the complete spectrum of ADC discovery, research, and production, meeting all reqired clinical and regulatory standards.

CATALOG NUMBER 14

Product Line		Device/Consumable Name	Specification	Number
Smart-Automation System		INNOSMART® SFS	INNOSMART-SFS.01	IN-BP-001006
		(Full Configuration) INNOSMART® FFS	INNOSMART-FFS.01	IN-BP-001007
		(Standard Configuration) INNOSMART® FFS	INNOSMART-FFS.02	IN-BP-001008
		INNOSMART® MONOCLONE	INNOSMART-MONOCLONE.01	IN-BP-001009
		INNOSMART® DNEX	INNOSMART-DNEX.01	IN-BP-001010
		INNOSMART® D96	INNOSMART-D96.01	IN-BP-001011
		INNOSMART® D48	INNOSMART-D48.01	IN-BP-001012
Biological Culture Products	Series of Incubators	(Automated Mammalian Cell Culture) INNOSHAKER™ STAR	INNOSHAKER 500ASWC (Standard)	IN-BP-5001003
		(Automated Microorganisms Culture) INNOSHAKER™ STAR	INNOSHAKER 500AS (No Humidification No CO_2)	IN-BP-5001004
		INNOSHAKER™ PULSAR	INNOSHAKER PULSAR (Standard)	IN-BP-5001006
	Series of Reactors	INNOMENTOR™	INNOMENTOR.01	IN-BP-5002001
		INNOMENTOR™ PARALLEL	INNOMENTOR-PARALLEL.01	IN-BP-5002002
Analytical Devices		INNOMET™ READER	INNOMENTOR-READER.01	IN-BP-4001001
		INNOMET™ PURI	INNOMENTOR-PURI.01	IN-BP-4001003
GMP Production System		INNOFILL™	INNOFILL.01	IN-BP-2001002