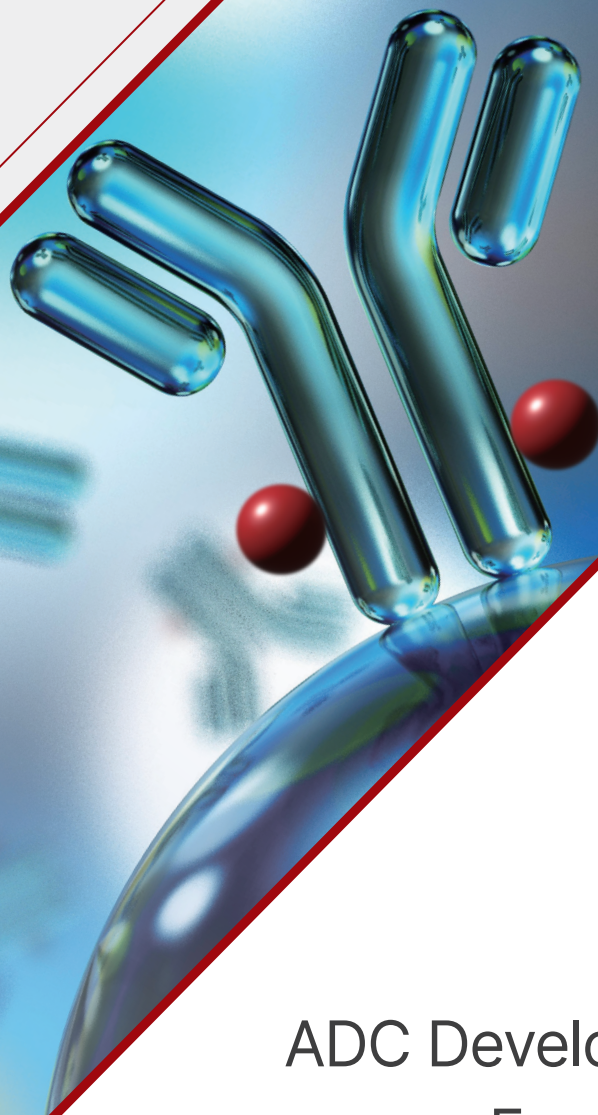




ADC Development Program
From Idea to Market

Reliable CDMO Partner
One-Stop Solutions for ADCs

■ About BINEX & KYONGBO

Your True and Reliable CDMO Partner, BINEX & KYONGBO

BINEX & KYONGBO are leading Contract Development and Manufacturing Organizations (CDMOs) with accumulated experience and expertise. With enhanced quality management systems and dedicated facilities, we offer ideal solutions for successful antibody-drug conjugates (ADCs) development.

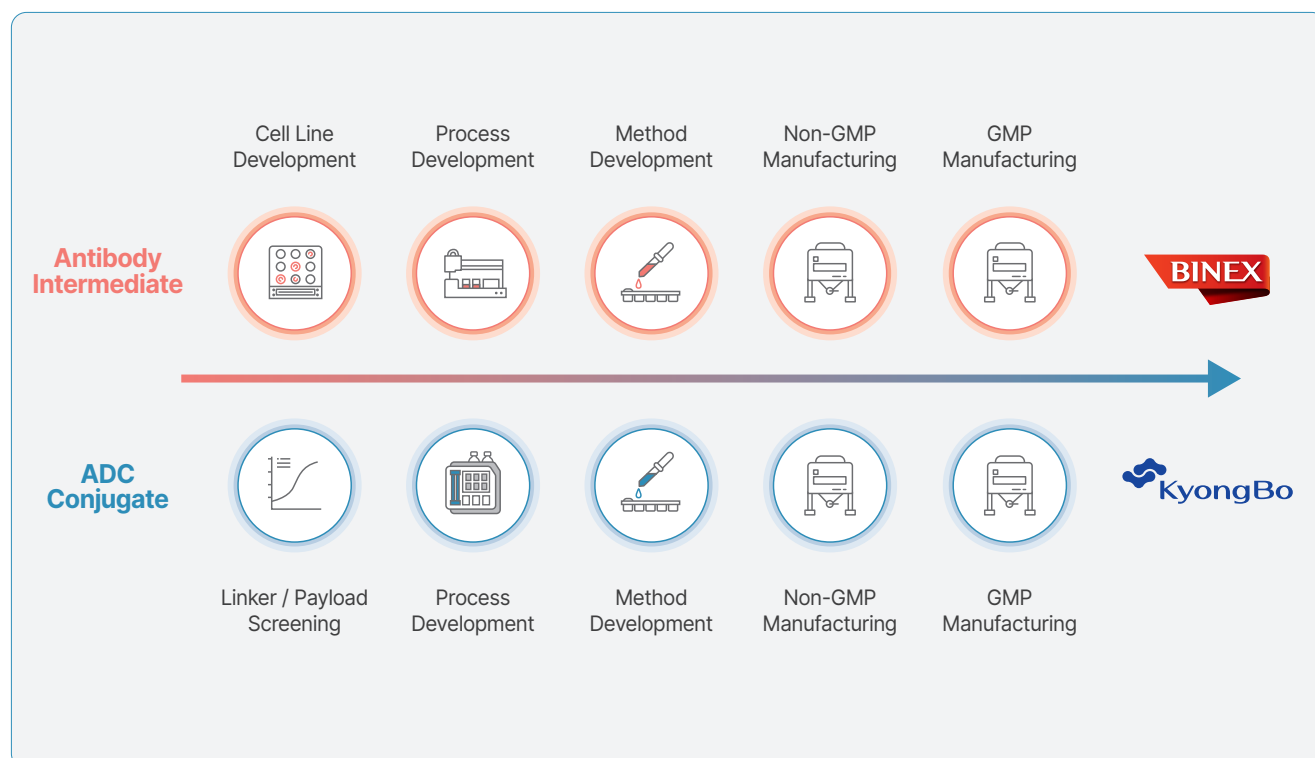
BINEX provides comprehensive CDMO services, catering to diverse needs from early-stage development (including cell line development, process development, and analytical method development) to GMP production and regulatory support. We are committed to provide client-oriented CDMO service based on our global track records and vast GMP manufacturing experience.

KYONGBO provides integrated services for ADCs to help clients' discovery from early development to pre-clinical, clinical and commercial manufacturing. We offer extensive services including payloads production, linker production, conjugation development, analytical method development, and sterile fill/finish. As a trusted CDMO partner, we provide integrated CDMO services for ADCs production to meet our clients' needs.

■ One-Stop ADC Development Program

BINEX & KYONGBO have launched an one-stop ADC development program, combining KYONGBO's experience in linker-payload development with BINEX's expertise in biologics development and GMP manufacturing.

Based on the combined expertise of BINEX & KYONGBO, this one-stop program covers cell line development, linker-payload screening, process and analytical method development, GMP manufacturing, and RA support.



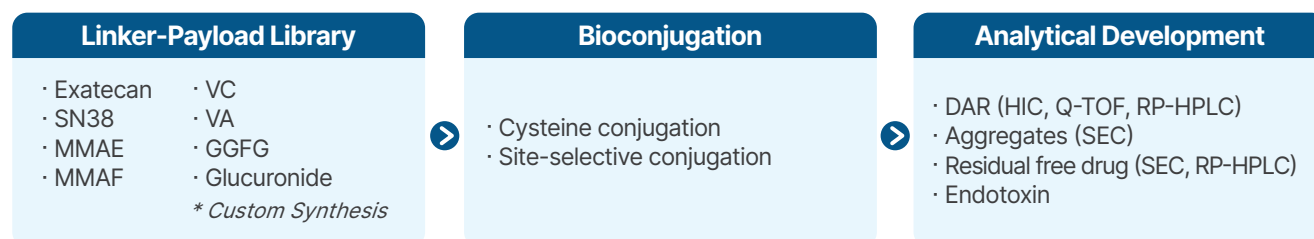
Cell Line Development

RCB preparation ensuring productivity, viability, monoclonality, sterility and stability



Linker/Payload Screening

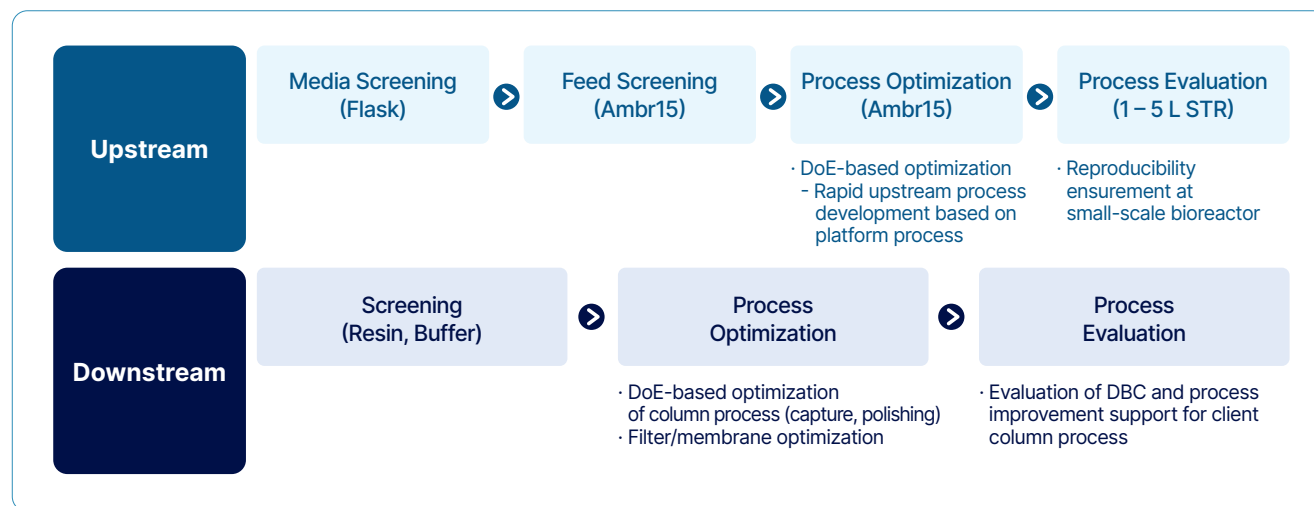
Various linker-payload combinations aligned with your ADC strategy



Process Development

Customized and optimized process development solutions

· Antibody Intermediate



· Linker-Payload

- Synthetic method development
- Optimal DoE, safety & environment controls
- Milligram to gram on lab scale
- Kilogram-scale under GMP conditions
- Pilot-scale (< 50 L) synthesis
- Full-scale (1,000 – 2,000 L) manufacturing
- High potency API manufacturing facilities
 - SafeBridge® OEL category 4

· ADC

- Process optimization (bioconjugation)
 - DAR, aggregates, free payloads, endotoxin, etc.
- Study of reaction conditions
 - pH, solvents, reaction time, etc.
- Bioconjugation
 - Cysteine conjugation
 - Lysine conjugation
 - Site-selective conjugation
- Purification
 - UFDF, SEC, HIC, IEX, Protein A

Analytical Method Development

Supports analytical method development for quality testing (IPC, release, and stability testing)

Attribute	Antibody Intermediate	Linker-Payload	ADC
General	· Appearance, pH, Osmolality	· Appearance, Color, Clarity, pH, Water content	· Appearance, Color, pH, Osmolality, Water content
Identity	· Western blot · DNA agarose-gel electrophoresis · SDS-PAGE · CE-SDS · IEF gel electrophoresis · icIEF/cIEF	· NMR · Mass · IR	· icIEF
DAR	-	-	· HPLC (HIC) · Q-TOF
Potency / Assay	· Binding ELISA · Cell based assay	· HPLC · Titration	· Binding ELISA
Purity	· HPLC (SEC, HIC, IEX, RP, AC) · UPLC (SEC, RP)	· HPLC (RP) · LC-Mass	· HPLC (SEC, IEX) · DAR
Impurity	· HCP · Residual protein A · HCD (qPCR)	· Organic impurity · Residual solvents · Heavy metal	· Unconjugated antibody · Residual free drug · Residual solvents · Heavy metal
Safety	· Endotoxin · Bioburden	· Endotoxin · Bioburden	· Endotoxin · Bioburden
Characterization (ADC)	· Peptide mapping · N/O-glycan analysis · Extinction coefficient	· Disulfide bond linkage · DAR distribution	· Conjugation site confirmation · SEC-MALS

Non-GMP Manufacturing

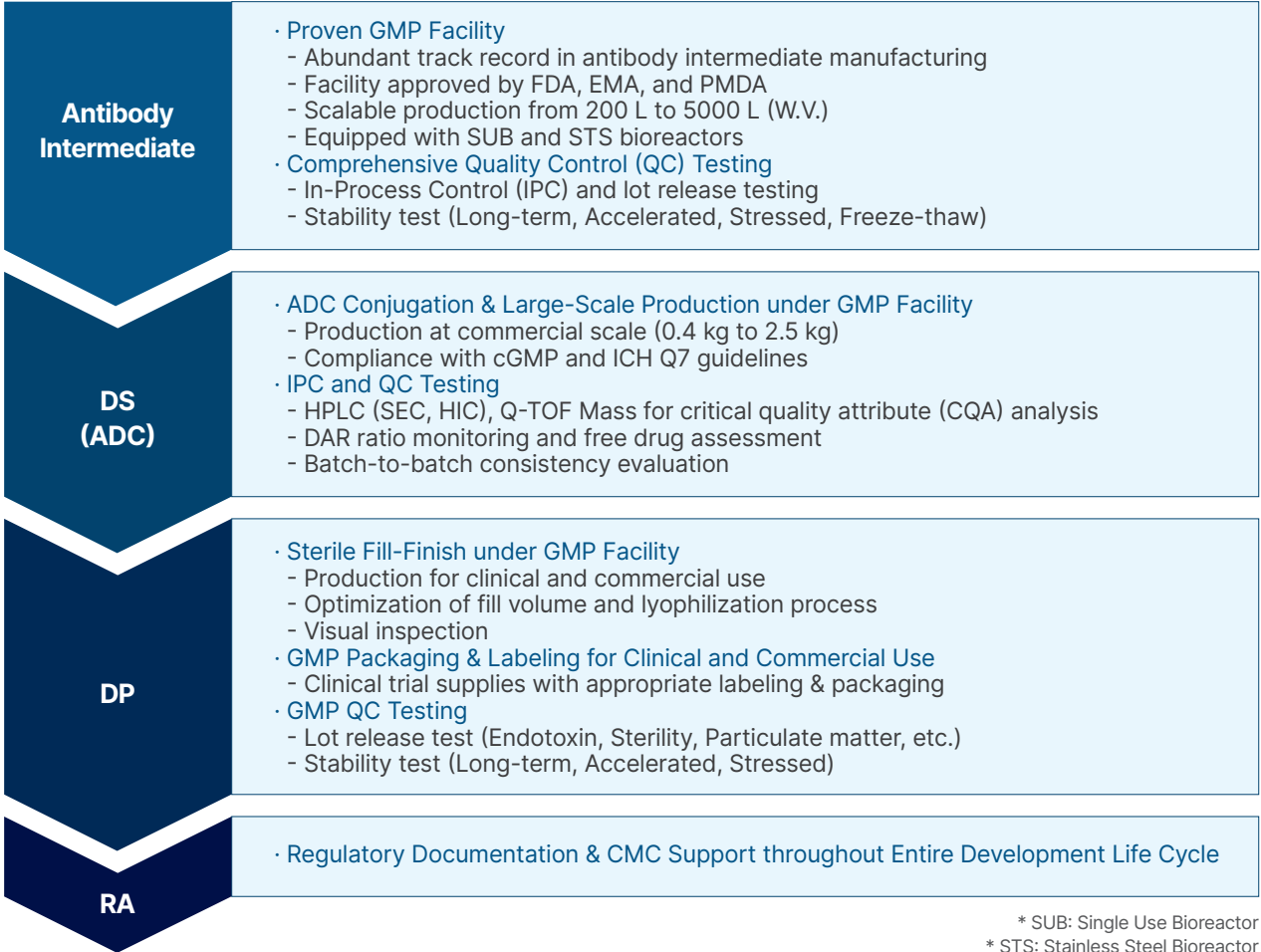
Comprehensive non-GMP production capabilities from lab to pilot scale

Antibody Intermediate	· Laboratory-Scale Production - Micro/Small-Scale bioreactors · Pilot-Scale Production for Research, According to Sample Requirements - Cultivation up to 50 L (W.V.) - Various column size for purification · Analysis of Research Materials based on Internal SOP · Stability Test of Antibody Intermediate · Antibody Intermediate Characterization
DS (ADC)	· ADC Process Development - Optimization of linker-to-antibody conjugation process - Study of reaction conditions (pH, solvents, reaction time, etc.) - Scale-up study · Small-Scale ADC DS Production for Preclinical Study - Gram-scale production - Analytical method development and characterization (HPLC, LC-MS, DAR analysis) · Pilot-Scale Production - Process optimization/verification for tech transfer to GMP
DP	· Small-Scale DP Production for Preclinical - Formulation development of sterile fill/finish (lyophilized and liquid formulation) - Stability test · Pilot-Scale DP Manufacturing & Packaging - Formulation studies and stability test - Feasibility assessment for clinical development · Process Optimization/Verification for Tech Transfer to GMP

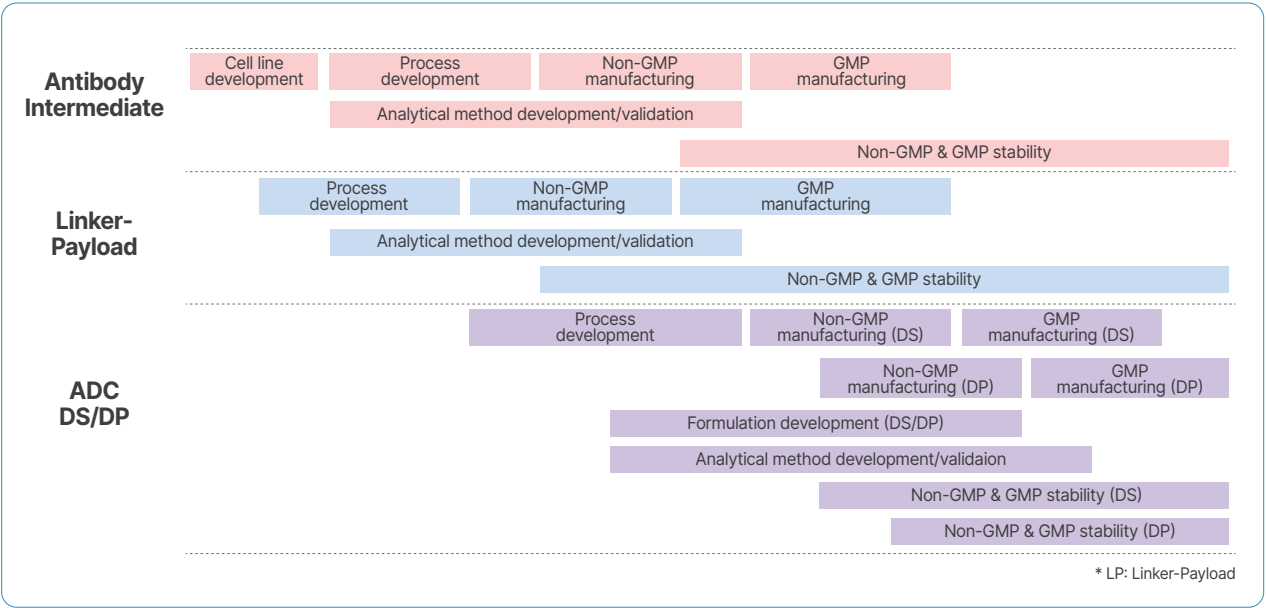
* W.V.: Working Volume

GMP Manufacturing

From clinical development to commercial production, for successful entry to the global market



One-Stop Service





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