



Integrated Process Development for Biologics

We provide comprehensive upstream and downstream process development—from cell line generation through fill-finish—ensuring a seamless transition from DNA to GMP production. Our integrated approach accelerates biologics development while maintaining quality and regulatory compliance.

High Expression Cell Line Development

MeCHOta® Host Cell Platform — Our proprietary CHO cell line is derived from ECACC CHO-K1 and adapted for high-performance suspension culture.

Key Features:

- Globally authorized with full traceability and regulatory compliance
- Comprehensive cell banking and testing solutions
- Matched expression vectors and media for high-yield, scalable expression
- We deliver production-ready clones in ~20 weeks with titers reaching up to 9 g/L
- Customizable workflow using our MeCHOta® platform or client-provided hosts



Upstream & Downstream Process Development

Platform-Based Development Strategy

Our process development follows scalable, phase-appropriate strategies optimized for regulatory compliance and tech transfer.

- Fed-batch and perfusion process optimization in scalable bioreactors
- Platform purification processes including Protein A, ion exchange, and polishing steps
- Process parameter definition aligned with CMC and QbD principles

Advantage:

- Reduced development timeline via standardized modules
- Scalable from 2L to 200L pilot runs
- Compatible with cGMP production workflows

Transferable and Scalable from Lab to Clinic

HiLand's integrated PD platform ensures:

- Seamless transition from research-grade to GMP manufacturing
- IND-enabling material supply
- Flexibility for mAbs, BsAbs, ADCs, and fusion proteins

**Formulation development**

HiLand Team offers comprehensive formulation capabilities and deep expertise across a broad range of biologic modalities, delivering tailored solutions from early development through clinical supply.

- Monoclonal antibodies, bispecifics, fusion proteins, nanobodies
- Both liquid and lyophilized formulations
- Support for IND-enabling studies and long-term stability programs

**Formulation Screening**

- Formulation selection and early formulation development
- Formulation screening with DOE design
- Influencing factor experiment / stability study
- Selection of excipients and packaging materials

**Formulation-Supporting Studies**

- Compatibility studies of excipients and packaging materials, and container closure integrity
- Freeze-thaw, agitation, photostability, and stress testing



Fill-Finish Development

- Identification of suitable fill-finish process strategy
- QbD-based process optimization & qualification
- Scale-up for vial and PFS formats, including tech transfer readiness

Protein Analysis & Assay Development

Assay Development Services

We support full assay development for release, stability, and comparability studies:

- Structural and physicochemical characterization
- Biological activity assays
- Product release testing aligned with regulatory guidelines

Platform Capabilities

Technical Platform	Assays
HPLC / UPLC	titer HPLC, SEC HPLC, CEX HPLC, peptide mapping, glycosylation, DAR value, sialic acid, extinction coefficient, tween
CE	iCIEF, CIEF, rCE SDS, nrCE SDS, CZE
ELISA	antigen binding, residual HCP, residual Protein A, residual insulin
PCR	residual HCD, copy number
BLI	affinity, FcγRIa / FcγRIIa / FcγRIIb / FcγRIIIa / FcγRIIIb / FcRn / C1q binding
Cell Assay	cell-based bioactivity, ADCC, ADCP, CDC
MS	denatured and non-denatured molecular weight, peptide mapping, disulfide bond, post-translational modifications, glycosylation site, conjugation site, sequence coverage, de novo sequencing



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