

Link to Enable Biotechnologies

Bio-Link provides products and process solutions in the life sciences industry. We focus on the development and production of the key processing equipment and consumables for recombinant protein drugs, vaccines, antibodies, cell therapies, gene therapies and other biological products. Our portfolio of offerings cover the entire upstream and downstream bioprocess such as cell culture, single-use mixing and storage, protein chromatography, filtration and ultrafiltration, hydration as well as process development and validation services.

Fluid management	Mixing and storage hardware and consumables (M/P/ S/C/customized)			Storage bottle (PC/PS)		Assembling components		
Hydration Products	Water for injection		Buffer/Process liquid		Customized products			
Downstream protein chromatography	Chromatography resins:	Size exclusion chromatography	Affinity chromatography	• Multimodal Chromatography	 Polymer 	 Ion exchange chromatography 	Hydrophobic interaction chromatography	Hydroxyapatite

Quality Management System Certificate







Nantong Single-use Bioprocessing Manufacturing Site



Lanzhou Chromatography Resins Manufacturing Site

> Fluid Management

BioHub® 2D storage bag



Bag chamber volumes:5 mL ~ 50 L Multiple fitting & tubing configurations Optional films for customization

BioHub® Cubic foldable plastic bin + Matched storage bag



Volume: 50/100/200/250 500/1000 L

BioHub® S Needle sampling bag Needle sampling bottle



Volume: 50mL, 100 mL, 250 mL, 500 mL, 1,000 mL Configuration: single-needle, single-bag; single-needle, 5-bag Fitting type: needle sampling valve (single-needle/dual-needle)

Volume: 20 mL, 50 mL, 125 mL, 250 mL Configuration: single-needle, singlebottle: single-needle.5-bottle Fitting type: needle sampling valve (single-needle/dual-needle)

BioHub® Single-Use Storage Bottles



Cap without tubing: Regular, 2-port,

Cap with tubing: C-Flex tubing, silicone tubing

BioHub® PVDF Fittings



BioHub® fittings are available with a variety of straight connectors, reducers, tees (Y- and T-shaped), crosses, flange covers, clamps, and tri-clamps.

BioHub® DS Single-Use **Desktop Mixer**



World First — NovaLinX® RNase-free **Disposable Consumables**

Master bag + Innovative design of double satellite bags

- Identical material/production environment of master bag and satellite bag, consistent gamma irradiation conditions
- Supplier: Satellite bag 1, for releasing RNase-tested products
- Customer: Satellite bag 2, for pre-use or post-use RNase inspection





ChromaX® Chromatography Resins

Hydroxyapatite Multimodal Chromatography

ChromLinX® Empty Chromatography Column 1 mL/4.7 mL/5 mL Chrom-Trap™ & Chrom-Screen™ Prepacked Chromatography Column





hromaX® Chromatography Resins	Product category				
Size exclusion chromatography	Chromstar 4FF/6FFChromstar CL-4B/CL-6BChromstar 4B/6B	 Geldex PG series Puredex G series Puredex LH-20			
lon exchange chromatography	MaXtar Q/DEAE/SMaXtar Q/SP HRMaXtar Q/SP HR XLQ/SP Chromstar BBO/DEAE/SP/S/CM Chromstar FF	 Q/DEAE/SP/CM Chromstar HP Q/SP Chromstar XL Q/SP Chromstar BB XL DEAE Puredex A50 CM Puredex C25 			
Affinity chromatography	Antibody purificationHistidine-tagged proteins purificationImmobilized metal ion affinitychromatography	GST-tagged proteins purification Other types			
Hydrophobic interaction chromatography	 MaXtar Phenyl (HS)/(LS) MaXtar Butyl/Octyl MaXtar Phenyl/Octyl/Bultyl HR Phenyl Chromstar 6FF (HS)/(LS) 	Octyl/Butyl Chromstar 4FFButyl-S Chromstar 6FFPhenyl/Butyl Chromstar HP			
Multimodal chromatography	MaXtar MMCMaXtar MMC HRMaXtar COLL 700MaXtar COLL 400	Maxtar MMAMaxtar MMA HRBaronCHT type IBaronCHT type II			
Polymer chromatography	Maxgo series				

Hydration Products



Comprehensive Validation and Analysis

- Continuous 15-day WFI test validation
- · Weekly testing of WFI QC inspection
- In Process WFI quality control
- Filling line: first & end sampling inspection







2D storage bad (500 mL - 20 L)

RNase-free WFI quality water available

Meeting multi-compendial (ChP, PhEur, USP, and JP) requirements

Services

Suzhou R&D Center

Upstream process Development

- Cell culture process development
- Stepless scale-up
- **Process optimization**

Downstream process Development

- Protein chromatography process development
- Stepless scale-up
- High-throughput process development
- Validation of resin service life

Training

- Application training
- Operation training

Bio-Link Validation and Analysis Center

Located in Nantong, Jiangsu, this center was established in February, 2022 and covers an area of 1,400 sqm. It is equipped with all kinds of large precision instruments, including inductively coupled plasma mass spectrometer, liquid mass spectrometer, gas mass spectrometer, TOC detector, automatic microplate reader, infrared detector, etc...

The center supports the analysis and detection of extractables and leachables, with a detection precision of up to PPT level. The platform is operated and managed in accordance with CMA and CNAS systems.



Extractable/Leachable study (E&L)

- Extractable study with BPOG & USP standard methods
- · Leachable study of customers' feed liquid
- Risk assessment



Microbiology test (BSL2)

- Bacterial viability test
- Bacterial challenge test of virus removal filter
- Microbial limit test
- Sterility test



Filter validation

- Chemical compatibility study
- Product-wet integrity test
- Adsorption study
- Integrity test



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Document no.: BLK-BR-20230419-01-EN