

Our Service
CAO

- Provide all necessary analytical support during process development.
- In-house analytical capability for more than 30 molecules, including various antibodies, proteins, toxins, vaccines, and peptides.

Cell line
development

**Feasibility test
Pool & Clone evaluation**

- SE-HPLC
- CE-SDS(R/NR)
- Intact MS
- icIEF
- Peptide mapping
- Full sequence coverage
- N-term/ C-term
- MoA: Binding affinity (Octet)

Long-term stability

- SE-HPLC
- CE-SDS(R/NR)
- CEX-HPLC
- AEX-HPLC
- MoA: Binding affinity (Octet)

USP Process
development

Confirmation run

- SE-HPLC
- HCP
- HCD

Purified Tox. Material

- SE-HPLC
- HCP
- HCD
- Endotoxin

DSP Process
development

Intermediate hold time test

- Protein content (UV)
- SE-HPLC
- IEX-HPLC

DP/Formulation
study

**Excipient selection &
Formulation optimization**

- DoE based study
- Charge variant (icIEF)
- CE-SDS(R/NR)
- SE-HPLC

Quality Evaluation

- More than 30 Characterization Services for Antibody and Recombinant Protein Therapeutics
- DoE based Process Development and Statistical Data Processing to confirm Inter-molecular Comparability

Quality attribute	Test method & equipment
Primary structure	Full amino acid sequencing (LC-MS/MS)
	N/C-term sequencing (LC-MS/MS)
	Peptide mapping (LC-MS/MS)
	Disulfide bond (LC-MS/MS)
Molecular weight	Intact MS (Reduced/Non-reduced)
Post-translational modification	PTM (Oxidation, Deamidation, etc.) (LC-MS/MS)
Glycosylation	N/O-Glycan site (LC-MS/MS)
	N-Glycan profile & identification (UPLC or LC-MS/MS)
	Total sialic acid (TSA)
	CE-SDS (Reduced/Non-reduced)
Physicochemical properties	AEX-HPLC
	SAX-HPLC
	CEX-HPLC
	HIC-HPLC
	RP-HPLC
Charge heterogeneity	Charge variant profile (icIEF)
	CD (Far/Near UV)
High-order structure	Differential scanning calorimetry (DSC)
	FT-IR
	Intrinsic and extrinsic fluorescence spectroscopy
Biological activity	Binding assay by BLI (Octet/ SPR)
Purity/impurity	SE-HPLC
	SE-HPLC with multi angle light scatter detector (SEC-MALS)
	Micro-flow imaging (MFI)
Process-related impurity	HCP (ELISA)
	HCD (RT-PCR)

Contract Development Analysis,
Manufacturing Services

CD'A'MO Service

Contract
Development
Analysis and
Manufacturing
Organization

CD'A'MO Service

About Us

Protium
Science

Established

May 10th, 2021



Business area

CDAMO (Contract Development, Analysis and Manufacturing Organization)



Website

www.protiumscience.com
https://www.linkedin.com/company/protium-science/



Contact

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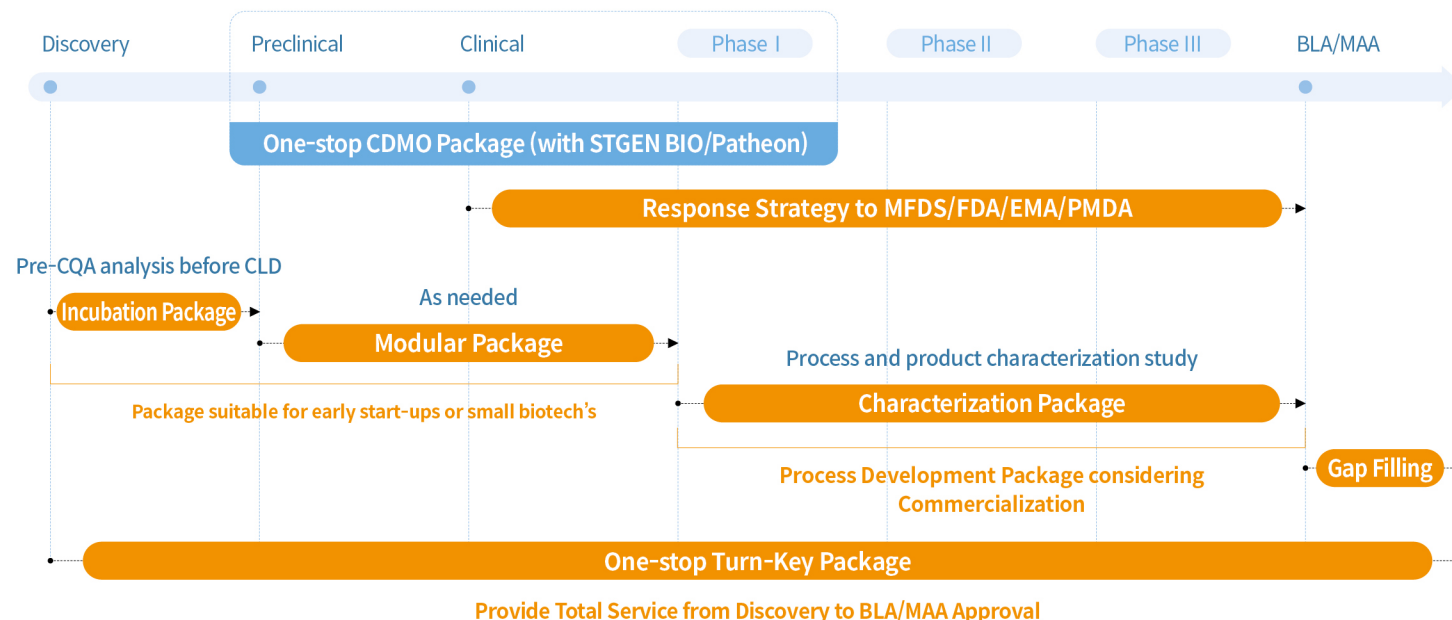
Process Innovation Center (HQ)

9F, U-space 1, Daewangpangyo-ro 660, Bundang-gu, Seongnam-si, Gyeonggi-do, Republic of Korea

Analytics Center of Excellence (Pangyo Technovalley 2)

6F, Pangyo IT Center, 30 Changup-ro 40 beon-gil, Sujeong-gu, Seongnam-si, Gyeonggi-do, Republic of Korea

Wide selections of service packages **save time and cost**



Our Service

CDO

Comprehensive CMC Development including Process Development and Product Characterization

One-stop CDMO Service

Area 1

QbD based Process Development

Cell line development

- Various Cell lines available (ExpiCHO-S, CHOZN, DG44, CHO-K1)
 - Beacon® technology
- Long-term stability, RCB banking

USP and DSP development

- Media (USP) & resin (DSP) screening
- Small scale process development & process lock
 - Scale-up study
- Tox. material production

Analytical method development

- MD/MQ for release test
- Characterization Study for DS / DP & Tox. material
 - CoA

Formulation/Drug product development

- Formulation development and optimization
 - DS/DP stability study
 - In-use stability

Area 2

GMP Production

One-stop CDMO service by alliances

- Technology transfer to CMO & manufacturing related studies
- Experiences in technology transfer to domestic & global CMOs
- Accelerated development & production timeline with GMP flexibility compared to existing CDMOs

Area 3

Consulting

- Development strategy
- M/WCB banking & Characteristic analysis
- Briefing Document/IMPD for IND submission
- Responses to authorities (FDA, EMA, PMDA, etc.)
 - Gap analysis
 - CTD writing

Area 4

Process Characterization

- Risk assessment
- Scale-down modeling
- Experiments based on DoE and RSM
- Parameter classification
 - Control strategy
 - Report (CTD grade)

Area 5

Other Services

- ADC conjugation & analysis
- Low molecular synthetic peptide analysis
 - Developability assessment
 - On-site/Off-site training
 - In-country testing & other QC tests
- Dedicated PM & High level QA support

Partners

BXPLANT

CrossPoint

HMIC

inno.N

KYONGBO

REYON

patheon

SARTORIUS

STGEN BIO

BIOLOGICS