sysgene



OVERVIEW 2026

# Advancing biologics. Enabling access.

Globally patented expression platforms.
Process development and GMP manufacture.
A focused bioprocess product portfolio.

We help manufacturers develop practical production routes for essential biologics, with affordability and product quality at the centre of the program.

TWO COMPLEMENTARY PLATFORM ROUTES

## Bacterial secretion

Extracellular secretion

## Mammalian expression

CHO/HEK-based expression

WHO WE ARE

# Making essential biologics more accessible

Founded in 2026, SysGene Biologics is guided by a simple belief: essential biologics should be accessible and affordable. We bring together biologics expertise, enabling manufacturing capability and focused bioprocess solutions to help manufacturers address production challenges and reduce costs while maintaining quality.

**2**

**Globally patented platforms**

Bacterial secretion and mammalian expression

**9**

**Focused bioprocess products**

Designed, developed and made on our own platforms

UP TO

**1,000 L**

**GMP microbial fermenters**

5,000 L planned in Hyderabad

MOLECULE FIRST

## The molecule determines the route, not a one-size-fits-all process.

Every program begins with the structure, function and quality requirements of your molecule, so the most appropriate platform and development strategy are selected.



- **Molecule assessment**
  Structure, function and quality requirements
- **Platform selection**
  Bacterial secretion or mammalian expression
- **Development & analytics**
  Upstream, downstream, characterization
- **Scale-up & GMP manufacture**
  Development: microbial up to 10 L; mammalian 5 L
  GMP microbial: 30, 100 & 1,000 L

**Proven in our own portfolio**

Every SysGene product is made on the same globally patented platforms we offer for development and technology-transfer programs.

BIOLOGICS 101

# Know your molecule: peptide, protein or antibody

The US FDA defines a protein as an alpha amino acid polymer with a specific, defined sequence of more than 40 amino acids; a polymer of 40 or fewer is a peptide. Size and structure shape every decision, from expression host to analytical strategy.



40 OR FEWER AMINO ACIDS

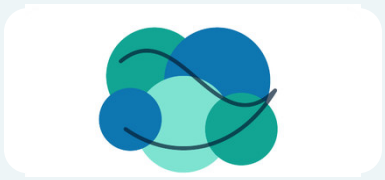
## Peptides

**MW ~0.5–5 kDa**

- Short linear or simple cyclic chains
- Lack tertiary folding; highly flexible in solution

**Analytical focus**

Molecular weight and LC-MS purity



MORE THAN 40 AMINO ACIDS

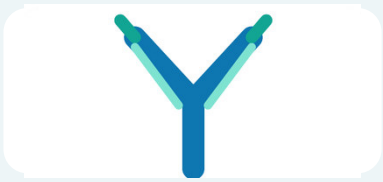
## Proteins

**MW ~10–100+ kDa**

- Complex folded 3D structures (alpha-helices, beta-sheets)
- Susceptible to denaturation and aggregation

**Analytical focus**

Secondary and tertiary folding, and activity



HETEROTETRAMER

## Monoclonal antibodies

**MW ~150 kDa**

- Y-shaped four-chain glycoprotein (two heavy, two light)
- Complex post-translational modifications (PTMs)

**Analytical focus**

Glycosylation, charge variants and binding

FROM SEQUENCE TO SUPPLY

## How a recombinant biologic is made

| 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|
| **Sequence & strategy** | **Expression** | **Culture** | **Downstream purification** | **Characterization & transfer** |
| Define the molecule and its target quality profile | A host or cell line produces the molecule | Fermenters or bioreactors, with media and feeds tuned to the molecule | Capture, polishing and buffer exchange | Prove identity, purity and function; document the process |

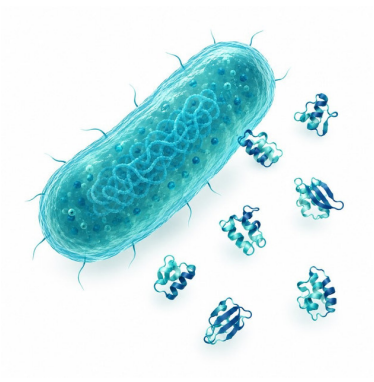
**WHY IT MATTERS**

Molecules requiring mammalian post-translational modifications use CHO/HEK expression for appropriate folding and processing. For compatible proteins and peptides, secretion into the culture medium can simplify downstream purification.

TWO PLATFORMS. ONE DEVELOPMENT PARTNER.

# Start with the molecule.

Choose the route around the molecule's structure, function and intended quality. Use mammalian expression when the molecule requires mammalian post-translational modifications.



MICROBIAL EXPRESSION

## Downstream purification starts outside the cell

E. coli / Pichia host capabilities. Bacterial secretion releases suitable proteins and peptides into the culture medium.



MAMMALIAN EXPRESSION

## A route for complex biologics

CHO/HEK-based expression for biologics requiring mammalian processing, with cell cycle independent expression of the recombinant protein.

MAKE THE PLATFORM CHOICE WORK DOWNSTREAM

**Molecule fit**

Structure, function and processing requirements.

**Process fit**

Downstream purification, impurities and operating conditions.

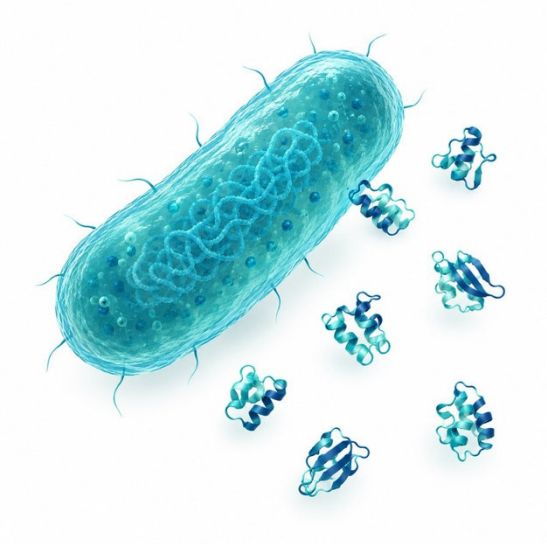
**Transfer fit**

Scale objectives, receiving facility and analytical needs.



GLOBALLY PATENTED BACTERIAL SECRETION PLATFORM

# Purification begins outside the cell.



For compatible proteins and peptides, secretion into the culture medium starts downstream purification outside the cell.
Microbial host capabilities include E. coli / Pichia.

WHY IT MATTERS

01

### Begin with the culture medium

Downstream purification starts from clarified culture supernatant.

02

### Simplify downstream purification

Where cell lysis, inclusion-body isolation and refolding can be avoided, fewer unit operations may need to be developed and transferred.

03

### Develop around the molecule

Media, feeds and cultivation conditions are tailored to the target protein. Batch or perfusion development is considered against program needs.

AN INTEGRATED PROCESS ROUTE

Culture → Clarification → Capture → Polishing

Suitability and process performance are evaluated for each molecule.

GLOBALLY PATENTED MAMMALIAN EXPRESSION PLATFORM

# Develop complexity with purpose.

A complementary CHO/HEK-based route for biologics whose function depends on mammalian folding, assembly or post-translational processing.



CONNECT EXPRESSION TO PRODUCT QUALITY

01

### Cell cycle independent expression

Expression of the recombinant protein, supported by cell-line, media and feed development aligned with productivity and quality requirements.

02

### Integrate purification early

Connect cell-culture development with downstream purification for monoclonal antibodies, Fc-fusion proteins and other recombinant proteins.

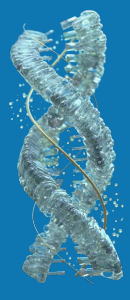
03

### Characterize what matters

Select structural and functional assessments around the molecule, including glycosylation, molecular integrity, binding and biological activity where relevant.

PLAN FOR THE NEXT DEVELOPMENT STAGE

Define the expression approach, analytical package and scale-up requirements together, so development decisions support the intended manufacturing route.



FROM SEQUENCE TO TRANSFER

# One connected development program.

Engage SysGene for a defined stage or an integrated program spanning expression, purification, characterization, GMP manufacture and technology transfer.



**Upstream development**



**Downstream purification**



**Scale-up & transfer**

## 01

### Upstream process development

Microbial hosts: E. coli / Pichia.
Mammalian systems: CHO/HEK.
Media, feeds and culture conditions tailored to productivity, quality and reproducible performance.

## 02

### Downstream purification

Harvest, clarification, affinity capture, chromatographic polishing, concentration and buffer exchange, developed as an integrated workflow.

## 03

### Analytics & characterization

Structural, functional and impurity assessments that guide process decisions, compare batches and evaluate the impact of process changes.

## 04

### Scale-up & GMP manufacture

Scale-up and technology transfer, including operating procedures, batch documentation and analytical methods, with training and technical support for the receiving facility.

- A transfer package shaped around the receiving facility and agreed acceptance criteria.

DEVELOPMENT & GMP MANUFACTURE

# Capacity for development and GMP manufacture.

Connect non-GMP microbial and mammalian development with GMP microbial manufacture, molecule-specific analytics and technology transfer.

## CAPACITY IN HYDERABAD, INDIA

### NON-GMP DEVELOPMENT

Microbial

**Up to 10 L**

Mammalian: 5 L bioreactor

### GMP MANUFACTURE

**30 & 100 L**

**1,000 L**

Microbial fermenters

### PLANNED

**5,000 L**

Planned microbial capacity

## ANALYTICS THAT SUPPORT SCALE-UP

| | |
|---|---|
| **Identity & structure** | Mass spectrometry, peptide mapping and structural analysis tailored to the molecule. |
| **Purity & integrity** | Chromatographic and electrophoretic assessment of purity, aggregation and molecular integrity. |
| **Biological function** | Binding and activity assays selected for the intended application and molecule class. |
| **Process impurities** | Host-cell proteins, residual DNA and endotoxin testing where relevant to the expression system. |

## QUALITY BUILT INTO THE PROGRAM

Development and analytical activities are aligned with relevant ICH guidance, including Q6B, Q5E and Q2(R2). Product grade, specifications and supporting documentation are confirmed for each requirement.

*Scale-up and product quality are assessed for each molecule. GMP or non-GMP programs are scoped to facility, product and regulatory fit; additional capacity and specialist capabilities may be delivered through qualified partners.*

ANALYTICS & CHARACTERIZATION

# Characterization for peptides, proteins and mAbs

SysGene characterizes molecules across primary, secondary and higher-order structure and biological function, with each analytical program tailored to the molecule class.

### Primary structure

Mass, sequence, disulfide bonds, PTMs, identity and purity

LC-MS/MS · MALDI-TOF · peptide mapping · Edman sequencing · RP-HPLC

### Secondary structure

Fold composition, structural fingerprint and thermal stability

CD · FTIR · Raman · DSC

### Higher-order structure

Tertiary fold, aggregation, fragmentation and oligomeric state

Fluorescence · SEC-MALS · SEC-HPLC · DLS

### Biological function

Binding affinity and kinetics, potency and Fc-mediated function

SPR · cell-based bioassays · ADCC / CDC

QUALITY STANDARDS

## The guidelines and grades we work to

### ICH-aligned development

Aligned with ICH Q6B (specifications and characterization), Q5E (comparability) and Q2(R2) (analytical validation). GMP standards based on ICH Q10.

### Product grades

Every product is made to its stated grade: research, multi-compendial or GMP. The grade and supporting documentation are confirmed per product.

### Multi-compendial standards

Specified against the relevant monographs of more than one pharmacopoeia: USP, Ph. Eur. and JP.

### Documented evidence

Electronic laboratory notebooks enable real-time data sharing. Claims identify validated specifications, representative results, development targets or external benchmarks.

NINE FOCUSED PRODUCT CATEGORIES

# Products for your bioprocess workflow.

Available for evaluation and commercial production using our process platforms. Discuss your application, required grade, specifications and supply needs.




AFFINITY RESIN

### Protein A Resins

mAbOn-A® and PLAG-On for antibody and immunoglobulin capture.




AFFINITY RESIN

### Protein L Resins

FabOn-L® for compatible kappa-containing antibody fragments and Fc-free formats. Compatibility requires evaluation.




PROCESS ENZYME

### DRNase®

Recombinant endonuclease for DNA and RNA reduction in bioprocessing.




RNA MANUFACTURING

### mRNA Manufacturing Enzymes

T7 RNA Polymerase, DNase I, IPPase and RNase Inhibitor for RNA-manufacturing workflows.




PROCESS ENZYME

### Trypsin

Protease for protein cleavage, preferentially after lysine and arginine residues.




PROCESS ENZYME

### Carboxypeptidase B

Exopeptidase for removal of C-terminal lysine or arginine residues.




RECOMBINANT PROTEIN

### Recombinant EGF

For research and cell-culture applications.




RECOMBINANT PROTEIN

### Interleukins

Cell therapy applications, including CAR-T cell culture. Confirm the required grade and product specification.




RECOMBINANT REAGENT

### Recombinant Streptavidin

For biotin-based detection, immobilization and affinity applications. Research and development use.

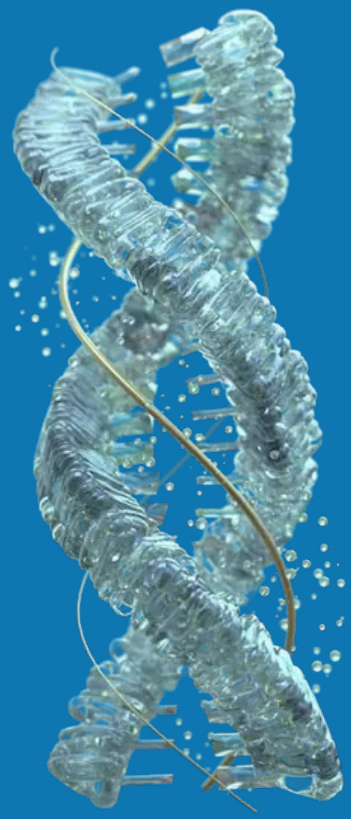
PRODUCT EVALUATION & SUPPLY

**Discuss samples, specifications and supply requirements.**

info@sysgene.com

*DNase I is distinct from DRNase® and is used for removal of DNA templates after transcription. Product grade, operating conditions and suitability are confirmed for the intended application.*

sysgene



START WITH YOUR NEXT CHALLENGE

# What are you developing or sourcing?

Bring us your molecule, process challenge or product requirement. Together, we can define a path for non-GMP development, GMP manufacture and supply.

- **Platform evaluation**
  E. coli / Pichia or CHO/HEK host assessment.
- **Process development**
  Non-GMP microbial and mammalian development.
- **GMP manufacture & transfer**
  GMP microbial scales: 30, 100 & 1,000 L.
- **Product evaluation & supply**
  Discuss samples, specifications and requirements.

LET US DISCUSS YOUR PROGRAM


## info@sysgene.com

www.sysgene.com

SysGene Biologics Private Limited
Hyderabad, Telangana, India


**Making essential biologics more accessible.**

EXPLORE SYSGENE

sysgene

SYSGENE BIOLOGICS

# Making essential biologics more accessible.

Bring us your molecule, process challenge or product requirement.

Together, we can define a path for non-GMP development, GMP manufacture and supply.

LET US DISCUSS YOUR PROGRAM

**info@sysgene.com**

www.sysgene.com

**SysGene Biologics Private Limited**

Hyderabad, Telangana, India