

# Mycenax Biotech Inc.

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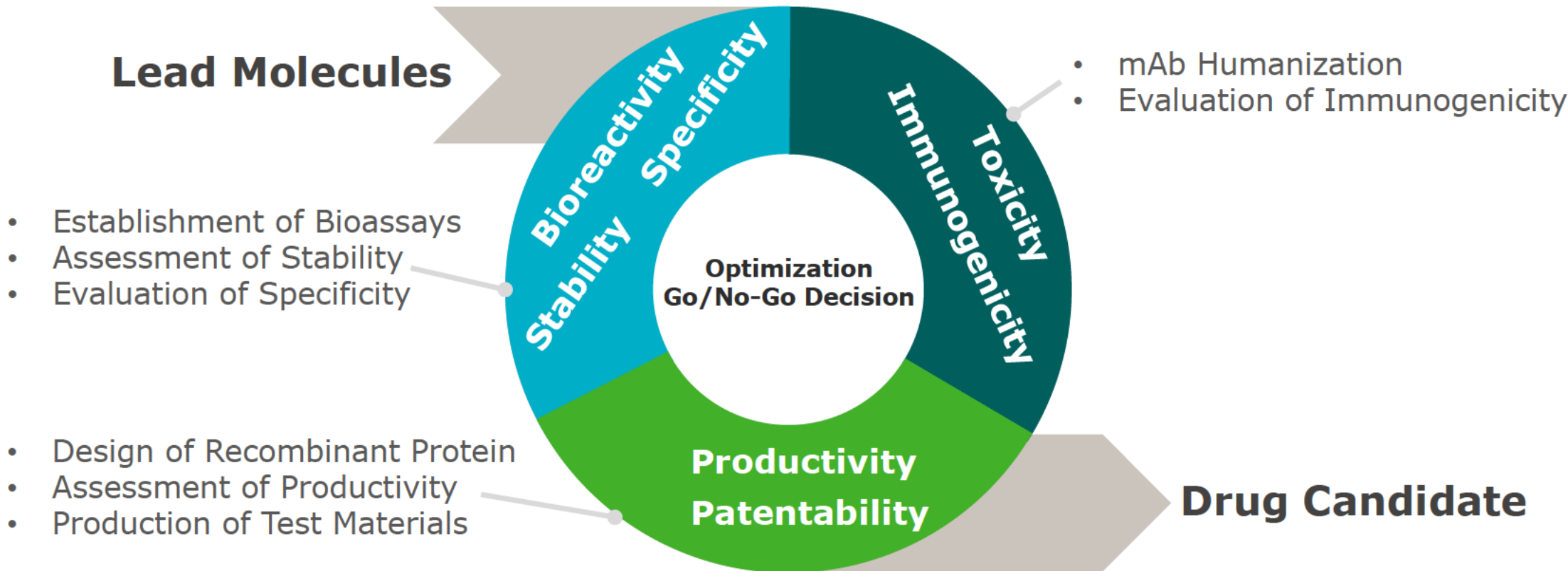
**MYCENAX**

# A Total Solution for Biologics Development

- **Established in 2001, A Taiwan-based CDMO Company**
- **Employees: 290+**
  - **80+** in Process Development (20% Ph.D., 70% MS)
  - **140+** in GMP and Quality Unit



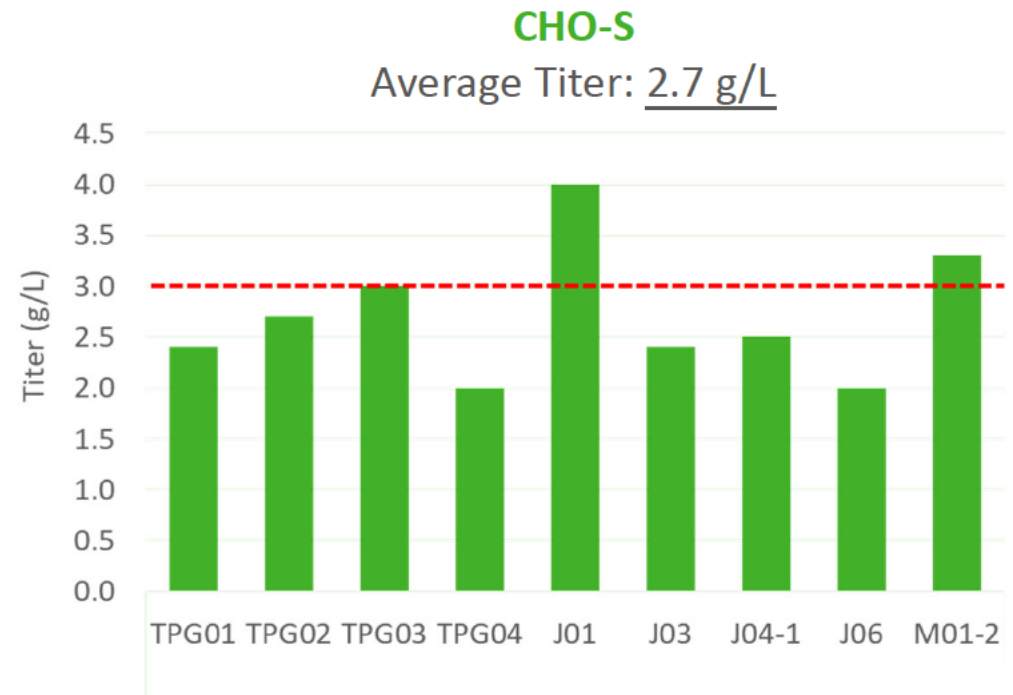
# Translational Medicine



# Cell Line Development (CLD)

## Cell Types

- CHO-S 
- CHOZN GS 
- Sp2/0



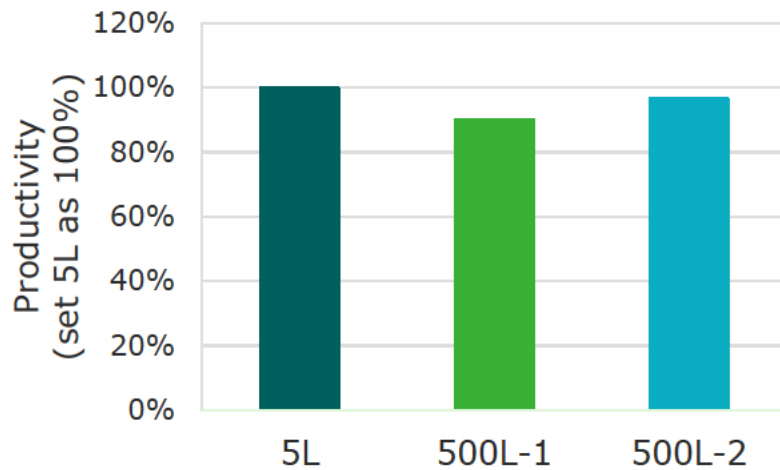
- 20+ clones with high titer and high quality
- Strategic partner for ThermoFisher for CLD in APAC



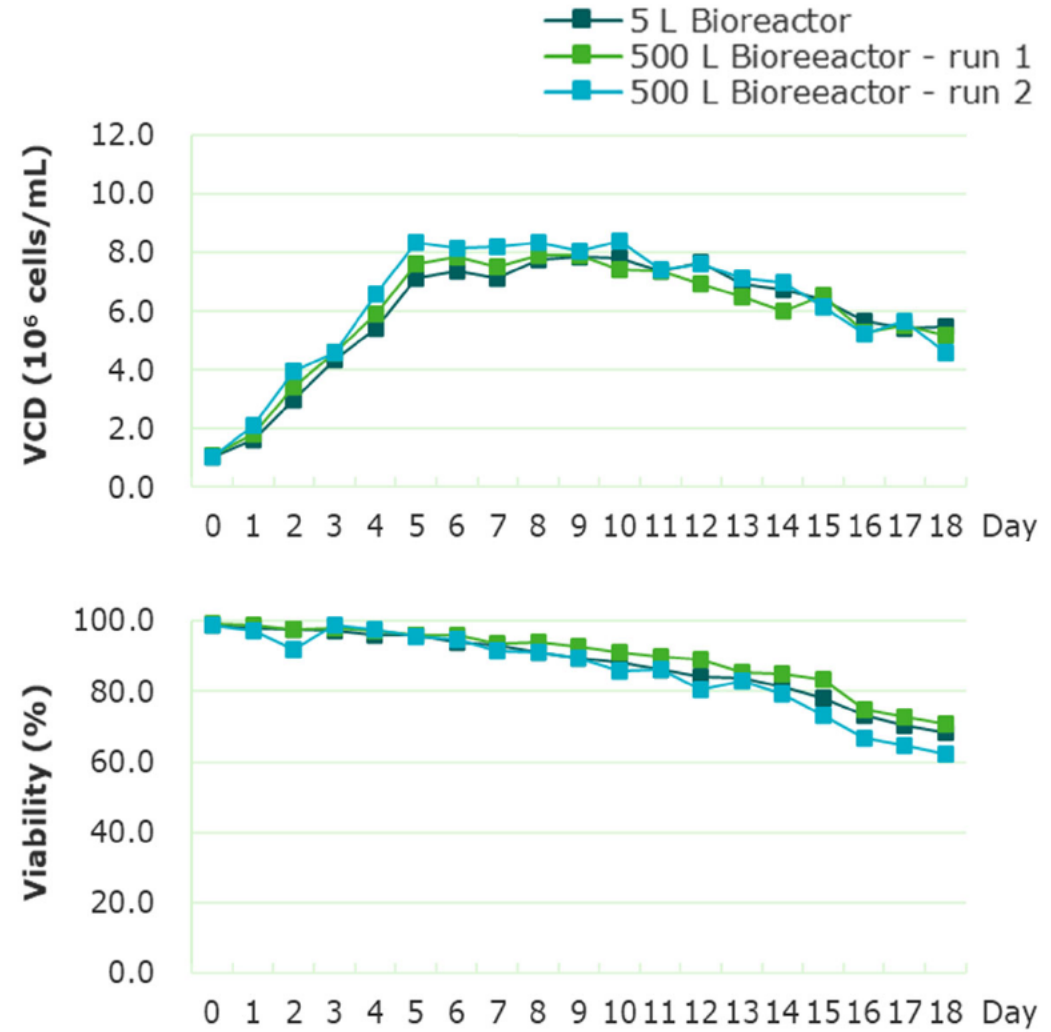
# Scale-up from 5L to 500L

## A CHO-S clone generated by Mycenax

- Growth performance and productivity of this clone are consistent in the 5L and 500L bioreactors.
- Product quality of product from 5L and the 500L bioreactors are comparable.



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# Cell Line Development

## Cell Types

- CHO-S



- CHOZN GS

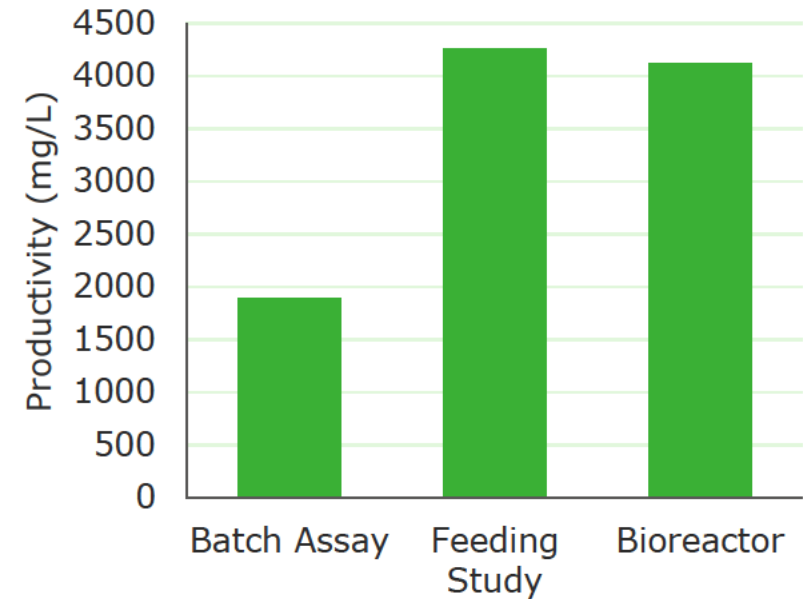
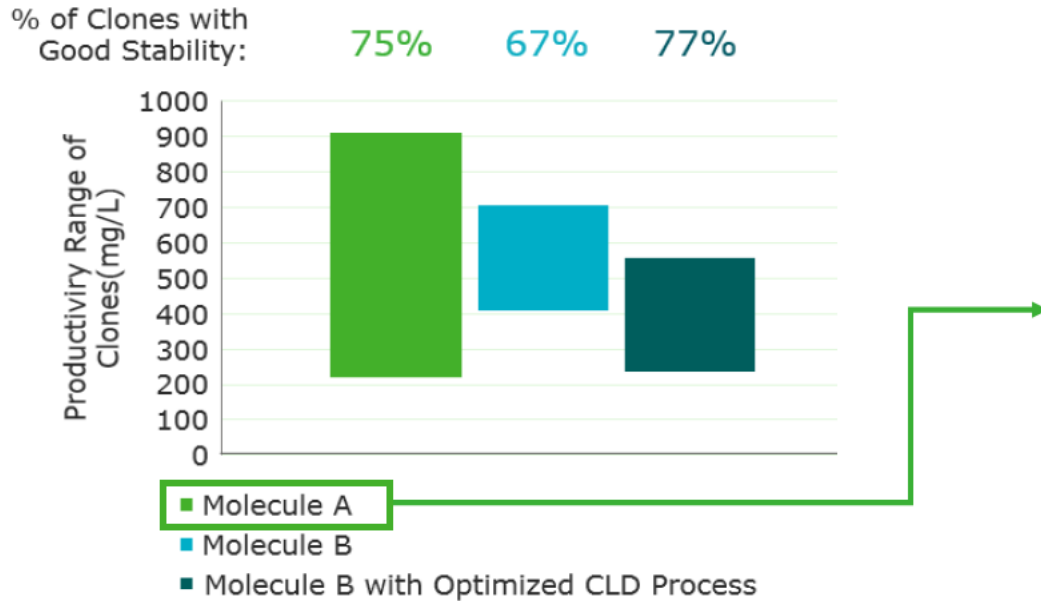


- Sp2/0

	<b>Parental Cell Line</b>	<ul style="list-style-type: none"> <li>• GS knockout CHOK1 with ZFN technology for stringent selection</li> </ul>
	<b>Media and Feeds</b>	<ul style="list-style-type: none"> <li>• Optimized cGMP media and feed</li> </ul>
	<b>Expression Vector</b>	<ul style="list-style-type: none"> <li>• IP free GS expression vector provided</li> </ul>
	<b>Cell Line Traceability and Documentation Package</b>	<ul style="list-style-type: none"> <li>• Comprehensive cell line history documentation to support regulatory filing</li> </ul>
	<b>Protocols and Technical Support</b>	<ul style="list-style-type: none"> <li>• Validated protocols for entire workflow. Technical support provided by R&amp;D team.</li> </ul>

• CHOZN GS, cell line derived from CHO-K1 and with the GS system, was introduced in MBI in 2018

# CHOZN GS: Good Productivity and Titer Stability



- These clones derived from the CHOZN system show high probability (>67%) of being stable (maintain productivity >70% of initial productivity after culturing for 60 generations).
- The productivity of the clones could reach > 3g/L after process optimization.

**Productivity After Process Optimization:**  
After process optimization for the clone expressing molecule A, the productivity increases to > 4g/L.

# Innovative Platform of Cell Line Development

- **Beacon® Optofluidic System:** A high throughput selection system
  - Uses a light-optical engine to guide cells in a nano-fluidic environment
  - Dispense single-cells into separate pens on a nano-chip (~1750 microwells)
- Mycenax is the leading Asian companies to use Beacon for CDMO service.

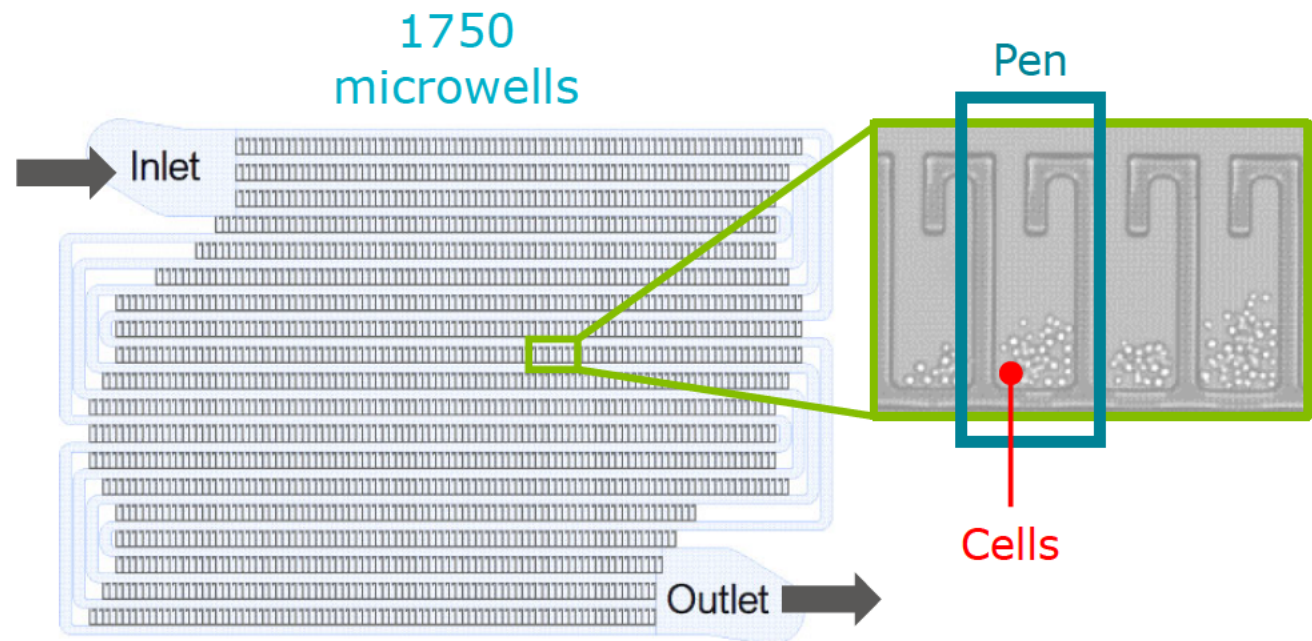


# The Core of Beacon<sup>®</sup> System- Optofluidics

- **Optics** + **Nanofluidics** = **Optofluidics**

## OptoSelect ChIPs

Characteristics	
Number of Pens	1750
Pen width	50 $\mu\text{m}$
Pen length	370 $\mu\text{m}$
Channel width	225 $\mu\text{m}$
Depth	40 $\mu\text{m}$
Number of channels	4
Volume pre pen	1.70 nL



# Beacon<sup>®</sup> Provides Good Clonality Evidence and Earlier Productivity Information of Single-cell Clones

## Good Clonality Evidence with Image-based system

- Automatic visual record of all clones when on-chip culture
- Early Cell Specific Productivity (Qp) Information
- Provides a Complete Image Data Package for Clonal Assurance

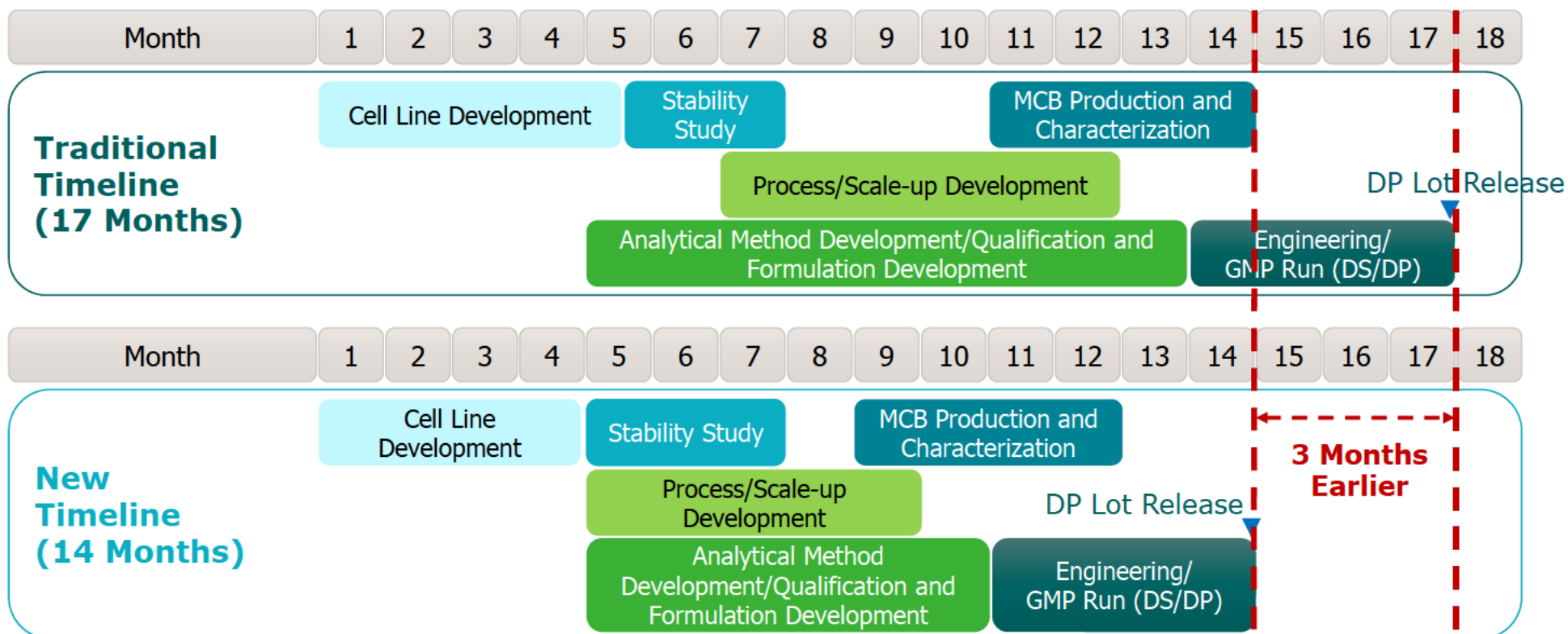


## Rapid CLD Selection System

- A high throughput selection system of cell candidates with best expression rate
- Shorten CLD timeline by 33%



# Faster Timeline in CLD and IND-Enabling Package



- With the combination of the CHOZN GS system and Beacon, we can significantly shorten the overall timeline from DNA to GMP and provide better cell clones with strong evidence of monoclonality.

# Upstream Process Development

**Mammalian Cell**

**Screen**  
Basal Media Components



Shake Flask

**Develop**  
Feeding Strategies



Sartorius ambr® 15

**Optimize/Verify**  
Process Parameters



Applikon Bioreactor

Sartorius BIOSTAT B

**Scale-Up**  
Pre-clinical Production

50L, 200L, 500L, 2000L



GE Xcellerex XDR

**Microbial Cell**



Shake Flask



Shake Flask



Sartorius BIOSTAT B

30L, 50L, 200L



GE XDR-50 MO



# Downstream Process Development

## For mAb Product

### 3 Steps Purification

- Increase Recovery (~80%)
- Improve Purity (> 95%)
- Inactivate/Remove virus



GE ÄKTA protein purification system

## For Non-mAb Product

### Product-Specific Purification Steps

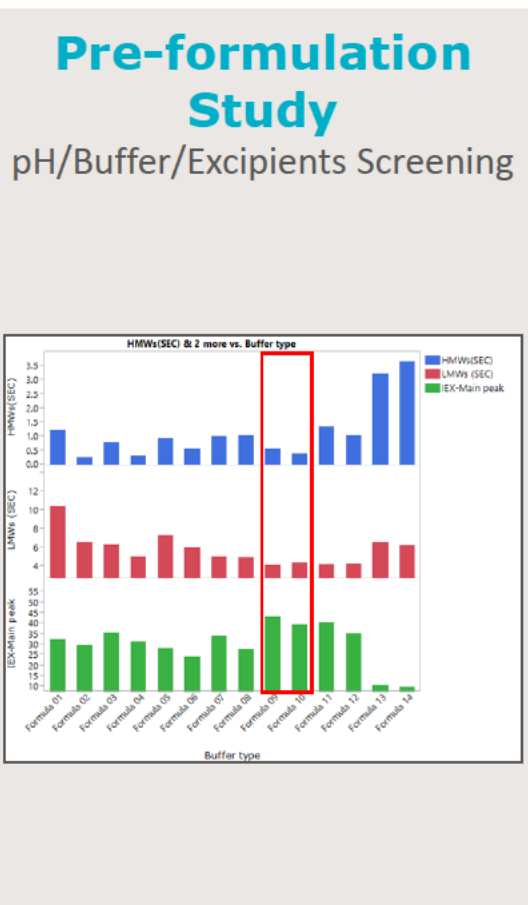
- Maintain Bioactivity
- Increase Recovery
- Improve Purity
- Remove Endotoxin

# Formulation Development

Liquid Formulation

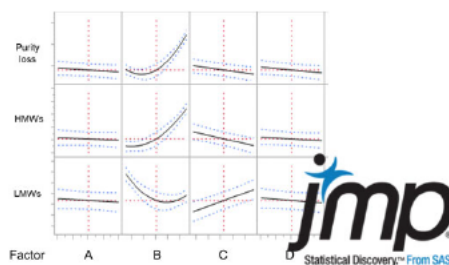
Lyophilized Formulation

MYCENAX

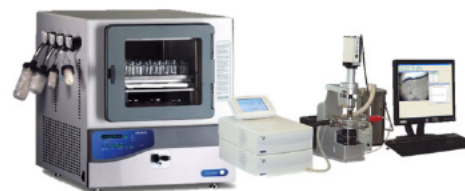


### Formulation Optimization

Identify the optimal range



### Lyophilization Process



Bulking agent selection  
Critical Temperature (Tg')

### Stability Study

Long term/ Accelerated study



HPLC



DLS

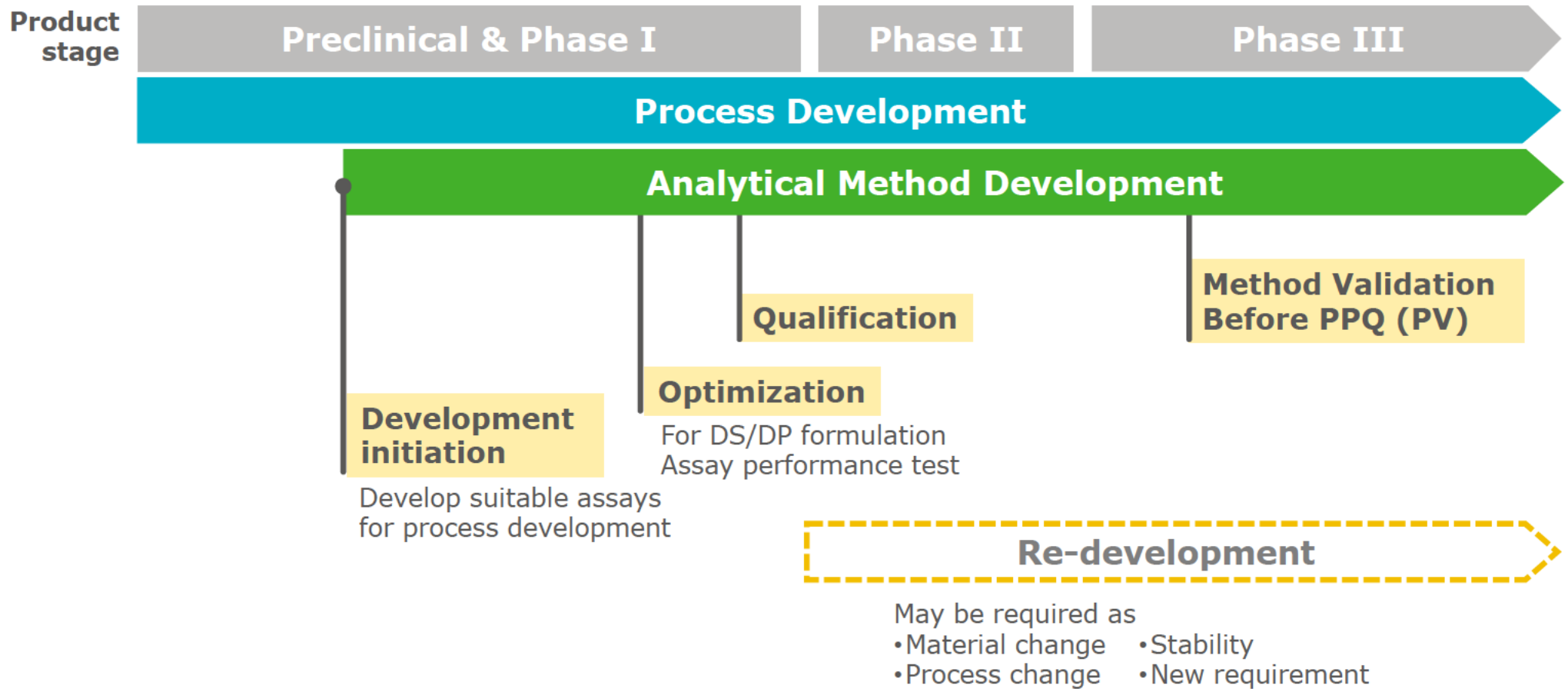


FlowCam



PA800

# Analytical Method Development



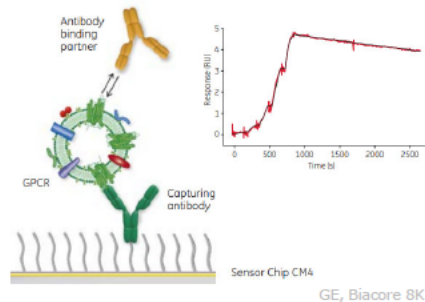
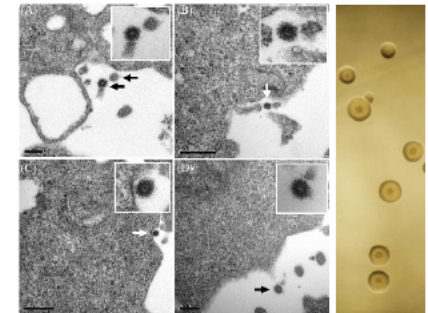
# Characterization

## Cell line characterization (outsource)

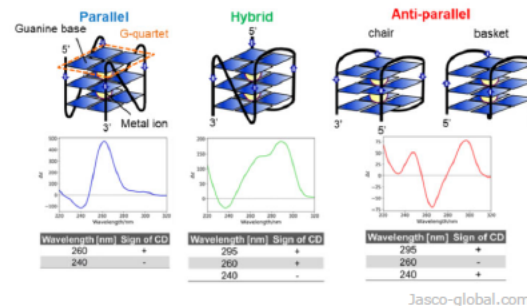
- Performed for MCB, WCB, EPC or CAL
- Viral safety, endogenous retrovirus and adventitious pathogen will be tested.
- Identity, purity and stability will be confirmed.
- Combine the results of the viral safety test and the viral clearance method, we help clients to answer the questions of virus safety issue in CTD.



ICH (Q5A, Q5B, Q5D)



Biological Activities



High Order Structure

## Protein characterization

- General properties
- Biological activity
- Immunochemical properties
- Physicochemical properties
- Structural properties
- Purity, impurity and contaminations

# MBI's GMP Facility

## GMP Facility 1



For Pre-clinical to  
Phase III projects

## GMP Facility 2

To be finished in 2021



For Phase III and  
Commercial Production

# GMP Facility 1

1

**Mammalian cell**

- Single-use bioreactors, **50L, 200L, 500L, 2000L**
- Up to 13 batches a year

2

***E. coli***

- Single use (**50L**) and stainless (**200L**) bioreactors
- up to 15 batches a year

3

**Cell therapy**

- Upgrade clean room to meet FDA requirement
- **200L** NK cell process for P1 in USA (August 2020)

4

**Aseptic fill and finish**

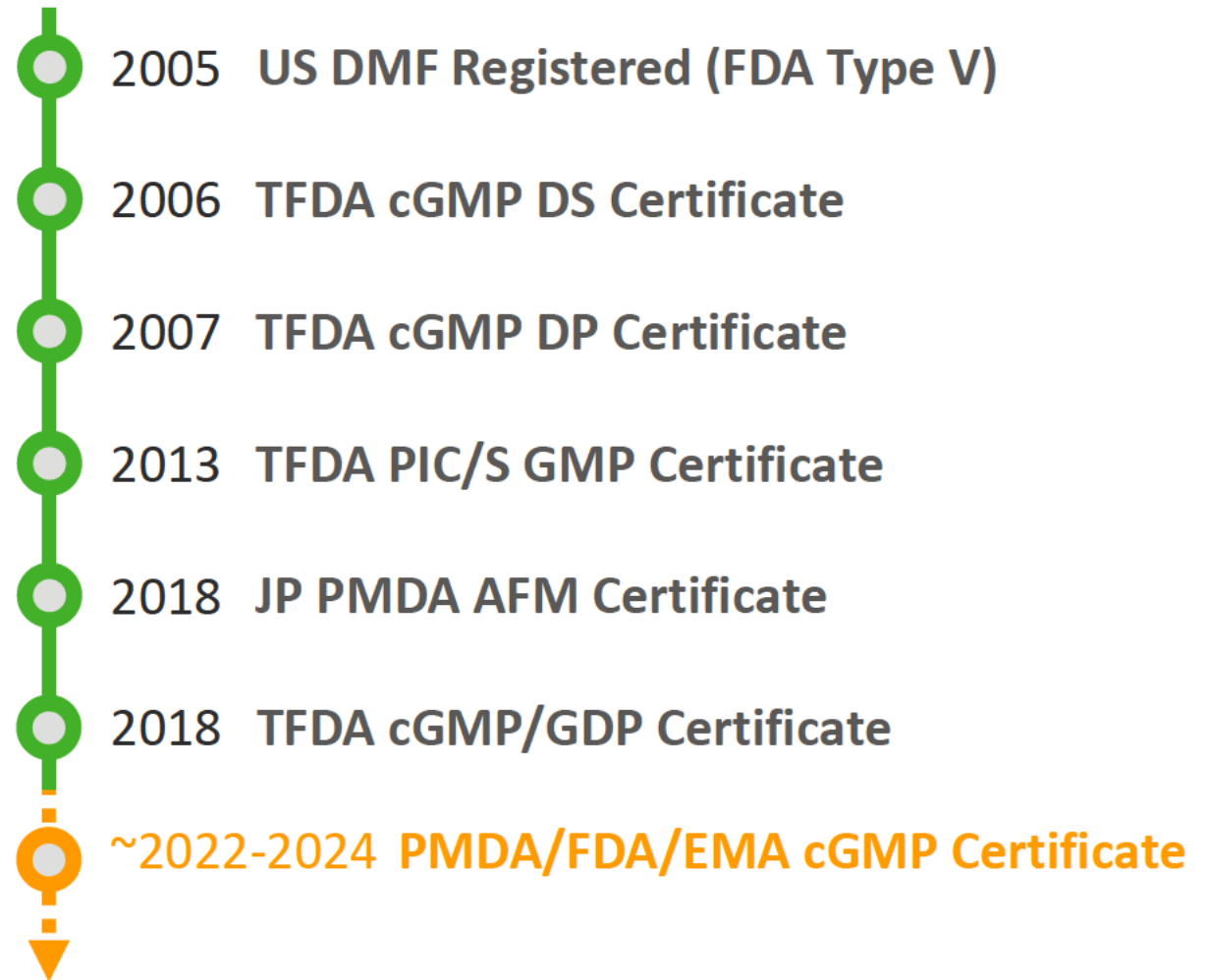
Liquid	Type	Batch Size
Vial	2R-10R	Up to 10,000
Pre-filled Syringe	0.5-1 mL	Up to 10,000
Cartridge	3 mL	Up to 8,000

Lyophilized	Type	Batch Size
Vial	2R-10R	Up to 3,500

- up to 40 batches a year

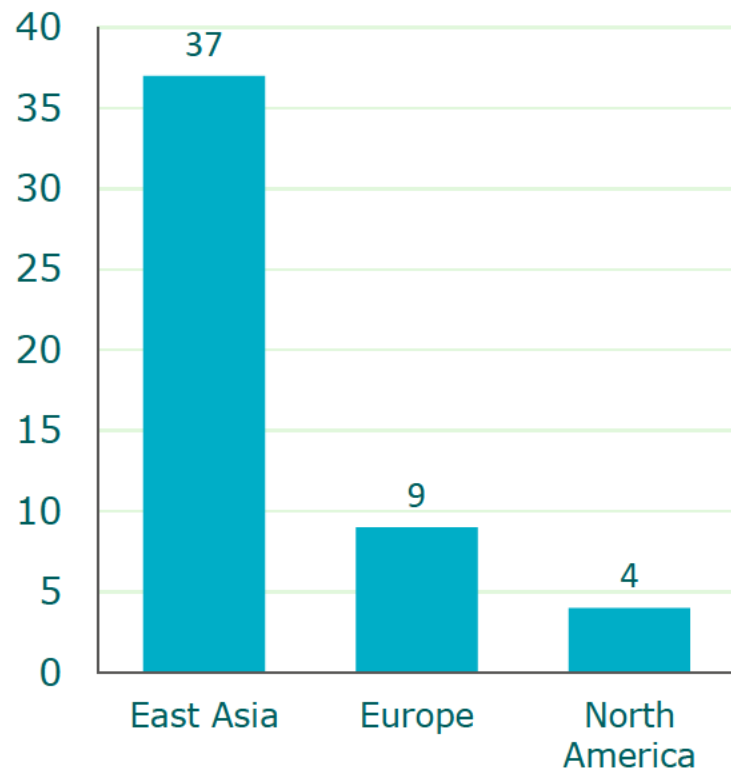


# Regulatory Milestone in GMP Facility 1



# Audit Records of GMP Facility 1

## Customer Audit



- Audit by
  - **2 times** by EU Qualified Person (QP) in 2017 and 2019
  - **10 times** by TFDA
    - 2018 gets the Marketing Approval of TuNEX® from TFDA
  - Customer
    - Gedeon Richter
    - SamChunDang Pharm., Co., Ltd.

**PPD**<sup>®</sup>

**XENDO**  
SOLUTIONS FOR LIFE SCIENCES



**MYCENAX**



# GMP Facility 2 – Current Progress

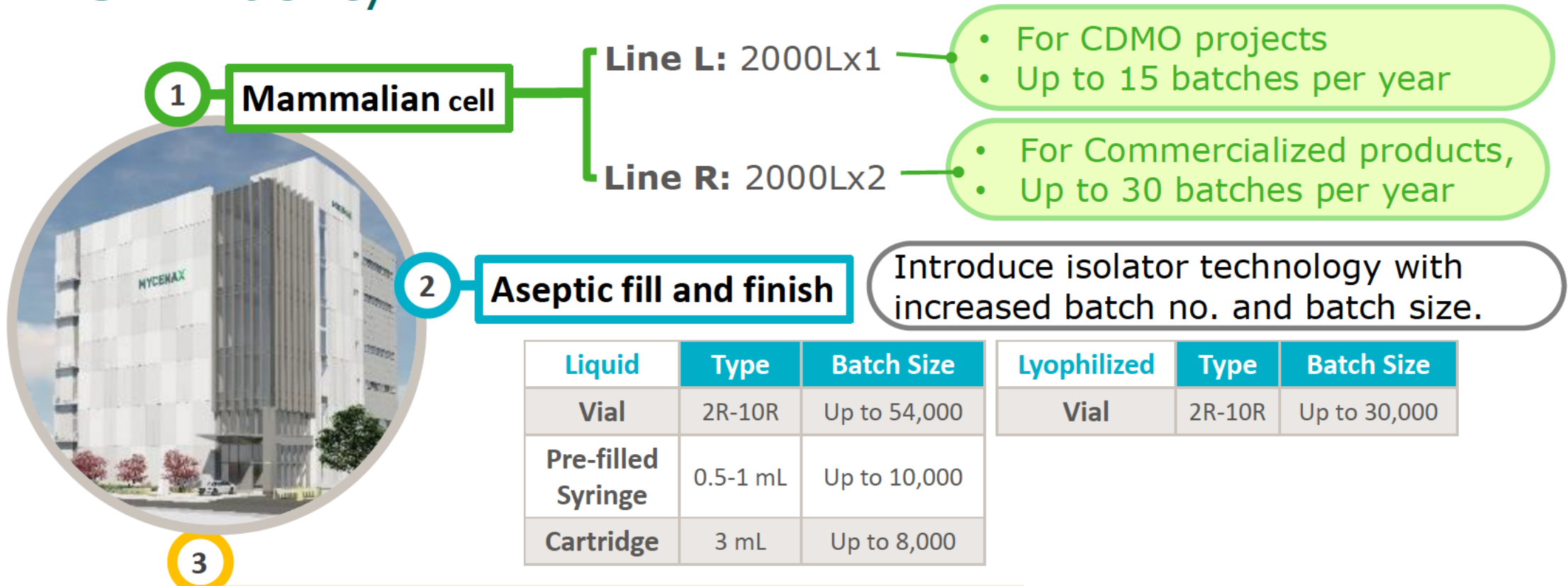


Aug. 2020 Groundbreaking Ceremony



Dec. 2020 Beam Raising Ceremony

# GMP Facility 2



Liquid	Type	Batch Size	Lyophilized	Type	Batch Size
Vial	2R-10R	Up to 54,000	Vial	2R-10R	Up to 30,000
Pre-filled Syringe	0.5-1 mL	Up to 10,000			
Cartridge	3 mL	Up to 8,000			

PMDA/FDA/EMA cGMP Certificate in **2024-2025**

# CDMO Project Track Records

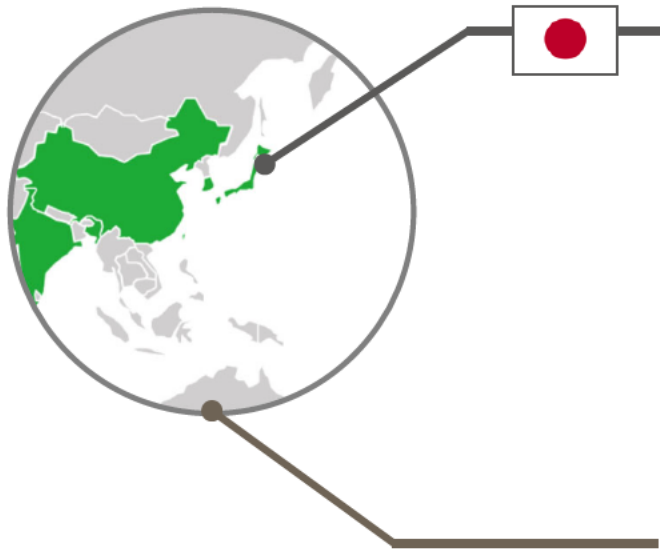
## Mammalian Projects

Client	Target Market	Product Type	Current Stage
MBI	TW	TuNEX	NDA approval (TW)
SCD (KR)	US EU	Biosimilar	Phase III
J16 (JP)	US JP	Recombinant Enzyme for Metabolic Disease	Phase II/III
YB (TW)	US TW	Allogeneic Cell Therapy for Cancer	US Phase I
BS (AU)	US EU	Biosimilar DS Obtained from Continuous Process	EU Phase I
HMBD (SG)	US	mAb for cancer	Pre-IND

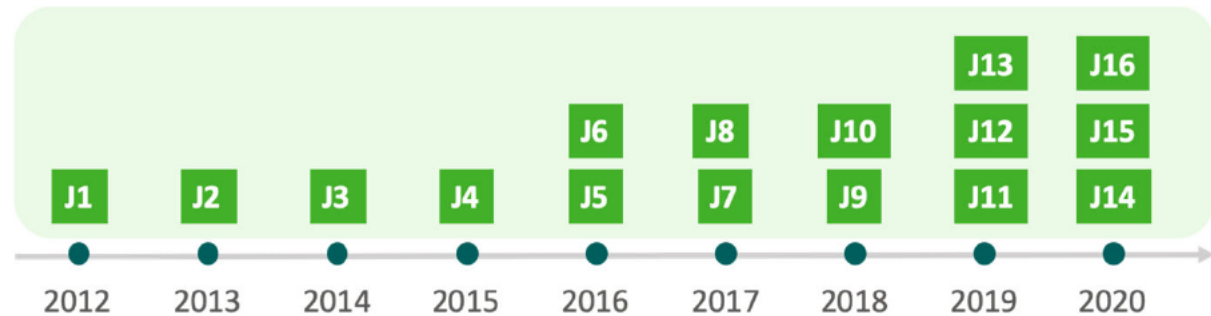
## *E. coli* Projects

Client	Target Market	Product Type	Current Stage
J4 (JP)	JP	Biosimilar Drug Substance	Site Transfer (JP Phase III)
UH (TW)	US TW	Recombinant Protein for Vaccine	Planning to Phase III
AN (US)	US	Enzyme for Cancer	US Phase I
BG (TW)	US TW JP	Recombinant Protein	IDE Pre-IDE Phase I
PR (CN)	US CN	Recombinant Protein for Cancer	Pre-IND
LT (TW)	US TW	Recombinant Protein for Cancer	Pre-IND

# Customers around the world



- **16** Customers in Japan
- Ranged from Start-ups to International Pharma
- Long-term Cooperation with **8** Listed Companies



- Generate **~80%** Income from **Japan, Korea** and **Singapore**
- Other Markets: Taiwan, China, Europe, and North America



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