

bora bio



# Corporate Introduction

Making Success More Certain

MAR 2024

# Bora Group by the numbers

**2.2 Billion USD** Market Cap\*

**1250+** Employees

**7** Manufacturing Sites

**98%** On-Time Delivery

**1.2B+** Annual Units Produced

**0** Major Quality Observations

# Bora Group: A Reliable Partner for over 50 Years

Publicly Traded on the Taiwan Stock Exchange

## 2007

Bora Pharmaceuticals is Established as a Development Scale CDMO Headquartered in Taipei, Taiwan.



## 2017

Bora Initial Public Offering (IPO) on the Taipei Stock Exchange (TICKER 6472.TWO).



## 2020

Bora Acquires GSK Mississauga Facility and establishes a North American Headquarters.



## 2022

Bora Acquires TWi assets, adding two manufacturing facilities to the network



## 2002

Bobby Sheng becomes Chairman and CEO of Hoan Pharmaceuticals.



## 2013

Bora Acquires Eisai PICS Tainan Facility.



## 2018

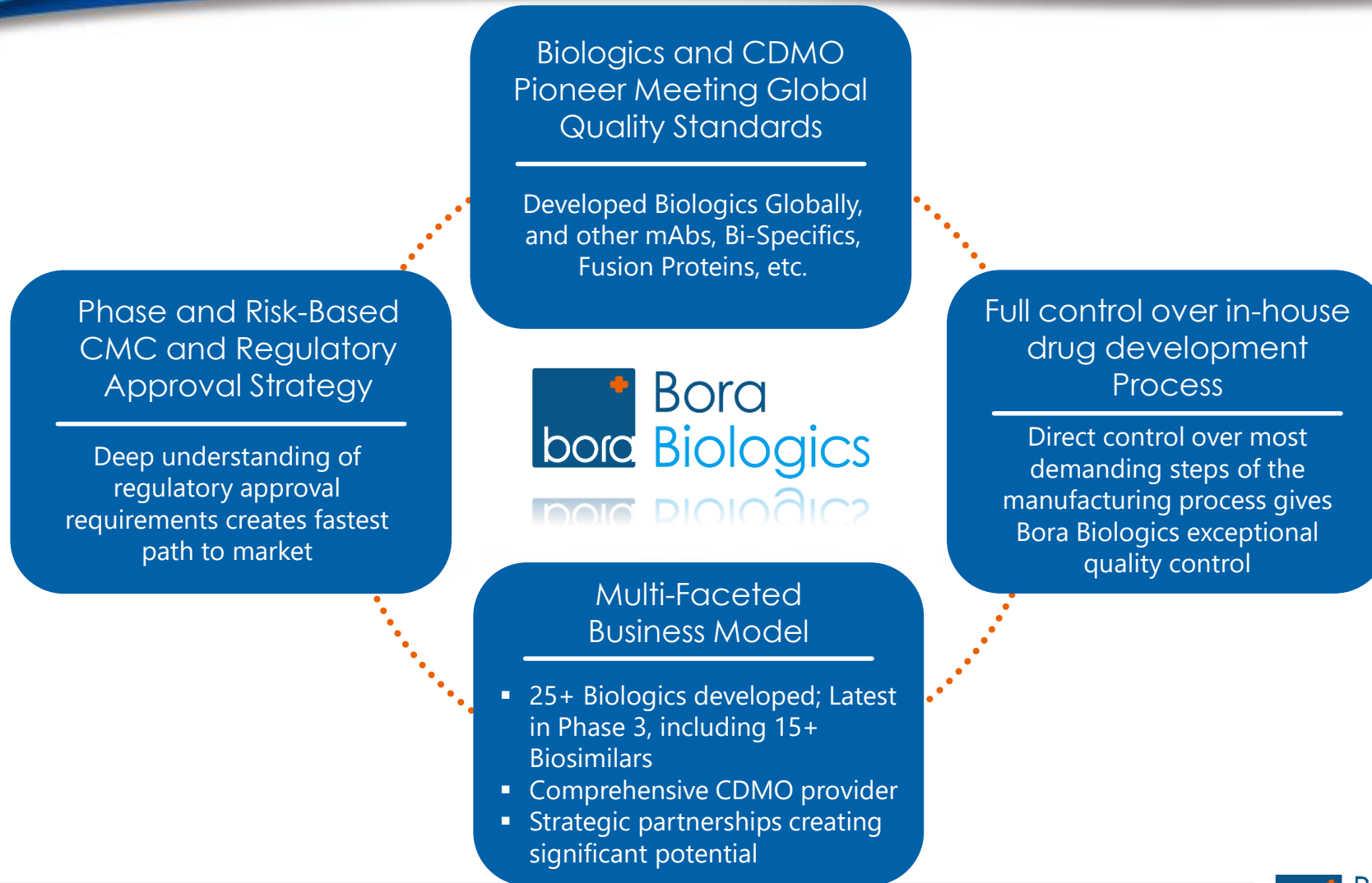
Bora Acquires Impax/Amneal's USFDA Zhunan Facility.



## 2022

Bora Acquires Eden Biologics Zhubei facility. Bora Biologics is established.

# Bora: A Unique Company w/ a History of mAbs & Biologics



# Why Bora?

## Insight to the Client Mindset

- Our history as a drug developer now transformed into CDMO gives us insight to the client mindset
- How the project should unfold
- The type of communication and frequency that is optimal
- The transparency needed to ensure that when trouble arises it's quickly thought through for solutions, issues communicated and remedies applied

## Origins as a Biosimilar Drug Developer

- Bora acquired facilities, equipment, and hired 98% of the staff performing the development activities
- Bora Biologics currently has ZERO investment in any legacy products ensuring no conflict of interest but all the wisdom of a drug development team

## Detail-oriented Team & Approach

- Thinking through each step
- Pinpointing where to **take smart risks to save time**
- Knowing where to **avoid risk to mitigate dangers** to the program

# The Team's The Thing

Manufacturing partnerships thrive with **great communication.**

Bora Biologics differentiates itself with:

Cohesive team with low turnover – significant difference than typical CMO.

Effective communication and program execution facilitated by the team's long-standing familiarity.

The platform approach integrates cell line development, process, and analytical development for robust manufacturing programs.

This approach accelerates project timelines by iteratively designing and refining the program.

# PMO – Experience & Ensuring Success

Bora Bio's PMO has extensive experience dealing with **big pharma** and **early-stage companies**. Specifically for early-stage companies, **program design** aspect is heavily guided by the project management with oversight to the IND event.

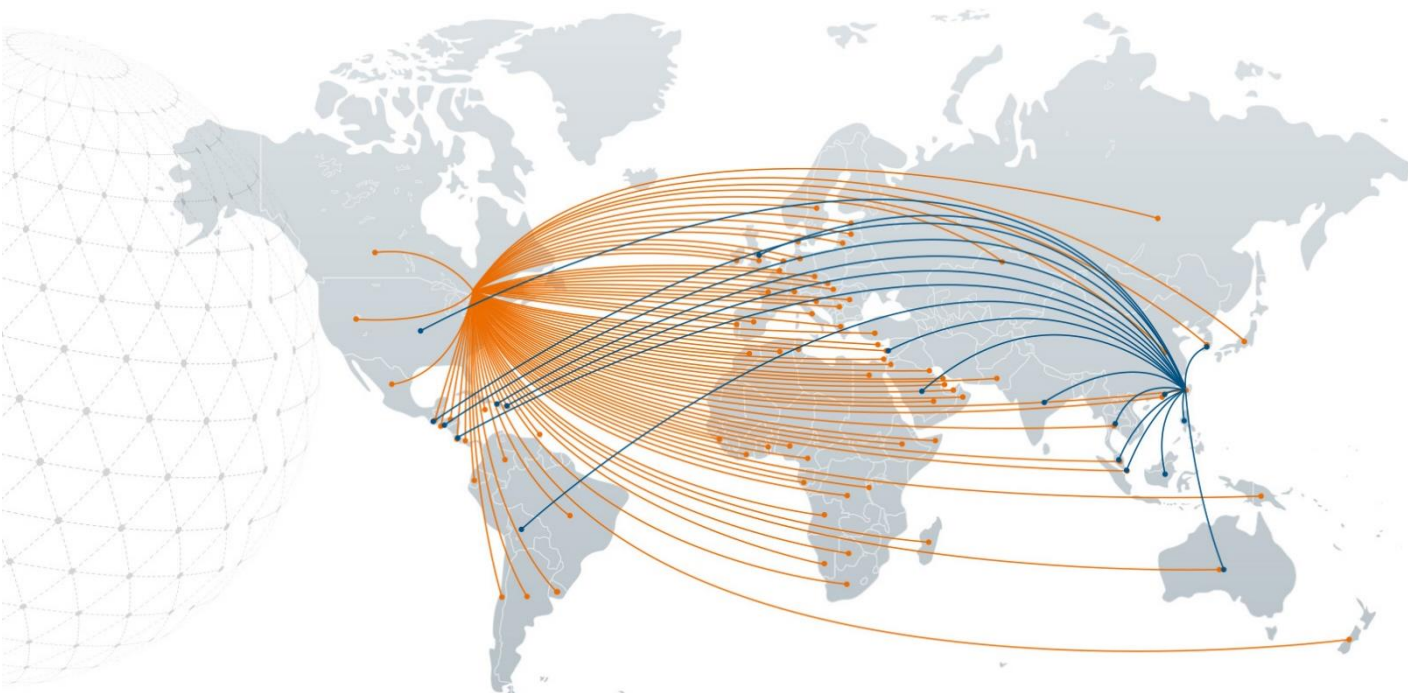
## PMO Experience

- **35+** International projects managed
- Dual language in English and Chinese

## PMO Expertise

- Timeline & cost/budget management
- Regulatory landscape
- Key liaison to internal technical SME
- Strong communication skills
- Quick responses and resolutions to issues

# Bora Biologics: A Globally Recognized CDMO



## BORA BIOLOGICS' cGMP SITE

- **Bora Biologics'** Pre-Clinical and Clinical Production Facility, 48,438 sq. ft.
- Currently, 2x500L bioreactor trains, expanding via 2K build/buy plan
- Zhubei Facility: cGMP, ICH, FDA, EMA, TFDA, PIC/S standards
- 15+ Ongoing CDMO Client Projects
- 66+ batches manufactured cGMP for 24+ different products

**Bora Group**



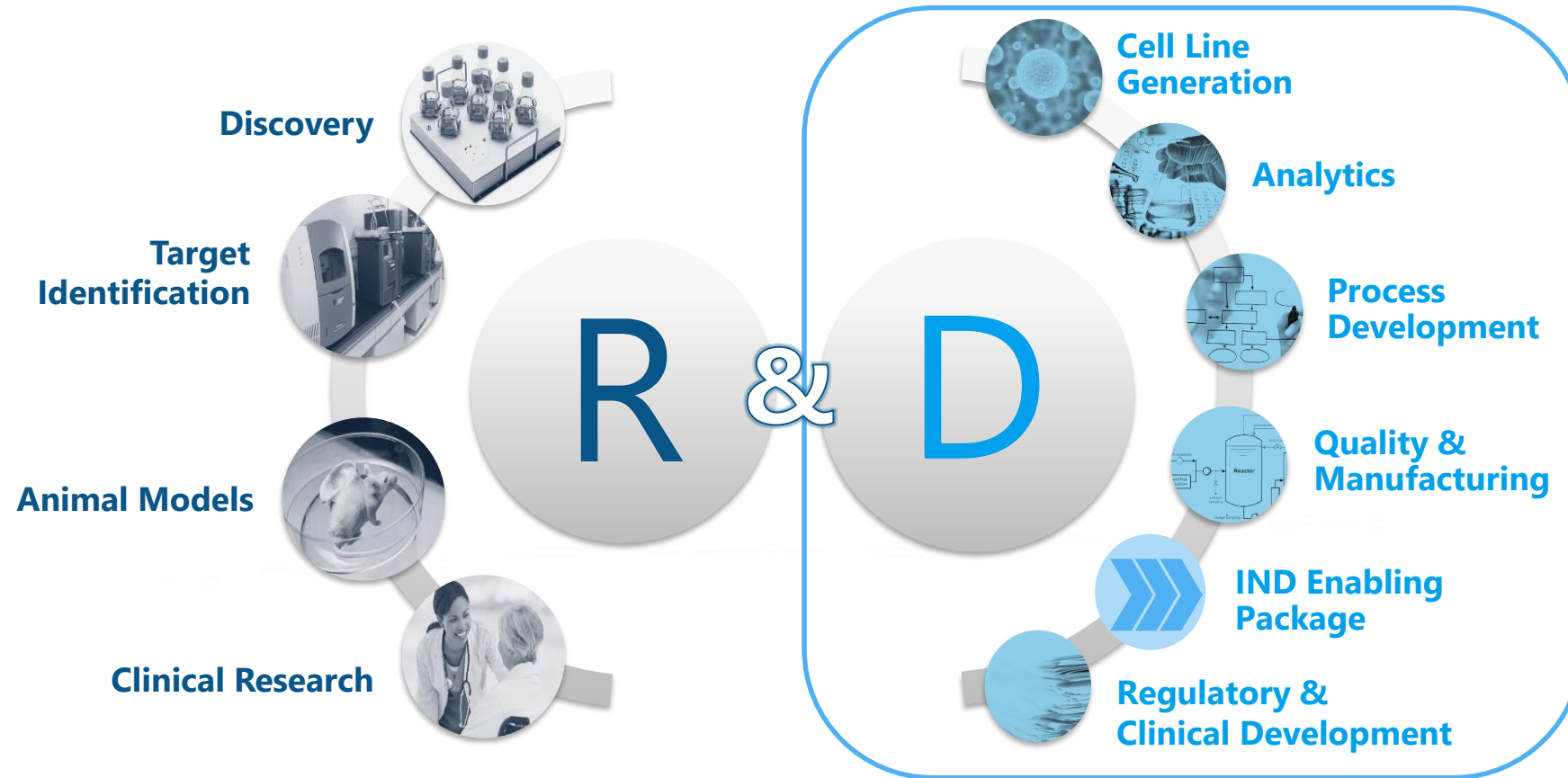
Taoyuan Facility / Zhunan Facility /  
Tainan Facility / Bora Biologics / TWI Facilities



Mississauga Facility



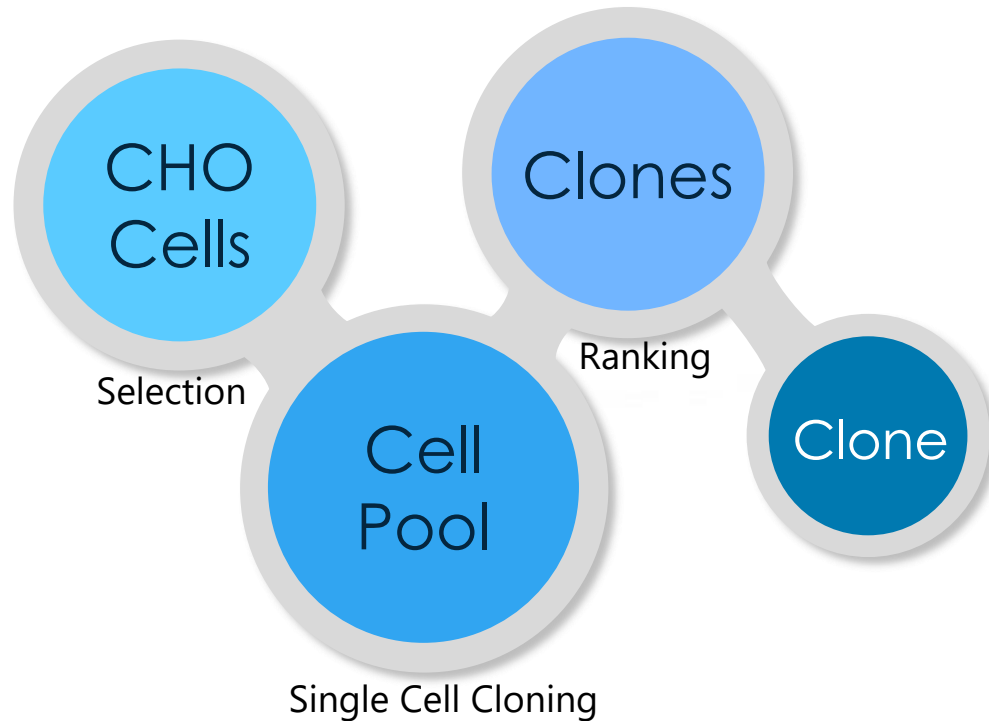
# Providing Full Development Solutions



Bora Bio will support all **DEVELOPMENT** activities

# In-House Cell Line Development

Cell Line Development  
for therapeutic protein  
production



## Host cell bank qualification

CHO-K-derived cell line with clear history



## Cell line development & monitoring

Accurate predictions using early data



## Compliance with ICH

Monoclonality and documented traceability



## Freedom-to-operate

Host cell line and vectors developed In-House



## Performance

**4-6 g/L** Titer (Pre-Process Development & Optimization) with proven track record

# Cell Line Development Advantages

**Bora Biologics** has an advantage over competitors by producing Cell Lines efficiently with exceptional quality, based on continuous improvement of the established technologies.

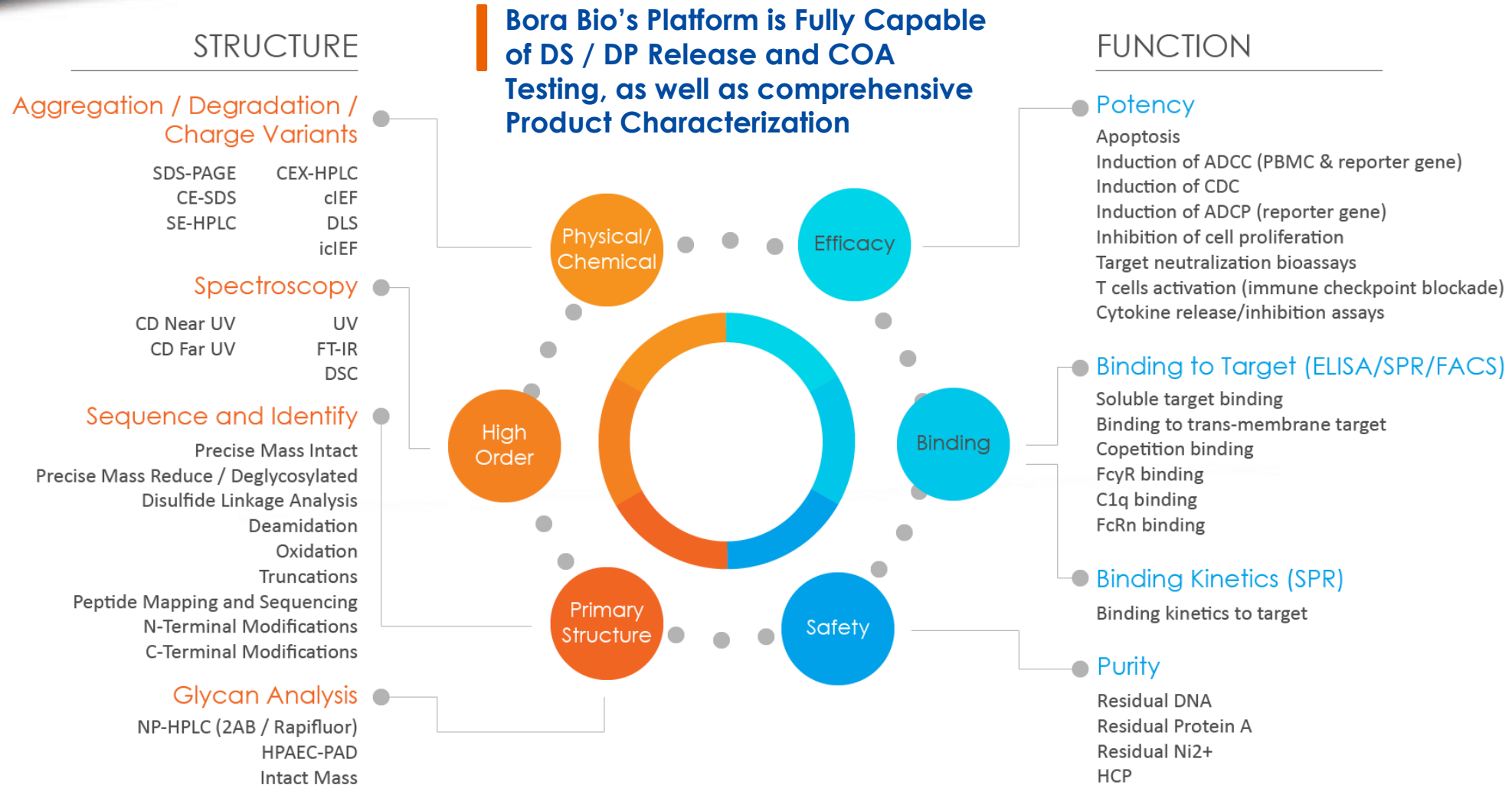
## State-of-the-Art Technologies

Introduction of a **Single-Cell Printer** (Cytena) as part of our Cell Line Development (CLD) process has significantly reduced the CLD timeline from 5-6 months to **4-4.5 months**.

Statistical modeling allows for an **accurate prediction** based on the performance of the cell pools (early CLD), eliminating the need to evaluate thousands of clones.

Bora Biologics has a **solid productivity record** for clone titers for ALL Client programs using our **CHO-K1** expression system.

# Full Range Capabilities: Analytical Development



# Formulation Development & Expertise

## Tox Formulation

- Stable pH range evaluation
- Platform liquid formulation adaptation
- Liquid formulation stability monitoring
- Force degradation study

## Clinical Formulation

- Formulation optimization per route administration: IV, SC, Inh, Opth.
- Formulation optimization per dosage form: liquid and lyophilized
- Lyophilization process development
- Multiregional excipients selection
- Fit for purpose Container Closure application/evaluation i.e. vial/stopper, PFS, Pen, PE/PC container, etc.
- Optimized formulation stability
- In use stability study

## Commercial Formulation

- Formulation optimization to achieve targeted shelf life
- Formulation robustness study (DOE)
- Secondary packaging material design
- Photostability in final container closure system (including secondary packaging) per ICH
- Univariate and multivariate formulation robustness study

## Expert in Formulation Development for DS and DP

### *Drug Product Process Development*

- *F/F CMO sourcing*
- *QBD approach implementation*
- *DP process characterization*
- *Critical process parameters evaluation and control*
- *Extractables and leachables study*

### *Stability*

- *DS / DP stability per ICH*
- *DS freeze/thaw study*
- *DP photostability per ICH*
- *Mechanical stress study*
- *Force degradation study*
- *Temperature excursion study*
- *Shelf-life determination by statistical analysis*

# Stand Alone Analytical Study Design & Execution

## Analytical Stand-alone Services for comprehensive product characterization, release testing, & stability

### Experience

- Decade of experience with detailed method development, qualification, and testing
- Standard stability indicating methods & stability programs
- Expert across multiple protein classes and platforms

### Quality and Regulatory

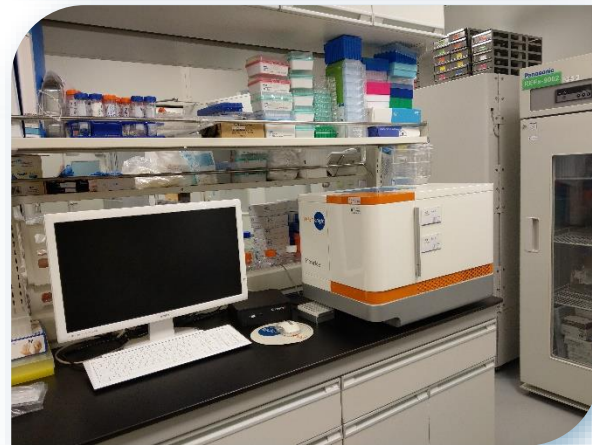
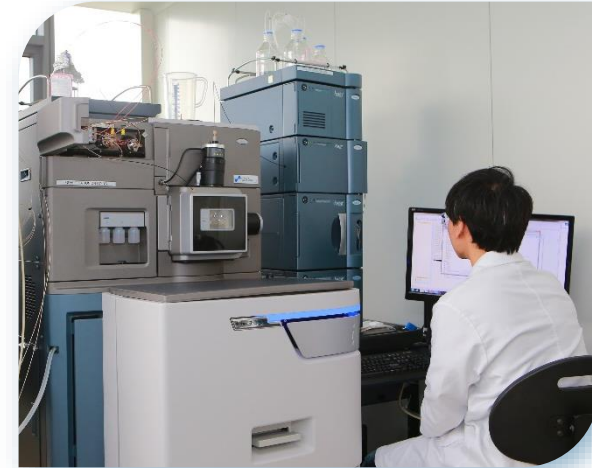
- cGMP Compliance
- Strong track record of compliance
- Works extremely close to QC to ensure all Method Transfers

### Facilities

- Comprehensive array of equipment to apply to studies
- 2 Large Analytical Labs
- 1 Large Dedicated Formulation Lab w/ Pilot Lyo

### Program Management

- Flexible and responsive to client/program needs
- Attention to detail and timelines
- Full Turnkey PM from Bora



# Bioassay

Comprehensive experience developing, validating cell-based bioassay and binding assays under cGMPs

## Potency

- Apoptosis
- Induction of ADCC (PBMC & reporter gene)
- Induction of CDC
- Induction of ADCP (reporter gene)
- Inhibition of cell proliferation
- Target neutralization bioassays
- T cells activation (immune checkpoint blockade)
- Cytokine release/inhibition assays

## Binding to Target (Elisa/SPR/FACS)

- Soluble target binding
- Binding to trans-membrane target
- Competition binding
- FcyR binding
- C1q binding
- FcRn binding




# cGMP State-of-the-Art MFG Plant

## Bora Biologics


Taiwan Facility:  
A Clinical Manufacturing Plant

The Bora Biologics cGMP Manufacturing facility is designed with a commitment to unwavering quality and discipline.


By adopting single-use technology very early on, Bora has truly been a pioneer in the industry for sustainability and at the forefront of the newest technologies.



Cell Banking  
M/WCB  
capabilities onsite



Purification suites,  
media and buffer  
prep areas and  
autoclave/wash  
areas are all  
built-in.



The bioreactor hall  
currently houses  
2x50L & 2x500L  
bioreactors and  
expanding with an  
additional 2x500L  
bioreactors.



# Successful Tech Transfers & Scale-Up to 2000L

Project	50L or 500L GMP (Zhubei)	2000L GMP (other)	Clinical Trial Material Supply Phases
1	24 batches	4 batches	Phase 1 & 3 supply
2	3 batches	-	Phase 1 supply
3	-	3 batches	Phase 1 supply
4	10 batches	-	Phase 1 & 3 supply
5	1 batch	4 batches	Phase 1 & 3 supply
6	4 batches	4 batches	Phase 1 & 3 supply
7	3 batches	-	Phase 1 supply
8	8 batches	-	Phase 1 & 3 supply
9	4 batches	-	Phase 1 & 3 supply

- Completed over **30+ 500L GMP batches** for the CTM supply of Phase 1 & 3 Clinical Trials since 2013
- Successfully transferred programs to commercial facilities and completed **15+ 2000L GMP batches**
- Bora Biologics has comprehensive **Technology Transfer** documents including Guidance & SOP's

# Quality: The Foundation of Bora Biologics

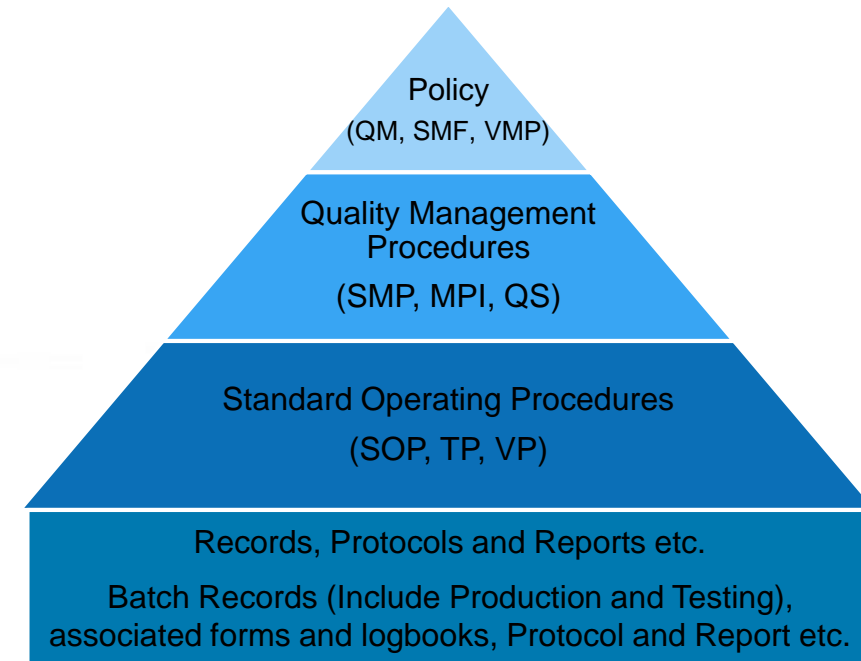
**World-Class Quality System** built from deep industry experience and meeting Global Compliance standards.

Fully dedicated Quality Unit to ensure quality standards are at the highest level for global compliance and achieved GMP re-certification in less than **2.5 months from the Taiwan FDA**.

Bora Biologics' facility passed **9 EU QP (Qualified Person) inspections** and always accommodated client audits successfully.

Implemented modern Quality Management tools including **TrackWise, Facility Monitoring System (FMS), Blue Mountain and electronic Document Management Program (DMP)** and further adopting Bora Group's best practices and systems such as **SAP**.

## **Bora Biologics'** Commitment to Quality



# Bora Bio's Proven Track Record & Successes



## cGMP MFG Batches used in Global Clinical Trials

- **60+ batches** produced using our cGMP Manufacturing Plant with 100% success rate continuously since 2014.
- **Recent Client/Partner Success:**
  - Project 1: Client's **Phase 3** Clinical Trial Material produced by Bora Bio used in [Europe \(EMA\)](#).
  - Project 2: Client's **Phase 2a/2b** Clinical Trial Material produced by Bora Bio accepted by [US FDA](#).
  - Project 3: Client's **Phase 1** Clinical Trial Material produced by Bora Bio submitted in [China \(NMPA\)](#).

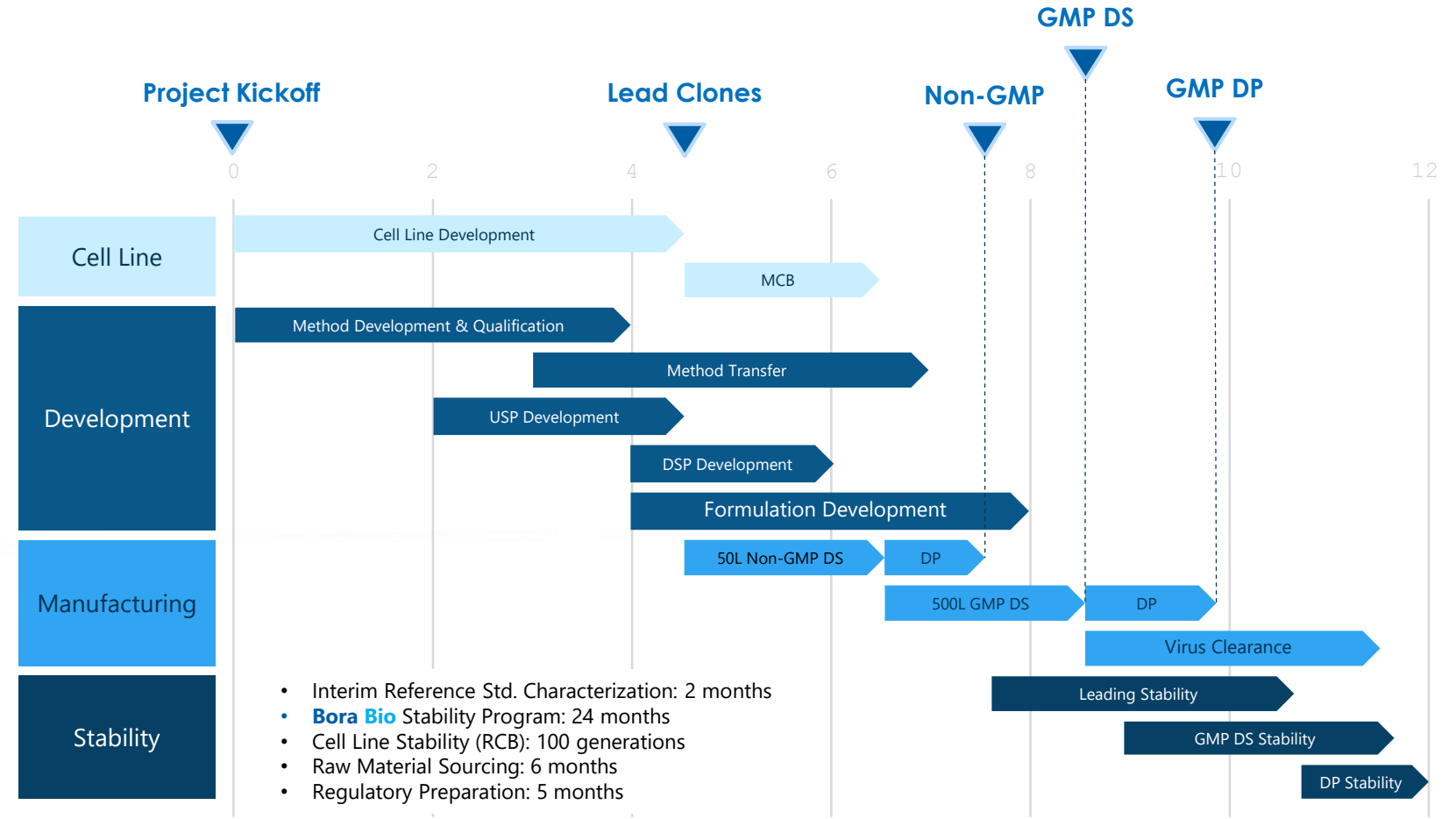
## Scalable Biologics Manufacturing Platform

- Delivering a scalable platform technology that supports superior product quality and yield for **mAbs, Bi-Specifics, Fc Fusion Proteins, Enzymes, Recombinant Proteins, and Antigens for Vaccines** among others

# Timeline from DNA to Drug Product: 10 Months

DNA to DP Enabling Package less than 10 Months

**Bora Biologics** can provide a comprehensive solution supporting its clients from early-stage bio-therapeutic development through late-stage clinical manufacturing, catering to the evolving needs of the dynamic global biopharmaceutical industry.



# Bora Biologics – The Customer-Centric Partner

## Integrated Disruptive Biologics Platform

Comprehensive service capabilities with exceptional quality and global qualifications.



## State-of-the-Art Manufacturing Facility

Sustainable single-use manufacturing site with solid track record and expansion potential.



**Making  
Success More  
Certain**

[www.boracdm.com](http://www.boracdm.com)

## Focus on Customer Satisfaction

Dedication to clients enabling flexible offerings and efficient service delivery.



## Global Expertise and Quality produced in Asia

International expertise and know-how coupled with Industry Standard policies.



## Highly Experienced Leadership Team

Strong management team with in-depth biotech industry knowledge and extensive experience.



## Comprehensive Product Experience and Protein Characterizations

Experience consists of all biologics as well as NME's and other complex drugs.





borabiologics

Thank You !