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Our CRDMO Business Model Explained

May 2025

Stock Code: 2269.HK

CRDMO Business Model

CRDMO

- The CRDMO business model provides integrated, end-to-end solutions that enable partners to discover, develop and manufacture biologics.
- The model has been validated in the past decade, resulting in the largest biologics pipeline and a leading position in Development (D).
- Both Research (R) & Manufacturing (M) have reached inflection points & are well positioned for sustained growth ahead.

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R

Research = Fully Integrated Project (FIP) + CRO

FIP supports clients from initial concept through IND submission, seamlessly integrating with CMC & downstream process development. Leveraging its proprietary technology platforms & cutting-edge capabilities, FIP is entitled to receive **upfront payment**, potential **milestone payments** and **sales royalties** when clients license IP from the Group.

D

Development

Our industry-leading Development team continues to optimize delivery timeline while maintaining uncompromising quality, reducing the development cycle for mAb projects from **DNA to IND** to just **9 months**.

M

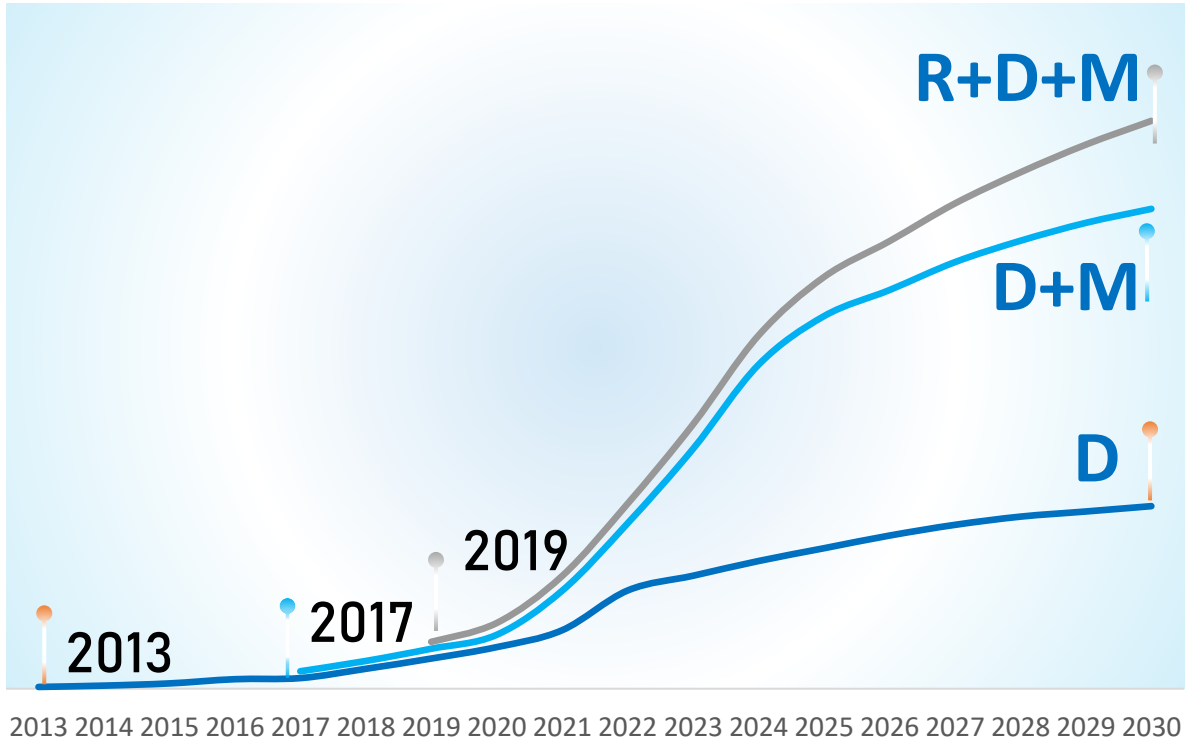
Manufacturing

The Group's biologics cGMP DS manufacturing facilities exclusively utilize single-use bioreactors. Our **scale-out** approach offers reduced scale-up risks, increased flexibility and easier validation & qualification processes for **late-stage & commercial projects of all sizes**.

CRDMO Business Model Supports Long-term Growth

Biologics Development Process	Typical Duration	Typical Revenue
Pre-IND		
Research	Through molecule's life cycle	**Upfront payment up to $40m+/program Milestone fee up to $200m+ /program Royalty fee up to 10% of drug sales**
DNA to IND	6-15 Months	**US$5-8m**
Post-IND		
Early-Phase (Phases I & II) Clinical Development	3 Years	**US$4-6m**
Late-Phase (Phase III) Clinical Development	3-5 Years	**US$20-50m**
Commercial Manufacturing	Annually	**US$50-100m annually**

Our Three Long-Term Growth Curves



Project Retention High

- **90+% of R projects that advanced to D were retained at WuXi Biologics**
- **90+% of D projects that progressed to M remained with WuXi Biologics**

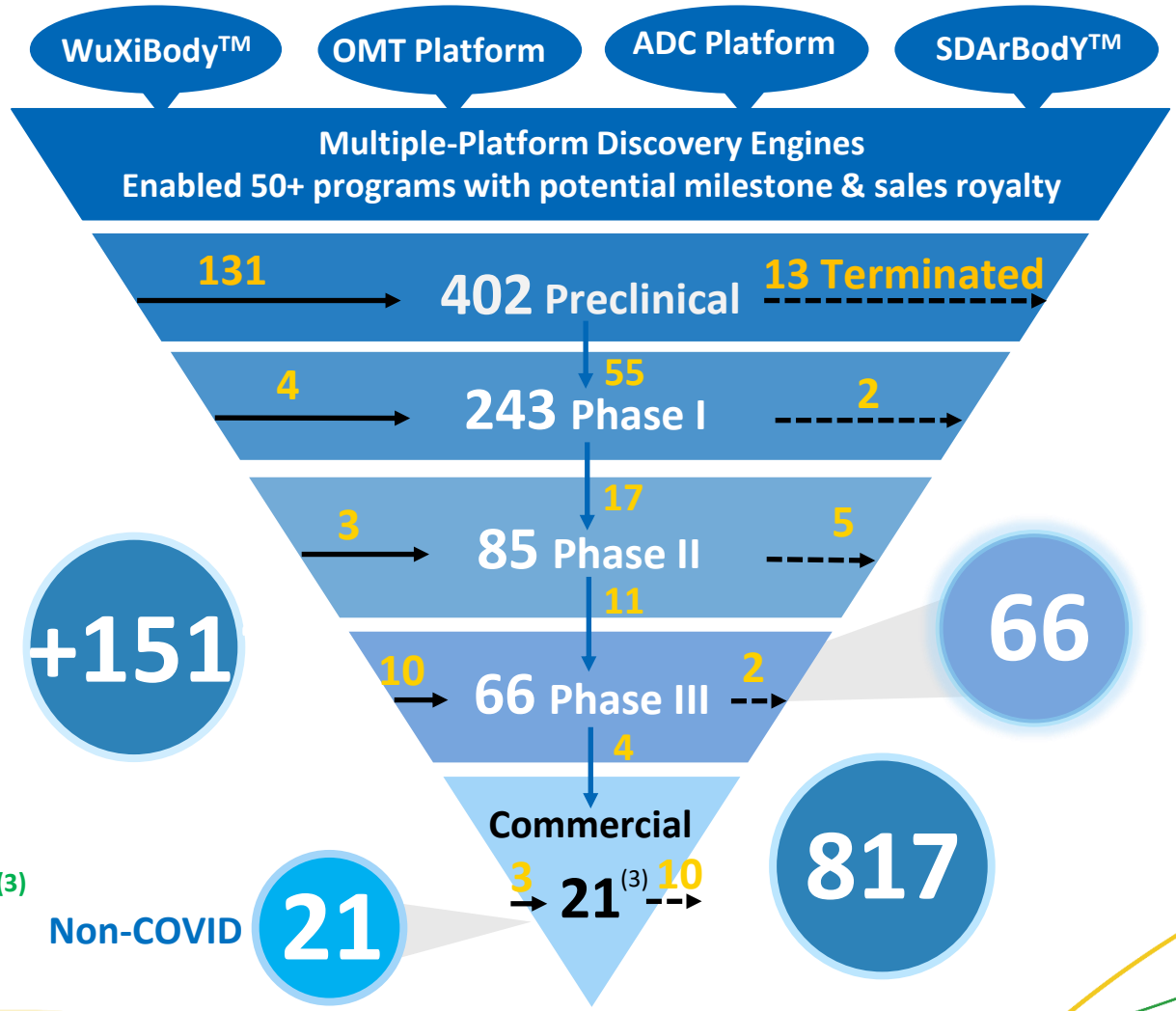
151 New Projects Added in 2024 Reflecting Recovery of Global Biotech & Robust Business Trend

- Leveraging its robust R&D capabilities and strong execution, the Company continued to enable customers while advancing our "Follow and Win the Molecule" strategies
- Signed 151 new projects in 2024, underscoring the Company's robust business momentum & sustained growth capability
  - Over half of the 151 new projects from the U.S.
- 1 pre-IND project transferred out due to client's concern on geopolitical dynamics
- Won 20 projects in 2024, including 13 late stage & CMO projects, of which most are from the U.S.
  - Vast majority of these 13 projects are complex modalities (bsAb, ADC, recombinant proteins, etc.)
- 66 late-stage & 21 non-COVID CMO projects: poised for future growth in manufacturing

"R"

"D" +18% YoY

"M" +31% YoY(3)



Notes:
1. As of Dec 31, 2024
2. The commercial manufacturing projects refer to the projects approved by regulatory authorities and signed CMO contracts with the Group
3. Terminated projects include 8 COVID CMO and 2 non-COVID CMO; Growth in non-covid M projects.

Research Services Have Enabled 50+ Programs for Global Clients to Date

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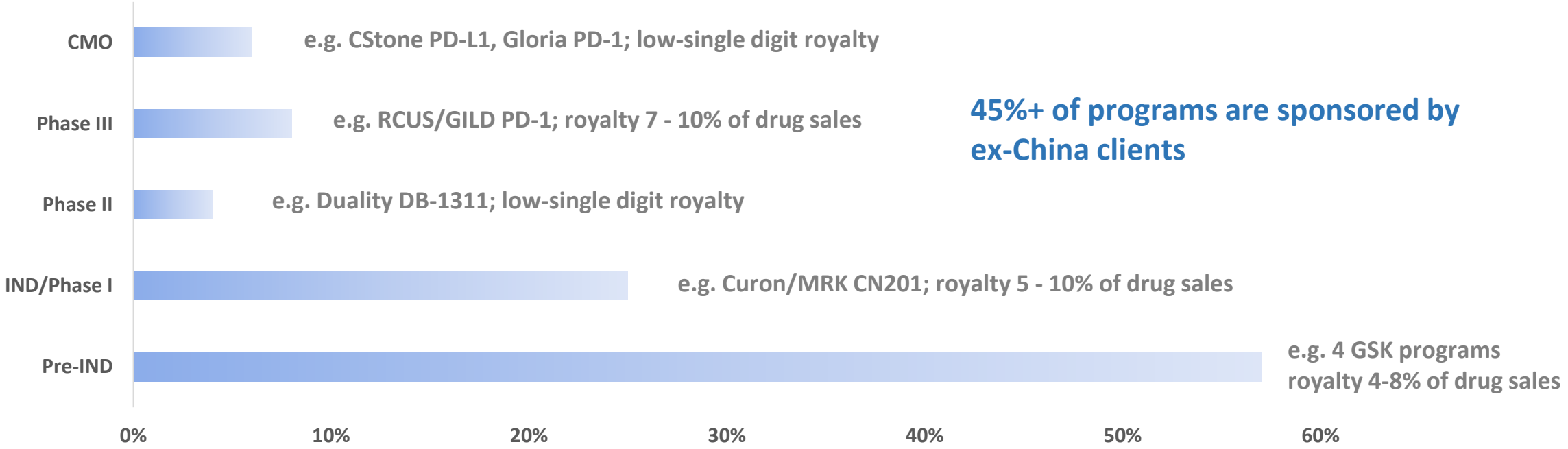
R Project Distribution by Phase (as of Feb'25)



45%+ of programs are sponsored by ex-China clients

Previous analyses provide an industry benchmark of 10% for the success rate in clinical development... Based on 18 leading pharmaceutical companies (2006-2022) and 274 new drug approvals, reveals an average likelihood of first approval rate of 14%, broadly ranging from 8% to 23%.

Drug Discovery Today 2025

Revenue Potential for RDM from a typical program

	Most programs		CD3 TCEs programs	
	Revenue	**GPM%**	**Revenue**	**GPM%**
R		80%+		80%+
Upfront (1x)	up to $30+m		up to $40+m	
Milestone (cumulative)	up to $200m+		up to $200m+	
Royalties (recurring)	up to $100m/yr for every $1b sales		up to $100m/yr for every $1b sales	
D	fluctuates depending on clinical trial needs	50%+	fluctuates depending on clinical trial needs	50%+
M	$50m+/yr per $1b sales	45%+	A few batches/yr for CD3 TCEs	45%+

- R: contract to revenue conversion could be as quick as 4-10 weeks
- D: typical contract to revenue conversion cycle in 6-15 months
- M: typical contract to revenue conversion cycle in 2-10 years

Accelerating IND Timelines:
9-month Packages with GMP Materials Produced in North America

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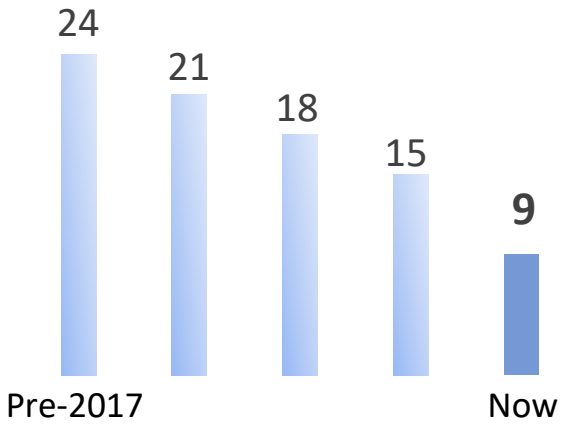
9-Month from DNA to IND Accelerated Timeline for mAb (GMP DS & DP mfg. in Cranbury, NJ)

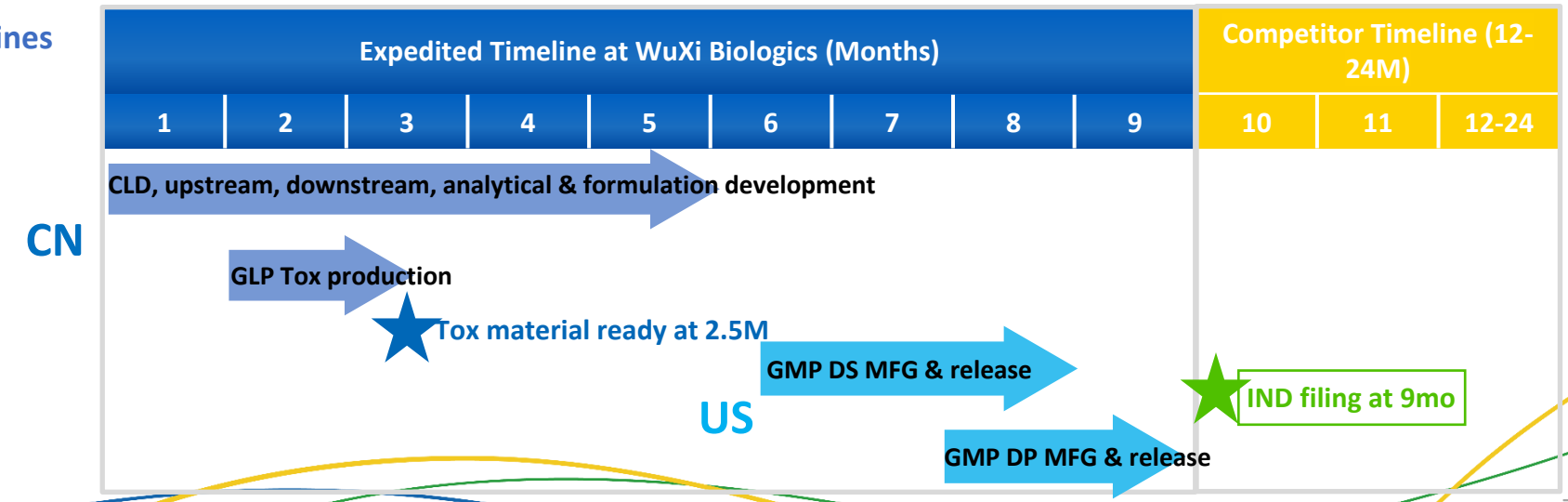
- Leveraging deep PD expertise from China team
- One-stop service within the WuXi Bio network
- **DS/DP GMP production in US, proximity to clients for enhanced collaboration**
- **MCB and GMP DS/DP all stored in US for future resupply runs**
- Additional 3 mos required for bispecifics & fusion proteins

A recent autoimmune project was delivered in 6 months

DNA | Process | NPP | DS MFG | DP MFG | IND

WuXi Bio has been shrinking IND timelines from 24 to 9 mos





FDA Plan to Phase Out Animal Testing Requirement for mAb Potentially a Tailwind

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FDA Announces Plan to Phase Out Animal Testing Requirement for Monoclonal Antibodies and Other Drugs

April 10, 2025

"The FDA's animal testing requirement will be reduced, refined, or potentially replaced using a range of approaches, including AI-based models... and organoid toxicity testing (so-called NAMs). Implementation begins immediately for IND applications, where inclusion of NAMs data is encouraged... The agency will also begin to use real-world safety data from other countries with comparable regulatory standards."

Animal testing requirement in Toxicology studies is costly & could easily take 6+ months

- Exploratory toxicology (pilot studies): 1+ months
- GLP-compliant repeat-dose toxicology (often in two species): 3+ months
- Safety pharmacology / PK studies / tissue cross-reactivity: may add 1+ months
- Data analysis & IND preparation: 1+ months

- **Our IND enabling package (DNA to IND) is typically priced excluding Tox studies (performed by 3rd party vendors selected by the client);**
- **The phase-out of animal testing requirement could meaningfully lower the total cost of an IND application – a potential tailwind for demand;**
- ***It will shorten overall timeline, enabling us to more consistently offer a <9mo IND package and further strengthen our market leadership vs. peers.***

Single-Use Technology Scaled Out to Large Batch Sizes Comparable to Stainless Steel Tanks

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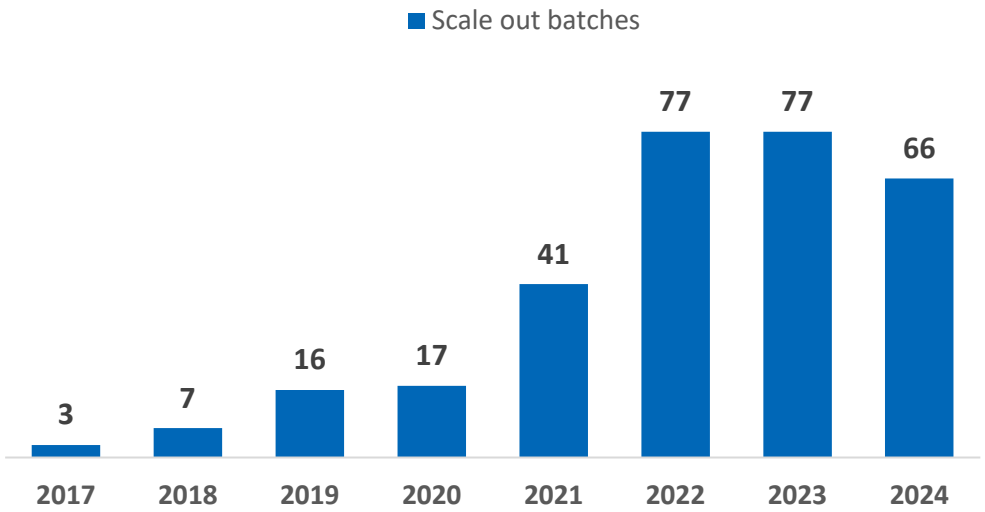
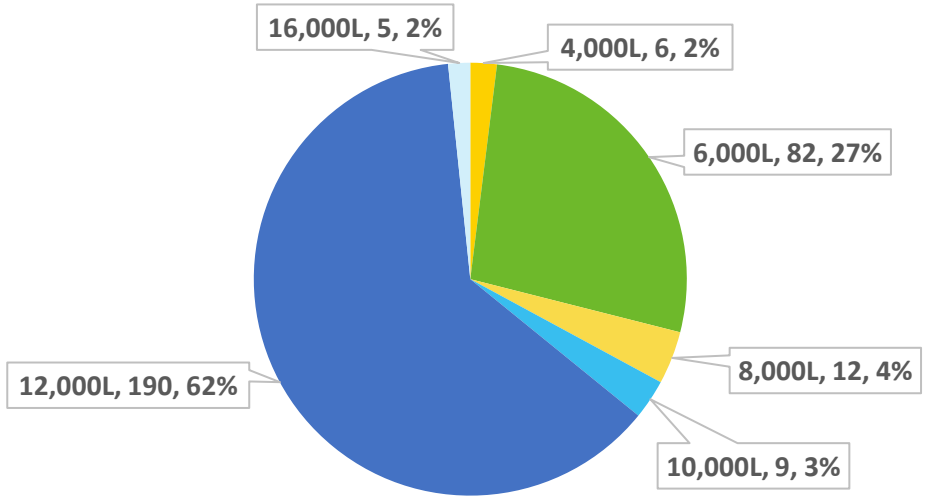
Number of Successful Scale Out Batches (by year)



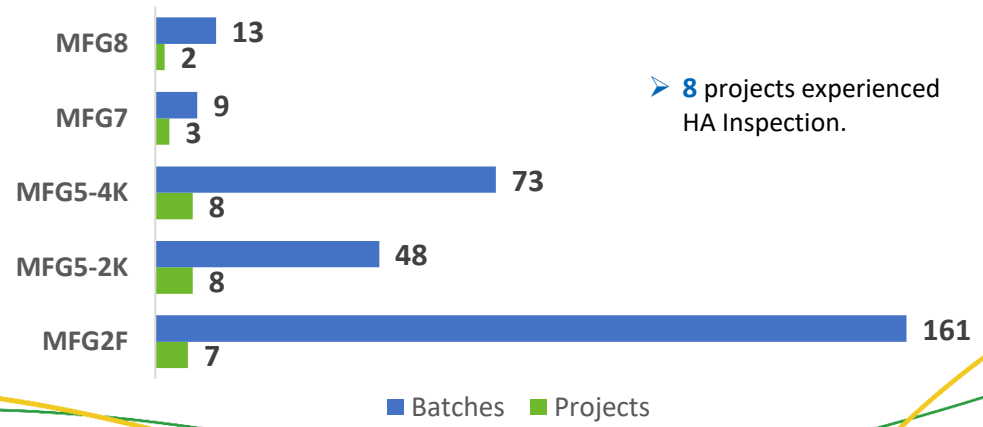
Number of Successful Scale Out Batches (by scale)



- **304** batches, **5** manufacturing facilities, **2** countries
- **97%** successful rate overall, **99%** in the past 3 years

Disposable manufacturing proven to be **cost-competitive, flexible & agile,** effectively accommodating **both small- and large-volume** products

Successful Scale out info-by MFG#



- **8** projects experienced HA Inspection.

Case 1: Successful Scale-out for a Win-the-Molecule Project to 10,000L

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Technical strength & speed enabled 10,000 L scale-out & FDA approval

- WuXi Bio's rapid tech transfer, process optimization, and regulatory expertise supported seamless scale-out to 10,000L using 5 x 2,000L bioreactors (comparable to stainless steel tanks), culminating in FDA approval and commercial readiness.
- Client batch forecast (29 DS + DP batches under planning for 2026E, 19 DS + DP batches for 2025E, vs. 3 DP + DS batches in 2024A) suggests robust growth trajectory.

Gen 1 process

- Project transferred from another CDMO to WuXi Bio
- Work with Client A to finalize tech transfer and 1st DS & DP manufacturing

Gen 2 process

- Gen 2 process transferred to WuXi Bio due to delays at original CDMO
- DS & DP TTs; 1st DS & DP manufacturing
- Successful PPQ execution for both DS and DP
- Product rights licensed to Client B and Client C
- **FDA PLI**
- **FDA approval; NMPA PAI**

Gen 3 process

- Gen 3 process development with Client B to enhance yield using WXB's cell line

Case 2: Successful Scale-out from 2,000L to 12,000L at Higher Titer

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Scale-out & high-titer process enabled FDA approval with improved product COGS

- Partnering **from IND to launch**, WuXi Bio supported 3 generations of process development, culminating in FDA approval in 2025 for Process 3.0
  - Process 3.0 uses intensified fed-batch & WuXia™ 3.0 high-titer cell line, achieved **8g/L** (up from 2.4g/L for process 2.0 under traditional fed-batch), significantly improving product COGS.
- Robust execution across all 3 process generations highlights WuXi Bio's deep technical strength, regulatory expertise, and long-term client trust.