Beyond the Buzzword: What ‘Commercial-Ready’ Really Means in Cell and Gene Therapy

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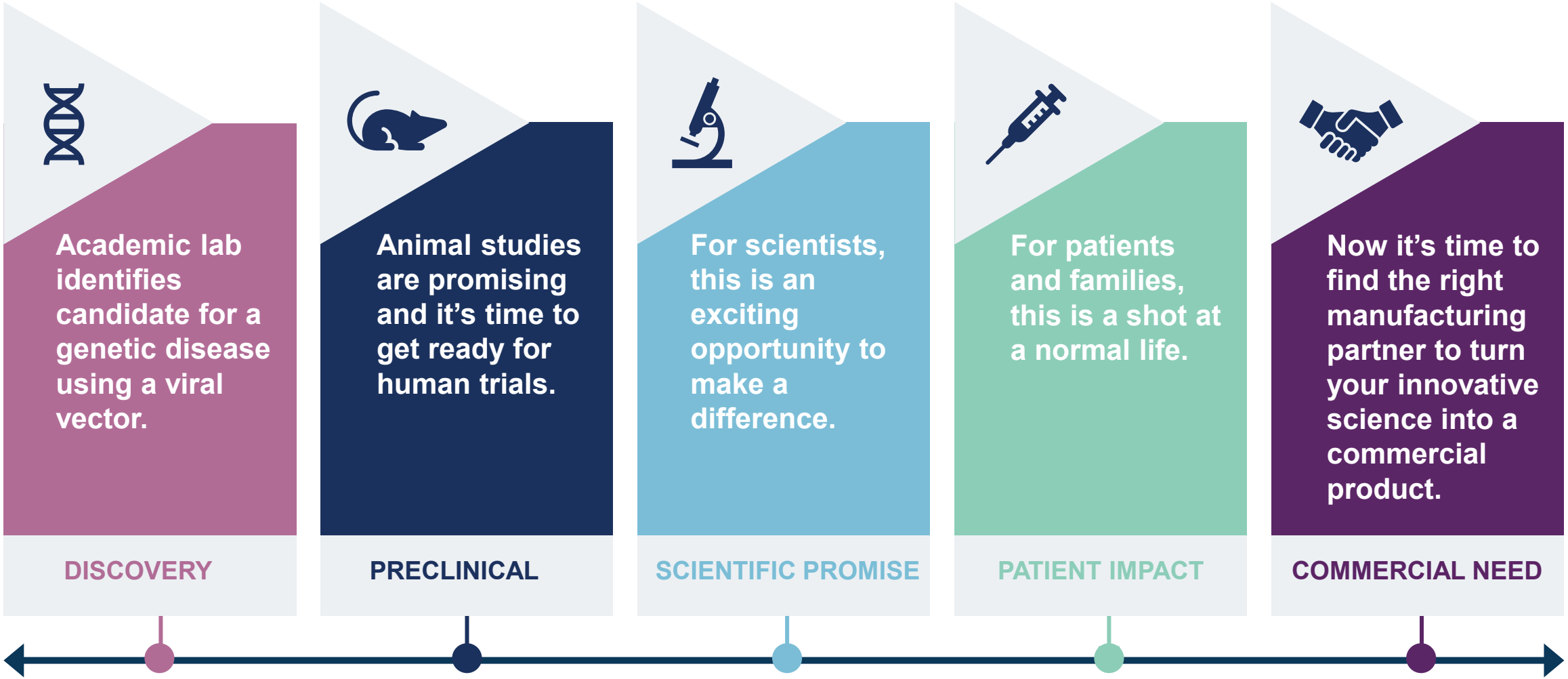
The journey to commercializing a new potential therapeutic

What it takes to turn breakthrough science into a therapy

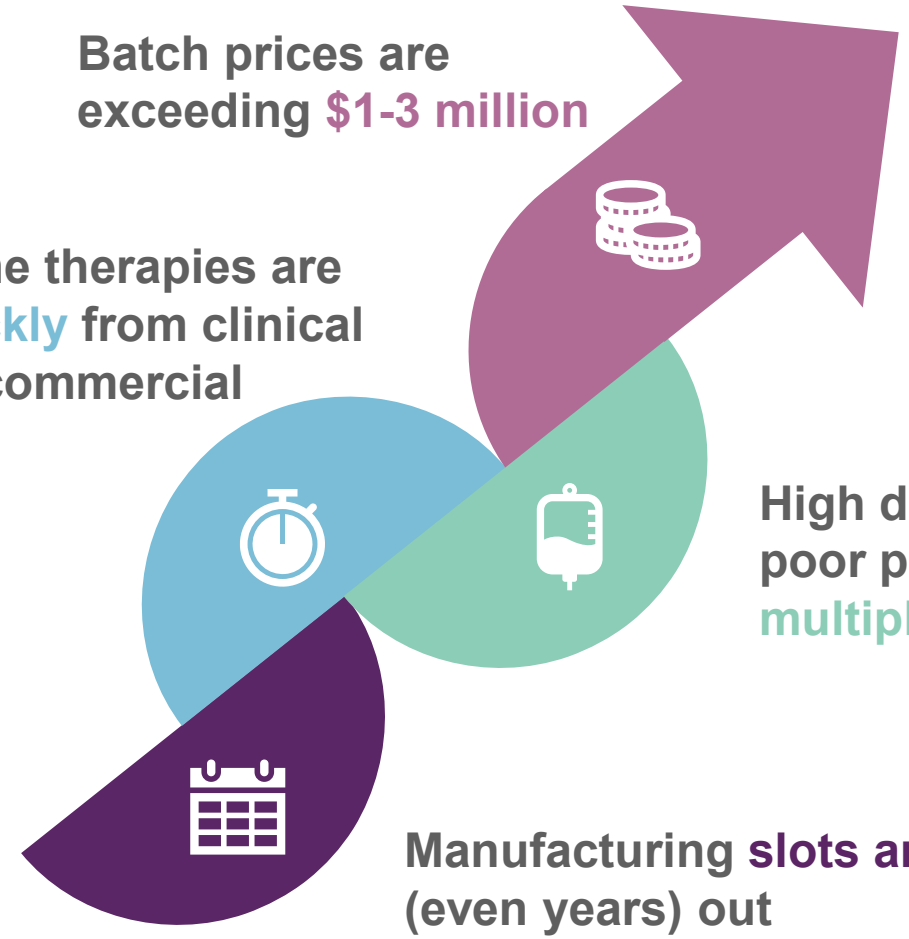


The importance of CDMO selection in a constrained market

Market dynamics are raising the stakes for manufacturing partnerships

Batch prices are exceeding $1-3 million

Cell and gene therapies are moving quickly from clinical promise to commercial reality



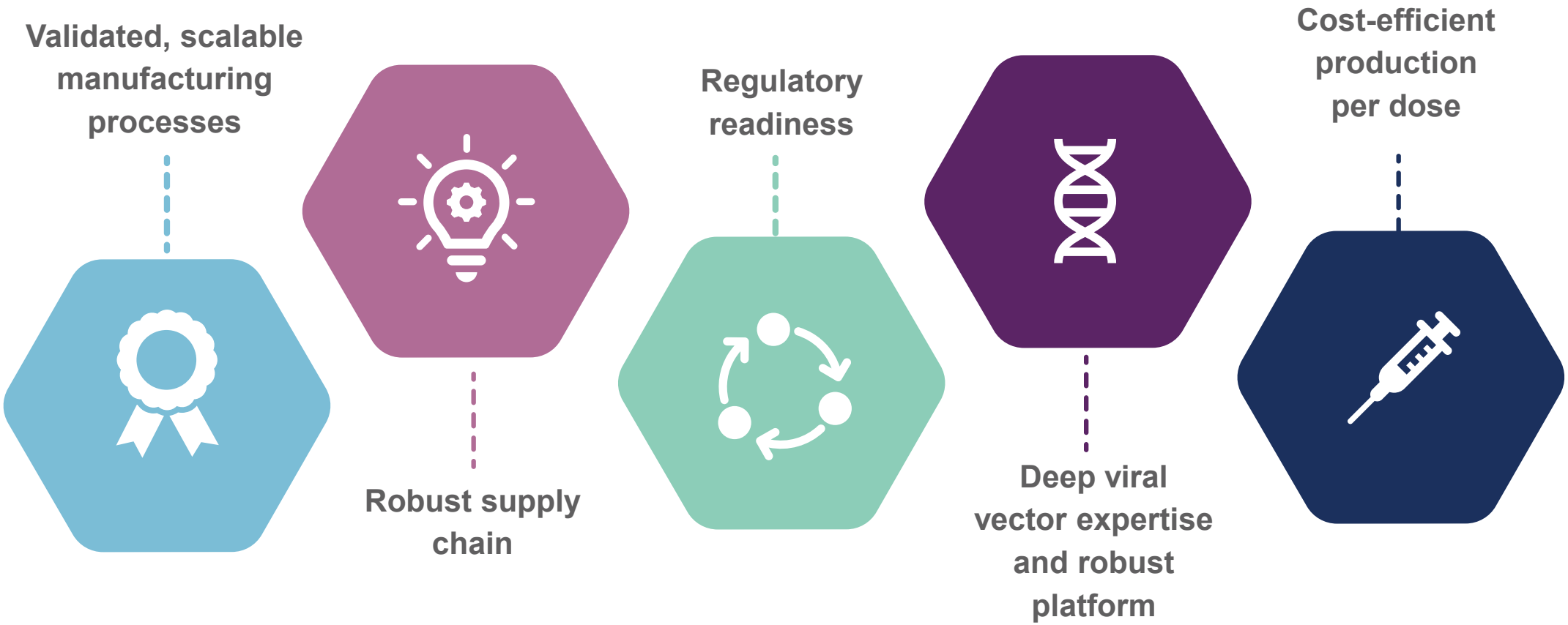
High dose requirements and poor productivity means multiple batches

Manufacturing slots are booked months (even years) out

So, how do you find the right CDMO partner who will help you deliver the best product for your trials and commercial supply?

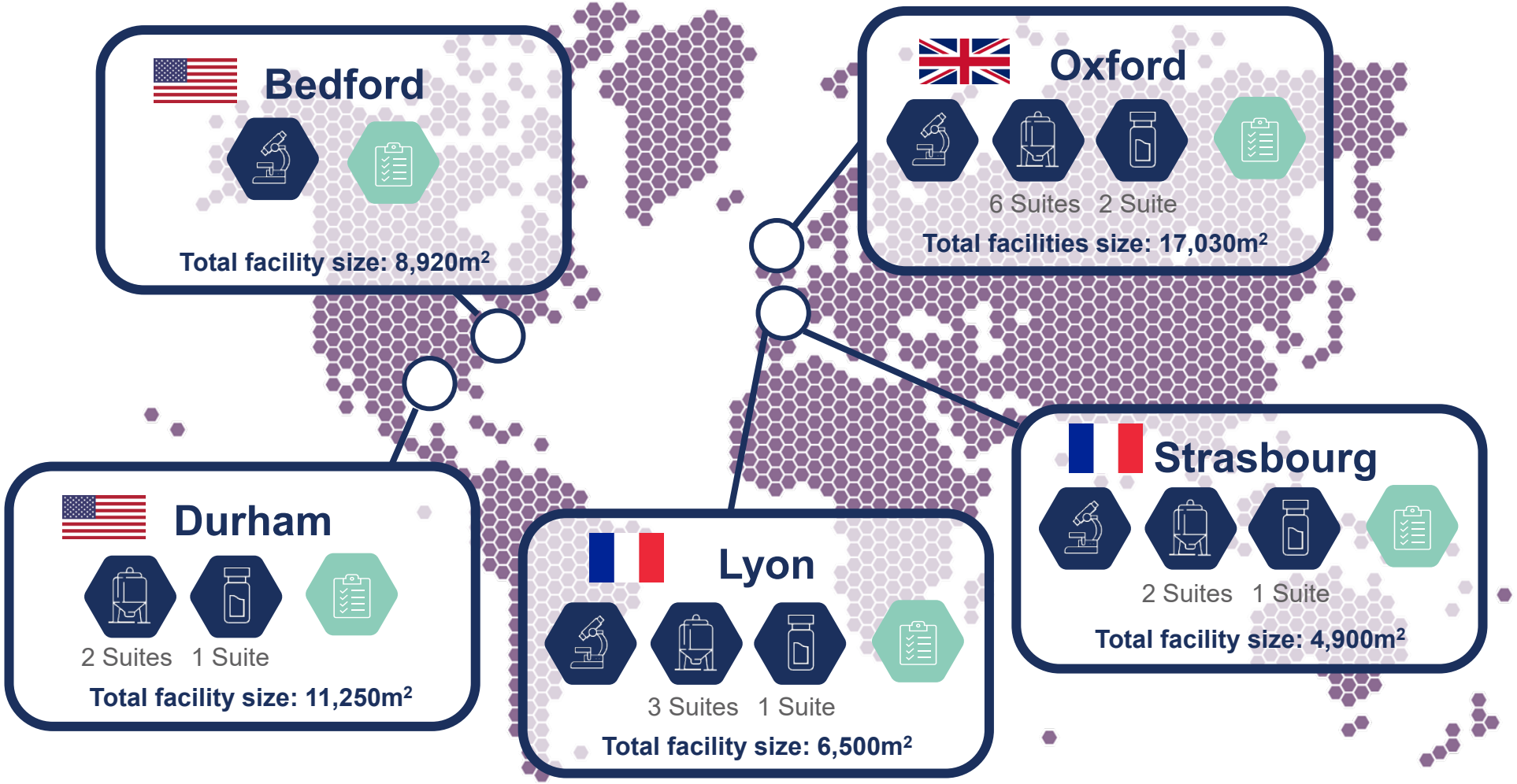
What does “commercial ready” mean to OXB?

Cell and gene therapies are commercial-ready when biology, process, and delivery are scalable together



Validated, scalable GMP manufacturing through OXB's global network

Unified global network offers robust supply chain and backup sites



We have been inspected and approved by:

- FDA
- MHRA
- EMA
- Anvisa
- PMDA

Development | Vector product | Vector substance | Analytical

Expanding to OXB Durham brings commercial manufacturing to the US - A strategic acquisition to expand

FDA Approved — State of the art viral vector manufacturing facility

23,000 Sq. Ft. Production Area — Strong drug substance and drug product capabilities

45,000 Sq. Ft. of grey space — Significant manufacturing expansion potential

5,000 Sq. Ft. quality control lab space — Track record of leading quality control

12 Clients served since inception — Served diversified client base across biotech and large pharma

OXB Durham
Centre of Excellence
for AAV manufacture

OXB Durham offers rapid expansion capacity

Suite C and Grey space can enable rapid expansion to increase manufacturing

Suite C **Grey space**

Suite C: batch production expansion by ~100%

- Suite C is available for the addition of vector manufacturing capacity of ~50 batches annually.
- Designed to feature a cell expansion suite, two upstream processing trains with bioreactor trains up to 1000L and a downstream suite.

Grey Space: 45,000 sq .ft. for additional expansion

- Potential to be repurposed to support drug substance, drug product and/or fill-finish.
- Fill-finish expansion in grey space already mapped out for rapid deployment if required
- Split into two zones to give various layout options.

Our robust QMS enforces our quality standards, mitigates risks and promotes continuous improvement

We have been inspected and approved by global regulatory authorities:

- **FDA**
- **MHRA**
- **EMA**
- **Anvisa**
- **PMDA**

30+ successful regulatory inspections

No written observations in latest FDA inspection in our facilities in the UK

In addition, we are routinely inspected by our clients and have been a key supplier for clinical and commercial C&GT products for 7+ years

OXB's regulatory track record provides a strong foundation for successful clinical trials and commercial products

We leverage our **global regulatory track record** to support your regulatory planning and preparations

45+ Regulatory submissions

100+ Successful audits

>40 Countries where products using our vector has been approved

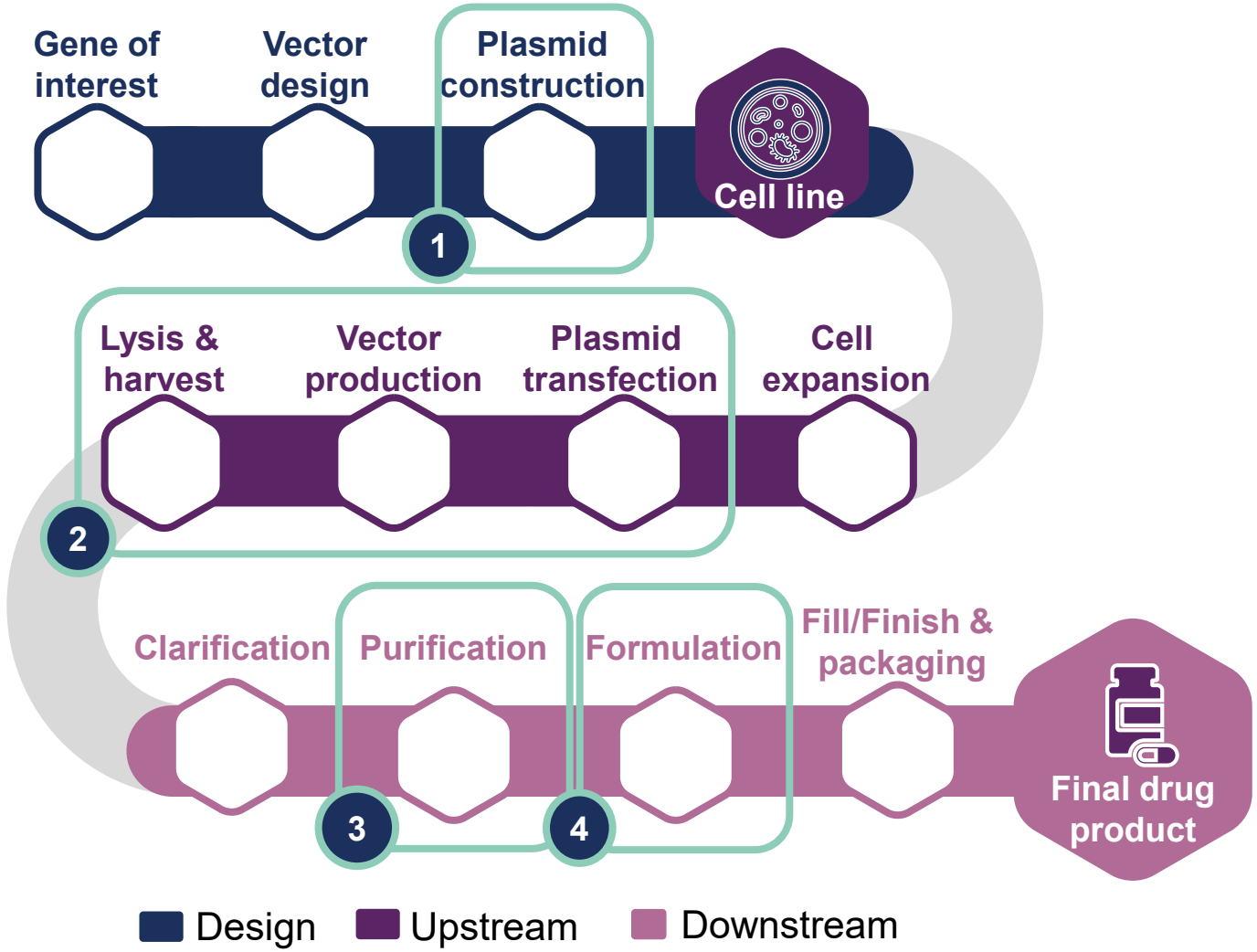
1 Drug Masterfile for UK facilities to support applications reviewed by FDA

Our experts have **extensive experience** interacting with regulatory bodies

- **Prepare for regulatory meetings and respond to regulatory questions,** including pre-submission meetings
- **Provide expert consultation on CMC dossier**, drafting and reviewing key documents for submission readiness
- **Establish working relationship** with regulatory bodies to consult on expedited development path for novel therapies
- **Redaction of quality section** for IND, CTA and BLA filings
- **Regulatory advice** on the optimum selection of assays

Leverage OXB's deep expertise and platforms in CGT

Example: The inAAVate™ platform



Our platform technologies

1. **Dual plasmid and pHelper:** improved productivity and packaging efficiency
2. **Vector production and Lysis:** optimized and scalable process for improved productivity and packaging
3. **Purification:** robust and scalable AF and AEX process for high% full capsid and control of PTMs for improved potency
4. **Formulation:** broad applicability to multiple serotypes. Demonstrated stability for 18 months at 2 – 8^{O}C

Seamless integration into the inAAVate™ platform offers high productivity

Key drivers of up to 10x productivity gain:

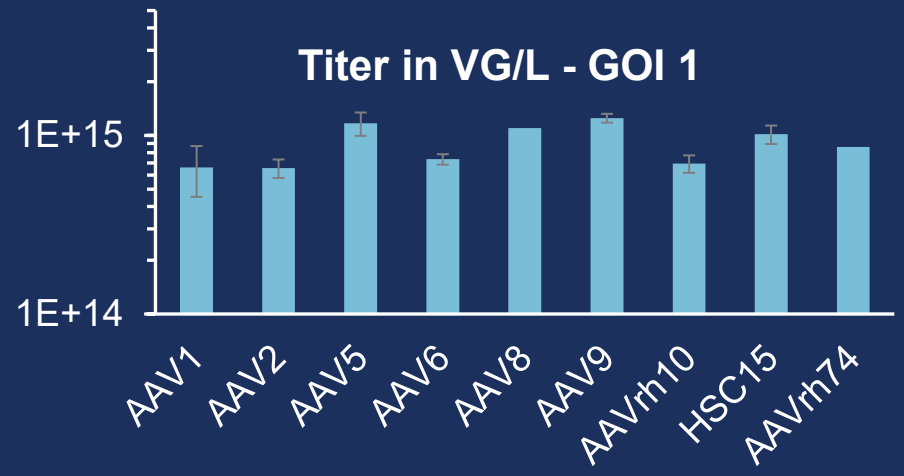
- Dual plasmid transfection & construct design
- Transfection density increase
- DNA amount & plasmid ratio optimization

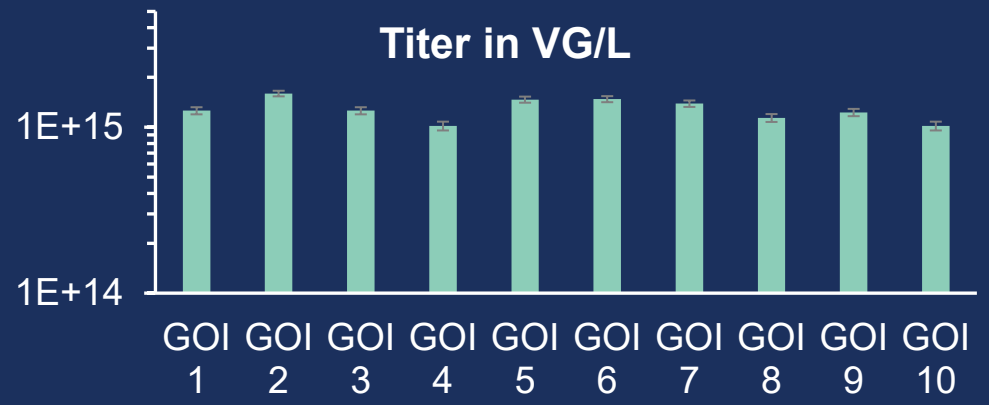
Process improvements:

- Process parameter optimization (e.g., pH)
- Productivity additive
- Transfection preparation control

View the article:

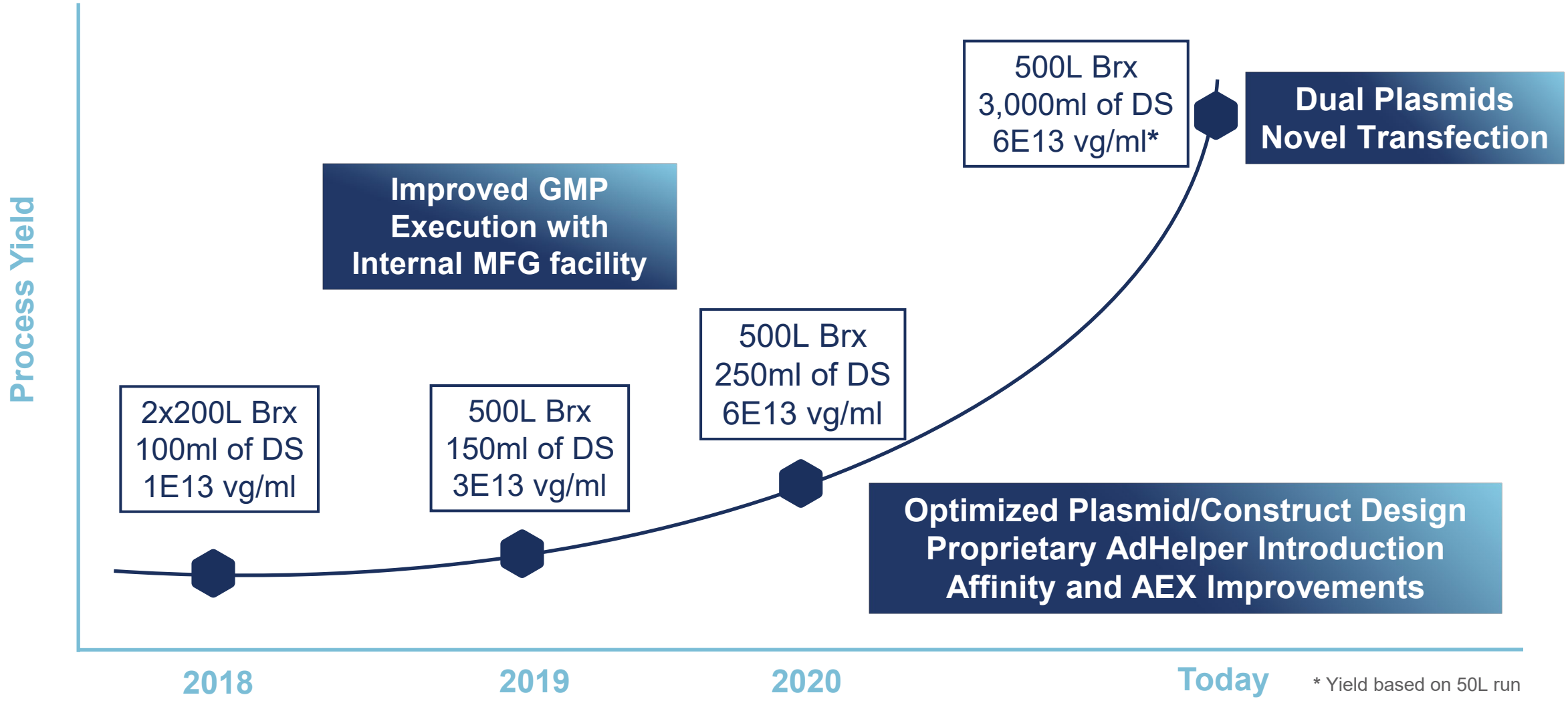
Consistently high titers achieved without DNA and plasmid ratio optimization





Clade F Serotypes

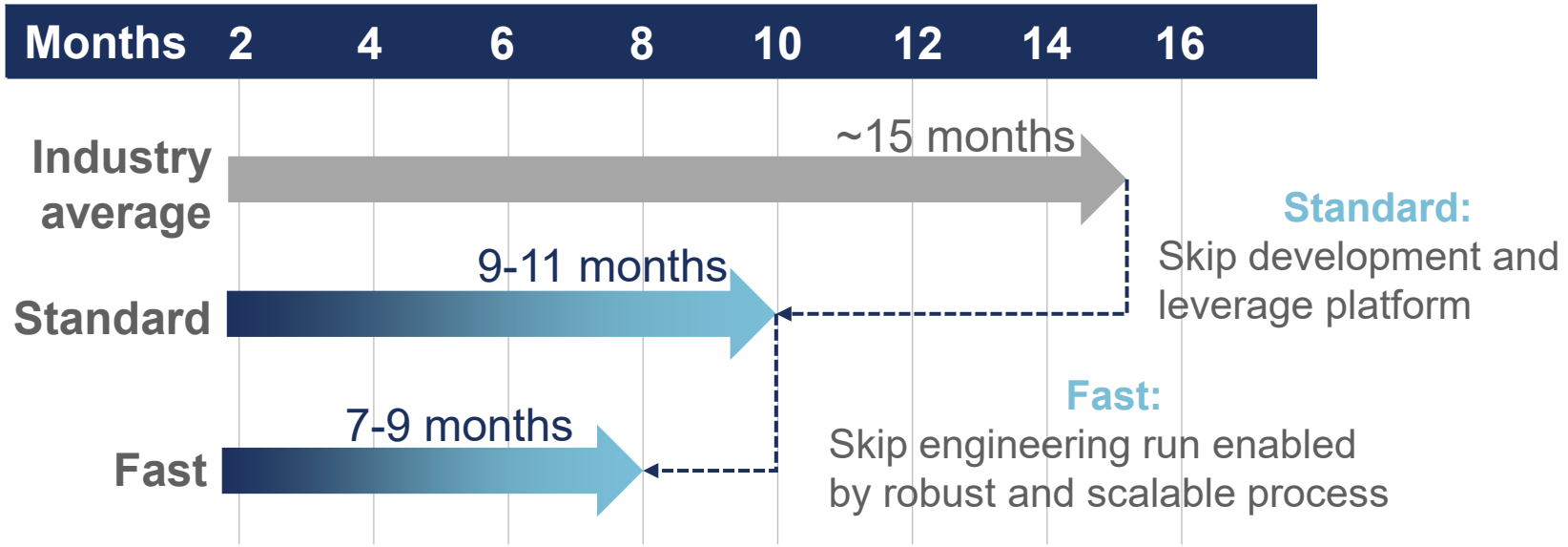
Increased productivity of the inAAVate platform improves purity and cost of goods



* Yield based on 50L run

How the inAAVate™ platform streamlines your path to clinic

Speeding up the process is key to **accelerating clinical trials**, maintaining a competitive edge, and ultimately enabling **faster access to transformative treatments**.



How do we achieve these timelines?

- ✓ Key innovations throughout the upstream and downstream process leading to higher titers and consistent performance at any scale
- ✓ Expertise for accelerated analytical development and qualification

14 *Subject to technical evaluation.*

Wrap up: What does commercial ready mean to OXB?

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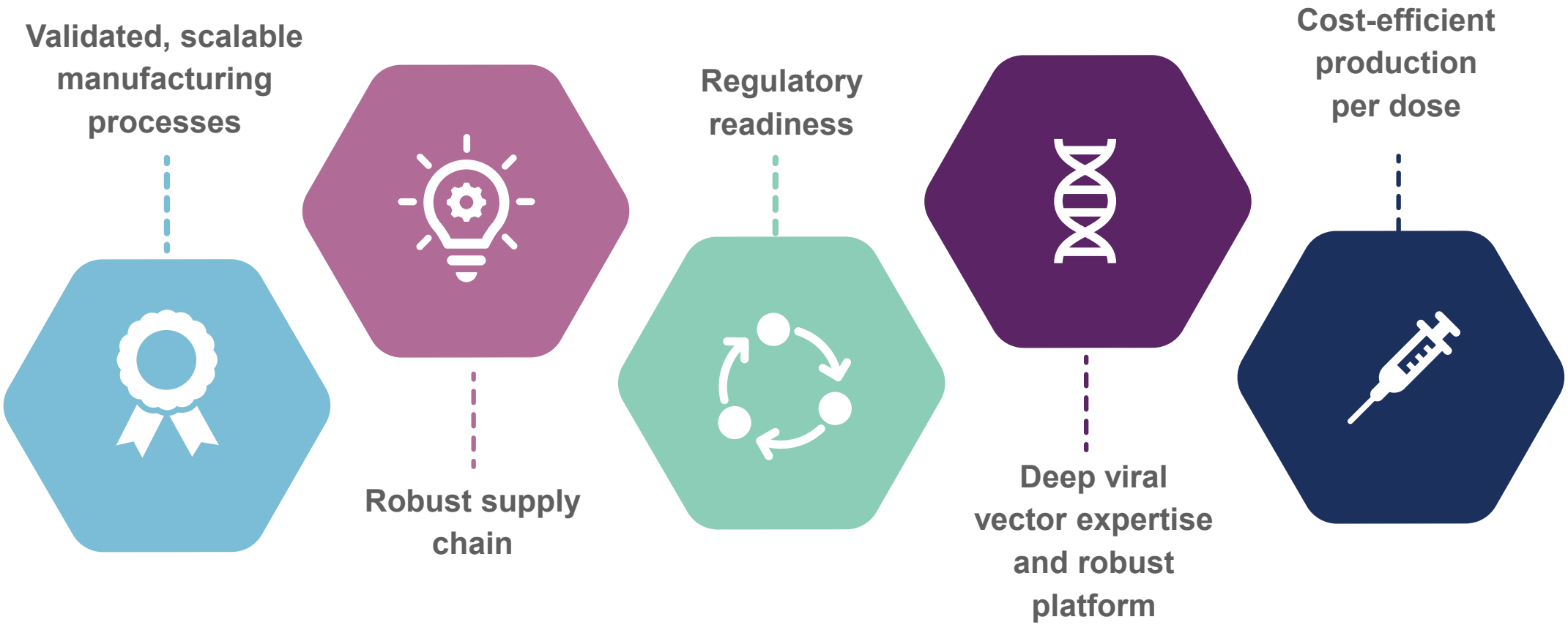

Q&A

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Let’s deliver
life-changing
therapies together

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