Accelerate time to clinic
A process and analytics platform approach

Ify Iwuchukwu PhD

VP Development Services, Head of Process and Analytical Development

Legal disclaimer

This presentation does not constitute an offer to sell or a solicitation of offers to buy Ordinary Shares (the “Securities”). Although reasonable care has been taken to ensure that the facts stated in this presentation are accurate and that the opinions expressed are fair and reasonable, the contents of this presentation have not been formally verified by Oxford Biomedica plc (“OXB” or the “Company”) or any other person. Accordingly, no representation or warranty, expressed or implied, is made as to the fairness, accuracy, completeness or correctness of the information and opinions contained in this presentation, and no reliance should be placed on such information or opinions. Further, the information in this presentation is not complete and may be changed. Neither the Company nor any of its respective members, directors, officers or employees nor any other person accepts any liability whatsoever for any loss howsoever arising from any use of such information or opinions or otherwise arising in connection with this presentation.

This presentation may contain forward-looking statements that reflect the Company's current expectations regarding future events, its liquidity and results of operations and its future working capital requirements. Forward-looking statements involve risks and uncertainties. Actual events could differ materially from those projected herein and may depend on a number of factors.

OXB

CELEBRATING 30 Years of Innovation and Excellence

Our track record

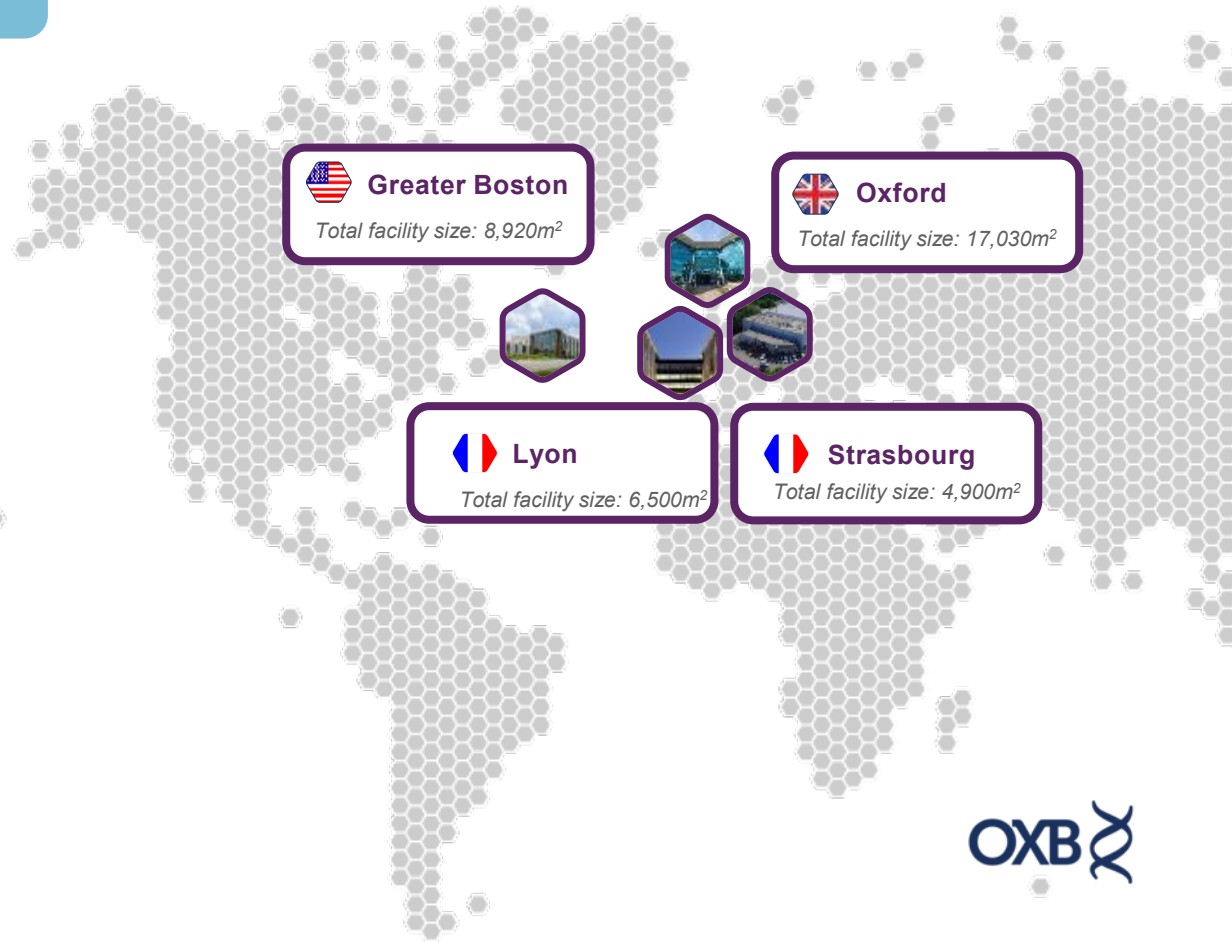
30+
Years of manufacturing experience

960+
Successful GMP batches since 2014

45+
Client programmes

30+
IND submissions

65+
Successful audits



OXB

Agenda

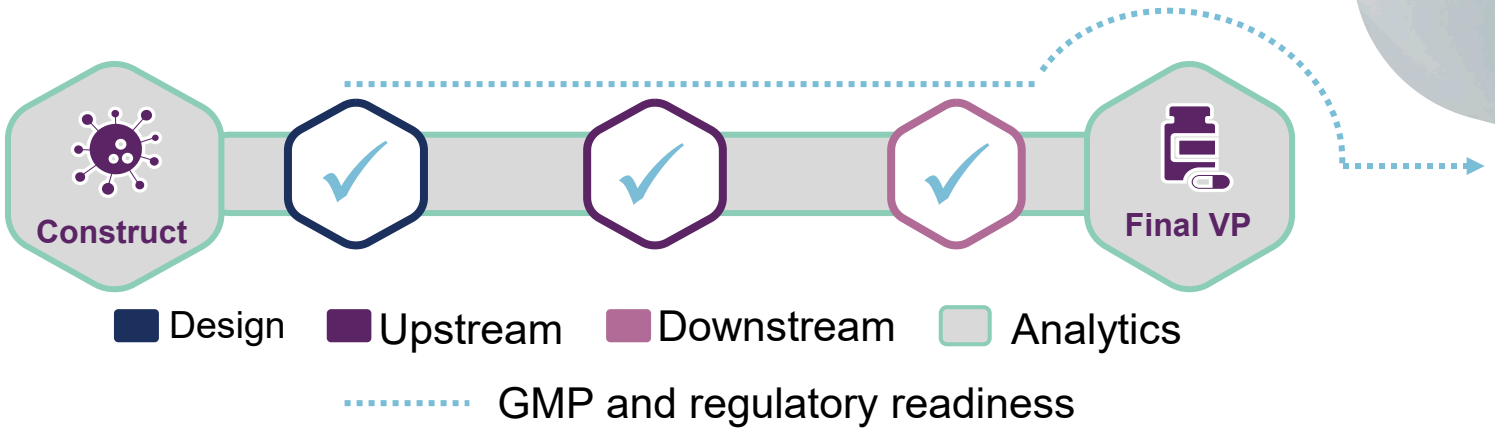
1. Introducing the manufacturing platform
2. Transformation of our process for higher titers and consistent performance at any scale
3. Leveraging our expertise for accelerated analytical development and qualification
4. Putting our platform to action: case studies
5. Q&A

Introducing the manufacturing platform

Platforms at OXB deliver more than just tools, they deliver results

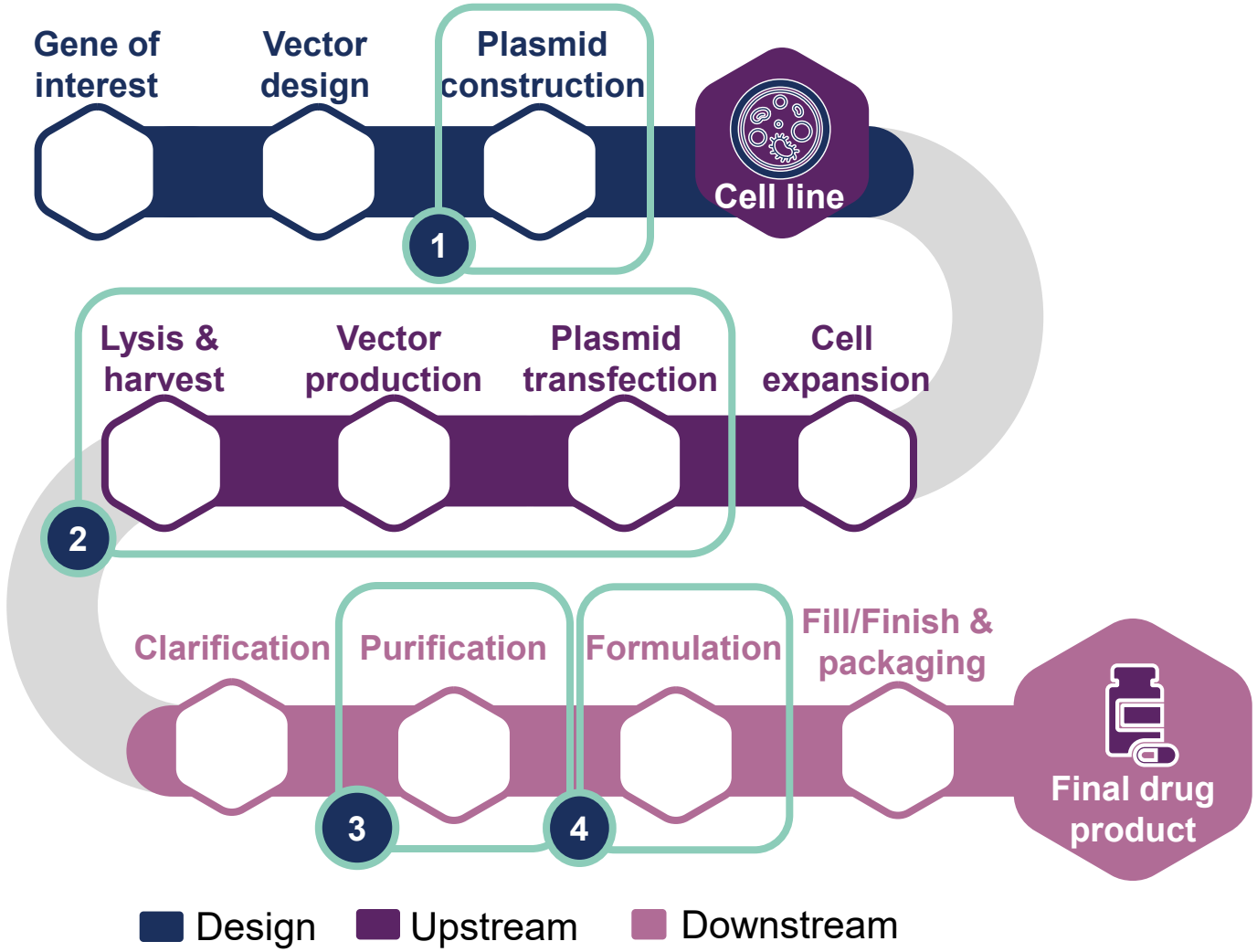
What is a “platform” at OXB?

- A **standardized, end-to-end process**
- Seamless integration of **proprietary technologies and processes** that drive performance
- Built for **consistency, speed, scalability, and regulatory confidence**



The inAAVate™ platform

End-to-end AAV manufacturing with built-in innovation



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

Cutting-edge innovation that helps tackle complex problems quickly & efficiently

Our tailored solutions:

- **Development project**
- **Custom solutions**
- **Technology transfer**
- **Process scale up**

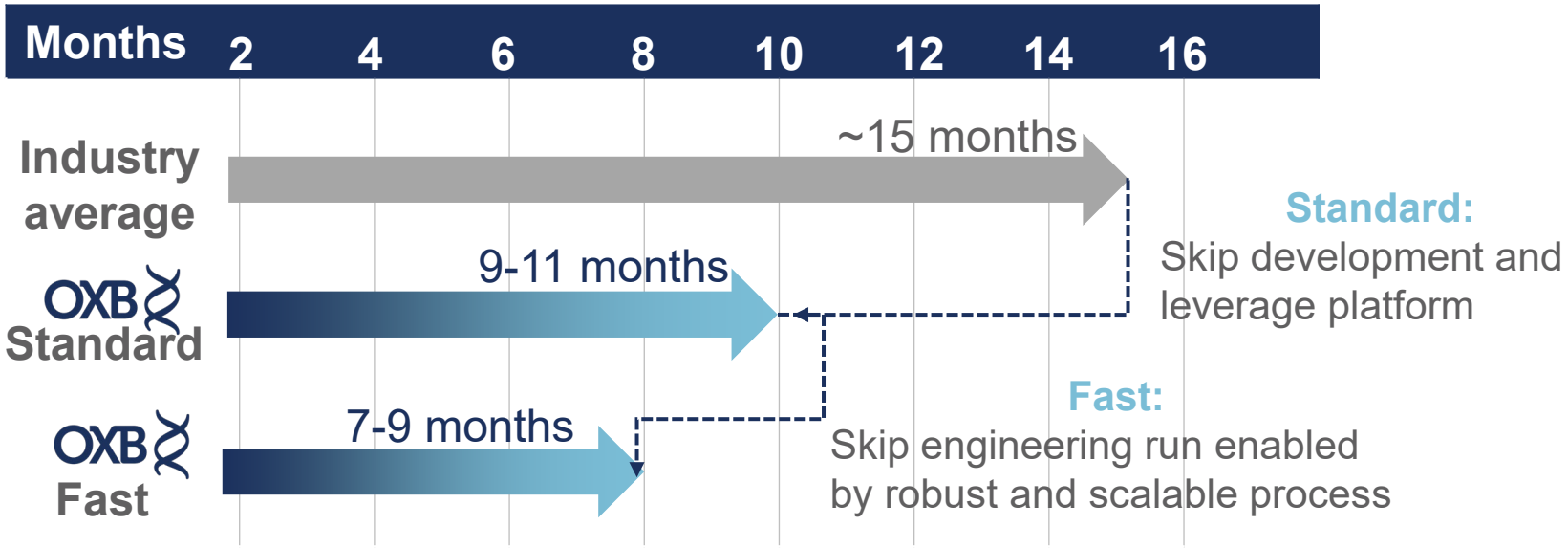
Key performance indicators

	Description	inAAVate™ platform
Titre	Total viral genomes for GMP grade batches	1.5E+17 $_{VG}$ at 500L scale with 90% full capsids
Speed	Timelines available from start of project initiation to GMP release	7-9 months
GMP batches	GMP batched successfully released	50+
Regulatory submissions	Successful submissions BLA / IND / MAA	6
Assays	Percentage performed inhouse	90%
Innovation	Core platform technology	Dual-plasmid, robust AEX platform and formulation

Industry standard Upper quartile

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**.

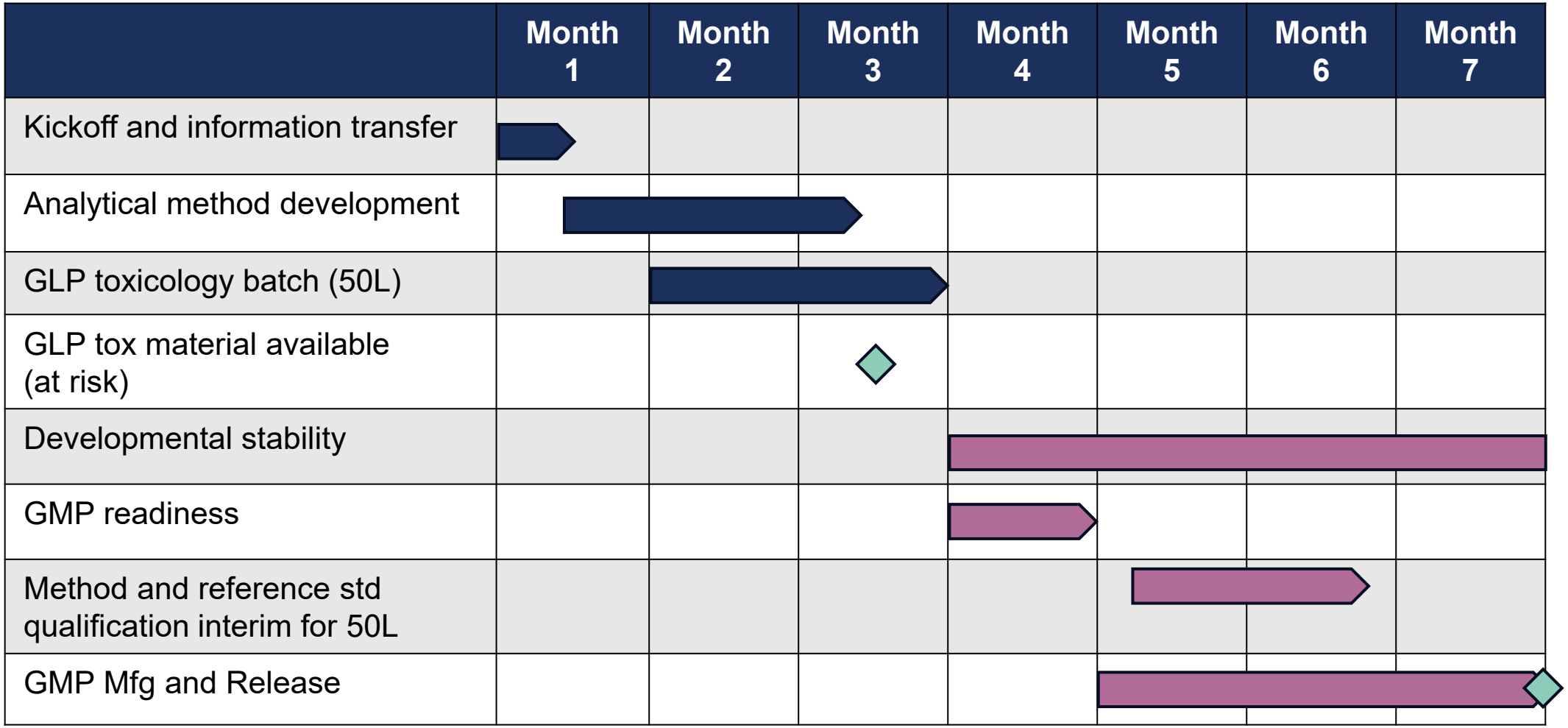


How do we achieve these timelines?

- ✓ **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**

Established fast track project timeline

7 months to GMP Release leveraging OXB triple plasmid transfection platform



- Enabled by pre-established BOM and process description and scalable platform process
- Additional 2 months for dual plasmid to enable synthesis and cloning of dual plasmid

Transformation of our process for higher titers and consistent performance at any scale

Plug-and-play process results high productivity with seamless integration

Key drivers of up to 10x productivity gain:

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

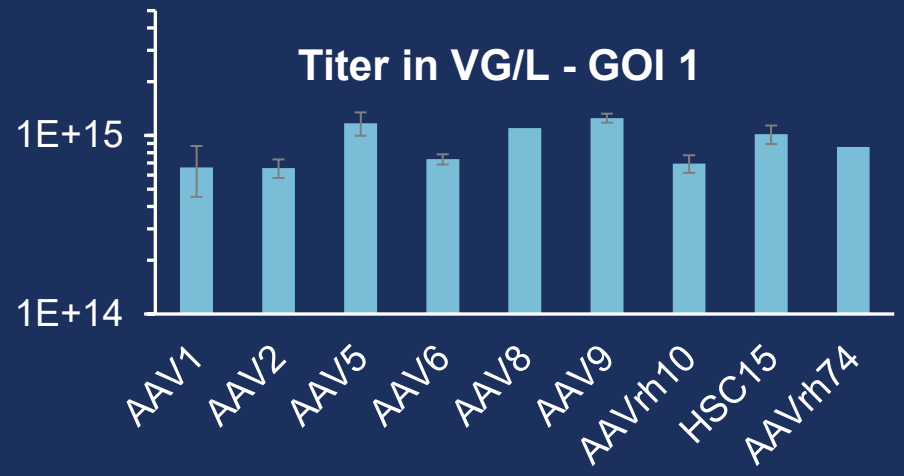
Process improvements:

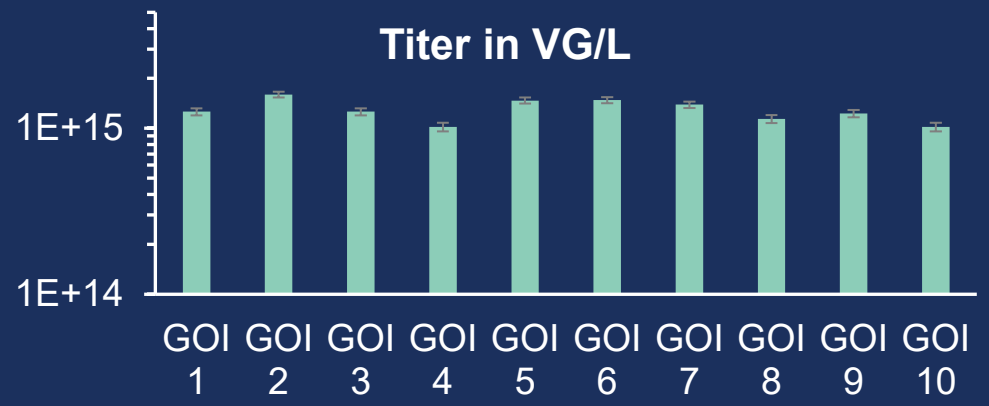
- Process parameter optimization (e.g., pH)
- Productivity additive
- Transfection preparation control

For more data on this topic, be sure to visit:
Poster by OXB's Katrina Costa-Grant during the poster session on May 15 @ 5:30 pm in Hall I2
Oral presentation by OXB's Dicky Gilmore on May 16 @ 3:45 pm in New Orleans Theater C

View the article:

Consistently high titers achieved without DNA and plasmid ratio optimization



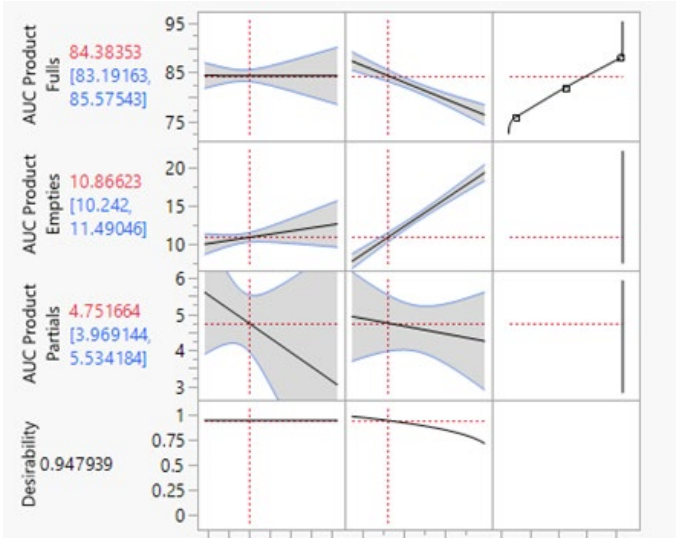


Clade F Serotypes

OXB

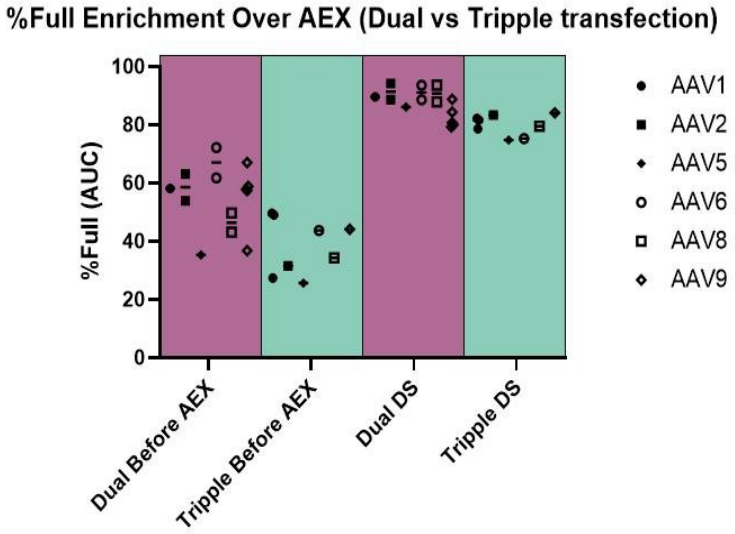
Multi-serotype AEX toolbox delivers higher purity without need for development

Defined design space



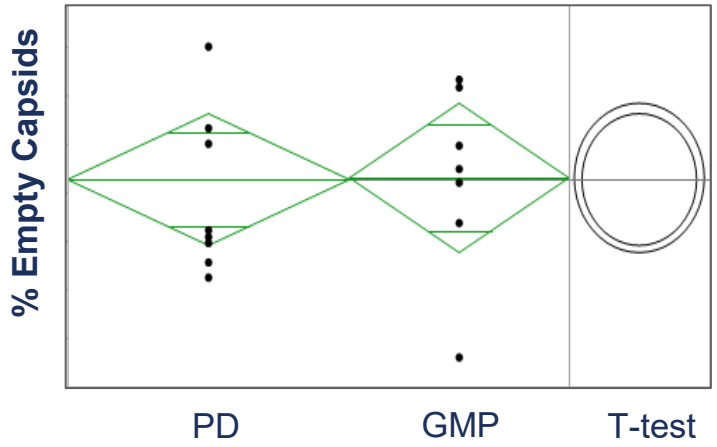
Leverage DoE results, AEX operation space is narrowed down to optimum range for multiple serotypes.

%Full enrichment over AEX (dual vs. triple transfection)



Most AAV serotypes tested with the optimum process range demonstrated up to 90%+ full capsids.

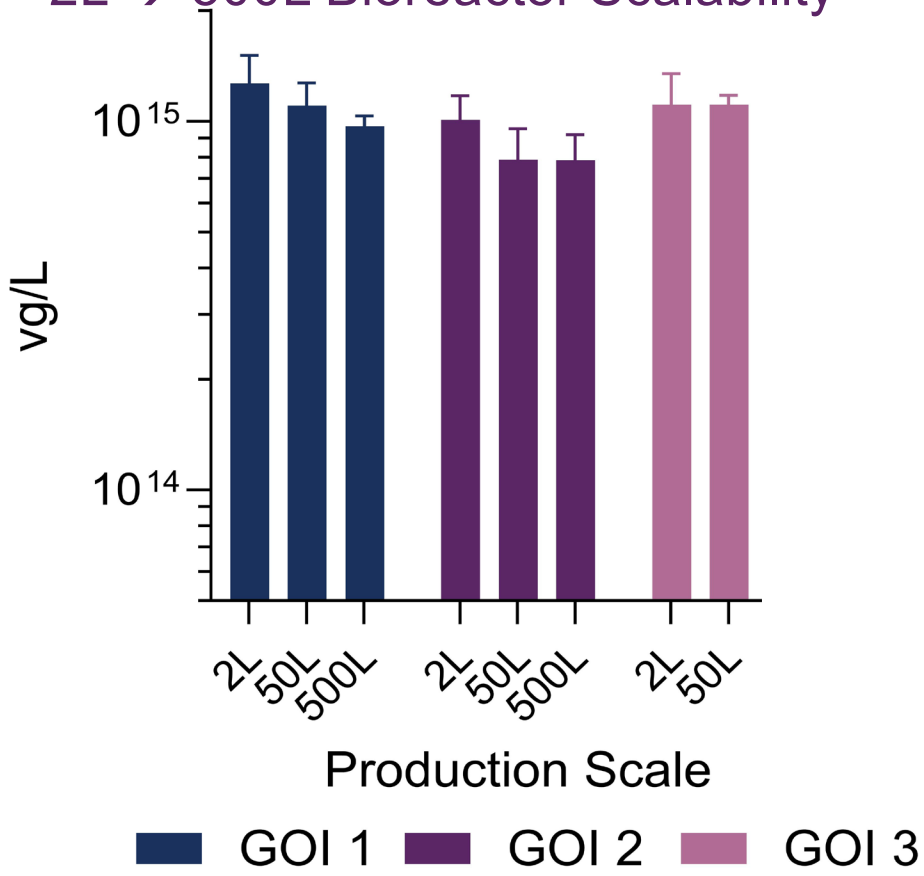
Scalable product quality



Scalability is maintained from PD bench scale to GMP full scale.

Maintain consistent productivity and performance at all scales

2L → 500L Bioreactor Scalability

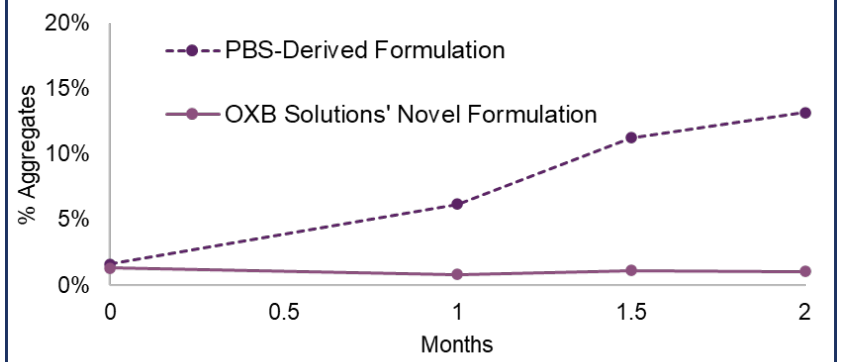


Scale up without compromising product quality

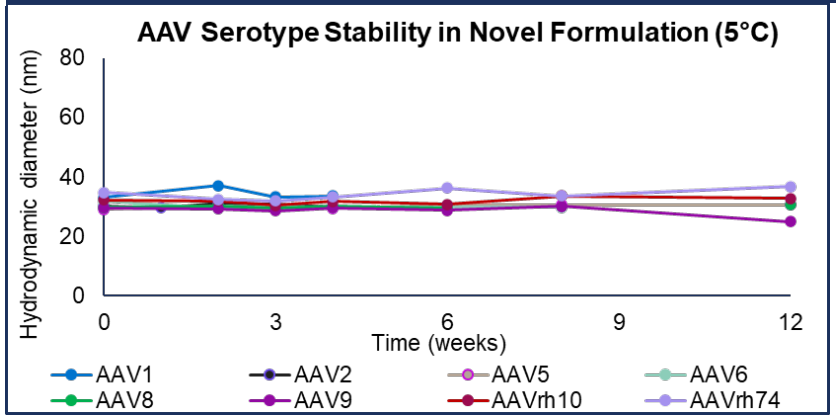
	Scale		
	2L	**50L**	**500L**
Empty	3.5%	8.4%	9.4%
Partial	3.7%	4.7%	4.4%
Full	92.9%	86.9%	86.3%
Aggregate	1.4%	0.8%	0.6%
Purity	99.5%	99.4%	99.9%

Suite of optimized formulations for superior drug product stability

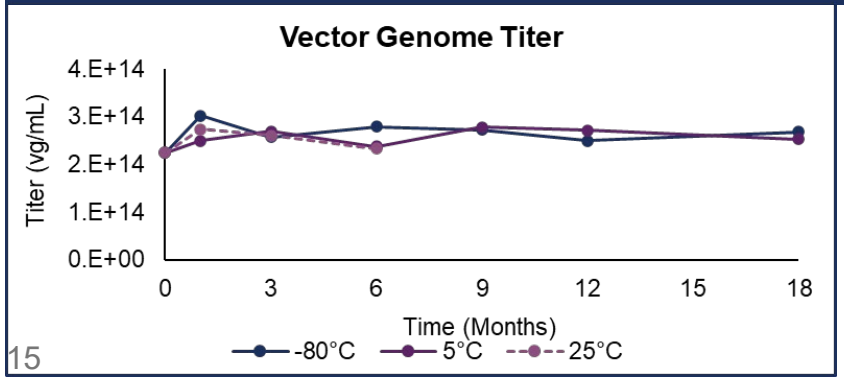
Aggregation protection on accelerated stability

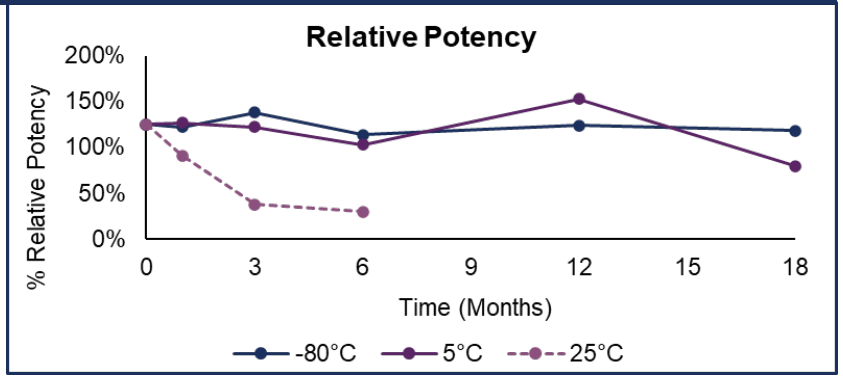


Optimized for multiple serotypes



AAV9 stability at high titer (3E14 vg/mL); Equivalent stability profiles at ultracold and refrigerated storage





Benefits of our formulations include:

- ✓ Superior stability to PBS
- ✓ Broad applicability across serotypes and routes of administration
- ✓ Superior shelf-life and cold chain optimized
- ✓ Suite of formulations for CNS, ocular, IV

Leveraging our expertise for accelerated analytical development and qualification

90% of methods performed in-house to accelerate batch release

90% Analytical methods performed in-house

24 Routine methods to test product quality on every lot

19 Additional methods to characterize product

Method type	Method
Capsid-specific	Capsid titer
	Capsid AAV Identity
	Purity
	Aggregation
	Peptide mapping/PTMs
Product-specific	VG titer
	Infectivity
	Transgene Expression (%RGE)
	Potency (%RP)
	% Empty, % Partial and % Full
Host cell Impurities	Host Cell DNA
	Host Cell Protein
Product- and Process-Related Impurities	10+ residual methods
	Formulation contents
Safety	Adventitious viruses
	Replication-Competent AAV
	Sterility
	Mycoplasma
	Bioburden
	Endotoxin

Platform method

Platform with some product-specific development

Full development

Outsourced

Robust assay qualification in 2 months to fast track GMP manufacturing

- Assays qualified in QC-ready format to **reduce tech transfer timelines and accelerate time to GMP release**
- OXB's robust qualification matrix ensure that all platform assays are qualified for your product
- All release assays are qualified in **~ 2 months leveraging qualified platform assays**

	Qualification strategy	Parameters assessed
Dosing assay (i.e., VG Titer)	Early-phase Validation	Accuracy, Linearity, Precision, Range, Specificity, Matrix Study
Product-specific (i.e., potency)	Qualification	Accuracy, Linearity, Precision, Range, Specificity
Platform assay	Platform Method Qualification*	Accuracy, Linearity, Range

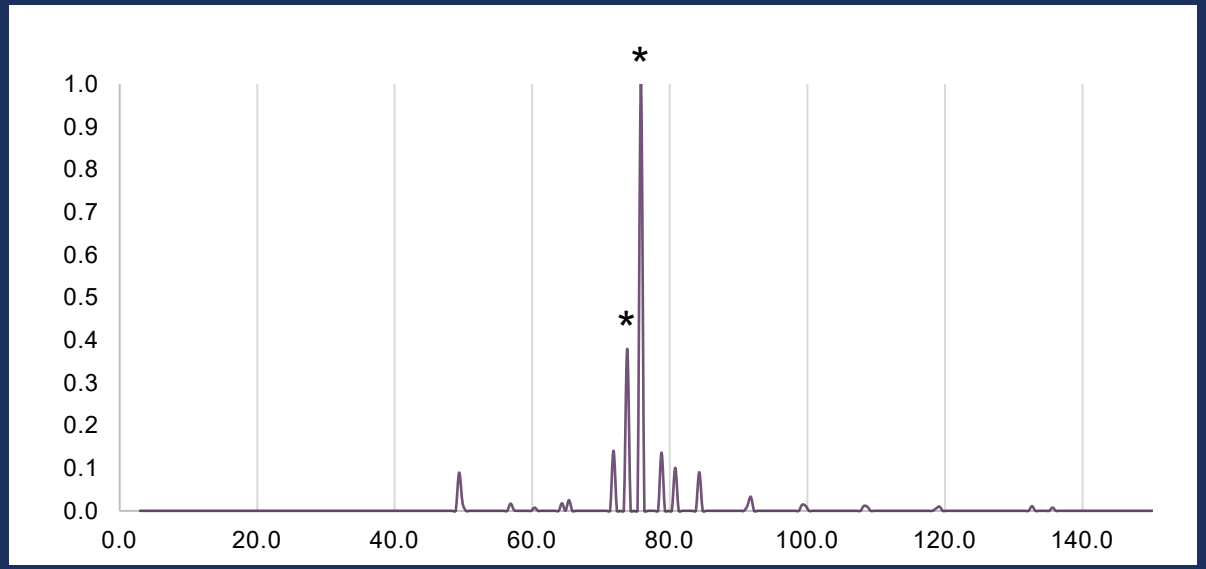
** Platform assays are already fully qualified; the Platform Method Qualification is done on the specific product ensure the assay is fit-for-purpose*

Early phase product characterization to enable early detection of critical issues

- Our qualified platform AUC assay allows for **early detection of subtle product quality issues**, including minor overpackaging and genome truncations.
- Other assays, including mass photometry, are unable to catch these discrepancies .
- LCMS assay leveraged early on to detect post-translational modification, peptide insertions etc.

Download our paper for more data on this topic

Analytical Ultracentrifugation (AUC) provides high-resolution separation of viral particles

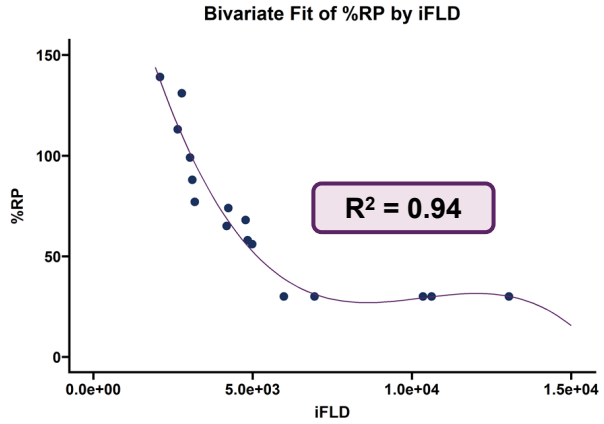


* ~200 bp difference in full capsid species

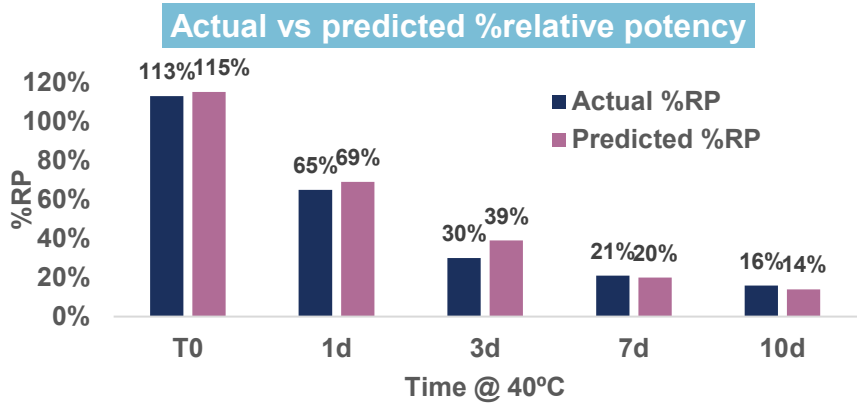
Expertise for accelerated analytical development

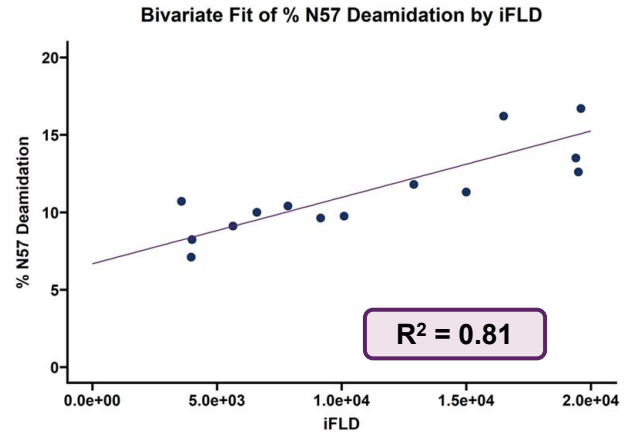
- Expert AAV analytics team enabled **rapid development of vector genome titer and gene expression assays within just 2 months**
- Gene expression assay provides early potency readout to guide key development decisions
- OXB database enables rapid, cost-effective potency and PTM assessment without lengthy LCMS timelines

Attend our oral presentation on **May 16 @ 5 pm in room 288-290** for a deep dive on this data!

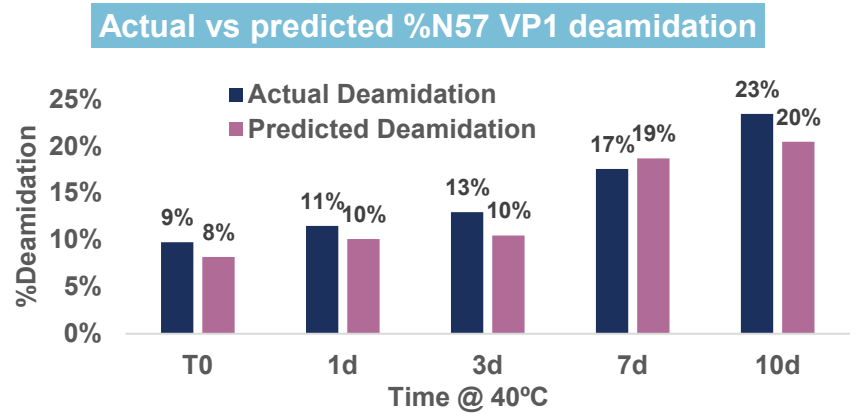


Increased in initial fluorescence correlates with a decrease in relative potency





Increased in initial fluorescence correlates with an increase in VP1 N57 deamidation



Putting our platform to action

Case studies

Rapid AAV manufacturing of engineered capsid

Case study #1

Background: The client struggled with 3 previous CDMOs with no or low product recovered and <35% full vector after several months of PD. While facing a tight timeline before animal study, they required reliable production of their engineered AAV capsids.

Challenges

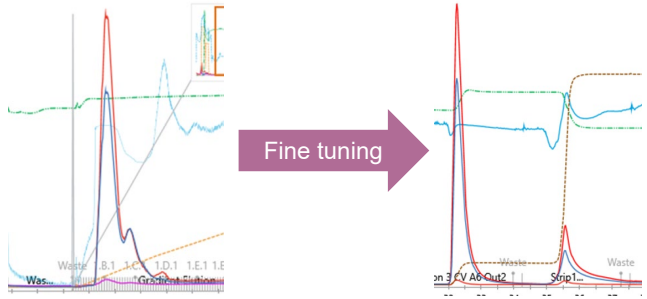
1. Engineered capsid had atypical conductivity/charge
2. Outside standard AAV parameters
3. “Conventional” purification methods failed to deliver

Our approach

1. Leveraged expertise in AEX design space –quick feasibility screening
2. Fine-tuned our AEX process conditions to handle the unusual vector properties
3. Optimized for high % full & yield

Results

- ☑ Vector with 92% full capsid delivered in just 6 weeks
- ☑ Client met preclinical animal study deadline
- ☑ Now advancing into IND-enabling studies



Quick feasibility screening using OXB platform

Fine tuning and implementation of isocratic elution

Accelerated functional potency assay development and qualification

Case study #2

Background: Our client needed to accelerate potency assay development to meet their IND filing timeline. CDMOs typically quote 12 months for functional potency assay development and qualification.

Challenges

1. Client required a 6-month method development, GMP transfer, and assay qualification to ensure IND filing was not delayed

Our approach

1. Robust development plan by OXB's experienced bioassay development team to ensure success delivery in 6 months
2. Leveraged cross-trained AD/QC team to eliminate lengthy GMP transfer timeline and accelerate qualification

Results

- ☑ Qualified functional potency assay delivered on-time

Parameter	Result
Accuracy	103% Recovery
Intermediate Precision	7% CV
Repeatability	9% CV
Range	50-225% Relative Potency

What is our value proposition and why OXB

Faster to clinic, without compromise

- ✓ 7–9-months timeline from project start to GMP release
- ✓ Proven fast-track pathways with built-in scalability

Proven platform, streamlined process

- ✓ InAAVate™ platform is optimized for speed, quality, and flexibility
- ✓ Pre-qualified assays reduce method development time by months

Decisions backed by data, delivered sooner

- ✓ Rapid feasibility screening and at-risk GLP tox material generation
- ✓ Early readouts on potency, deamidation, and vector quality

Results that advance your program

- ✓ Delivered >90% full capsid AAV in 6 weeks for studies
- ✓ Functional assay development & qualification in 6 months

Let's connect – 3 easy ways:

1. **Visit Booth 1611** to speak with our experts and explore the right solution for your needs
2. **Attend our presentations on Friday:**
   - *Enhancing Upstream Processes for High-Yield, High-Quality AAV Vector Production Using a Novel In-House Cell Line*
     3:45-4:00 pm in NOLA Theater C
   - *Diving Deeper: Using a SYBR Gold Capsid Ejection Assay as an Orthogonal Method of Measuring Potency and VP1 Deamidation in AAV9 Drug Product Samples*
     5:00-5:15 pm in Room 288-290
3. **Email us at partnering@oxb.com** and we'll follow up directly

Q&A