FORGE BIOLOGICS
A member of Ajinomoto Bio-Pharma Services

SCALING UPDATES

Aug 5, 2026

This month's newsletter is 995 words—a 4-minute read.

David Dismuke
Chief Technical Officer

We spend a lot of time talking about what's in the lab. We're deep into summer now, so today I'm curious about what's in your headphones. These have been my go-to summer songs. Don't judge me! What should I be listening to next?

2026

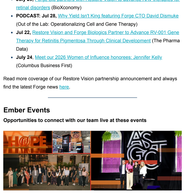
DAVID DISMUKE'S SUMMER PLAYLIST

Boys of Summer	Don Henley
Beach Side	Kings of Leon
Vacation	The Go Go's
Cake by the Ocean	DNCE
Bummerland	AJR

- **From the Lab:** Behind the scenes in Quality with Lisa Genko Fisher!
- **"Viral" News:** Announcing our partnership with Restore Vision.
- **Ember Events:** Meet with our team at the Bioprocessing Summit this month.
- **Dr. Barrett's Bench to Batch Advice:** Eyeing the end game.
- **Genes of Interest:** Ensuring cGMP compliance with Dominick Westlund.
- **Top Trending Post:** Our team at JSGCT1
- **Gene-ius Jobs:** Lead GMP Technician, Downstream (2nd Shift).

From the Lab

23 Questions with Lisa: making sure the show goes on every batch, every time



Lisa Genko Fisher explains how her job in Quality Assurance is very much like that of a stage manager.

This episode of 23 Questions highlights our Quality team, one that plays a role in every stage of our production. Learn more about quality at Forge, the standards that guide our work, Lisa's love of theater, and her personal connection to our work.

View the video here.

"Viral" News

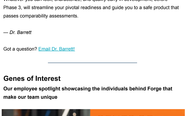
The latest and greatest news about Forge

- **PRESS RELEASE: July 21,** Restore Vision and Forge Biologics Announce AAV Development and cGMP Manufacturing Partnership
- **July 29,** Forge Bio partners with Restore Vision to advance AAV therapies for retinal disorders (BioXconomy)
- **PODCAST: Jul 28,** Why Yield Isn't King featuring Forge CTO David Dismuke (Out of the Lab: Operationalizing Cell and Gene Therapy)
- **Jul 22,** Restore Vision and Forge Biologics Partner to Advance RV-001 Gene Therapy for Retinitis Pigmentosa Through Clinical Development (The Pharma Data)
- **July 24,** Meet our 2026 Women of Influence honorees: Jennifer Kelly (Columbus Business First)

Read more coverage of our Restore Vision partnership announcement and always find the latest Forge news here.

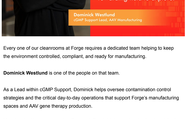
Ember Events

Opportunities to connect with our team live at these events



- **Aug 10-13**: Bioprocessing Summit / Boston
- **Sept 14**: ASGCT Policy Summit / Washington DC
- **Oct 5-7:** ARM's Cell & Gene Meeting on the Mesa / Phoenix
- **Oct 27-30:** ESGCT 29th Annual Congress / Hamburg

Can't make it to an upcoming event? Connect with us virtually.



Every AAV program comes with critical manufacturing decisions and a labyrinth of options. In this advice column, our **Head of Technical Sales and Scientific Advisory** Dr. Brianna Barrett, Ph.D., answers real developer questions about program manufacturing strategy with practical guidance shaped by supporting over 60 gene therapy programs. Consider it direct access to a manufacturing strategist from early planning through delivery.

Dear Dr. Barrett,

What manufacturing considerations are there when advancing a gene therapy program from Phase 1/2 clinical to Phase 3/pivotal trials?

— Pivoting to Pivotal

Dear Pivoting to Pivotal,

Great question, and one that catches a lot of programs off guard. Phase 1/2 manufacturing is built for speed and flexibility. Phase 3 manufacturing has to be built for consistency, and comparability, and that shift touches nearly every part of the process. A few areas to focus on:

Process lock and comparability. Incorporating process changes from early manufacturing learnings can result in substantial program gains. However, the key to late-phase is process lock of your commercial representative process. Strategically incorporating process changes early to reduce rework and additional regulatory paperwork can make the transition to late-phase smooth. All process changes should be assessed for potential impact to product comparability, such as potency, purity, and impurity profiles.

Analytical readiness. Assays that were fit for purpose or assessed as 'report result' on an early phase CoA, need to mature into qualified, and then validated, commercial ready methods with tighter specifications. A phase appropriate framework can still be utilized as you advance through the clinical phases towards commercial. To release a pivotal lot, a validated dsPCR titer assay is typically recommended, while most other product specific analytics may be working through qualifications or pre-validation stages. Regulatory bodies may also provide additional guidance specific to your product.

Raw material program. A phase appropriate raw material program will increase the rigor around sampling and testing of input materials. A risk assessment of all materials on your locked bill of materials (BOM) will guide appropriate testing plans for your process. For a pivotal manufacturing run, identification testing is required for all raw materials used and an assessment of raw materials critical quality attributes is also beneficial.

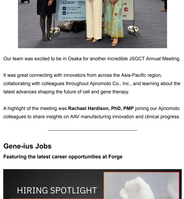
The lesson: planning for pivotal is a large step towards planning for commercial. Whatever you can lock, characterize, and qualify early in development, before Phase 3, will streamline your pivotal readiness and guide you to a safe product that passes comparability assessments.

— Dr. Barrett

Got a question? Email Dr. Barrett!

Genes of Interest

Our employee spotlight showcasing the individuals behind Forge that make our team unique



Every one of our cleanrooms at Forge requires a dedicated team helping to keep the environment controlled, compliant, and ready for manufacturing.

Dominick Westlund is one of the people on that team.

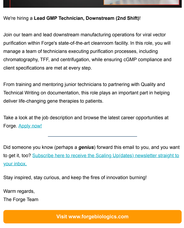
As a Lead within cGMP Support, Dominick helps oversee contamination control strategies and the critical day-to-day operations that support Forge's manufacturing spaces and AAV gene therapy production.

Most inspired by our core value Engaged, Dominick is passionate about contributing to work that creates meaningful impact for patients and supporting continuous improvement across teams.

Get to know Dominick in our latest Genes of Interest spotlight!

Top Trending Post

Live from Osaka Japan for JSGCT1



Our team was excited to be in Osaka for another incredible JSGCT Annual Meeting.

It was great connecting with innovators from across the Asia-Pacific region, collaborating with colleagues throughout Ajinomoto Co., Inc., and learning about the latest advances shaping the future of cell and gene therapy.

A highlight of the meeting was **Rachael Hardison, PhD, PMP** joining our Ajinomoto colleagues to share insights on AAV manufacturing innovation and clinical progress.

Gene-ius Jobs

Featuring the latest career opportunities at Forge

We're hiring a **Lead GMP Technician, Downstream (2nd Shift)**!

Join our team and lead downstream manufacturing operations for viral vector purification within Forge's state-of-the-art cleanroom facility. In this role, you will manage a team of technicians executing purification processes, including chromatography, TFF, and centrifugation, while ensuring cGMP compliance and client specifications are met at every step.

From training and mentoring junior technicians to partnering with Quality and Technical Writing on documentation, this role plays an important part in helping deliver life-changing gene therapies to patients.

Take a look at the job description and browse the latest career opportunities at Forge. Apply now!

Did someone you know perhaps a **genius**) forward this email to you, and you want to get it, too? Subscribe here to receive the Scaling Up(dates) newsletter straight to your inbox.

Stay inspired, stay curious, and keep the fires of innovation burning!

Warm regards,
The Forge Team

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