SCALING UPDATES

October 23, 2026
This month's newsletter is 905 words—a 4-minute read.



David Shveska
Chief Technical Officer

ARMs latest sector data reflects a maturing gene therapy industry, with dozens of programs now in Phase 3 clinical development. In our latest publication in Endpoints News, "Pacing the Journey: A Framework to Commercial Readiness," Jay Bouc, Ph.D., and Keerthana Subramanian explain how being prepared for the "marathon" can help developers cross the finish line as they approach commercialization.

- **From the Lab**: "Pacing the Journey: A Framework to Commercial Readiness."
- **"Viral" News**: A partnership with the TECPR2 Research Foundation, plus two Forge leaders honored with industry and regional awards.
- **Ember Events**: Meet with our team at ESGCT in Hamburg this month.
- **Dr. Barrett's Bench to Batch Advice**: Pondering the Pilot.
- **Genes of Interest**: Linsey Vanderberry on keeping a facility production-ready.
- **Top Trending Post**: Finding hope everywhere at Forge.
- **Gene-ius Jobs**: We're hiring a Scientist I, Quality Control Analytical.

From the Lab

Forge experts pen new article: "Pacing the Journey: A Framework to Commercial Readiness"



Gene therapy development and manufacturing is a long race, and it's better to find the gaps well before mile 20.

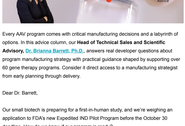
In a new *Endpoints News* article, Forge's **Jay Bouc, Ph.D**., and **Keerthana Subramanian** explain how to build a process characterization strategy that goes the distance to commercial readiness. Common gaps include an outdated risk assessment, a scale-down model without the right supporting data, analytics that can't keep pace, and weak traceability between studies. All of these are easier to address before filing pressure sets in.

Jay and Keerthana also share our integrated framework for building process understanding across the product lifecycle.

Read the full article here.

"Viral" News

The latest and greatest news about Forge



PRESS RELEASE: TECPR2 Research Foundation and Forge Biologics Announce AAV Development and Manufacturing Partnership to Advance Gene Therapy for TECPR2, **Sept 29**

- **Oct 13**, Innovators in Healthcare and Life Sciences Awards: Here are the 2026 honorees (Columbus Business First), featuring David Dismuke!
- **Oct 6**, Introducing BioSpace's 2026 40 Under 40 Winners (BioSpace), featuring Samantha Piteri-Molina!
- **Sept 29**, Forge, TECPR2 Research Foundation Strike AAV Gene Therapy Development, Manufacturing Partnership (Contract Pharma)
- **Sept 16**, Regulatory Flexibility, Global Alignment, and the Path to Access: Takeaways from ASGCT's 2026 Policy Summit (ASGCT)

You can always find the latest Forge news here.

Ember Events

Opportunities to connect with our team live at these events



Great to see so many of our partners at Meeting on the Mesa! Up next:

- **Oct 27-30**: ESGCT 28th Annual Congress / Hamburg
- **Nov 12-14**: ASGCT Breakthroughs in Cell & Gene Therapy / Nashville

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,

Our small biotech is preparing for a first-in-human study, and we're weighing an application to FDA's new Expedited IND Pilot Program before the October 30 deadline. How do we know if our program is ready?

--Pondering the Pilot

Dear Pondering the Pilot,

I checked in with our regulatory experts at Forge to help answer your question. Here's what my colleague **Claire Mazeau** had to say.

The pilot lets FDA, through the help of a Qualified Research Institution (QRI), review IND components on a rolling basis as they're completed, with the goal of identifying and resolving any issues earlier in the review cycle and long before the initiation of Phase 1 clinical trial. To benefit from it, your program should be far enough along that an IND is achievable, and early enough that QRI and FDA input can still shape development. Here's where we'd focus:

Check your stage. FDA expects CMC and nonclinical development to be sufficiently advanced. A nearly final package leaves little room for meaningful input. Look at what work remains and where earlier engagement could inform your strategy.

Know your CMC baseline. Look at how mature your process, analytical methods, and characterization strategy are, along with the data you have and the gaps you already know about. The goal isn't simply a faster IND. It's raising the right CMC questions while there's still time to address them.

Choose the right QRI and align your team. Each application names one qualified research institution (QRI), and FDA evaluates the sponsor and QRI as a single package. Look for expertise that fits your program, including process and analytical development and building the CMC module of the IND. QRIs can contract with outside experts, and you can keep working with CROs and CDMOs. That makes it important to agree early on responsibilities, dependencies, and timing.

Map your gaps. You don't need every answer before you apply, but you should know where the major risks are. Assessing CMC readiness on a rolling basis can clarify what's complete, what's on the critical path, and which questions would benefit from earlier input.

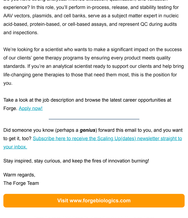
Ready, set, IND,

— Dr. Barrett

Got a question? Email Dr. Barrett!

Genes of Interest

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



Keeping a cGMP facility production-ready takes a lot of work behind the scenes.

Linsey Vanderberry, Senior Manager of cGMP Support, leads the team that handles sanitization, tubing assembly production, and third-shift monitoring. Her team works with Manufacturing, Facilities and Engineering, Quality Control, Quality Assurance, and Supply Chain so our cleanrooms are ready for production. Guided by our value of Purpose-driven, Linsey is most inspired by her children and stays focused on why we're here: helping our clients deliver safe gene therapies to patients who often have few other treatment options.

Outside of work, her playlist runs from hip-hop and K-pop to bluegrass, and it often ends with a 45-minute "Tweezer" by Phish.

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

Top Trending Post

Where hope connects our team, clients, and patients.

At Forge, HOPE stands for our core values: Hardworking, Open, Purpose-driven, and Engaged. Hope is also what we share with our clients and the patient communities we collectively serve.

Our new video shows where that hope comes from: our team, our facility, and our community, all working toward the programs our clients are bringing to patients.

Watch the video here.

Gene-ius Jobs

Featuring the latest career opportunities at Forge

We're hiring a **Scientist I, Quality Control Analytical**!

Do you have strong analytical method execution, qualification, and validation experience? In this role, you'll perform in-process, release, and stability testing for AAV vectors, plasmids, and cell banks, serve as a subject matter expert in nucleic acid-based, protein-based, or cell-based assays, and represent QC during audits and inspections.

We're looking for a scientist who wants to make a significant impact on the success of our clients' gene therapy programs by ensuring every product meets quality standards. If you're an analytical scientist ready to support our clients and help bring life-changing gene therapies to those that need them most, this is the position for you.

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 Updates newsletter straight to your inbox.

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

Warm regards,
The Forge Team

Visit www.forgebiologics.com

Forge Biologics, 3900 Gantz Rd, Grove City, OH 43123, United States
Unsubscribe Manage preferences