FORGE BIOLOGICS
A member of Ajinomoto BioPharma Services

SCALING UPDATES

February 11, 2026
This month's newsletter is 535 words—a 3-minute read.

David Stamuke
Chief Technical Officer

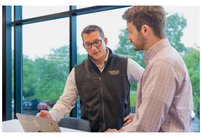
Happy International Women and Girls in Science Day! I'm fortunate to work alongside exceptional women at Forge and to learn from the many collaborators and mentors who have helped shape our field.

Welcome to the February issue of Scaling Updates). This month, we're introducing Dr. Barrett's Bench to Batch, an advice column answering AAV developer questions on manufacturing decisions, scale-up strategy, and preparing for cGMP readiness. Have a question? Email Dr. Barrett!

- **From the Lab**: Signals of progress in FDA's Rare Disease Agenda.
- **"Viral" News**: Forge comments on FDA's PreCheck, and more.
- **Ember Events**: Connect with our team live at ATW this month.
- **Dr. Barrett's Bench to Batch Advice**: Trying to start right.
- **Genes of Interest:** A spotlight on Analytical Development with Alicia Doyle.
- **Factoid of the Month:** How many bioreactors can we fill with Forge coffee?
- **Gene-ius Jobs:** Scientist II, Upstream Process Development.

From the Lab

FDA's Rare Disease Agenda Highlights More Predictable Development and Manufacturing Pathways as a 2026 Priority

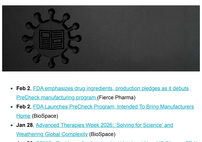


Our Chief Regulatory Officer, Chris Shilling, shares his perspective on the FDA's 2026 Rare Disease Innovation Hub Strategic Agenda, which signals meaningful progress for rare disease sponsors, particularly through expanded knowledge-sharing between CDER and CBER. Greater alignment could lead to clearer expectations and earlier regulatory dialogue, helping developers spend less time navigating uncertainty and more time advancing development and manufacturing strategies.

To learn more, read our Chief Regulatory Officer's full breakdown of the new agenda.

"Viral" News

The latest and greatest news about Forge



- **Feb 2**, FDA emphasizes drug ingredients, production pledges as it debuts PreCheck manufacturing program (**Fierce Pharma**)
- **Feb 2**, FDA Launches PreCheck Program, Intended To Bring Manufacturers Home (BioSpace)
- **Jan 28**, Advanced Therapies Week 2026: 'Solving for Science' and Weathering Global Complexity (BioSpace)
- **Jan 20**, CDMOs Pin Hopes for Accelerating Uptake at New US Sites on FDA's PreCheck Program (**BioSpace**)

You can always find more Forge news here.

Ember Events

Opportunities to connect with our team live at these events

- **Feb 9-12**: Advanced Therapies Week / San Diego
- **March 7**: AAV Gene Therapy Safety Mechanisms and Risk Mitigation - A Workshop Presented by ASGCT & ARM / Orlando
- **April 28-30**: Cell & Gene Meeting on the Med / Rome

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 new 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,
I have a lead AAV candidate and we're getting ready to engage a CDMO. What are the first manufacturing decisions we should be thinking about?
— Trying to Start Right

Dear Trying to Start Right,
The right first step depends on your program's goal.

If you're still unsure how your AAV will perform during manufacturing, start with a molecular development consultation. An early review of construct design can identify risks to productivity, quality, or safety before they surface at scale.

If maximizing yield is the priority, a transfection Design of Experiments (DoE) is often the most effective place to begin. It helps to pinpoint optimal transfection conditions and this has historically led our clients toward substantial yield gains (up to 22-fold 🤯) when approached methodically. This starting point can avoid rework later.

Many developers pair one of these approaches with a small-scale platform pilot run to generate early performance data. Even a quick pilot run alongside strong analytics helps gain insight into future product critical quality attributes (CQAs) that will guide development through cGMP.

Starting with clear goals and early data is one of the most tried and true reliable ways to reduce risk and set your program up for success. Happy evaluating, and may your data guide the way!
— Dr. Barrett

Got a question? Email Dr. Barrett!

Genes of Interest

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

Fueling curiosity through science and community. Meet **Alicia Doyle**, Associate Scientist II on our Analytical Development (AD) team.

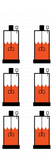
Alicia supports both client and internal in-process sample processing, helping keep critical development work moving forward. She runs assays like ddPCR, one of the 30+ assays the AD team performs to ensure our programs are backed by strong, reliable analytics.

Outside the lab, Alicia is the friend who swears she won't go overboard on a small get-together and then creates the best parties for her friends complete with themed cakes, and balloon arches.

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

Factoid of the Month

Ever wonder how much all those cups of coffee we drink add up to? We did the math...



At Forge, we are fueled by our passion for our mission and getting to work with incredible and talented colleagues every day.

Coffee fuels us too! ☕

Together, we drank 124,800 cups of coffee last year at the Hearth. That's nearly 30,000 liters, **enough to fill a 5,000 liter bioreactor six times**.

Gene-ius Jobs

Featuring the latest career opportunities at Forge

We're seeking a **Scientist II - Upstream Process Development** to lead and execute upstream process development strategies that advance scalable AAV manufacturing.

Your technical leadership and scientific expertise will be instrumental in managing process performance, supporting scale-up and tech transfer, and driving the development of robust manufacturing methods that help bring life-changing gene therapies to patients around the world.

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

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