Anna Welch
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To: Anna Rose Welch <immamanufacturingexpert@hotmail.com>

Hi Anna,

Below, please find the most recent edition of the C&G manufacturing must-reads newsletter, as well as a (preliminary) invite to an upcoming conversation I will be having that may be of interest to you.

Happy reading!

Best,

Anna Rose
Director, Cell & Gene Collaborative

INVITE: On **September 16th, from 12-1 PM ET**, I will be sitting down for an informal discussion with USP's Fouad Atouf, VP, Global Biologics, Science & Standards to discuss the recently announced USP/NIST/NIIMBL AAV analytical initiative, as well as his perspectives on the future of standardization in the AAV analytical space. We'd love to have you join us to listen, ask your own questions, and/or share your experiences. **If you'd like to attend/participate, please reply to this note, and I will provide you with the zoom link join us.**

"How Do I Regulate Thee? Let Me Count The Ways"

- AVROBIO CEO Geoff McKay waxes poetic on the FDA's CMC goalposts in this *Cell & Gene* contributed column. I took it a step (or ten) further and turned his words (loosely speaking) into a truly ghastly Shakespearean sonnet. If you've ever wondered what rhymes with "comparability," the answer is absolutely nothing. Slant-rhymes FTW.
- In recent weeks, Janet Woodcock has indicated that the FDA is planning to restore *domestic* facility investigations, starting primarily with high-risk establishments.
- The WHO has a two-for-one deal this week: it just released an updated version of its "Good Manufacturing Practices For Investigational Products" (FYI don't open in Safari) AND a draft guidance on "Good Practices For Research & Development Facilities Of Pharmaceutical Products." Ready, set, comment (by Aug. 31st)!

C&G "Marco Polo:" Finding Talent Outside Of Your Swimming Pool

- This just in — You're all unicorns. But, as I write in a new blog post, I liked this expert's take on one particular type of "unicorn" that is critical to the future of advanced therapy manufacturing.

- Once you have your talent, make sure you know how to use it well. This was one of five brief takeaways for small C&G biotechs from a Phacilitate webinar on building a successful C&G manufacturing pipeline.

I'm all 'bout That AAV, AAV, No Lenti*

**Lenti folks, never fear, I've got some good stuff for you in my next round…*

- I love this interview with UCSF associate professor Nicole Paulk on the future of AAV and the areas garnering the greatest amount of research today. A few months ago, I had an inordinate amount of fun putting together a mock Q&A on AAV's future, in which Paulk and several other experts featured prominently.
- Big news out of USP, NIST, and NIIMBL: the organizations have launched a new collaboration to determine the best analytical strategies for measuring AAV critical quality attributes. The goal is to have this (must-watch) study lead to the establishment of future reference standards.
- The FDA will be holding a two-day public meeting on **September 2 & 3** from 10 AM-6 PM ET to discuss AAV toxicity. However, last I checked, Britney Spears will (sadly) not be in attendance to sing "Toxic" to kickstart the conversation.

Keep Calm & "Do The Dew-"* Diligence With Your CDMOs

**Mountain Dew did not sponsor this newsletter*

- In the second installment of my three-part outsourcing article series, Mark Davis, principle and founder of NegotiumBio, urges innovators to stay the course with their due-diligence of outsourcing partners, even though the great conflagration of CDMO demand is making it a seller's market.
- CDMO consolidation got you down? You're not alone; my colleague over at *Outsourced Pharma* identifies what one advanced therapy maker hopes is the future of ATMP outsourcing: The right-sized, full-service CMO.

Ancillary Materials

- If volcano boarding, vitrified brains, and "seal-o-scopes" excite you, I've got some (not even *remotely* work-related) articles you're going to want to read.