

Anna Rose Welch

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

Hi Anna,

Hope you're doing well!

Please find below some of the most interesting manufacturing-centric articles I've tracked down for you in the past couple of weeks.

As always, feel free to let me know if you particularly enjoyed any of these articles or if you'd like me to be on the lookout for other topics to include in future newsletters.

Happy reading!

Best,

Anna Rose
Director, Cell & Gene Collaborative

Regulators On The Future Of Gene Therapy: Check Back In A Few Years

- I really liked [this *Medicine Maker* interview with the FDA's Peter Marks](#). In particular, check out his thoughts on what it will take to manufacture gene therapies at scale.
- As you may or may not know, the FDA held a marathon advisory committee meeting in early September on the safety profile of AAV vectors. Here are the juiciest tidbits from the meeting — though, be warned, few solutions/actionable proposals were raised because the future and science are hard:
 - [Empty capsids continue to raise question \(and hackles\)](#) on both the industry and regulator sides of the aisle. Regulators still don't have enough information on the impact empty capsids have on safety. In turn, it remains unclear in which situations and how strongly regulators should be pushing back on the presence of empty capsids.
 - Despite safety concerns posed by higher doses, the panel did not express [any intentions to cap total vector genome dose/patient or capsid dose](#). A lack of reference standards and variabilities in assay design and accuracy are some factors making setting such limits a challenge.
 - Experts on the committee agree [that animal models are ill-equipped](#) to demonstrate AAV oncogenicity risks in humans. However, though standardization of preclinical dose and animal study designs is needed, many also emphasized it's still too early to provide general recommendations.

“Pass Go & Collect \$200” (Million) For Your Manufacturing Strategy

- The C&G industry has benefited from a surplus of funding over the past year. How can C&G therapy players best plan for and allocate that money towards their manufacturing paradigms? I sat down with two partners at the VC firm Syncona to [get some answers on how best to play — and win — this game of C&G manufacturing monopoly](#).

Capacity: Everyone’s Favorite Rollercoaster

- In [the final installment](#) of my three-part article series with Mark Davis, principle and founder of Negotium Bio, Davis offers what is becoming an increasingly popular opinion about how our current capacity crunch — especially for viral vectors — is likely to shake out.
- One-size does not fit all when it comes to the build-vs.-buy debate. But what if one single strategy doesn’t fit one company? In [a recent blog post](#), I wax poetic on the refreshing amount of fluidity that exists (or perhaps should exist) in companies’ quests for manufacturing capacity.
- ICYMI: In May, GlobalData released a report entitled “[The Outlook For Viral Vector Contract Manufacturing](#): Gene Therapies, Cell Therapies, and COVID-19 Vaccines.” The report will cost a few Benjamins to download, but the press release highlights three potential solutions to our current viral vector capacity crunch.
- [This BioProcess International article](#) examines the (aptly described) “see-saw” of the current in-house vs. outsourced debate. While there have been a number of innovator facilities snapped up by CDMOs in the past few months, some experts warn we shouldn’t get carried away into assuming outsourcing has won the debate.

Thou Shalt Not Patent *That*: The Moral Of This CAR-T Story

- In an intriguing move, [The U.S. Court of Appeals overturned a previous Federal Circuit verdict from 2017](#) which ruled that Kite had infringed one of Juno’s CAR-T patents claiming a CD19-specific single-chain antibody variable fragment (scFv). Now, the Court of Appeals is setting the record straight: Juno’s patent was much too broad and lacked sufficient detail to claim ownership of that particular technology. Kite emerges victorious.

“Ancillary Materials”

- This week on “things ARW found on the internet that *won’t* help us do our jobs better,” we have: the fluorescent inner workings of a termite gut; things that go bump in the dark under Antarctic ice shelves; and a curious Norwegian sign. [Click here for fun](#).