## **CELL & GENE THERAPY INSIGHTS**

## **COVID-19 vaccine approvals:** key lessons for mRNA therapeutics

The development of mRNA therapeutics is not a new phenomenon, but the key role played by mRNA-based vaccines in battling the COVID-19 pandemic has resulted a rapid acceleration in the development timeframe of this technology field. In a recent expert roundtable discussion, we spoke to a panel of experts within the field to better understand what lessons the vaccine and therapeutic fields can learn from each other. Here, we sum up some of their key thoughts.

Cell & Gene Therapy Insights 2021; 7(11), 1559–1559

DOI: 10.18609/cgti.2021.209



Venkata Indurthi Vice President Research and Development, Aldevron The COVID-19 vaccine has accelerated the platform by about 10 years and changed the picture for RNA completely. Now people understand the potential of RNA, more and more people in the space want to promote more and more tools, but that would add to some of the challenges, such as a shortage of raw materials. I see mRNA being one of the most revolutionary technologies in vaccine and therapeutic spaces.

We've learned that mRNA-based drugs can be quickly scaled up to make very consistent products. And mRNA is now a proven, safe, and efficacious modality for drug delivery. There are massive datasets coming out of the vaccine programs, involving hundreds of thousands of doses in all sorts of patients, which will be invaluable to those developing mRNA therapeutics. Once tissue-specific delivery is solved, the sky is the limit for

solved, the sky is the limit for the mRNA space.



Joseph Barberio Director, mRNA Process Development, Strand Therapeutics

DOI: 10.18609/cgti.2021.209 Cell & Gene Therapy Insights - ISSN: 2059-7800



## Scott Zobbi

Senior Manager Business Development for Custom POROS Resins, Bioproduction Division, Thermo Fisher Scientific



Christoph Kröner Director DNA Process Development & Cap Technology, BioNTech SE

/////

A year ago, there were no approved mRNA therapies; this year there are two approved mRNA therapies with commitment for billions

of doses. The industry is having to build supply chains from scratch for a majority of the reagents, lipids, and raw materials needed. There is a huge investment going on right now to build out that supply chain, but it still takes time.

I find it frustrating when you hear people saying 'if BioNTech or Moderna just shared their sequence and their information we could be producing million-dose batches tomorrow.' My answer would be, with what? Even if you knew how to make it, there are no reagents, no enzymes, no NTPs available. That's why I think the focus needs to be on the key vendors who already have the infrastructure in place, like BioNTech, Pfizer, Moderna, CureVac.

Analytics is one of the main challenges that we face – mRNA is a large molecule with a complex secondary structure. Having the mRNA as a full-length homogeneous configuration is the aim, but that's not what we get after *in vitro* transcription.

For example, *in vitro* transcription can produce shorter, double-stranded mRNAs. Acquiring knowledge about this completely heterogeneous population of mRNA is very important. In the future, I believe we need to go down to single-molecule analysis of the mRNA.



1559