The challenge of quality control for adenovirus and RNA-based vaccines

Claudia Benati, Senior Scientific Director at Eurofins BioPharma Product Testing (Eurofins BPT) and Qualified person for Advanced Therapies (ATMPs), and Dr Anke McCartney, Global Key Account Manager, Eurofins BPT, discuss the challenges faced by the pharmaceutical industry in the field of analytical testing of COVID-19 vaccines in these unprecedented times of quick market launches and pressure on product availability and safety.

Many vaccines that are currently authorised or undergoing large-scale clinical trials in Europe come from recently licensed technologies (recombinant protein vaccines and vectored vaccines) or completely new technology (messenger RNA [mRNA]vaccines). Do these new technologies come with new analytical requirements?

BENATI: Yes. mRNA vaccines have their own unique analytical requirements distinct from traditional vaccines and biologics. However, at Eurofins BPT, supporting RNA-based drug development candidates is not a new activity and a lot of analytical methods are already routinely carried out, such as purity for Starting Materials by LC/MS, identity by reverse transcription (RT) Sanger sequencing, total RNA by spectroscopy, potency by cell-based ELISA, residuals as plasmid DNA by PCR, etc. for vaccines quality attributes analysis.

In the same way, several years of experience enable our labs to test all the quality attributes of vector vaccines: virus identity by ID-PCR, virus protein fingerprinting by RP-HPLC, residuals by qPCR and ELISA methodologies, potency as Transgene expression by cell based-ELISA, etc.

Which challenges are the first approved vaccines facing when it comes to production?

McCARTNEY: Next to the build-up of sufficient production capacity and the enormous logistical efforts, one of the other challenges the industry is facing is the rapid surge in new analytical testing capacity needs as development processes are cut from the typical 'several years' to an unprecedented ten months.

How does Eurofins act to support its clients?

McCARTNEY: We at Eurofins BPT have been able to support our clients by realising large extensions of our BSL2 laboratory space in several locations in the US and Europe in a very short time. The solutions put in place now allow clients to use the Eurofins harmonised network of laboratories in a very efficient way for their vaccine release programmes, bundling the testing from various drug substance and drug product manufacturers engaged.

Our ability to scale up the laboratory footprint, expand our staffing levels at short notice and to provide an integrated service offering over several continents has enabled clients to establish release testing at various CMOs. The Eurofins team reduced the complexity and saved time in the testing environment, and enabled fast production scale up and regulatory filing, giving our clients a competitive advantage in answering the pandemic.

Why do companies choose Eurofins' services?

McCARTNEY: It is the combination of both Eurofins' large capacities and the comprehensiveness of services and service models which makes Eurofins a strong reliable partner.

Eurofins not only helps its clients ensure a safe and on-time release of large volumes of vaccines onto the market, but also supports at many steps of the production process.

Furthermore, clients choose to avail of our different business models to address their rapidly increasing testing needs in their own facilities. By engaging our insourcing solution Professional Scientific Services® (PSS) they can have qualified staff for their defined scopes of work quickly. The clients had trust that they could rely on our decade-long laboratory management experience. Instead of challenging their own management with a multitude of individuals hired through temporary agencies, they are able to work with Eurofins' managed teams established by us on their premises, providing quality results quickly. The teams support new equipment validations, the transfer of methods from the development into the routine testing laboratories and the testing of COVID-19 vaccine release and stability samples to give just a few examples.

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