

Scientific Symposium

Quality matters: how to determine CQAs of nucleic acid therapeutics and their carriers?

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Abstract

After several decades focusing on protein analytics, the biopharma community is now faced with the challenge of determining critical quality attributes (CQAs) for emerging, more complex nucleic acid (NA) therapeutics and their carrier systems. Low molecular weight NA therapeutics, such as antisense oligonucleotides or small interfering RNA, can be thoroughly characterized for CQAs like identity and purity using a variety of analytical tools. However, analyzing higher molecular weight molecules, such as guide RNA, messenger RNA, or plasmid therapeutics, presents a significant challenge for many techniques.

A particular challenge arises from the need to package NA therapeutics for delivery and protection. For these, clear CQAs have yet to be defined, and reliable analytical test methods are still being optimized.

In this talk, we highlight the advantages and limitations of analytical techniques used to determine CQAs of NA therapeutics, presenting examples from different NA classes. We provide insights into the physicochemical analysis of viral and lipid-based nanoparticles, offering valuable information on the characteristics of these complex systems for therapeutic use.





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