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SPEAKER INTERVIEW

6th Annual
Gene Therapy Analytical Development & CMC Summit

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What advancements in gene therapy analytical development are you most excited about right now?

I'm excited about the potential of sequencing technologies to reveal the qualitative nature of residual DNA impurities in gene therapy products.

These insights allow us to better understand the specific characteristics of these fragments, such as their origin, structure, and potential biological activity, which in turn drives the development of more precise and reliable quantitative analytical techniques.

In your view, why is the 6th Gene Therapy Analytical Development & CMC event a must-attend for professionals in this space?

Attending the 6th Gene Therapy Analytical Development & CMC event is invaluable for learning about the latest analytical techniques, regulatory trends, and gaining insight from experienced professionals who are making contributions to the field of gene therapy.

As a scientist involved in method development, attending provides a great opportunity to enhance skills and contribute to better, safer therapies.

VIEW THE FULL EVENT GUIDE

What exciting projects or initiatives are you currently working on that are advancing the field of gene therapy analytical & CMC development?

I'm currently working on developing in vitro methods to analyze and understand the functionality of residual DNA fragments larger than 200 bp in gene therapy products.

This project is exciting because it addresses a critical safety concern, ensuring that these fragments don't interfere with patient outcomes, particularly in terms of immunogenicity or unintended integration. By developing these techniques, we aim to adhere to regulatory standards and ensure the overall safety of gene therapies.

What's one major takeaway you want attendees to leave your session with that could make an immediate impact in their work?

One major takeaway I'd like attendees to leave the session with is the importance of selecting the right analytical method for residual DNA detection to meet regulatory agency guidance and ensure product safety.

By understanding the trade-offs between technologies like dPCR and qPCR, as well as the implications of using long versus short-read sequencing, attendees can make informed decisions that directly enhance the detection and characterization of residual DNA impurities.