

9th Annual IABS Statistics Workshop Applying Statistics and Data Science to Evolving Technical and Regulatory Paradigms

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Title: Overview of NGS technology and application of NGS for gene therapy

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Next-Generation Sequencing (NGS) technology offers unparalleled access to genomic information, revolutionizing the development of gene therapy products. NGS assay can be employed to identify genetic variations, verify viral genomes, and quantify impurities in drug products, thus playing a vital role in guaranteeing product quality and safety. This technology also serves as a potent tool for characterizing individual DNA or RNA sequences in drug products, frequently used to address inquiries or concerns raised by health authorities. Data scientists are crucial in the realm of NGS assay development and data interpretation. Their responsibilities involve designing and implementing robust data processing pipelines, as well as employing statistical models and machine learning algorithms to analyze and interpret complex biological data.