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Evaluation of genetic stability of transgenes in vaccine

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Based on health regulatory recommendations, the characteristics profile (e.g., identity, safety, potency, consistency, etc.) of a vaccine candidate should be established prior to initiation of a clinical phase study. Genetic instability of the genes or transgenes within a vaccine may lead to inconsistent expression of complementing gene products and altered cellular properties. Therefore, it is important to demonstrate consistent and stable gene copy numbers over the generation length of a production run. We have previously developed a digital PCR (dPCR) assay to monitor the stability of the UL5 and UL29 transgenes in a manufactured cell line (AV529) by comparison of transgene copy numbers in the master cell bank with their copy numbers in the extended cell bank. Our developed approach was able to count the number of UL5 and UL29 transgenes directly rather than relying on a reference standard or endogenous control, quantified the absolute numbers of target molecules and not the relative numbers. Our dPCR based approach was able to overcome some of the issues associated with conventional qPCR. Herein, we developed a digital PCR approach for the determination of the gene copy numbers in not only simple (amplified DNA fragments) but also complex matrices (genomic DNA in *Mycoplasma arginine* and a candidate HSV type II vaccine (HSV529)). The amount of gene copy numbers in *Mycoplasma arginine* and viral genomes per unit sample of HSV529 is also compared to other methods.

Biography

Ali Azizi holds a PhD in Microbiology and Immunology from the University of Ottawa and has more than 15 years of experience in industry and academia environments. He is currently working as a Senior Scientist at Sanofi Pasteur and acting as a part-time Lecturer at various Universities. He has contributed to over 30 scientific publications and has acted as a Reviewer for several peer reviewed journals, international conferences and governmental organizations. He has also co-authored two patents related to vaccine technologies. He has collaborated effectively with several partners and international organizations on various vaccine trials performed in North America and overseas.

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