**Building of a Gene Therapy Facility: A Singapore Experience**

In recent years, using gene-modified cell therapy products for treatment of diseases has gained traction. This is largely due to the improved safety profile of the newer generation of viral vectors and several of such therapies have already obtained marketing authorisation. With time, the number of available treatment and demand are likely to increase. As these products can only be produced ex-vivo using patients’ cells, there is a need for a production site within Singapore that meet both biosafety and good manufacturing practice (GMP) requirements.

The Cell Therapy Facility at Health Sciences Authority, Singapore houses two independent clean room facilities. The older of the two was constructed in 2006 and it was used to prepare cell therapy products intended for haematopoietic transplantation and immunotherapy. Operations were relocated to a bigger facility in 2011 to accommodate an increasing demand for such products. This facility had since obtained GMP compliance status from the local regulatory body and JACIE accreditation. With current advances in the gene therapy field, it is timely that the older facility can be placed into better use by converting it into a separate Gene Therapy Facility for viral vector related cell manufacturing.

However, as compared to building a new facility from scratch, modification of an existing facility came with a different set of challenges. The design and layout of the Gene therapy Facility had to comply to GMP regulations while navigating the constraints of an existing pre-defined space and retaining most of the original infrastructure such as the air control and mechanical ventilation systems. Eventually, the space was retro-fitted to include one large negative-pressured grade B processing suite (bubble air-locked design) with single-pass entry and exit for a unidirectional personnel flow. Additional rooms were incorporated for a two-stage gowning process prior to entry into the suite. Multiple pass-through windows were installed for proper movement of cell therapy products, supplies and waste. One limitation of this design was that only a single product could be processed at a time and handling of multiple products had to be managed with proper process controls such as time segregation, and proper decontamination and changeover procedures.