

IMSUT Hospital

Therapeutic Vector Development Center

治療ベクター開発センター

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The Therapeutic Vector Development Center (TVDC), formerly known as the Core Facility for Therapeutic Vectors, was established in 2002 as the first facility in Japanese academic institutions for the clinical-grade production of viral and cellular vectors. TVDC is designed to support clinical trials requiring the production of recombinant viral vectors, genetic modification, and/or ex vivo manipulation of patient-derived tissues or cells under Good Gene, Cellular, and Tissue-based Products Manufacturing Practice (GCTP) conditions.

Maintenance of the Standard Operating Procedures (SOPs)

The GCTP (former cGMP) compliance is maintained by the regularly revised SOPs that document all the elements of laboratory work, including both tangible and intangible factors like equipment, facility design, personnel, etc.

ISO certification

The management system of TVDC was re-qualified as ISO 9001-certified in 2023, which has been regularly performed by an independent organization to meet the requirement for ISO 9001 standard.

Validation of TVDC

The TVDC consists of two units; 1) the Vector Unit, the primary suite for viral vector production and ex vivo transduction; 2) the Cell Unit, the suite for cell processing capable of generating therapeutic cells

such as dendritic cells for immunotherapy and gene therapy. Each unit has two independent compartments maintained at a Class 10,000 clean level. The facility and equipment are regularly validated in accordance with the SOPs to fulfill the cGMP standard. In 2024, a new Vector Unit (Vector Unit II) was built on the 3rd floor of Building No.1.

Production of clinical grade oncolytic HSV-1

Multiple lots of clinical-grade oncolytic herpes simplex virus type 1 (HSV-1), including G47Δ and various armed third-generation oncolytic HSV-1, have been produced in the Vector Unit (recent Vector Unit I) by the laboratory specialists of the Division of Innovative Cancer Therapy.

Oncolytic MV project

A clinical-grade oncolytic measles virus (MV) was produced by the Laboratory Animal Research Center and stored in the Vector Unit.