

ABSTRACT: Accelerating cell and gene therapies into the clinic with in-house manufacturing at Sheba Medical Center

Company name: Advanced Biotherapy Center, Sheba Medical Center

Website: <https://eng.sheba.co.il/The-Advanced-Biotherapy-Center-ABC>

Presenter name: Dr. Jonathan Esensten

Presenter title: Director, Advanced Biotherapy Center, Sheba Medical Center

Email: Jonathan.Esensten@sheba.health.gov.il

CATEGORY: Biotech/Pharma

SESSION

- Personalized Pathways; Genetic and cellular based Advances for Rare and Complex Disease

- **Executive Summary / Investment Rational**

The Advanced Biotherapy Center (ABC) at Sheba Medical Center is an academic research, development, and manufacturing laboratory for cell, gene, and tissue therapies. We work under cGMP appropriate for advanced therapy medicinal products (ATMP) per EMA regulatory guidance. The multidisciplinary team at ABC provides development, manufacturing, and analytic services for cell and gene therapy. ABC also supports investigator-initiated trials with academic groups.

- **Core Technology**

We manufacture gamma retroviral vectors for both preclinical research and at clinical grade for use in cell and gene therapy clinical trials. We provide development, manufacturing, and regulatory support for phase 1/2 cell therapy clinical trials, including comprehensive QA and QC. We can tech transfer a manufacturing process to another manufacturing site if necessary, as a project scales up and requires a dedicated GMP facility.

- **Product Profile/Pipeline**

The ABC center currently manufactures cell, gene, and tissue therapy products that are administered to patients in approved clinical trials. Specific areas of expertise include CAR T and CRISPR-based approaches. We provide cleanroom access for academic groups and companies that want to perform their own product manufacturing under cGMP.

- **Business Strategy**

ABC serves as an academic contract development and manufacturing organization (CDMO). We provide both manufacturing and analytic services for a fee. We are dedicated to early adoption of closed, automated manufacturing

technologies to ensure that high quality cell and gene therapies can be scaled up and out to reach commercial viability.

- **What's Next?**

We are open to partnering with biotech and pharma partners to advance cell, gene, and tissue therapy both in Israel and internationally.